United States Court of Appeals for the Federal Circuit

STAR SCIENTIFIC, INC.,
Plaintiff-Appellant,

v.

R.J. REYNOLDS TOBACCO COMPANY (A NORTH CAROLINA CORPORATION) AND R.J. REYNOLDS TOBACCO COMPANY (A NEW JERSEY CORPORATION),
Defendants-Appellees.

2010-1183

Appeal from the United States District Court for the District of Maryland in consolidated case nos. 01-CV-1504 and 02-CV-2504, Senior Judge Marvin J. Garbis.

Decided: August 26, 2011

CARTER G. PHILLIPS, Sidley Austin, LLP, of Washington, DC, argued for plaintiff-appellant. With him on the brief were ERIC A. SHUMSKY, MICHAEL D. HATCHER and QUIN M. SORENSON. Of counsel on the brief were RICHARD MCMILLAN, JR., MARK M. SUPKO and JEFFREY D. AHDOOT, of Crowell & Moring, LLP, of Washington, DC.

MEREDITH MARTIN ADDY, Brinks, Hoefer, Gilson & Lione, of Chicago, Illinois, argued for defendants-appellees. On the brief were RICHARD A. KAPLAN, RALPH J. GABRIC, CYNTHIA A. HOMAN, DANIELLE ANNE PHILLIP and JULIE L. LEICHTMAN. Of counsel was K. SHANNON MRKSICH.

Before RADER, *Chief Judge*, LINN, and DYK *Circuit Judges*.

Opinion for the court filed by *Chief Judge* RADER. Opinion concurring-in-part and dissenting-in-part filed by *Circuit Judge* DYK.

RADER, *Chief Judge*,

Appellant Star Scientific, Inc. ("Star") appeals the denial of its motion for judgment as a matter of law ("JMOL") and in the alternative a new trial after a jury verdict of non-infringement and invalidity of U.S. Patent Nos. 6,202,649 ("'649 patent") and 6,425,401 ("'401 patent") (collectively, "Williams patents"). *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, No. 8:01-cv-1504, Dkt. No. 1146 (D. Md. Dec. 21, 2009). This court affirms the denial of Star's JMOL of infringement and the denial of Star's motion for a new trial but reverses the district court's denial of Star's JMOL on validity.

I.

Star is the exclusive licensee of the Williams patents, which claim tobacco curing methods. Curing dries the tobacco leaves before shipment to tobacco companies. One prior art curing method—"air curing"—places tobacco leaves in a barn to dry without any added heat. In the United States, curing is generally performed in heated curing barns through a method called "flue curing," which uses diesel gas or propane gas heaters.

Until the 1970s, most curing occurred in indirect-fired barns that heated and dried the tobacco in an environment separated from the exhaust gases released by the heaters. In the 1970s, in an effort to save money, tobacco farmers switched to direct-fired barns, which mixed the combustion exhaust with the curing tobacco. The combustion gases (including carbon monoxide, carbon dioxide, and water vapor) can create an anaerobic, or oxygen-free, environment. This anaerobic environment in direct-fired barns can lead to the formation of a family of chemical compounds called tobacco-specific nitrosamines ("TSNAs") on curing tobacco leaves. Tobacco can acquire four varieties of TSNAs, known by the abbreviations NNN, NNK, NAB, and NAT.

These TSNAs arise because anaerobic conditions stimulate microbes on tobacco plants to produce the enzyme, nitrate reductase, which converts nitrate to nitrite and nitric oxide. Nitric oxide reacts with precursor tobacco alkaloids to form TSNAs.

Because some TSNAs are known carcinogens, tobacco companies have long sought curing methods that minimize or eliminate TSNA formation on cured tobacco plants. The Williams patents claim a tobacco curing method that "substantially prevent[s]" the formation of at least one TSNA during curing. Star employee Jonnie Williams ("Williams") is the named inventor.

Star first filed a provisional patent application on September 15, 1998. On September 15, 1999, Star filed a non-provisional application, which issued on March 20, 2001 as the '649 patent. The application leading to the '401 patent is a continuation of the application that matured into the '649 patent. In the time between the provisional application and the non-provisional application, Williams developed the "StarCure" process, the commercial embodiment of the invention. The parties

agree the StarCure process is the best mode of practicing the claimed invention.

The Williams patents work with air curing and both indirect and direct flue curing methods. '649 patent col.2 ll.53-66; col.3 ll.1-24. Williams' method creates a "controlled environment" that controls "at least one of humidity, rate of temperature exchange, temperature, airflow, CO [carbon monoxide] level, CO_2 [carbon dioxide] level, O_2 [oxygen] level, and arrangement of the tobacco plant." *Id.* at Abstract. The Williams patents define "controlling the conditions" as "determining and selecting an appropriate humidity, rate of temperature exchange, temperature, airflow, CO level, CO_2 level, O_2 level, and arrangement of the tobacco leaves to prevent or reduce the formation of at least one TSNA." *Id.* col.5 ll.65-68, col.6 ll.1-4. The Williams patents teach that "the practice of tobacco curing is more of an art than a science, because curing conditions during any given cure must be adjusted to take into account" many variables. *Id.* col.6 ll.35-37. Those variables include "differences in leaves harvested from various stalk positions, difference among curing barns in terms of where they are used" and more. *Id.* col.6 ll.35-41. However, the Williams patents elaborate that "one of ordinary skill in the art of tobacco curing would understand that the outer parameters of the present invention, in its broadest forms, are variable to a certain extent depending on the precise confluence of [these numerous factors] for any given harvest." *Id.* col.6 ll.51-55.

In general, the Williams patents posit that sustaining an aerobic environment during tobacco curing will prevent TSNA formation. *Id.* col.7 ll.53-55. For purposes of infringement, the parties agreed that the combined elements of claims 4 and 12 of the '649 patent were representative. J.A. at 46387-90. Those claims recite:

> 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.*

'649 patent col.20 ll.18-33 (emphasis added).

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

Id. col.20 ll.50-51 (emphasis added).

From 1998 through 2001, Star had agreements with Brown & Williamson to cure low-TSNA tobacco using Williams' patented method. Star made millions of dollars in licensing fees for rights to the Williams patents. However, defendants-appellees R.J. Reynolds Tobacco Company ("RJR") terminated those agreements with Star upon acquisition of Brown & Williamson.

RJR conducted its own research to develop curing methods to minimize TSNA formation on cured tobacco. One RJR researcher, David Peele ("Peele"), filed a patent

application in April of 1999, which issued as U.S. Patent No. 6,805,134 ("Peele patent" or "'134 patent") on October 19, 2004.

The Peele patent claims a method of reducing TSNA formation by using "a heating source that is not a direct-fire heating source" to "avoid contact with, or exposure to, tobacco being subjected to flue-curing processing steps with nitric oxide gases." '134 patent col.3 ll.37-47. To reduce exposure of curing tobacco leaves to nitric oxide gases, Peele provides a method of retrofitting direct-fire flue curing barns with heat exchangers to effectively turn them into indirect-fire flue curing barns ("Peele method"). By 2000, RJR required every farmer in its chain to retrofit their barns in accordance with the Peele method.

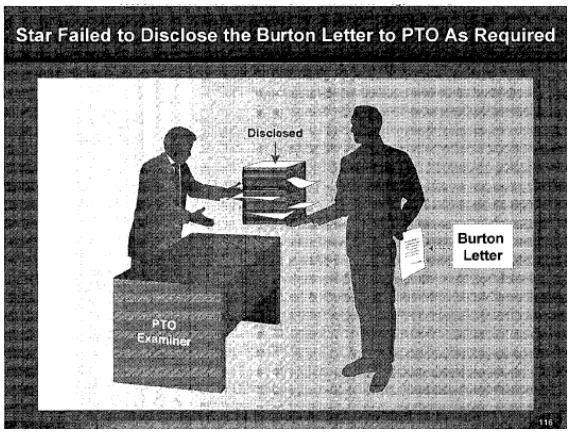
On May 23, 2001, Star filed a complaint against RJR, alleging infringement of the '649 patent, and subsequently filed an amended complaint further alleging infringement of the '401 patent. RJR denied infringement and claimed both patents were unenforceable for inequitable conduct, and invalid for anticipation, obviousness, indefiniteness, and failure to disclose the inventor's best mode.

After a bench trial, the district court held the Williams patents unenforceable for inequitable conduct and granted summary judgment of invalidity for indefiniteness. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.,* No. 8:01-cv-1504, Dkt. No. 712, slip op. at 46 (D. Md. June 26, 2007) (finding the Williams patents unenforceable for inequitable conduct based on the nondisclosure of a document ("Burton letter")); *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.,* No. 8:01-cv-1504, Dkt. No. 711, slip op. at 12-14 (D. Md. June 22, 2007) (finding the Williams patents invalid for indefiniteness). Additionally, the district court granted summary judgment to RJR on the filing date question. *Star Scientific, Inc., v. R.J. Reynolds*

Tobacco Co., No. 8:01-cv-1504, Dkt. No. 703, slip op. at 1-12 (D. Md. Jan. 19, 2007). The district court found new matter in Star's non-provisional application and held that the Williams patents were entitled to the September 15, 1999 non-provisional filing date and not the September 15, 1998 priority date of the provisional application. *Id.* Because the non-provisional application includes a new example calling for "air flow of approximately 25,000 CFM," but the provisional application disclosed a minimum airflow of "at least 28,000 CFM," *id.* at 11, the court found that no reasonable fact finder could find that the 25,000 CFM airflow rate in the non-provisional application had been disclosed in the provisional application. *Id.* at 12.

On appeal, this court reversed the findings of unenforceability and invalidity. *Star Scientific, Inc., v. R.J. Reynolds Tobacco Co.,* 537 F.3d 1357 (Fed. Cir. 2008) (*reh'g en banc denied* Oct. 22, 2008) ("*Star I*"). This court held that the claim term "anaerobic condition" was not indefinite and consequently reversed the district court's grant of summary judgment of invalidity. *Id.* at 1371. This court also found that the Williams patents were not unenforceable for inequitable conduct. *Id.* at 1365. In reversing the district court's inequitable conduct finding, this court held that RJR failed to show the withheld prior art, including the Burton letter, renders either of the Williams patents unenforceable. *Id.* At that time, this court did not review the district court's priority date determination. This court also did not address anticipation and best mode because the trial court denied RJR's summary judgment motions on those grounds. *Id.* at 1365 n.6. Therefore, this court remanded this case to the district court for proceedings on infringement ("*Star II*"). *Id.* at 1373.

On remand, *Star II* featured a 20-day jury trial with 24 witnesses and over 4,000 pages of transcript. Despite this court's decision in *Star I* that the Williams patents were not unenforceable for inequitable conduct, RJR's attorneys continually argued, particularly during closing argument, that Star's failure to produce the Burton letter to the United States Patent and Trademark Office ("Patent Office") was significant evidence in support of invalidity. J.A. at 46806-07 ("The Burton letter is again from an invalidity standpoint. . . . The important point here is this was information the Patent Office did not have in front of it."). RJR projected a slide show for the jury during its closing argument; one slide showed a shadowy figure holding a piece of paper labeled "Burton Letter" behind his back ("Burton slide"):



J.A. at 43788.

RJR's primary invalidity expert, Dr. Lambert Otten ("Dr. Otten"), opined that the Williams patents were obvious in light of the combination of a review article by Anna Wiernik et al., titled "Effect of Air-Curing on the Chemical Composition of Tobacco" ("Wiernik") and Japanese Patent No. 51-144535, titled "Method for Curing Domestic Tobacco Leaves," with the named inventor Hideyuki Tohno ("Tohno"). Dr. Otten further testified

that three prior art references anticipate the Williams patents: (1) the Peele method; (2) an alleged public use at the Spindletop Research Facility used by RJR ("Spindletop"); and (3) an alleged public use at Hassel Brown's farm, a tobacco farm under contract with RJR.

RJR also argued that the Williams patents were indefinite. Supported by Dr. Otten's testimony, RJR argued that one skilled in the art would not understand a "controlled environment" after reviewing the Williams patents. Accordingly, RJR argued the Williams patents were indefinite because one of ordinary skill would be unable to determine the difference between "conventional processes" and the "controlled environment" required by the Williams patents. RJR pointed to several parts of the Williams patents where values for temperature and humidity for the invention overlap with values assigned to "conventional processes."

Star's primary infringement expert was Dr. Richard Lee ("Dr. Lee"). Dr. Lee's testimony focused on the oxygen levels in RJR's curing barns and that the resulting cured tobacco had low TSNA levels, showing that the anaerobic conditions that lead to TSNA had been "substantially prevented." J.A. at 45775-77.

A June 16, 2009 special verdict, based on the September 15, 1999 priority date assigned by the court in *Star I,* found RJR's curing process to be non-infringing and the Williams patents invalid as anticipated, obvious, failing to disclose best mode, and indefinite. J.A. at 30-33. The district court later denied Star's motion for JMOL. *Star,* Dkt. No. 1146 at 1-12. The district court's memorandum and order upheld the jury's verdict that the Peele method did not infringe the Williams patents. *Id.* at 4. The district court further noted that the jury likely did and "most certainly should have" rejected Dr. Lee's expert testimony. *Id.* at 5. The district court elaborated that,

even if Dr. Lee's testimony was not mooted by the verdict, the district court would grant JMOL of non-infringement and exclude Dr. Lee's testimony as not meeting the *Daubert* standard. *Id.* In addition to finding no direct infringement, the court also denied Star's motion for JMOL on indirect infringement. Further, the court denied Star's appeal of evidentiary rulings and excusing a juror. *Id.* at 5-7. The court denied Star's motion for JMOL to reverse the jury's findings of indefiniteness, failure to disclose best mode, anticipation, and obviousness on the basis that "the jury had ample evidence on which to find that RJR had proven, by clear and convincing evidence, that the Patents-in-Suit were invalid." *Id.* at 7-8. This appeal followed. This court has jurisdiction under 28 U.S.C. § 1295(a)(1).

After oral argument in this case, the Patent Office, in light of an *ex parte* reexamination request by Star, confirmed that the claims of the Williams patents deserve the priority date of the provisional application, namely September 15, 1998. The Patent Office also found that claims 4, 12, and 20 of the '649 patent, and claim 41 of the '401 patent, were obvious over Tohno, Wiernik, and several other references asserted by RJR. Because of the earlier effective filing date, the Patent Office did not consider the Peele reference as prior art.

II.

A. Priority Date

This court first reviews the district court's summary judgment ruling that the asserted claims of the Williams patents are not entitled to the provisional application priority date. *Star*, Dkt. No. 703 at 1-12. This court reviews both the district court's grant of summary judgment and determination of priority date without defer-

ence. *Research Corp. Techs. Inc. v. Microsoft Corp.,* 627 F.3d 859, 867 (Fed. Cir. 2010).

Claims deserve the provisional application's earlier filing date so long as that application contains adequate written description under 35 U.S.C. § 112. *Trading Techs. Int'l. Inc. v. Espeed Inc.,* 595 F.3d 1340, 1350 (Fed. Cir. 2010). Consistent with 35 U.S.C. § 112 ¶ 1, the written description of the provisional application must enable one of ordinary skill in the art to practice the invention claimed in the non-provisional application. *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.,* 298 F.3d 1290, 1294 (Fed. Cir. 2002).

In this case, the asserted claims deserve the September 15, 1998 priority date of the provisional application. The provisional application's written description discloses that the minimum air flow "may be about 28,000 CFM at 1" static pressure in a typical curing barn," but that the "minimum flow of air *may vary according to conditions* and may be determined on a routine basis." J.A. at 62198 (emphasis added). Claim 3 of the provisional application further clarifies that the claimed invention covers a "flow . . . sufficient to prevent an anaerobic condition" around the curing tobacco. J.A. 62205. Because the provisional application teaches one of ordinary skill that a minimum air flow "may vary," one of ordinary skill would know that the conditions in a curing barn could demand an air flow of 25,000 CFM. The district court's reliance on specifically disclosed air flow rates improperly narrowed the scope of the provisional application based on an added example in the later-filed non-provisional application that discloses a process for curing using an "air flow of approximately 25,000 CFM." Indeed, the Patent Office's recent reexamination confirms that September 15, 1998 is the proper priority date.

The September 15, 1998 priority date has several significant implications on this appeal. First, the Peele reference, with an effective filing date of April 26, 1999, is not prior art. Second, because the StarCure process was developed by Williams after September of 1998, failure to disclose this process cannot constitute a failure to disclose the best mode of practicing the invention. *Star*, Dkt. No. 703 at 11.

B. Evidentiary Objections

Star contends that the trial court committed numerous reversible evidentiary errors. Star seeks reversal and remand for a new trial based on the court's exclusion of proffered data, failure to exclude the Burton slide, reproduced above, failure to exclude arguments made by RJR about failure to produce the Burton letter to the Patent Office, and other arguments made by RJR during trial.

This court reviews a district court's decision to exclude evidence under the law of the regional circuit. *Del. Valley Floral Grp., Inc. v. Shaw Rose Nets, LLC*, 597 F.3d 1374, 1379 (Fed. Cir. 2010). The Fourth Circuit reviews a district court's decision to admit or exclude evidence for an abuse of discretion. *Buckley v. Mukasey*, 538 F.3d 306, 317 (4th Cir. 2008). Even if an evidentiary ruling constitutes an abuse of discretion, it is only reversible when it affects a party's substantive rights. *Id.*

The district court did not commit reversible error in its evidentiary rulings. Because inequitable conduct was not at issue in the trial, this court finds the presentation of the Burton slide troubling. The Burton slide, showing a shadowy figure conspicuously holding a piece of paper behind his back, does not support any claim at issue in this case. As a practical matter, however, Star did not show the presentation of the Burton slide affected its substantive rights. Accordingly, this court detects no

abuse of discretion in the trial court's evidentiary decisions.

III.

This court reviews the denial of JMOL without deference under the same standard applied by the trial court. *Lucent Techs, Inc. v. Gateway, Inc.,* 580 F.3d 1301, 1309 (Fed. Cir. 2009). The Fourth Circuit reviews a motion for JMOL without deference in the light most favorable to the nonmoving party. *A Helping Hand, LLC v. Baltimore Cnty.,* 515 F.3d 356, 365 (4th Cir. 2008). "Judgment as a matter of law is proper only if 'there can be but one reasonable conclusion as to the verdict.'" *Ocheltree v. Scollon Prods., Inc.,* 335 F.3d 325, 331 (4th Cir. 2003) (en banc). A denial of a motion for a new trial is reviewed for an abuse of discretion. *Verizon Servs. Corp. v. Cox Fibernet Va., Inc.,* 602 F.3d 1325, 1331 (Fed. Cir. 2010) (applying Fourth Circuit law). A new trial is granted in the Fourth Circuit only when there is conduct "so grievous as to have rendered the trial unfair." *Id.*

This court reverses the district court's denial of Star's motion for JMOL on issues involving the validity of the Williams patents. This court affirms the district court's denial of Star's motion for JMOL with regard to infringement. This court evaluates best mode, indefiniteness, obviousness, anticipation, and infringement in turn.

A. Best Mode

The best mode requirement contains two elements. First, the court must determine whether the inventor possessed a best mode of practicing the claimed invention at the time of filing the patent application. *Green Edge Enter., LLC v. Rubber Mulch Etc., LLC,* 620 F.3d 1287, 1296 (Fed. Cir. 2010). This first step is subjective and focuses on the inventor's preference for a best mode of practicing the invention at the time of the application's

filing date. *Id.* (citing *N. Telecom Ltd. v. Samsung Elecs. Co.,* 215 F.3d 1281, 1286 (Fed. Cir. 2000)). The second step is an objective inquiry to determine whether the inventor concealed from the public the best mode of practicing the invention. *Id.* (citing *Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 928 (Fed. Cir. 1990)).

RJR concedes that Williams had not yet contemplated a best mode as of September 15, 1998. Appellee Br. at 26. As discussed above, September 15, 1998 is the proper priority date for the asserted claims of the Williams patents. Therefore, at the time of filing, the record shows no best mode violation. Without evidence that Williams had possession of a best mode of practicing the claimed invention at the time of filing, the record cannot support invalidity under the best mode requirement. This court reverses the district court's finding that the Williams patents are invalid for failure to disclose the best mode of practicing the claimed invention.

B. Indefiniteness

Indefiniteness is a purely legal issue that this court reviews without deference. *Bancorp Serv., LLC v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1372 (Fed. Cir. 2004). This court only finds claims "not amenable to construction" or "insolubly ambiguous" to be indefinite. *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005) (citations omitted). Thus, a construed claim can be indefinite if the construction remains insolubly ambiguous, meaning it fails to provide sufficient clarity about the bounds of the claim to one skilled in the art. *Star I*, 537 F.3d at 1371 (citations omitted). Absolute clarity is not required to find a claim term definite. This court has held that a claim term may be definite even when discerning the meaning is a "formidable [task] and the conclusion may be one over which reasonable persons will disagree." *Source Search Tech., LLC v. Lendingtree,*

LLC, 588 F.3d 1063, 1076 (Fed. Cir. 2009) (citing *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001)).

The district court construed the claim term "controlled environment" to mean "controlling one or more of humidity, temperature and airflow in the curing barn, in a manner different from conventional curing, in order to substantially prevent the formation of TSNAs." *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, No. 8:01-cv-01504, Dkt. No. 458, slip op. at 2 (D. Md. March 31, 2004). The parties do not contest that an ordinarily skilled artisan knows the meaning of the term "controlled environment," but they dispute whether a person of ordinary skill would know how to establish a controlled environment to perform the claimed method. Here, indefiniteness requires a showing that a person of ordinary skill would find "controlled environment" to be insolubly ambiguous.

From that perspective, this record does not present reasonable grounds for showing that "controlled environment" is indefinite. The jury's verdict assumes that a person of skill in the art would not recognize a "controlled environment" because the Williams patents do not give exact numbers measuring humidity, temperature, and airflow in a conventional curing barn. However, the record repeatedly shows that a person of skill in the art of tobacco curing would possess adequate understanding to manipulate these variables to create a controlled environment. Indeed, because conventional curing varies depending on the conditions for each cure, specific numerical values are not needed for one skilled in the art to implement conventional curing. As described in the '649 patent:

> [T]he practice of tobacco curing is more of an art than a science, because curing conditions during

> any given cure must be adjusted to take into account such factors as varietal differences, differences in leaves harvested from various stalk positions, differences among curing barns in terms of where they are used, and environmental variations

'649 patent col.6 ll.35-41. The '649 patent further explains that "the controlled conditions described herein [are] according to conventional methods commonly and commercially used in the U.S." *Id.* col.6 ll.16-18. The later-filed Peele patent, assigned to RJR, confirms that:

> [V]arieties of Virginia tobacco that can be grown and cured in accordance with [the Peele method] will be readily apparent to those skilled in the art of tobacco growing, harvesting, and processing, and tobacco manufacture. The manner of which Virginia tobacco is grown, harvested, and processed is well known.

'134 patent col.4 ll.3-8. Moreover, the record demonstrates that tobacco curing variables are well known in the tobacco industry. In that context, the term "controlled environment" falls well within the bounds of ordinary skill in the art. Thus, this term is not insolubly ambiguous and is not indefinite.

C. Obviousness

Under 35 U.S.C. § 103(a), a patent is invalid "if the differences between the [claimed] subject matter . . . and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." Obviousness is a determination of law based on underlying determinations of fact. *Geo M. Martin Co. v. Alliance Mach. Sys. Int'l*, 618 F.3d 1294, 1300 (Fed. Cir. 2010). These factual determinations

include the scope and content of the prior art, the level of ordinary skill in the art, the differences between the claimed invention and the prior art, and secondary considerations of nonobviousness. *KSR Int'l Co. v. Teleflex, Inc.,* 550 U.S. 398, 406 (2007) (citing *Graham v. John Deere Co*., 383 U.S. 1, 17-18 (1966)).

Whether prior art invalidates a patent claim as obvious is determined from the perspective of one of ordinary skill in the art. *Id.* at 420 ("The question is not whether the combination was obvious to the patentee but whether the combination was obvious to a person with ordinary skill in the art."). Through the lens of one of ordinary skill in the art, even when all claim limitations are found in prior art references, the fact-finder must not only determine what the prior art teaches, but whether prior art teaches away from the claimed invention and whether there is a motivation to combine teachings from separate references. *See Dystar Textilfarben GMBH & Co. Deutschland KG v. C.H. Patrick Co.,* 464 F.3d 1356, 1360 (Fed. Cir. 2006) (citing *In re Fulton*, 391 F.3d 1195, 1199-1200 (Fed. Cir. 2004)). Ultimately, obviousness requires careful judgment and analysis in light of technical facts. *KSR,* 383 U.S. at 419; *see also Motorola, Inc. v. Interdigital Tech. Corp.,* 121 F.3d 1461, 1472 (Fed. Cir. 1997) ("[T]here is no requirement that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art.").

Importantly, the great challenge of the obviousness judgment is proceeding without any hint of hindsight. *See ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546 (Fed. Cir. 1998) (observing that obviousness "cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented

invention"). Further, secondary considerations "may often be the most probative and cogent evidence [of non-obviousness] in the record." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983).

Dr. Otten testified that a combination of two prior art references, Tohno and Wiernik, rendered the '649 patent obvious. Specifically, he testified that a person of ordinary skill in the art would combine Wiernik's teaching (that TSNAs form from high humidity, optimal temperature, and anoxia) with Tohno's teaching (that an increased airflow helps avoid an oxygen deficient condition) to generate the claimed curing methods.

Wiernik is a literature survey from 1995 that summarizes studies conducted over a decade that primarily "concentrate[] on the formation of tobacco-specific nitrosamines." J.A. 64530. Wiernik teaches that artisans in tobacco curing "recognized" the role of microbial mediated reduction of nitrate to nitrite and "verified" that nitrite has a key limiting role in TSNA formation. J.A. 64531. Wiernik tentatively proposes conditions that could lead to TSNA formation on curing tobacco leaves "after the end of yellowing when the leaves turn brown." *Id.* Wiernik observes that "it *seems* that microorganisms . . . have little chance to produce nitrite and TSNA." J.A. 64545 (emphasis added). However, Wiernik adds that when nutrients are made available to microorganisms through cell death, nitrite "*may*" be produced under "favourable [sic] conditions, i.e. high humidity, optimal temperature and anoxia." *Id.* (emphasis added).

Tohno is a Japanese patent application from 1978. J.A. 60769-60772. Tohno teaches a method to "shorten the curing period, prevent a fast curing action, and eliminate the drawback of [having a 'nasty odor' in a tobacco product]." J.A. 60772. Tohno teaches a method involving manipulation of air flow, humidity, and temperature to

"achiev[e] short-term curing." *Id.* Tohno touts its prescribed environment as "promoting the browning action" that leads to accelerated curing. *Id.* Tohno does not mention TSNAs and does not associate its increased air flow with TSNA formation or cell death.

Even if the record showed some motivation or suggestion to combine these references, the combination of Tohno and Wiernik would still not present a clear and convincing instance of obviousness. Tohno describes an alternative quick bulk curing method with increased air flow that ameliorates abnormal "smoking properties," J.A. 60770, including a "nasty odor," J.A. 60771, observed in tobacco cured by standard bulk curing techniques. Tohno generally attributes the bad odor caused by other techniques to an abundance of "unnecessary gases" and claims a method to exclude those "unnecessary gases" to "promot[e] the activation of the enzyme contained in the tobacco leaves, thus achieving a short-term curing." J.A. 60771-72. Tohno does not mention TSNAs and does not provide a link between the oxygen levels (inherent in increasing air flow) and precursor tobacco alkaloids or the activation or inhibition of nitrate reductase—both critical targets of the Williams patents.

Wiernik's general teachings also produce little to render the Williams patents obvious. Wiernik speculates that microorganisms are influenced by environmental factors during the end of yellowing or the beginning of the browning stage of curing to potentially facilitate the production of TSNAs. Wiernik's speculative and tentative disclosure of what "might" or "may" lead to nitrite and TSNA production does not sufficiently direct or instruct one of skill in this art. *See Abbott Labs. v. Andrx Pharm., Inc.*, 452 F.3d 1331, 1336 (Fed. Cir. 2006) (stating that a person of ordinary skill possesses the "understandings and knowledge reflected in the prior art"). Further, as

noted before, the record contains no evidence suggesting a motivation to combine an article on remedying a foul odor in tobacco with a summary of studies about TSNA formation. In sum, this record shows no clear and convincing evidence of a prima facie case of obviousness.

Both Wiernik and Tohno fail to teach the claim limitation of curing with "air free of combustion gases." '649 patent col.20 ll.27-28. Tohno nowhere discusses expelling gases from the curing chamber. Instead, Tohno describes a method of establishing "sufficient ventilation" to "supply O_2" in order to "shorten the curing period, prevent a fast curing action, and eliminate the drawback of smoking property." J.A. 60771-72. Wiernik also fails to teach the need to eliminate combustion gases and therefore lacks any disclosure for "air free of combustion exhaust gases." Instead, Wiernik concludes "the intricate and complex mechanisms of [curing] are not fully understood[,] [a] deeper insight into these reactions would enable an optimization of the curing procedure." J.A. 64565.

Moreover, the record contains many secondary considerations that support nonobviousness. The record shows a substantial need in the industry for curing methods that minimized or eliminated the formation of TSNAs. The record also contains numerous scientific articles counseling that eliminating or minimizing carcinogens in tobacco has been a long-felt industry need. To that end, the record showed decades of unsuccessful attempts at reducing TSNA levels to the extent achieved by the Williams patents. *See* J.A. 45521-23 (testimony that RJR had a "Nitrosamine taskforce" from around 1990 until about 1995 with a mission to "understand nitrosamines and apply that understanding for a competitive advantage"). The record also evinced unexpected results that met a long felt industry need. For example, at trial, Williams testified that after presenting his low-TSNA

tobacco products at an industry conference "everyone wanted to get acquainted," including "all of the major tobacco companies." J.A. 45326. Finally, as evidenced by Brown & Williamson's licenses, which cost millions of dollars, Williams' invention had achieved considerable market acceptance and commercial success.

D. Anticipation

The jury verdict did not identify which prior art reference supplied clear and convincing evidence to anticipate the Williams patents. J.A. 33. Because Dr. Otten testified that three pieces of prior art anticipated the Williams patents, this court considers those prior art references: the Peele method and the alleged public uses at Spindletop and Brown. J.A. 60664.

Under 35 U.S.C. § 102(b), a patent may not issue if the claimed invention was in public use in this country more than one year before the patent's critical date. *See, e.g., Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 974 (Fed. Cir. 2010). Here, as discussed above, the effective filing date is September 15, 1998. Because the record shows that the Peele method was not used more than one year before the effective filing date, this reference does not qualify as anticipatory prior art. Because no reasonable jury could find by clear and convincing evidence that either the Spindletop or Brown farms were anticipatory public uses, this court reverses the district court's denial of Star's motion for JMOL for anticipation on the basis of Peele.

A public use under Section 102(b) includes any public use of the claimed invention by a person other than the inventor who is "under no limitation, restriction, or obligation of secrecy to the inventor." *Clock Spring, L.P. v. Wrapmaster, Inc.,* 560 F.3d 1317, 1325 (Fed. Cir. 2009) (quoting *Adenta GmbH v. OrthoArm, Inc.,* 501 F.3d 1364,

1371 (Fed. Cir. 2007)). An anticipatory public use under § 102(b) must exhibit all of the claim limitations. *Id.* at 1325. In this case, the record does not show at any point that the methods used at Spindletop included the limitation that "uncured" tobacco was placed in a controlled environment. *See* '649 patent col.20 l.23.

Dr. Otten testified that the method used at Spindletop included transferring stalks that had spent at least five days in "air curing barns" into the controlled environment of a rapid drying chamber. J.A. 46551-52. RJR's opposition to Star's motion for JMOL clarifies that "[o]n the sixth day, *after the end of yellowing*, the tobacco was removed from *the barn* and quick-dried[.]" J.A. 44679 (emphases added). Spindletop does not qualify as an anticipatory prior public use because the tobacco cured in Spindletop's controlled environment was not uncured, as required by the Williams patents.

A jury could not reasonably find by clear and convincing evidence that Brown's method of curing met the claim limitation "substantially prevent the formation of . . . at least one nitrosamine," '649 patent col.20 ll.24-25, more than a year before the Williams patents' September 15, 1998 priority date. The district court construed "substantially prevent the formation of . . . at least one nitrosamine" to mean "the level of at least one of the nitrosamines falls within the following ranges: less than about 0.05 μg/g [0.05 ppm] for NNN, less than about 0.10 μg/g [0.10 ppm] for NAT plus NAB, and less than about 0.05 μg/g [0.05 ppm] for NNK." J.A. 13053. Because by 2002 Mr. Brown had retrofitted his barns in accordance with the Peele method, RJR's proffered TSNA data was divided between pre-retrofit data collected in 1996 and1998 and post-retrofit data collected in 2002. *See* J.A. 64018. RJR's data from the 1996 and 1998 pre-retrofit barns does not provide under any reasonable interpreta-

tion clear and convincing evidence that this claim limitation was met. *See*, *e.g.*, J.A. 60670.

One sample from Brown's 1996 crop and seventeen samples from Brown's 1998 crop and were tested for each of the four TSNAs, resulting in sixty-eight individual readings for 1998. J.A. 64009. Thirty-four of the sixty-eight 1998 tests came back with a 0.00 reading, *id.*, which was only explained by RJR as being "below the detection limit" of the test. J.A. 46556, 3438:10-11. The lone 1996 test returned with "ND" or non-detectable readings for each TSNA. J.A. 60670.

Dr. Otten testified that the detection limit was 0.15 ppm. J.A. 46555-56. No reasonable juror could conclude that a series of tests from 1998, less than a year prior to the patents' priority date, let alone one test from 1996, with readings of "ND" or "0.00" can serve as clear and convincing evidence that Brown's curing techniques anticipate the Williams patents, which require TSNA levels below 0.05 ppm or 0.10 ppm, where a "0.00" or "ND" result only provides that the concentration of TSNAs is below the 0.15 ppm detection threshold. Accordingly, this court finds that no reasonable juror could find the Williams patents anticipated.

E. Infringement

The jury returned a special verdict finding that Star did not show infringement of the Williams patents by a preponderance of the evidence. The district court denied Star's motions for JMOL and, in the alternative, a new trial.

To prove infringement, a plaintiff must prove the presence of each and every claim element or its equivalent in the accused method or device. *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1301 (Fed. Cir. 2011). Infringement is a question of fact reviewed for substantial

evidence. *Id.* (citing *Finisar Corp. v. DirecTV Group, Inc.,* 523 F.3d 1323, 1332 (Fed. Cir. 2008)).

Star's expert testimony was dispositive in this case. The record shows that Star presented Dr. Lee as its "primary evidence of infringement[.]" J.A. 36951. In fact, upon the court's threat to conditionally limit or exclude Dr. Lee's testimony, Star conceded that "for all practical cases" there would be no case of infringement. J.A. 36950. Indeed, the district court remarked that the jury "as it most certainly should have, rejected Dr. Lee's opinion altogether." J.A. 52. In fact, the district court indicated that, had the jury not discredited Dr. Lee, the court "would now exclude Dr. Lee's testimony as not meeting the *Daubert* standard." *Id.*

Dr. Otten testified that farmers curing tobacco for RJR did not infringe the Williams patents. Included in his testimony were test results from 200 barns of 57 farmers growing tobacco used by RJR. J.A. 45779, 45868-69. The jury heard Dr. Otten testify that the famers had not substantially prevented anaerobic conditions and Dr. Otten showed them that TSNA levels measured from the farmers' barns were above the levels claimed in the Williams patents. J.A. 46328-29.

The jury is entitled to credit or discredit testimony before it. In this situation, where expert testimony was needed to establish infringement, it was not unreasonable for the jury to discredit the testimony of Star's expert and find that the Williams patents were not infringed. *See Verizon*, 602 F.3d at 1341 (denying motion for JMOL when jury found noninfringement after weighing conflicting expert testimony); *see also Kinetic Concepts, Inc. v. Blue Sky Med. Group, Inc.,* 554 F.3d 1010, 1024 (Fed. Cir. 2009) (finding that a jury can accept the testimony it finds most persuasive). In light of Star's heavy reliance on Dr.

Lee's testimony, this court affirms the district court's denial of Star's motion for JMOL.[1]

Star advances several arguments for a new trial. However, Star's arguments need not be addressed because this court's grant of JMOL of validity moots any alleged errors pertaining to validity. This court notes that correction of any alleged error would not have changed the result in this case because there was substantial untainted evidence before the jury to support a verdict of non-infringement. *See Verizon*, 602 F.3d at 1342 ("We may affirm the jury's findings on infringement if substantial evidence in the record appears in the record supporting the jury's verdict and if correction of alleged errors would not have changed the result given the evidence presented."(citations omitted)). It was not an abuse of discretion for the district court to deny Star's motion for a new trial.

IV.

Accordingly, this court affirms the district court's denial of JMOL on noninfringement and reverses the district court's denial of JMOL on invalidity.

AFFIRMED-IN-PART AND REVERSED-IN-PART

Each party shall bear its own costs.

[1] Because this court affirms the district court's denial of JMOL on the jury verdict of noninfringement, Star's arguments that RJR is liable for direct infringement under 35 U.S.C. § 271(g) are not addressed in this opinion.

United States Court of Appeals for the Federal Circuit

STAR SCIENTIFIC, INC.,
Plaintiff-Appellant,

v.

R.J. REYNOLDS TOBACCO COMPANY (A NORTH CAROLINA CORPORATION) AND R.J. REYNOLDS TOBACCO COMPANY (A NEW JERSEY CORPORATION),
Defendants-Appellees.

2010-1183

Appeal from the United States District Court for the District of Maryland in consolidated case nos. 01-CV-1504 and 02-CV-2504, Senior Judge Marvin J. Garbis.

DYK, *Circuit Judge*, concurring-in-part and dissenting-in-part.

Although I agree with the majority with respect to infringement, I would find the patents-at-issue invalid for indefiniteness, and respectfully dissent from the majority's contrary holding. Because I would hold the patents invalid for indefiniteness, I find it unnecessary to reach any of the other invalidity challenges.

The Patent Act requires that claims "particularly point[ ] out and distinctly claim[ ] the subject matter

which the applicant regards as his invention." 35 U.S.C. § 112. A claim term is not indefinite simply because "it poses a difficult issue of claim construction"; rather, the claims are indefinite "only if reasonable efforts at claim construction prove futile." *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001). In other words, "if reasonable efforts at claim construction result in a definition that does not provide sufficient particularity and clarity to inform skilled artisans of the bounds of the claim, the claim is insolubly ambiguous and invalid for indefiniteness." *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1371 (citing *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249–51 (Fed. Cir. 2008).

Here, the district court construed the term "controlled environment" to mean "controlling one or more of humidity, temperature, and airflow in the curing barn, in a manner different from conventional curing, in order to substantially prevent the formation of TSNAs." *See Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, No. 8:01-cv-0154-MJG, slip op. at 2 (D. Md. Mar. 31, 2004). The majority concludes that "a person of skill in the art of tobacco curing would possess adequate understanding to manipulate these variables to create a controlled environment" because "tobacco curing variables are well known to the tobacco industry." Maj. op. at 16–17.

The majority characterizes the patents as "explain[ing] that 'the controlled conditions described herein [are] according to conventional methods commonly and commercially used in the U.S.'" *Id.* at 16 (quoting '649 patent, col.6 ll.16–18). But that is the opposite of what the patents actually state. The patents state:

> In this disclosure, tobacco that has been "conventionally cured" is tobacco that has been air-

> cured or flue-cured, without the controlled conditions described herein, according to conventional methods commonly and commercially used in the U.S.

'649 patent, col.6 ll.14–18; '401 patent, col.6 ll.19–23. Thus, far from equating the claimed "controlled environment" to conventional curing, the patents make clear that conventional curing is conducted "*without* the controlled conditions described herein." *Id.* (emphasis added).

The specifications elsewhere directly contradict the majority's conclusion, explaining that the claimed "controlled environment" is something different from conventional curing methods. The specifications criticize conventional curing processes on the ground that they "do not provide suitable conditions (e.g., adequate oxygen flow) and fail to prevent an anaerobic condition in the vicinity of the tobacco leaves." '649 patent, col.7 ll.65–67; '401 patent, col.8 ll.2–4. Specifically, the specifications characterize the conventional air curing process as "subjecting the [tobacco] to air curing without controlling the ambient conditions (e.g., air flow through the barn, temperature, humidity, and the like)." '649 patent, col.3 ll.20–24; '401 patent, col.3 ll.24–28. Indeed, the patents teach that "the practice of tobacco curing is more of an art than a science, because curing conditions during any given cure must be adjusted to take into account" many variables. '649 patent, col.6 ll.35–37; '401 patent, col.6 ll.39–41.

To determine whether a claim is invalid for indefiniteness, a court must determine "whether those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986). Expert testimony may be helpful in

making this determination. *See Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1348 (Fed. Cir. 2005) (holding that a court may "rely on extrinsic evidence, such as expert testimony," to determine whether the claims are indefinite) (internal quotation marks and citation omitted); *Seattle Box Co., Inc. v. Indus. Crating & Packing, Inc.*, 731 F.2d 818, 826 (Fed. Cir. 1984) (stating that, in making legal determinations, the court may rely on expert testimony to aid in understanding the patent). Here, R.J. Reynolds' expert testified that a person of ordinary skill in the art would be unable to draw the line between conventional curing methods and the "controlled environment" required by the claims. J.A. 46543–45. Specifically, he noted that one of ordinary skill in the art would understand the "controlled environment" limitation to require the "control [of] humidity, temperature, and airflow in a way that's different from [conventional curing processes], and with the objective and the purpose of substantially preventing the formation of TSNAs." J.A. 46543. He noted, however, that the patents do not provide sufficient guidance for one of skill in the art to determine the ranges of temperature, humidity, and airflow "covered by the [term] controlled environment that are also not covered by the conventional curing processes." J.A. 46545. Further, when pressed on the issue, Star's expert could not provide any guidance regarding the difference between the airflow in a conventional curing process and that required in a "controlled environment," noting that it would be impossible to pinpoint values for the temperature, airflow, and humidity required by the claims because barn conditions are continually changing. J.A. 45680.

In sum, the patents describe the claimed "controlled environment" as something different from conventional curing methods, but fail to explain those differences in a

way that would permit a skilled artisan to determine the bounds of the claims. To add to the confusion, the patents define conventional curing methods as air-curing or flue-curing "without the controlled conditions" required by the claims. Under this court's established test for definiteness, such circularity is insufficient to inform skilled artisans of the bounds of the claims.