

# United States Court of Appeals for the Federal Circuit

2007-1448

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.

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Appealed from: United States District Court for the District of Maryland

Senior Judge Marvin J. Garbis

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Defendants-Appellees.

Appeal from the United States District Court for the District of Maryland in case no. 8:01-cv-1504, Senior Judge Marvin J. Garbis.

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DECIDED: August 25, 2008

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Before MICHEL, Chief Judge, SCHALL and DYK, Circuit Judges.

MICHEL, Chief Judge.

Plaintiff-Appellant Star Scientific, Inc. ("Star") appeals from a final judgment in favor of Defendants-Appellees R.J. Reynolds Tobacco Company (N.C.) and R.J. Reynolds Tobacco Company (N.J.) (collectively, "RJR"). The district court entered memoranda and orders: (1) holding, after a bench trial, that Star's U.S. Patent Nos. 6,202,649 ("the '649 patent") and 6,425,401 ("the '401 patent") are unenforceable due to inequitable conduct; and (2) granting summary judgment of invalidity of all asserted claims of the '649 and '401 patents due to indefiniteness. See Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., No. 8:01-cv-1504, slip op. at 46 (D. Md. June 26, 2007)

("Inequitable Conduct Order"); Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., No. 8:01-cv-1504, slip op. at 12-14 (D. Md. June 22, 2007) ("Indefiniteness Order").

Because the district court's judgment as to inequitable conduct was based on factual findings that we deem clearly erroneous, we reverse the judgment of unenforceability of the '649 and '401 patents. We also reverse the grant of summary judgment as to indefiniteness because we conclude that the claim term at issue, "anaerobic condition," is not indefinite, and we remand for further proceedings on infringement and validity.

## I. BACKGROUND

### A. Tobacco Curing Technology

Fresh tobacco ("green tobacco") must be dried in a process called "curing" before it is suitable for consumption as cigarettes or other such products. Curing is done in curing "barns," and commercial tobacco companies like RJR cure their tobacco in bulk-curing barns in which substantial quantities of harvested tobacco are cured together in large stacks. Smaller operations may use the older and long-used technology of "stick barns" in which much smaller quantities of tobacco are cured.

Four major mechanisms of curing have been used in the United States:

- (1) air curing, where the tobacco is air-dried without the application of heat;
- (2) radiant heat indirect-fired curing ("radiant heat curing"), where fuel (typically oil) is burned and the hot exhaust gases are passed through pipes running through the barn such that the hot pipes radiate heat into the barn to dry the tobacco, but the exhaust gases are then expelled outside the barn;

- (3) direct-fired curing, where fuel (typically propane) is burned and the hot exhaust gases themselves are blown directly into the barn to dry the tobacco; and
- (4) forced air indirect-fired curing, where fuel is burned to heat clean air that is then blown into the barn to dry the tobacco, while the exhaust gases from the fuel burning are expelled outside the barn.

In the 1960s, the primary method used by American tobacco companies was radiant heat curing. By the 1970s, most companies switched to direct-fired curing, which was the predominant method used until at least the late 1990s.

Cured tobacco contains a number of hazardous chemicals, including carcinogens known as tobacco specific nitrosamines ("TSNAs"), which are not present in green tobacco. In the 1990s, researchers began to explore TSNA formation in tobacco and discovered links between TSNAs and direct-fired curing. As a result, some researchers began to investigate how curing methods could be altered to minimize TSNA formation.

#### B. The '649 Patent

In August 1998, Jonnie Williams of Star engaged attorney Romulo Delmendo of Sughrue, Mion, Zinn, Macpeak & Seas ("the Sughrue firm") to prosecute a patent application on a tobacco curing process aimed at lowering TSNA levels. Williams, the inventor, believed that TSNAs were formed due to the presence of microbes on the tobacco leaves. According to this theory, ambient oxygen in the vicinity of the drying leaves is reduced during cure by the production of carbon dioxide as the green tobacco leaves degrade and by the oxygen-poor combustion gases blown in during direct-fired curing. The microbes thus must operate anaerobically and obtain oxygen through

reduction-oxidation reactions involving nitrates also produced from leaf degradation. Those reactions produce nitrites, which in turn form TSNAs through further chemical reactions. Williams' method sought to prevent TSNA formation by lessening the drop in oxygen levels through control of airflow, humidity and temperature inside the curing barn, thereby reducing the microbes' need to resort to anaerobic processes.

As part of the preparation of Williams' patent application, Delmendo was sent a letter on August 28, 1998, by scientist and Star consultant Dr. Harold Burton ("the Burton letter"). Burton wrote to relate his recent observation that Chinese tobacco products contain very low TSNA levels. The Burton letter further stated:

Since China is a developing country, they are still use [sic] the old curing technology that was abandoned in the US during the sixties. It seemed to me that the probable cause for the absence of TSNA was their use of the old [radiant heat] flue-curing techniques.

J.A. at A6237. Delmendo testified that although he was initially concerned about the information, he then spoke with Burton, analyzed the letter, and ultimately concluded that neither it nor its content was material to the contemplated patent application.

Delmendo filed with the United States Patent and Trademark Office ("PTO") a provisional patent application, Application Serial No. 60/100,372 ("the Provisional"), on behalf of Williams on September 15, 1998. The application disclosed that some nations, including China, still utilize radiant heat curing. J.A. at A5808-09. The disclosure also stated: "It has been determined that [the radiant heat] process as applied to tobacco grown in the United States yields tobacco products with high levels of TSNA." Id. at A5809. Williams testified that this statement was based on inferences he drew from information he received from Brown & Williamson, another tobacco

company, indicating that Brazilian tobacco cured using radiant heat techniques resulted in TSNA levels of 2-3 ppm.

Shortly after the Provisional was filed, Williams received samples from two Virginia farms that still used radiant heat curing and forwarded them to Burton for measurements of TSNA content. The first, from the Jennings farm, contained 1.0-1.5 ppm TSNA ("the Jennings data"). The second, from the Curran farm, contained 0.39 ppm ("the Curran data"). Unlike the Jennings data, however, the Curran data was derived from a partially-cured sample; the sample was partially-cured using radiant heat curing, but Williams' associate completed the cure using a microwave prior to Burton's tests.<sup>1</sup> Williams informed Delmendo of the Jennings data over the phone but never showed him the actual data in document form. He did not inform Delmendo of the Curran data. Delmendo testified that he and Williams considered the Jennings data to be relevant but not a significant concern because Williams' method produced a significantly greater reduction in TSNA.<sup>2</sup>

On September 15, 1999, exactly one year after filing the Provisional, Delmendo filed Application Serial No. 09/397,018 ("the '018 application") on behalf of Williams. The '018 application's draft specification adopted most of the Provisional's disclosure but deleted the statement that radiant heat curing of U.S.-grown tobacco produced "high levels of TSNA." Instead, it stated:

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<sup>1</sup> It is undisputed that microwave curing produces vastly lower TSNA levels than any indirect-fired or direct-fired curing process.

<sup>2</sup> According to Delmendo, he understood that direct-fired curing produced TSNA levels exceeding 3.0 ppm, thus the 1.0-1.5 ppm produced by the indirect-fired process on the Jennings farm was "somewhat reduced." J.A. at A219. By contrast, Williams informed Delmendo that his process reduced TSNA levels much further to the 0.1-0.2 ppm range.

In flue curing processes that utilize a heat exchanger capable of providing relatively low airflow through the curing barn, I have discovered that it is possible to somewhat reduce the TSNA levels by not venting combustive exhaust gases into the curing apparatus or barn. The preferred aspects of the present invention are premised on the discovery that other parameters, as identified above (e.g., airflow), can be adjusted to ensure the prevention or reduction of at least one TSNA regardless of the ambient conditions.

'649 patent col.6 ll.22-30 (emphasis added). Delmendo testified that this new disclosure was based on his discussion of the Jennings data with Williams.

Shortly after the filing of the '018 application, Williams and Star elected to terminate the Sughrue attorneys' involvement in the prosecution and replace them with attorneys from Banner & Witcoff ("the Banner firm"), including Paul Rivard and Dale Hoscheit. Hoscheit testified that he met with Delmendo and others from the Sughrue firm to discuss the transfer of files and the status of pending applications. Paul Perito, a partner of the law firm Paul, Hastings, Janofsky & Walker ("Paul Hastings") who became the chairman of Star, tapped Scott Flicker from Paul Hastings to facilitate the transfer of files from the Sughrue firm to the Banner firm. Upon receiving the files, Rivard searched them for prior art but did not notice the Burton letter.

On February 15, 2000, Rivard filed a Petition to Make Special regarding the '018 application, including an Information Disclosure Statement ("IDS") discussing and distinguishing certain prior art. The IDS did not include the Burton letter. The Petition was ultimately granted, and the application was allowed on September 14, 2000, and ultimately issued on March 20, 2001, as the '649 patent.

### C. The '401 Patent and the Present Litigation

On September 25, 2000, on behalf of Williams, Rivard filed Application Serial No. 09/668,144 ("the '144 application"), a continuation of the '018 application. Rivard also

filed a Petition to Make Special for the '144 application with an accompanying IDS listing many of the same references as his earlier IDS for the petition regarding the '018 application. This IDS also did not include the Burton letter.

Star filed the present suit on May 23, 2001, alleging that RJR infringed claims 4, 12 and 20 of the '649 patent. As the litigation proceeded, Rivard periodically filed supplemental IDSs to the '144 application to disclose to the PTO some of the additional prior art raised by RJR against the '649 patent during discovery. For example, on June 12, 2001, Rivard disclosed RJR's Application Serial No. 09/735,177, which was published on April 26, 2001. Rivard also disclosed RJR's interrogatory responses regarding invalidity along with the cited references. These disclosures continued after the '144 application was allowed in January 2002. In April 2002, the issue fee for the '144 application was paid.

In June 2002, while waiting for the '144 application to issue as a patent, Rivard became aware of the Burton letter and Curran data when Star's trial counsel, Crowell & Moring ("Crowell"), informed him that RJR had raised those documents in the litigation. Rivard's initial reaction was that they should be disclosed out of an abundance of caution. Several Crowell attorneys exchanged e-mails amongst themselves discussing whether they thought the Burton letter and/or Curran data was required to be disclosed to the PTO given that the '144 application had yet to be issued; several agreed that it may be best to "err on the side of disclosure." J.A. at A10998-99. Meanwhile, Rivard and Hoscheit at the Banner firm conferred and ultimately decided that the Burton letter and the Curran data were not material and thus did not need to be disclosed to the PTO. They were never disclosed to the PTO. The '144 application thus issued as



expected on July 30, 2002, as the '401 patent. Star immediately moved to amend its complaint to add allegations that RJR was infringing claim 41 of the '401 patent as well.

#### D. Claim Construction, Trial and Summary Judgment

Claim 4 of the '649 patent is representative of all of the asserted claims:

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.

The district court construed three terms relevant to this appeal: "substantially prevent the formation of at least one nitrosamine," "controlled environment," and "anaerobic condition."

The 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  $\mu\text{g/g}$  for NNN, less than about 0.10  $\mu\text{g/g}$  for NAT plus NAG, and less than about 0.05  $\mu\text{g/g}$  for NNK."<sup>3</sup> Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., No. 8:01-cv-1504, slip op. at 2 (D. Md. Mar. 31, 2004) ("Markman Order"). The court then construed "controlled environment" to mean "controlling one or more of humidity, temperature and airflow in the curing barn, in a

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<sup>3</sup> These abbreviations (e.g., NNN, NNK) represent different known TSNAs. These units of measurement, micrograms per gram ( $\mu\text{g/g}$ ), are equivalent to parts per million (ppm).

manner different from conventional curing, in order to substantially prevent the formation of TSNAs." Id. Finally, the court construed "anaerobic condition" to mean "an oxygen deficient condition (such as is created by an atmosphere of combustion gases or from the release of carbon dioxide by the plant during cure) which promotes microbial nitrate reductase activity."<sup>4</sup> Id. at 1-2. These claim constructions are not disputed in this appeal.

The district court held a bench trial on RJR's inequitable conduct defense in January and February of 2005. Star and RJR also filed cross motions for summary judgment on RJR's indefiniteness defense, and RJR filed another summary judgment motion on its anticipation and best mode defenses.

On January 19, 2007, the district court issued its decisions on the parties' summary judgment motions. The court granted RJR's motion for summary judgment that the asserted claims of both patents are invalid for indefiniteness, holding that the term "anaerobic condition" was indefinite. Indefiniteness Order, slip op. at 12-14.<sup>5</sup> The court also denied RJR's motion for summary judgment that the asserted claims are invalid due to anticipation and violations of the best mode requirement, holding that Star raised genuine issues of material fact as to those defenses.<sup>6</sup> Star Scientific, Inc. v. R.J.

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<sup>4</sup> Nitrate reductase is the enzyme used by the microbes on the surface of curing tobacco leaves to catalyze some of the chemical reactions that ultimately produce TSNAs.

<sup>5</sup> The district court replaced its January 19, 2007 opinion regarding indefiniteness with a corrected opinion on June 22, 2007, to rectify a minor clerical error.

<sup>6</sup> The district court purported to grant partial summary judgment to RJR by holding that neither asserted patent could claim priority to the filing date of the Provisional, a predicate to RJR's invalidity arguments. Anticipation Order, slip op. at 16. Star argues that this decision was erroneous and should be reversed. However, this holding is not properly before this court since it did not form the basis of any judgment. Priority date in and of itself is not a claim or defense on which summary judgment can

Reynolds Tobacco Co., No. 8:01-cv-1504, slip op. at 12-15 (D. Md. Jan. 19, 2007) ("Anticipation Order").

On June 26, 2007, the district court issued a decision on RJR's inequitable conduct defense. The court held both of Star's asserted patents unenforceable due to inequitable conduct and entered final judgment in favor of RJR. See Inequitable Conduct Order, slip op. at 46. Star timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

## II. DISCUSSION

### A. Inequitable Conduct

#### 1.

We review the district court's inequitable conduct determination under a two-tier standard; we review the underlying factual determinations for clear error, but we review the ultimate decision as to inequitable conduct for an abuse of discretion. Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1364-65 (Fed. Cir. 2007). If the district court's determination of inequitable conduct is based on a clearly erroneous finding of materiality and/or intent, it constitutes an abuse of discretion and must be reversed. Impax Labs., Inc. v. Aventis Pharms. Inc., 468 F.3d 1366, 1375 (Fed. Cir. 2006). With respect to the '649 patent, we hold that the district court clearly erred in finding that RJR had proven that Williams and Star had an intent to deceive the PTO. With respect to the '401 patent, we hold that the district court clearly erred in finding that the information contained in the Burton letter and Curran data was material.

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be granted, and the district court denied RJR's motion for summary judgment on anticipation and best mode, which RJR does not cross-appeal.

The burden of proving inequitable conduct lies with the accused infringer. Ulead Sys., Inc. v. Lex Computer & Mgmt. Corp., 351 F.3d 1139, 1146 (Fed. Cir. 2003). To successfully prove inequitable conduct, the accused infringer must present "evidence that the applicant (1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive the [PTO]." Cargill, 476 F.3d at 1363 (citing Impax Labs., 468 F.3d at 1374). Further, at least a threshold level of each element—i.e., both materiality and intent to deceive—must be proven by clear and convincing evidence. Id.; Digital Control Inc. v. Charles Mach. Works, 437 F.3d 1309, 1313 (Fed. Cir. 2006). And even if this elevated evidentiary burden is met as to both elements, the district court must still balance the equities to determine whether the applicant's conduct before the PTO was egregious enough to warrant holding the entire patent unenforceable. Monsanto Co. v. Bayer Bioscience B.V., 363 F.3d 1235, 1239 (Fed. Cir. 2004). Thus, even if a threshold level of both materiality and intent to deceive are proven by clear and convincing evidence, the court may still decline to render the patent unenforceable.

The need to strictly enforce the burden of proof and elevated standard of proof in the inequitable conduct context is paramount because the penalty for inequitable conduct is so severe, the loss of the entire patent even where every claim clearly meets every requirement of patentability. This penalty was originally applied only in cases of "fraud on the Patent Office." See Hazel-Atlas Glass Co. v. Hartford-Empire Co., 322 U.S. 238, 250-51 (1944); see also Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945) ("The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent [grants]

spring from backgrounds free from fraud or other inequitable conduct and that such [grants] are kept within their legitimate scope."); Digital Control, 437 F.3d at 1315 (discussing the roots of inequitable conduct in common law fraud). Subsequent case law has broadened the doctrine to encompass misconduct less egregious than fraud, see for example Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1069-70 (Fed. Cir. 1998), but the severity of the penalty has not changed, and thus courts must be vigilant in not permitting the defense to be applied too lightly. Just as it is inequitable to permit a patentee who obtained his patent through deliberate misrepresentations or omissions of material information to enforce the patent against others, it is also inequitable to strike down an entire patent where the patentee only committed minor missteps or acted with minimal culpability or in good faith. As a result, courts must ensure that an accused infringer asserting inequitable conduct has met his burden on materiality and deceptive intent with clear and convincing evidence before exercising its discretion on whether to render a patent unenforceable.

With regard to the deceptive intent prong, we have emphasized that "materiality does not presume intent, which is a separate and essential component of inequitable conduct." GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1274 (Fed. Cir. 2001). Moreover, as we explained in Molins PLC v. Textron, Inc.:

[T]he alleged conduct must not amount merely to the improper performance of, or omission of, an act one ought to have performed. Rather, clear and convincing evidence must prove that an applicant had the specific intent to . . . mislead[] or deceiv[e] the PTO. In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference.

48 F.3d 1172, 1181 (Fed. Cir. 1995) (emphases added). Thus, the fact that information later found material was not disclosed cannot, by itself, satisfy the deceptive intent element of inequitable conduct. M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., 439 F.3d 1335, 1340 (Fed. Cir. 2006). Rather, to prevail on the defense, the accused infringer must prove by clear and convincing evidence that the material information was withheld with the specific intent to deceive the PTO. Id.; see also Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc) (holding even gross negligence insufficient to prove intent to deceive).

We have also held that because direct evidence of deceptive intent is rarely available, such intent can be inferred from indirect and circumstantial evidence. Cargill, 476 F.3d at 1364. But such evidence must still be clear and convincing, and inferences drawn from lesser evidence cannot satisfy the deceptive intent requirement. See Ferring, 437 F.3d at 1186 ("The predicate facts must be proven by clear and convincing evidence."). Further, the inference must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard. Scanner Techs. Corp. v. ICOS Vision Sys. Corp., 528 F.3d 1365, 1376 (Fed. Cir. 2008) ("Whenever evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally reasonable inference.").

With respect to the materiality prong, we have held that "information is material when a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." Symantec Corp. v. Computer Assocs. Int'l, Inc.,

522 F.3d 1279, 1297 (Fed. Cir. 2008); see also Digital Control, Inc. v. Charles Mach. Works, 437 F.3d 1309, 1314 (Fed. Cir. 2006). It is well-established, however, that information is not material if it is cumulative of other information already disclosed to the PTO. Honeywell Int'l Inc. v. Universal Avionics Sys. Corp., 488 F.3d 982, 1000 (Fed. Cir. 2007) ("Information cumulative of other information already before the Patent Office is not material."); 37 C.F.R. § 1.56(b) ("[I]nformation is material to patentability when it is not cumulative to information already of record or being made of record in the application . . . .").

If a threshold level of intent to deceive or materiality is not established by clear and convincing evidence, the district court does not have any discretion to exercise and cannot hold the patent unenforceable regardless of the relative equities or how it might balance them. See Nordberg, Inc. v. Telsmith, Inc., 82 F.3d 394, 398 (Fed. Cir. 1996) (holding that the district court properly refrained from balancing materiality and intent when a threshold showing of intent to deceive was not clearly and convincingly made). Only after adequate showings are made as to both materiality and deceptive intent may the district court look to the equities by weighing the facts underlying those showings. "The more material the omission or the misrepresentation, the lower [the] level of intent [is] required to establish inequitable conduct, and vice versa." Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256 (Fed. Cir. 1997). At this second stage, however, the question is no longer whether materiality and/or intent to deceive were proven with evidence that is sufficiently clear and convincing. While the facts of materiality and intent to deceive must be proven by clear and convincing evidence, the district court must balance the substance of those now-proven facts and all the equities

of the case to determine whether the severe penalty of unenforceability should be imposed. It is this balancing that is committed to the district court's discretion. Molins, 48 F.3d at 1178.

2.

Here, the district court's finding of deceptive intent as to both patents-in-suit was based primarily on its acceptance of RJR's theory that Williams and Star conspired to deliberately prevent Delmendo and his colleagues at the Sughrue firm from disclosing the Burton letter to the PTO by replacing them with the Banner firm and purposely keeping the Banner firm ignorant of the Burton letter. We hold that this "quarantine" theory was not supported by clear and convincing evidence.<sup>7</sup> As a result, we hold that the district court's finding of deceptive intent with regard to the '649 patent was clearly erroneous.<sup>8</sup>

Star's witnesses testified that the reasons behind the replacement of the Sughrue firm were that a key partner passed away and that Williams observed a Sughrue attorney perform unsatisfactorily in an unrelated prosecution. The district court

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<sup>7</sup> The district court also inferred intent to deceive from the statement in the Provisional that prior art radiant heat curing produced high levels of TSNAs in American tobacco. There is no dispute that this statement was inaccurate. While we do not hold that inaccurate statements made in provisional applications cannot evidence an intent to deceive, we note that provisional applications are not examined and that the alleged misrepresentation here was corrected prior to examination of the non-provisional applications. As such, we hold that this statement is not clear and convincing evidence of deceptive intent.

<sup>8</sup> Thus, we need not address whether the district court's finding of materiality as to the '649 patent was clearly erroneous. Regarding the '401 patent, the district court's finding of deceptive intent was in part based on additional evidence concerning events following the issuance of the '649 patent. As explained further below, we need not decide whether that deceptive intent finding was also clearly erroneous because we find the district court's finding of materiality as to the '401 patent clearly erroneous.



indicated that it viewed this testimony as not credible and that this credibility determination was a major basis for its finding of deceptive intent. Certainly, credibility determinations are an aspect of fact-finding that appellate courts should rarely reverse. But even if Star's explanations are not to be believed, it remained RJR's burden to prove its allegation regarding the reason for the Sughrue firm's dismissal. RJR cannot carry its burden simply because Star failed to prove a credible alternative explanation. See M. Eagles Tool Warehouse, 439 F.3d at 1341 ("When the absence of a good faith explanation is the only evidence of intent, however, that evidence alone does not constitute clear and convincing evidence warranting an inference of intent."). The patentee need not offer any good faith explanation unless the accused infringer first carried his burden to prove a threshold level of intent to deceive by clear and convincing evidence. Nordberg, 82 F.3d at 398. Only when the accused infringer has met this burden is it incumbent upon the patentee to rebut the evidence of deceptive intent with a good faith explanation for the alleged misconduct. See id.

In reviewing the affirmative evidence, it becomes clear that RJR's evidence had a major gap—RJR failed to elicit any testimony or submit any other evidence indicating that Star knew what the Burton letter said prior to replacing the Sughrue firm, or that the letter was a reason for changing firms. RJR admitted at oral argument that it failed to even ask Williams or Star's other executives about these critical facts, and RJR failed to identify any testimony or other evidence when specifically asked by us to do so in supplemental briefing. Further, a review of the record shows that Williams actually testified, in response to a different question, that he had never seen the Burton letter prior to his deposition in the present litigation. This statement was never impeached,

questioned, or explored by RJR's counsel. RJR identified Perito, Star's chairman, as the officer who made the decision to terminate the Sughrue firm, but Perito was never asked whether he had knowledge of the Burton letter or whether it played any role in his decision to change firms. As noted earlier, the district court may infer facts supporting an intent to deceive from indirect evidence. Cargill, 476 F.3d at 1364. But no inference can be drawn if there is no evidence, direct or indirect, that can support the inference. RJR's lack of any evidence at all on the crux of its theory, let alone clear and convincing evidence, demonstrates that it failed to carry its burden.

Other facts and inferences relied on by the district court do not plug this hole in RJR's evidence. First, the district court found that Delmendo had concerns about whether the information in the Burton letter should be disclosed to the PTO, the suggested inference being that Star would have been motivated to replace him to ensure he did not disclose the letter to the PTO. Indeed, both Delmendo's testimony and his written notes provide evidence supporting the finding that he had such concerns. However, he was not asked whether he ever expressed those concerns to Williams or anyone else at Star. No Star witness was asked whether Delmendo expressed his concerns to them either. This record cannot support an inference that Star was motivated to replace Delmendo due to his concerns about the Burton letter since there is no evidence, let alone clear and convincing evidence, that Star even knew about the letter or his concerns. Again, RJR failed to carry its burden of proof.

Second, the district court also found that Perito's use of an intermediary, Flicker of Paul Hastings, to facilitate the transfer of files from the Sughrue firm to the Banner firm evidenced an intent to prevent any communication between the firms. The

inference drawn, therefore, was that Star was deliberately insulating the Banner lawyers from the Sughrue lawyers to prevent the former from learning of Delmendo's concerns regarding the Burton letter. But RJR's failure to adduce any evidence that Star knew of Delmendo's concerns or the Burton letter's contents renders this inference clearly erroneous as well. Moreover, Hoscheit of the Banner firm specifically testified that he did meet with the Sughrue attorneys, and the district court did not indicate that it found this testimony or Hoscheit in general to not be credible. In fact, it did not address this testimony at all. Furthermore, the district court rejected RJR's allegation that the Sughrue files, and the Burton letter in particular, were tampered with before being conveyed to the Banner firm. Thus, the Banner firm was clearly given the Burton letter. Yet again, RJR failed to provide clear and convincing evidence to support its allegations.

We also question the district court's reliance on the admitted fact that Star never instructed Rivard or his colleagues at the Banner firm to disclose the Burton letter, nor specifically brought it to their attention prior to June 2002. As already noted, RJR failed to provide evidence that Star knew anything about the Burton letter's contents or that the letter raised any concerns relevant to the prosecution of its patents. Thus, the evidence does not support an inference that Star's failure to bring the Burton letter to the Banner firm's attention was motivated by a deceptive intent to keep it from the examiner. And there is no evidence indicating that Williams, Star or their attorneys at the Banner firm became aware of the Burton letter before June 2002, well after the '649 patent issued in March 20, 2001. Given the heavy reliance by the district court on the Burton letter and RJR's "quarantine" theory, the numerous evidentiary failings relating to

this theory gives us a "definite and firm conviction" that the resulting finding of deceptive intent as to the '649 patent was clearly erroneous.<sup>9</sup> See Molins, 48 F.3d at 1178.

3.

Because the district court's finding of deceptive intent as to the '401 patent was also heavily based on RJR's "quarantine" theory, that finding is also weakened by the failings in that theory. But the district court also relied on additional evidence to find inequitable conduct as to the '401 patent. As Star concedes, its attorneys at the Banner firm were made aware of the Burton letter and Curran data in June 2002, at which time the '401 patent had not yet been issued.<sup>10</sup> Although Star had the opportunity to disclose them at that time, it did not disclose either document to the PTO. While the district court's finding of deceptive intent even with regard to this additional evidence may be flawed in some respects, we reverse the holding of inequitable conduct as to the '401 patent because the district court's finding of materiality was clearly erroneous.

The district court found that the Burton letter and Curran data disclosed "the essential fact that the prior art could yield low TSNA tobacco at least some of the time," and that this fact was "manifestly material." Inequitable Conduct Order, slip op. at 41-42. However, in the course of the prosecution of the '401 patent, Star disclosed to the PTO other references that made this information contained in the Burton letter and

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<sup>9</sup> To the extent the district court also relied on the non-disclosure of the Curran data, we note that even the district court acknowledged that the materiality of the Curran data was questionable given that the Curran tobacco was partially cured using a microwave.

<sup>10</sup> It is clear that the events in June 2002 and the events that followed cannot render the '649 patent unenforceable due to inequitable conduct because the '649 patent had already issued.

Curran data clearly cumulative.<sup>11</sup> Star points to the disclosure of several references, including RJR's interrogatory responses from this litigation and the language of the '401 patent's specification.

The '401 patent's specification, like the '649 patent's specification, states:

In flue curing processes that utilize a heat exchanger capable of providing relatively low airflow through the curing barn, I have discovered that it is possible to somewhat reduce the TSNA levels by not venting combusive exhaust gases into the curing apparatus or barn.

'401 patent, col.6 ll.27-31 (emphasis added). Thus, the specification points out that "somewhat reduce[d]" levels of TSNA were previously attainable. This alone may not render cumulative the Burton letter's disclosure that low to undetectable levels of TSNA were previously unattainable, but another disclosure fills this gap.

In particular, Star disclosed RJR's interrogatory responses produced during the '649 patent infringement litigation. Of particular relevance is interrogatory question number 1:

Describe in detail all research, field tests or other studies that you or others on your behalf have conducted, sponsored, or participated in regarding TSNA formation and/or reduction (including, without limitation, work conducted in Greece, Turkey or North Carolina), including the results of such research, test or study, and any documents concerning such research, test or study.

J.A. at 6303. RJR's response to that interrogatory provided that: "Reynolds recognized in or about 1994 that tobacco (whether flue-cured or burley) cured in the indirect fired barns had significantly reduced levels of TSNAs as compared to the commercial direct-fired, bulk curing barns at Reynolds' Avoca facility." J.A. at 6305 (emphasis added).

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<sup>11</sup> These disclosures were made after the '649 patent was issued, thus our analysis of materiality here applies only to the '401 patent. As already discussed, we reverse the holding of inequitable conduct as to the '649 patent due to the clearly erroneous finding of deceptive intent with regard to that patent.

Also, "[b]y about 1997, Reynolds recognized that it was the absence of combustion exhaust gases in the indirect fired barns that was responsible for the significantly reduced TSNA levels obtained in flue-cured tobacco cured in those barns." Id. (emphasis added). "Reynolds then confirmed that tobacco cured in existing commercial, indirect-fired, bulk curing barns also contained significantly reduced levels of TSNAs as compared to tobacco cured in the commercial, gas-fired, bulk curing barns." J.A. at 6305-06 (emphasis added). The interrogatory response also provided a specific example: "Data collected in 1996 from tobacco cured in one of Hassell Brown's indirect fired barns, which was heated with a heat exchanger, revealed that flue-cured tobacco cured in this barn had undetectable levels of TSNAs." J.A. at 6306 (emphasis added).

We conclude that this interrogatory response, which Star disclosed to the PTO, contained the critical information that the prior art had achieved low to insignificant levels of TSNA, and that the information contained in the Burton letter and in the Curran data would therefore have been cumulative in the '401 prosecution by the time the Banner lawyers were made aware of them in June 2002. Because cumulative information is not material, we hold that the district court clearly erred in finding that the information contained in the Burton letter and in the Curran data was material to the prosecution of the '401 patent. Under these circumstances, the finding of inequitable conduct with respect to the '401 patent must also be set aside. Therefore, we reverse the judgment of unenforceability of both the '649 and '401 patents.

## B. Indefiniteness

Though we reverse the district court's holding of inequitable conduct, its judgment of no liability for infringement may still be affirmed if we uphold the district court's grant of summary judgment as to claim indefiniteness because it covered all asserted claims of both patents. We review both a district court's grant of summary judgment and a holding of claim indefiniteness de novo. Datamize, LLC v. Plumtree Software, Inc., 417 F.3d 1342, 1347 (Fed. Cir. 2005). The district court held that the term "anaerobic condition" is indefinite and thus, since it appears in every asserted independent claim, held that all asserted claims are invalid as indefinite. Indefiniteness Order, slip op. at 12-14. However, because the claim term "anaerobic condition" is not indefinite, we also reverse the grant of summary judgment.

The requirement of claim definiteness is set forth in 35 U.S.C. § 112, ¶ 2, which requires claims "particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." We have held that "[o]nly claims not amenable to construction or insolubly ambiguous are indefinite." Datamize, 417 F.3d at 1347 (citations omitted). A claim term is not indefinite just because "it poses a difficult issue of claim construction." Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001). Rather, the standard is whether "the claims [are] amenable to construction, however difficult that task may be." Id. "By finding claims indefinite only if reasonable efforts at claim construction prove futile, we accord respect to the statutory presumption of patent validity . . . ." Id.

The parties do not dispute the claim constructions reached by the district court, and the district court did construe all terms relevant to this appeal. In and of itself, a

reduction of the meaning of a claim term into words is not dispositive of whether the term is definite. Halliburton Energy Serv., Inc. v. M-I LLC, 514 F.3d 1244, 1251 (Fed. Cir. 2008). And 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. See id. at 1249-51.

The district court construed the term "anaerobic condition" to mean "an oxygen deficient condition (such as is created by an atmosphere of combustion gases or from the release of carbon dioxide by the plant during cure) which promotes microbial nitrate reductase activity." Markman Order, slip op. at 1-2. Thus, a skilled artisan would know that the claim term contemplates only conditions where the dearth of oxygen promotes the activity of the nitrate reductase enzyme. It is undisputed that those of ordinary skill would understand from the patents' specifications that the significance of nitrate reductase activity to the claimed invention is that it produces nitrites, which then form TSNA's. See '649 patent col.7 ll.39-55; '401 patent col.7 ll.43-59. Therefore, from the claim term "anaerobic condition" and the intrinsic record, a skilled artisan would discern that the term delineates those conditions where the shortage of oxygen results in increased TSNA formation. This is further supported by statements to that effect in the patents' specifications. See, e.g., '649 patent col.4 ll.36-39 ("For example, it is postulated that if the conditions [contemplated for the present invention] are made aerobic, the microbes will consume oxygen in the atmosphere for their energy source, and therefore no nitrites will form.").



We have stated that "[w]hen a word of degree is used . . . the patent's specification [must] provide[] some standard for measuring that degree" to be definite. Datamize, 417 F.3d at 1351 (quoting Seattle Box Co. v. Indus. Crating & Packing, Inc., 731 F.2d 818, 826 (Fed. Cir. 1984)). Here, the term "anaerobic condition" is in effect a term of degree because its bounds depend on the degree of oxygen deficiency. And as the district court determined in its claim construction, the intrinsic record provides a standard for measuring that degree and assessing the bounds of "anaerobic condition" as required by Datamize, namely the level of TSNA formation. In fact, the claims explicitly refer to the standard, requiring that the tobacco be cured in a "controlled environment" that prevents an "anaerobic condition" in order to "substantially prevent the formation of at least one nitrosamine." See '649 patent cl.4.

The district court further determined that TSNA formation is itself a well-defined standard as disclosed by the asserted patents. It construed the term "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  $\mu\text{g/g}$  for NNN, less than about 0.10  $\mu\text{g/g}$  for NAT plus NAG, and less than about 0.05  $\mu\text{g/g}$  for NNK." Markman Order, slip op. at 2. In other words, the district court was able to discern from the intrinsic record that TSNA formation, as contemplated by the asserted patents, is tied to highly specific measurements of four very specific chemical compounds. Far from being insolubly ambiguous, a skilled artisan could determine whether an "anaerobic condition" was present—or, rather, was prevented—simply by measuring the levels of NNN, NAT, NAG, and NNK.

The district court's contrary conclusion was based on its misunderstanding that claim definiteness requires that a potential infringer be able to determine if a process infringes before practicing the claimed process.<sup>12</sup> But we disclaimed any such approach in Invitrogen Corp. v. Biocrest Manufacturing, L.P., 424 F.3d 1374, 1384 (Fed. Cir. 2005). We explained that Stratagene, in making a similar argument, was "really talking about the difficulty of avoiding infringement, not indefiniteness of the claim." Id. "The test for indefiniteness does not depend on a potential infringer's ability to ascertain the nature of its own accused product to determine infringement, but instead on whether the claim delineates to a skilled artisan the bounds of the invention." Id. (citing SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1341 (Fed. Cir. 2005)); see also Datamize, 417 F.2d at 1354 (holding that "indefiniteness does not depend on the difficulty experienced by a particular person in comparing the claims with the prior art or the claims with allegedly infringing products or acts"). As construed by the district court, the term "anaerobic condition" clearly delineates the bounds of claim scope and thus is not indefinite. The district court's grant of summary judgment of indefiniteness must therefore be reversed.

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<sup>12</sup> The district court misunderstood our decision in Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1383-84 (Fed. Cir. 2003). There, we rejected a proposed construction that, if adopted, would have rendered the term indefinite because a given composition could both infringe and not infringe simultaneously. We did not hold the claim term at issue to be indefinite; in fact, after rejecting that proposed construction, we arrived at the correct construction which did not render the term indefinite. Id. at 1384. And while we emphasized that a claim is indefinite if a skilled artisan cannot determine if an accused product infringes or not, we did not hold that the infringement determination must be able to be made at any particular time.

## CONCLUSION

For the reasons provided above, we reverse the district court's judgment of unenforceability of both asserted patents due to inequitable conduct. We also reverse the district court's grant of summary judgment of invalidity of all asserted claims due to indefiniteness and remand for further proceedings on the infringement complaint consistent with this opinion.

REVERSED and REMANDED