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**IN THE  
UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT**

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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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**Appeal from the United States District Court  
for the District of Maryland, Northern Division  
Case No. 01-CV-1504 (Consolidated with 02-CV-2504)  
Judge Marvin J. Garbis**

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**PLAINTIFF-APPELLANT STAR SCIENTIFIC, INC.'S REPLY BRIEF**

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December 21, 2007

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## CERTIFICATE OF INTEREST

Counsel for Appellant Star Scientific, Inc. certifies the following:

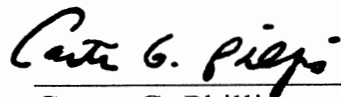
1. The full name of the party represented by me is Star Scientific, Inc.
2. The name of the real party in interest represented by me is Star Scientific, Inc.
3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by me are:

Not applicable.

4. The names of all law firms and the partners or associates that appeared for any of the parties represented by me in the trial court or are expected to appear in this Court are:

Crowell & Moring LLP (Richard McMillan, Jr.; Clifton S. Elgarten; Kathryn D. Kirmayer; Mark M. Supko; Jonathan H. Pittman; Michael I. Coe); Sidley Austin LLP (Carter G. Phillips, Eric A. Shumsky, Peter S. Choi).

Respectfully submitted,



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## REPLY BRIEF

### I. RJR HAS NOT SHOWN INEQUITABLE CONDUCT BY CLEAR AND CONVINCING EVIDENCE.

The district court's inequitable-conduct ruling is flawed as a matter of law because the court repeatedly ignored evidence. That was contrary to this Court's clear command that in evaluating inequitable conduct, the trial court must consider all the evidence, especially of good faith. The court also made basic errors regarding the evidence. RJR does not dispute that it bears a heavy burden in proving inequitable conduct. Star Br. 24-26. Instead, its basic response is a plea for deference. It repeatedly asserts that the judge heard testimony and determined credibility, *e.g.*, RJR Br. 1, that this Court may not "reweigh" evidence and, most pointedly, warns that this Court should not "step outside its appellate role," *id.* at 58.

The issue here, however, is not "mak[ing] new credibility determinations" or "adopt[ing] [one] version of the facts." RJR Br. 42. *Of course* this Court cannot reweigh evidence or reassess credibility. The court below, however, engaged in unfounded speculation that finds *no* support in the record – on issues such as the supposed file-transfer conspiracy, the so-called "quarantine," and the pressure purportedly applied to the Banner firm. No one testified to these events, so the court made no credibility findings, and no documents reference them; rather, the court's findings reflect unsupported conjecture. Moreover, the court made findings that

ignored or are directly contradicted by the evidence. The court ignored Delmendo's discussions with Burton, which made clear to Delmendo that the speculation evident on the face of Burton's letter rendered it unreliable for patent-examination purposes. The court ignored Delmendo's incorporation of the Jennings data into the non-provisional application. The court ignored the fact that the provisional application was not examined. The court ignored the fact that the Burton letter was in fact transferred to the Banner firm, which forecloses any speculation of a conspiracy to prevent Banner from learning about it. The court disregarded the undisputed evidence that Star's patent firms met. The court erroneously held that the Banner firm had *not* submitted to the PTO precisely the sort of information that it did in fact submit. And the court ignored, with neither explanation nor discussion, Hoscheit and Rivard's perfectly reasonable explanations for their actions.

Such "factfinding" merits no deference. And, in any event, "[u]nfounded speculation" does not constitute clear and convincing evidence, *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1571 (Fed. Cir. 1997), nor obviously do conclusions that ignore or misstate the record. Even if the court had made adverse credibility findings – rather than simply ignore the evidence – this also "does not constitute clear and convincing evidence." *Bose Corp. v. Consumers Union of U.S., Inc.*, 466 U.S. 485, 512-13 (1984) ("[n]ormally discredited testimony is not

considered a sufficient basis for drawing a contrary conclusion”). These basic principles hold especially true for inequitable conduct, where the court must “weigh all the evidence” of intent to deceive. *Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F.3d 1380, 1383-84 (Fed. Cir. 1998). Withholding information does not prove intent to deceive so long as there was even a “plausible” explanation for so doing, Star Br. 43-44 (citing cases), and here, the district court failed to consider, much less pass upon, thorough and reasonable explanations offered by multiple attorneys. Four respected law firms did not throw their reputations to the wind for Star Scientific, and the contrary finding below cannot be sustained.

#### **A. Materiality**

RJR bore the burden at trial of demonstrating by clear and convincing evidence that Star withheld “material” information from the examiner. Star Br. 25 & n.4 (citing cases). We have demonstrated (at 26-39) why none of the non-disclosed information was material – and certainly not clearly and convincingly so. RJR’s brief in no way undermines that showing.

##### **1. The Burton Letter**

This letter (A6237) is the linchpin of Judge Garbis’s decision, who believed it showed that Burton “knew” low TSNA’s could be achieved in the United States. Burton, however, testified to the contrary. A351(761:6-23). RJR argues (at 29)

that the letter “is the only document that connects keeping combustion exhaust gases out of the curing environment with avoiding an ‘anaerobic’ condition.” But this connection was expressly disclosed in the patents (A5840(7:56-8:7),A6016(7:60-8:11)), and RJR’s argument reflects its persistent misunderstanding of the invention, which is not simply the use of indirect heat to cure tobacco. The invention solves the problem that curing large batches of tightly packed tobacco results in anaerobic conditions around the leaves and promotes the growth of TSNA-producing bacteria. Prior art curing methods that did not use combustion exhaust gases (*i.e.*, indirect methods and air-curing) may have avoided one cause of anaerobic conditions, but did not require sufficient airflow through the tobacco to prevent anaerobic conditions consistently and substantially. The Williams invention for the first time addressed this problem. Star Br. 5-7,17-18.

The Burton letter was properly not disclosed because it concerned results obtained in a foreign country using a foreign strain of tobacco not common to the United States, using a different curing method than the patents-in-suit.<sup>1</sup> It did not offer – and Burton testified that he never intended to offer (A351(761:15-23)) – an opinion on TSNA levels produced in the United States, with U.S. tobaccos, using long-abandoned curing methods that he never had seen. A523(8:23-

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<sup>1</sup> At a minimum, this was the considered judgment of those who decided disclosure was not required, which negates intent. Star Br. 27-30; *infra* at 7-10,13-14,16-19.

9:20),A533(23:13-23),A537-538(68:20-70:17). The patents recognize that there were processes known in the art for reducing TSNA's from cured tobacco, such as Williams' own microwaving process, (A5837(2:48-53),A5838(3:57-61)), but they disclaimed the Chinese methods as different from the unique curing process that Williams invented and claimed in his patent applications (A5837-5838(2:53-3:3),A6013-6014(2:57-3:7)), and properly did not report Burton's further speculations.

That the letter was a collection of Burton's surmises and assumptions was confirmed by Burton in conversations with Delmendo. A216(82:22-83:3),A217(86:6-12),A226(122:18-124:15). The district court manifestly erred in ignoring Delmendo's inquiries of Burton, and especially in interpreting the letter inconsistent with those discussions and the letter's plain words. The Burton letter *never even mentions airflow*, the key aspect of the invention, and the record confirms that eliminating combustion exhaust gases – the focus of Burton's surmise – does not reliably produce low TSNA's. A6240,A6241-6243,A6269-6275,A6276-6277,A6278-6289.<sup>2</sup> And, contrary to the district court's findings, the fact that traditional curing methods that did *not* rely on controlled airflow could *on occasion* achieve low TSNA's was reported in the patent and to the PTO. A5837(2:48-

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<sup>2</sup> That such gases can create an anaerobic condition is disclosed in the patents, A5840(7:56-58), contrary to RJR's assertion (at 29) that only Burton made this disclosure.

53),A6013(2:53-56); *see also* A5834-5835,A6301-6328,A6329-6358,A6900-6907,A6997-7003.<sup>3</sup>

## 2. The Provisional Application

Next, RJR suggests (at 12-14) that the provisional application contained a misstatement. This contention appears only in the factual recitation, is bolstered by no legal argument whatsoever, and in any event is wrong. *See* Star Br. 30-35. Jonnie Williams told Delmendo that the techniques reflected in the Burton letter would result in high TSNAs if applied to U.S. tobacco, and he based this inference on: (1) information about comparable Brazilian tobacco; (2) information derived from one of RJR's competitors, Brown & Williamson; and (3) his understanding that the lack of airflow would lead to high TSNAs, A226(124:7-13),A287-289(418:13-423:17).<sup>4</sup>

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<sup>3</sup> Presumably to rescue this argument, RJR tries (at 8-9) to redirect the focus to the fact that patent claims are directed at a "plant." This is a canard. The district court made no reference to this issue, and all parties and the court consistently measured the evidence on the basis of the curing-barn environment to which the invention is directed. The claims refer to "a" plant, which this Court repeatedly has recognized to mean "one or more." *E.g., Scanner Tech. Corp. v. ICOS Vision Sys. Corp., N.V.*, 365 F.3d 1299, 1304 (Fed. Cir. 2004). This in context refers to a curing barn of tobacco, which is what the specification repeatedly reflects, A5834-5847,A6007-6024, and where the process is directed at more than one plant.

<sup>4</sup> Williams' determination that TSNAs measured in Brazil at 2-3 ppm are indicative of "high" U.S. levels was consistent with the fact that Brazilian tobacco (unlike Chinese tobacco) was similar to U.S. tobacco and (unlike Chinese tobacco) is cured for U.S. tobacco producers. A288(419:13-420:12),A288-289(422:10-423:12). Moreover, the upper range of 3 ppm was close to the 3.14 ppm that Williams had measured for direct-fired curing, and within the specified 0.36 ppm mar-

What is critical here is that Williams and Delmendo both explained the reasoned basis for their determination. A217(87:6-23),A226(124:4-15),A291(433:8-434:16); Star Br. 31-32. RJR does not rebut this undisputed testimony, nor could it; it simply disagrees with the witnesses' conclusions. For its part, the district court simply ignored this testimony. It stated (at A22) that the provisional should have disclosed the Jennings and Currin data – which was impossible because Williams did not obtain those data until after the provisional was filed, A291-292(434:3-435:20).

Just as important, the supposedly inaccurate statement is found only in the provisional application – it was *not* included in the final application – and therefore was never subject to examination. Star Br. 31. The essence of the materiality requirement is importance to the *examination* process, but provisional applications are not examined. 35 U.S.C. § 111(b)(8); MPEP § 201.04(b). RJR offers no rejoinder, other than – again – bare assertion, and does not explain how a statement not subject to examination can be deemed material to the patentability of a later-claimed invention.

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gin of error (*see* Comparative Example 5 (A5846,A6022)) for that measurement. Delmendo confirmed the pertinent statement with Burton before submitting the provisional. A217(87:6-23),A218(91:20-92:2),A226(124:4-15).

### 3. The Non-Provisional Application

RJR's remaining argument about inequitable conduct in the non-provisional application centers on the Jennings and Currin samples.

The Currin sample merits little discussion. It was adulterated. Star Br. 12, 35-36. Its unreliability was confirmed by two witnesses – Williams (A291-292(434:17-435:10),A294(443:6-444:3),A303(538:7-10)) and Jones (A352(766:22-767:24)) – contemporaneously corroborated in writing (A10641, Entry No. 16; A294(443:22-444:3)), and perfectly plain. Inventors obviously need not submit corrupted results or unreliable measurements to the PTO. Star Br. 25 & n.4 (citing cases). RJR's only response (at 48) is to call Williams' reason for non-disclosure a "fabricated rationalization[]." This hardly passes as argument, finds no support in the district court opinion, and is flatly contradicted by the record.<sup>5</sup>

The Jennings data were not withheld. Delmendo disclosed in the non-provisional what was inferable from Jennings. Star Br. 12-13, 33-35; A5839(6:23-31),A6015(6:27-35); *see also* A217(87:24-88:7),A219(95:18-96:13),A292(436:25-437:14). RJR argues (at 17-18) that the phrase "I have discovered" in the non-provisional (A5839(6:22-26)) means that Williams was referring to his *own* work,

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<sup>5</sup> RJR's reliance (at 48) on testimony that the lamina was "more or less cured," A337(706:14-22), ignores the undisputed facts that most TSNAs form after this point during the stem-drying phase of curing, A385-386(929:19-930:14),A360(798:12-799:14), and that the sample was microwaved before testing, A352(767:1-8),A361(800:8-10).

not to Jennings. But Delmendo's unrebutted testimony is that this statement referred to the prior art, and in particular TSNA reduction from 3 ppm to 1.5 ppm (A225(117:11-118:22)) – which is precisely the result Jennings showed (A292(437:6-14)),A22. Moreover, it is clear from context that the non-provisional was referring to the prior art. The Detailed Description of the Invention discusses prior art and contrasts it with the invention. *E.g.*, A5839(5:66-6:34). The relevant disclosure thus refers to what Williams had discovered from the Jennings sample – that TSNA's can be “somewhat reduced” simply by eliminating exhaust gases, as was done in the prior art.<sup>6</sup>

This is a complete response to the unsupported suggestion that Delmendo had a lingering “prior art concern” that was left unresolved (or, more nefariously, that led Star to switch counsel). Delmendo testified at trial about what his concern had been and how he resolved it, A219(94:24-96:13),A225(117:11-118:22), by providing this disclosure in the patent, A5839(6:23-31),A6015(6:27-35). The suggestion that some “lingering concern” led to Sughrue's termination is pure fabrication, and irreconcilable with the uncontroverted testimony about the reasons for the change in law firms, *see* Star Br. 42-43; A314(582:8-24).

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<sup>6</sup> RJR (at 18) criticizes the use of the term “somewhat reduced,” seemingly on the theory that a reduction from 3 ppm to 1.5 ppm is more than “somewhat.” Williams had measured his invention as reducing prior art levels by more than 90%, and the Jennings result at the rough median of these figures was reasonably described as “somewhat reduced.”

#### 4. The “Critical Fact,” and Counsel’s Statements About It

The patents-in-suit recite that “traditional curing” at times reported results as low as 0.2 ppm. A5837(2:48-52),A6013(2:52-56). As discovery in the litigation proceeded, additional information came to light that low TSNAs could sometimes, randomly and unpredictably, be obtained through older forms of indirect curing. *E.g.*, A6993-6994,A6900-6097,A6301-6328,A6329-6358,A6997-7003. Representative data were submitted to the PTO. *Id.*; Star Br. 38-39. (The district court’s contrary conclusion, A16-17,A42-43, is wholly unsupported, *see* Star Br. 15.) At the time they were submitted, such occasional results were understood not to demonstrate the inherency of the particular method claimed by Williams, but rather represented the accidental by-product of natural uncertainty in prior art curing processes. A422(1109:6-21).

Star’s counsel confirmed this understanding at trial: “[E]veryone involved on the patent side had the belief that, in an uncontrolled environment, it’s the very nature of an uncontrolled environment, that you can get it in some uncontrolled way. You can get uncontrolled results in some uncertain [way].” A422(1109:15-19); *see* Star Br. 36-37. RJR turns this statement on its head, arguing it means that “everyone knew” that prior art indirect-curing processes inherently achieved low to undetectable TSNAs. This reading is utterly unsupported by the transcript, or by anything else in the record. In fact, RJR’s own analysis – which Star submitted to

the PTO, A6900-6907 – demonstrated typical levels in the range of the Jennings sample,<sup>7</sup> and only occasional and accidental occurrences below that range.<sup>8</sup>

## 5. RJR's New Theories

RJR additionally advances several new theories. Each is mistaken.

*First*, RJR recounts the history of the district court's crime-fraud ruling (at 4-8), ostensibly to show that other judges agreed with Judge Garbis. But a crime-fraud ruling by its nature is different than an inequitable-conduct finding; the former addresses only whether there is prima-facie evidence of an issue to which privileged documents are relevant to allow the use of those documents at trial, while the latter reaches the merits of inequitable conduct once those documents and other evidence are considered. And, it simply is not correct that the judges have been unanimous in their rulings. Magistrate Judge Day thought the Burton letter relevant to *inventorship*, A82 (as had RJR, *see* Star Br. 28 n.7). Judge Williams confirmed Special Master Hampton's finding that "the Burton letter cannot

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<sup>7</sup> The overwhelming evidence – including presentations to RJR's own CEO – confirmed that indirect-fired bulk curing typically achieved TSNAs of 1-2 ppm, an order of magnitude above Williams' invention. A6278-6289, A485-486(317:13-321:15).

<sup>8</sup> The existence of these accidental occurrences was gradually discovered during the litigation from RJR productions. *E.g.*, A6306. RJR suggests (at 14) that Delmendo knew earlier, but the cited Delmendo testimony clearly refers to the Jennings result of 1.5 ppm. A219(94:15-96:13), A221(103:6-9). RJR's current assertion (at 54) that "Williams and his lawyers knew that prior art processes could achieve low to undetectable TSNAs" is supported by no citation, and in any event the patents disclose a 0.2 ppm result reported in the art, *see supra* at 10, *infra* at 12.

support a finding of anticipation,” A713 n.16; *see also* A746, and rejected outright any suggestion of an intent to deceive the PTO, specifically finding that “RJR ... did not present any such evidence of a ‘calculated intent to deceive’ by Star or anyone representing it during the prosecution of the patents-in-suit.” A733,A3132-3133(order adopting report and recommendation). In short, Judge Garbis found the Burton letter material based on an interpretation embraced by no other judge.

*Second*, RJR argues that Star misrepresented certain prior art in “petitions to make special” filed with the ‘649 and ‘401 applications. RJR Br. 22-24,27-28. RJR concedes (at 23) that Star’s statements about indirect bulk-curing methods are “literally true,” yet argues that Star’s statements are “inconsistent” with what was known about such processes, namely that they can produce reduced TSNA<sup>9</sup>. That a reduction could be achieved by other methods, however, is disclosed on the face of the patents, as are the facts that indirect bulk-curing “somewhat reduces” TSNA<sup>9</sup>, and that “traditional curing” was occasionally reported to have produced TSNA levels as low as 0.2 ppm. A5839(6:23-31),A6015(6:27-35). RJR also claims (at 22-23, 27-28) that Star misrepresented the Moore, Wilson and Azumano references in Information Disclosure Statements (“IDS”). However, as Rivard testified, he correctly and accurately described these references, and there is nothing

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<sup>9</sup> RJR cites an article from Rivard’s files that shows TSNA reduction from 5-7 ppm to 0.15 ppm. RJR Br. 23. Rivard explained, however, that these results reflected the practice of the invention, not prior art. A248(259:11-261:9).

in the record to suggest otherwise. A230-231(140:18-143:9),A236-237(164:8-167:6),A246(251:1-254:9),A255(289:2-290:16); *see also* A395(966:20-24),A395(967:9-969:3).

*Third*, RJR cites (at 23-24) miscellaneous articles and documents found in Rivard's files. As Rivard testified, the information in these documents was irrelevant or cumulative to what already had been disclosed. A247-A248(255:24-261:23). Much of it related to events well after the application had been submitted, or summarized implementations of new curing procedures performed after the invention and not in the prior art. *Id.* In proffering new explanations the district court did not reach, RJR must meet its burden by clear and convincing evidence. It has not done so, and there is no reason for this Court to adopt RJR's view of these disputed matters when the district court did not.

## **B. Intent**

Implicitly conceding that its evidence of intent is weak, RJR argues (at 54) that its burden of showing intent is low because the evidence of materiality is supposedly so weighty. This is wrong for all the reasons just explained. The thrust of RJR's remaining presentation is invective rather than argument. RJR asserts that there was a "cast of characters" (RJR Br. 56) and that the court "smelled a rat" (57), and demonizes the attorneys' explanations of what occurred as "unsupported and self-serving" (*id.*) and a "fairy tale" (55). This Court, however, requires that

good-faith explanations for allegedly improper disclosures be addressed fully. Star Br. 25-26, 43-44 (citing cases). Far from making adverse credibility findings, the district court failed to perform the requisite analysis. RJR's purple prose cannot cure that defect.

### **1. Early Prosecution**

The district court concluded (A23) that the provisional contained a misrepresentation, and that Delmendo "danced around" the matter in submitting a different disclosure in the non-provisional. *But see* Star Br. 33-35. Because the district court erroneously ignored Delmendo's explanation, RJR offers new justifications – not adopted by the district court – that focus on the Banner firm's intent at a later stage of the '649 prosecution. RJR Br. 16-17. These new justifications, however, cannot support the judgment below because the Burton letter, Currin data, and later-discovered RJR test results were not even known to Banner during the '649 prosecution. A229(135:4-136:18), A238(171:2-172:24), A244(244:11-16), A371(873:1-10). Moreover, Rivard, Hoscheit and Potenza all testified in detail about their submissions to the PTO,<sup>10</sup> their reactions to trial counsel's litigation

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<sup>10</sup> A245-A247(247:16-255:23), A248-A253(262:1-282:3), A373-A374(881:24-882:21), A374-A375(885:23-886:2), A379(902:14-903:10).

analysis letter,<sup>11</sup> and their conduct throughout prosecution.<sup>12</sup> Star Br. 45-47. RJR has furnished no basis to reject these reasonable explanations.

## 2. The “Quarantine”

The undisputed facts are these. Counsel met to transfer files between the Sughrue and Banner firms. The original, pink-colored facsimile of the Burton letter, as transmitted to Delmendo, was part of the transfer and remains in the Banner files. A305(543:20-546:9); Star Br. 38-43; RJR Br. 21 (conceding that the Burton letter was in Banner’s files). At closing argument, this ostensibly satisfied the district court, who cut short argument on the issue: “They [RJR] haven’t proved the conspiracy of changing firms in order to hide the Burton letter, so we don’t need..., you don’t have to debate this.” A427(1127:3-8). The district court’s finding of “quarantine” therefore was shocking. Because it is flatly inconsistent with the uncontradicted evidence, RJR is forced to defend it on the theory that the district court harbored unstated suspicions that the Burton letter was mishandled, RJR Br. 21, or could have deemed the file transfer “unusual,” *id.* at 59.<sup>13</sup> That the Bur-

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<sup>11</sup> A235-A236(159:17-162:9),A368-A369(861:9-863:10), A370(867:9-869:19),A381-A382(911:4-914:19).

<sup>12</sup> A254(285:18-286:24),A369(863:19-865:5).

<sup>13</sup> RJR suggests (at 59) that the assistance of Scott Flicker (of Paul Hastings) in the transition was somehow outside the “ordinary course.” But RJR presents no evidence that Flicker played a role in actually handling Sughrue files (which were transferred directly from Banner to Sughrue, A373(879:18-20)). The single document that RJR cites (A10652) refers to documents received by Flicker from “Star

ton letter was transmitted by Sughrue to Banner, however, forecloses the conclusion that there was some plot to keep it hidden.

Moreover, RJR does not provide any evidence – or even argument – to counter Star’s showing why the Sughrue firm was replaced. *Compare* Star Br. 42-43 *with* RJR Br. 19. It suggests that there is something suspicious in the lack of “contemporaneous documents” (RJR Br. 59), but even if this proved anything – and it does not – it surely does not overcome by clear and convincing evidence the undisputed testimony on this issue. And, it simply is not true that the district court weighed and found lacking what Reynolds characterizes as “Hoscheit’s scant testimony about an alleged meeting with Delmendo and others.” *Id.* at 58. Rather, the court ignored this testimony altogether. It is telling that the district court’s opinion is predicated in large measure on the supposedly improper firing and “quarantine” of Delmendo, yet RJR has no meaningful argument on this score.

### **3. The Attorneys’ Explanations**

The decision not to disclose Burton and Currin during the ‘401 prosecution was made only after patent attorneys thoroughly evaluated whether disclosure was required, and there is no record evidence to the contrary. Star Br. 16, 43-47. The district court ignored these explanations. RJR responds that disclosing the Burton letter was required because “Delmendo had prior art concerns” and “at least five

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Scientific’s files” (not Sughrue’s), a reference to separate files maintained by Star and then properly passed along by Flicker. A315(583:9-585:24).

attorneys recommended disclosure.” RJR Br. 45. We have explained why this is incorrect, and that Star’s attorneys reasonably determined that Burton was not material. Star Br. 43, 45-47. RJR offers just a bare assertion that the evaluation of materiality came “out of the blue.” RJR Br. 31. That is contrary to the evidence.

Rivard had conversations with Burton that convinced him that, as Burton conceded in the letter, he had no knowledge or expertise regarding flue curing practices or results *in the United States*. *E.g.*, A254(283:22-284:1). The Banner firm decided not to submit an IDS only after conducting precisely the reasoned analysis that one would expect of professional patent counsel. When the Burton letter and Currin data were called to the attention of Rivard and Hoscheit, they made an independent and detailed evaluation and reasonably concluded that the information was not material. Star Br. 45-47 (citing the record).

RJR does not dispute that by the time Rivard and Hoscheit made their assessment in connection with the ‘401 patent’s issuance, Banner had presented a great deal of prior art of precisely the type that the court held Star was trying to conceal. A245-247(247:16-255:23),A248-253(262:23-282:3),A6301-A6328,A6329-A6358,A6493-A6501,A6527-A6533,A6534-A6538,A6539-A6544,A6900-A6907,A6993-A6994. RJR concedes (at 32) that the issue fee payment date had passed and that any further disclosure would cause delay. It does not deny that the Manual of Patent Examining Procedures charges counsel

with withdrawing a patent from issue at that stage only upon good-faith belief that there is a “specific and significant defect” in the application. MPEP

§ 1308(A45923-45926).<sup>14</sup> Moreover, RJR does not dispute (at 31) that the contemporaneous email of Crowell attorneys, confirmed by trial testimony, reflected their belief that the Burton letter was *immaterial*, and that submission to the PTO, while not required, would indeed strengthen Star’s litigation position.

A268(342:6-20),A260(310:17-22),A10998-10999.<sup>15</sup> It is difficult to imagine a rational motive for concealing a letter already produced to an adversary in heated, public litigation.

RJR and the district court ignore these undisputed facts, and ignore Rivard and Hoscheit’s lengthy and unrebutted testimony that was corroborated by other witnesses. Each explained precisely what happened between the time they first considered disclosure and their ultimate decision not to disclose. The Burton letter was deemed not material because it was cumulative of, and less informative than, actual prior art already submitted; it was highly speculative; and it concerned a dis-

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<sup>14</sup> To have an IDS considered after the issue fee has been paid requires that the application be withdrawn from issuance. Withdrawal is permitted only for specified reasons, including (1) “an unequivocal statement that one or more claims are unpatentable”; (2) seeking “consideration of” a request for continued examination; or (3) “express abandonment of the application.” 37 C.F.R. § 1.313(c); *see also* MPEP § 1308.

<sup>15</sup> It is notable that although RJR had access even to attorney-client materials as a result of the erroneous crime-fraud ruling (Star Br. 30), it still was unable to put forward any meaningful evidence of intent.

tinctly different curing process than was claimed by Williams. Star Br. 10-11, 27-30. Rivard and Hoscheit reviewed the special Patent Office procedures that mandate heightened scrutiny for materials whose submission would require the patent's withdrawal from issuance; discussed and considered this over a period of days (RJR Br. 32-33 (admitting this)); reviewed submissions they already had made to the PTO; concluded the Burton letter and Currin data were speculative, not reliable and at most cumulative; and communicated their decision. Star Br. 29,45-47; *e.g.*, A239-242(173:4-187:7),A244(244:11-16),A253-254(282:4-286:24),A258(299:10-21),A258(301:9-302:10),A374-375(882:25-886:2),A375(887:3-24),A376(891:10-16),A376(892:14-20),A376-377(893:21-894:5),A379(902:14-903:10).

There is no contrary or competing evidence from which it could be concluded that Hoscheit and Rivard sought to deceive the PTO, *cf.* RJR Br. 20 (implicitly conceding that Hoscheit's testimony is un rebutted), and there is nothing suggesting that their determination came "out of the blue." There is no basis for RJR's suggestion (at 33) that the district court "did not believe" these attorneys acted in good faith. The court may have disagreed with their analysis of the need for disclosure, *see* A39 ("no valid justification"), but it failed to evaluate their good

faith. The undisputed evidence showed there was no intent to deceive, and the district court's reputation-damaging opinion to the contrary should be reversed.<sup>16</sup>

## **II. RJR HAS NOT SHOWN BY CLEAR AND CONVINCING EVIDENCE THAT STAR SCIENTIFIC'S PATENTS ARE INDEFINITE.**

On indefiniteness, RJR's brief is striking for what it does *not* argue, and for how completely it departs from the district court's rationale. RJR does not dispute that it can overcome the statutory presumption of validity "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). And, it does not deny that claim construction here was far from futile – the special master and two district court judges construed the term "anaerobic condition" in a perfectly reasonable fashion *that RJR has not contested*. RJR Br. 50-55. Under these circumstances, RJR

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<sup>16</sup> RJR's final argument (at 55) regarding intent – that certain law firms had a financial interest – merits only brief comment. Incentive does not equal intent. *In re Metoprolol Succinate Patent Litig.*, 494 F.3d 1011, 1020-21 (Fed. Cir. 2007). With respect to Hoscheit (Rivard was not even a Banner partner at the time) there was nothing unusual. Start-ups frequently employ stock options or warrants for compensation in patent matters. Indeed, contingent agreements are expressly countenanced for prosecution matters. 37 C.F.R. § 10.64(a)(2). Perito explained the arrangement at length, A309(559:23-561:1), and there is no evidence that Hoscheit's integrity, earned during 40 years as a patent prosecutor, A373(878:2-11), was compromised, A310(564:17-565:6). It is similarly unremarkable that Crowell & Moring's compensation has a "success" element, A267(337:12-338:7); partially contingent fees are important for small companies to vindicate their patent rights in the face of the enormous costs that large patent defendants can impose.

manifestly has not met its burden of showing indefiniteness by clear and convincing evidence (a standard that it also does not dispute, *cf.* Star Br. 49).<sup>17</sup>

The arguments that RJR does make badly miss the mark.

A. First, RJR argues (at 66) that a claim is indefinite when one skilled in the art cannot determine prior to engaging in potentially infringing activity whether infringement will occur. This Court has squarely rejected this reasoning, as we previously explained (at 56-57), and RJR has not cited, much less discussed, this settled authority. Instead, it contends (at 67) that *All Dental Prodx, LLC v. Advan-*

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<sup>17</sup> See also *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366 (Fed. Cir. 2004) (claims are indefinite only when they are “insolubly ambiguous without a discernible meaning after all reasonable attempts at construction”); *Exxon*, 265 F.3d at 1375 (indefiniteness is when claims are not “amenable to construction”); Star Br. 49-50.

RJR half-heartedly argues that “construed claims may be indefinite,” RJR Br. 61 (capitalization omitted), but fails to address the clear contrary authority in our brief, and misreads the cases it does cite. In none of its three cases was the relevant claim actually construed. *Honeywell Int’l, Inc. v. Int’l Trade Comm’n* held that the relevant claim could *not* be construed and was indefinite, 341 F.3d 1332, 1340 (Fed. Cir. 2003); the portion cited by RJR merely describes what an ALJ previously had done. *Union Pacific Resources Co. v. Chesapeake Energy Corp.* likewise did not construe the relevant claim. 236 F.3d 684, 689 (Fed. Cir. 2001) (“The precise meaning of the term ‘comparing’ in the claims, however, is not explained.”); *id.* at 692. *Standard Oil Co. v. American Cyanamid Co.*, repeatedly noted that the relevant term was ambiguous in the course of analyzing infringement and enablement, not claim construction, *see* 585 F. Supp. 1481, 1488, 1490 (E.D. La. 1984) – and carried forward that same conclusion when it reached indefiniteness, *id.* at 1490-91.

It is unsurprising that RJR cannot find a case where a construed claim was held indefinite. Claim construction and indefiniteness require fundamentally similar inquiries – both address the ordinary meaning of the claims to one skilled in the art.

*tage Dental Prods., Inc.* stands for the contrary proposition (although it makes no effort to reconcile the cases). *All Dental*, however, stands only for the uncontroversial proposition that the definiteness requirement serves a notice function. That case does *not* say that the potential infringer must be able to tell with certainty in advance that infringing activity will occur. 309 F.3d 774, 779-80 (Fed. Cir. 2002).

B. On the facts, RJR asserts that an anaerobic condition cannot be tested for, and so the term is indefinite, because “it is impossible ... to measure oxygen levels *at the leaf’s surface.*” RJR Br. 63 (emphasis added). But this is a straw man: The claims do not require measurements “at the leaf’s surface,” as the district court held in a claim construction that RJR did not appeal and does not mention. The claim language requires “airflow sufficient to substantially prevent an anaerobic condition *around the vicinity*” of the leaf. A5846(20:28-30) (emphasis added). Thus, the district court (at A737) adopted the report and recommendation construing the claims as “not requir[ing] that the prevention of an anaerobic condition be at the leaf surface, only ‘around the vicinity of said plant portion,’” A647 n.33. The feasibility of testing “around the vicinity of the leaf” is undisputed, and was performed by both parties. Star Br. 57-58; *see also* A675 (conditions at the

leaf surface can be inferred by measuring oxygen levels at locations in the barn),A27086-27087,A27093,A1397-1399(302:14-304:9).<sup>18</sup>

RJR next argues (at 63) that “scientists do not even know the particular oxygen levels that will trigger microbial nitrate reductase activity for approximately 90% of species,” and that “oxygen levels at the leaf’s surface ... change daily.” But again, the *claims* do not require knowledge of any specific “trigger” level of oxygen for individual microbes. The relevant question is whether there is an oxygen deficiency that “promote[s]” TSNA-producing microbial activity, and testing can be performed to determine whether oxygen deficiencies exist, whether nitrate reductase activity occurred, and whether TSNA levels increased. *Supra* at 23; A1405-1406(310:24-311:3). It would have been technically impossible for Williams to ascertain and spell out numerical airflow limits for every possible combination of curing conditions, and the law does not require precision beyond the

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<sup>18</sup> RJR’s only (partial) response is to collaterally attack the credentials of Star’s expert, Dr. Lee. RJR Br. 65. This is curious, given that RJR’s entire argument depends on a statement by Lee about testing at the leaf surface. *Id.* at 63. In any event, RJR never has challenged Lee’s credentials; it cannot do so collaterally for the first time here; and Lee’s credentials are irrelevant to whether this testing can be performed, which it can and was.

RJR misreads the record when it argues that Star “previously admitted that [oxygen levels in a curing barn] *cannot* be extrapolated to determine the relevant oxygen levels in contact with the leaf’s surface.” RJR Br. 65 (citing A35098-35100). The relevant interrogatory says nothing more than that preventing anaerobic conditions in certain areas of the barn (*i.e.*, between boxes or tobacco racks) would not suffice if anaerobic conditions were created in the immediate vicinity of the tobacco plant. A35099-100.

boundaries of science, as Judge Williams held in rejecting the very argument RJR makes here. A637(report and recommendation),A737-738(order adopting R&R). A claim need only be “as precise as the subject matter permits,” Star Br. 50 (citing cases), and the precision RJR seeks to impose is neither intended by the claims nor required as a matter of law.

RJR seeks to bolster this argument with reference to dicta regarding definiteness in *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1383 (Fed. Cir. 2003), but that case undermines rather than supports RJR’s position. In finding a claimed invention obvious, *Geneva* expressly approved, as here, the use of functional limitations to delimit a quantity recited in a claim. *Id.* at 1383-84 (citing *In re Halleck*, 422 F.2d 911, 914 (C.C.P.A. 1970)). RJR’s superficial treatment of *Geneva* ignores this holding, and ignores the unique circumstances of that case – it arose in the context of a chemical composition claim, and concerned an unusually broad construction proffered by the patentee to avoid invalidation for double patenting, with the anomalous result that a given commercial product could “simultaneously infringe and not infringe the claims.” *Id.* at 1384. That problem, however, could never arise in the context of Williams’ patented curing method; when the invention is practiced, an oxygen-deficient condition around the vicinity of the tobacco leaf either is or is not substantially prevented. And, while conditions in a curing barn may vary, determining the airflow necessary to

substantially prevent an anaerobic condition is within the ability of a person of ordinary skill without the need for undue experimentation, Star Br. 53-54,57-58, and that is all that is required for definiteness, *see Halleck*, 422 F.2d at 914.

C. Finally, RJR seeks affirmance on the basis of an argument that the district court rejected – that the term “controlled environment” is indefinite. RJR Br. 67-68; *see* A58-59. This term was construed, however, in a more-than-reasonable fashion, A738-739, which RJR has not challenged on appeal. Its sole argument appears to be that Star’s barn-design expert, Sturgill, was a person of ordinary skill in the art, and so his inability to provide a specific numeric value for “conventional” airflow should be taken as an admission of indefiniteness. RJR Br. 68. But, neither the claims nor the construction say *anything* about “conventional airflow” levels. The claims do not teach the use of one single airflow regardless of conditions; they recognize that curing environments vary, and a curing environment is “controlled” if it provides “airflow sufficient to substantially prevent an anaerobic condition.” A5846(20:27-29). The claims do not require a “controlled environment” without more; they require a “controlled environment *compris[ing]* a flow of air sufficient to avoid an anaerobic condition around the vicinity of said plant portion.” A5847(22:3-5) (emphasis added). The district court therefore properly recognized that the “comprising” language means that analyzing the definiteness of “controlled environment” requires a focus on “anaerobic condition.”

A60. And that term has been reasonably construed. A738-739. Sturgill's supposed admission is thus irrelevant to the structure of the claims.

Moreover, Sturgill was *not* skilled in the art of the claimed invention.

Throughout the case, he was recognized as possessing particular expertise concerning barn design, and the district court recognized that he was not skilled in the art.

A680 n.28, A1164-1172(68:4-76:11).

### **III. THE DISTRICT COURT ERRED IN REJECTING THE PRIORITY DATE OF THE PATENTS-IN-SUIT.**

A. We demonstrated in our opening brief (at 59-63) that the district court erred as a matter of law in comparing the specification of the provisional to the specification of the patents-in-suit rather than the patent claims, and that the court compounded this error by placing principal weight on specific numerical airflows that were mere examples.

Tellingly, RJR does not defend the district court's reasoning. Instead, it proffers a new theory that the term "controlled environment" meant something different in the provisional than in the issued claims. But this does not demonstrate a lack of written description for the later-claimed invention. In the provisional, the single occurrence of the term was in a discussion of the prior art, and it was used generically to refer to an environment that has been controlled. In the claims of the patents-in-suit, however, the words "controlled environment" are recited as an express limitation of the claimed invention, and the claims themselves define the

term. It is settled that a patentee can be his own lexicographer. Star Br. 52. RJR does not explain why a change in terminology defeats priority, and indeed it does not. A “prior application need not describe the claimed subject matter in exactly the same terms as used in the claims.” *Eiselstein v. Frank*, 52 F.3d 1035, 1038 (Fed. Cir. 1995); *Kao Corp. v. Unilever United States, Inc.*, 441 F.3d 963, 968 (Fed. Cir. 2006). The relevant question, after all, is whether “the inventor had possession of, as of the filing date of the application relied upon, the specific subject matter later claimed by him; *how the specification accomplishes this is not material.*” *In re Herschler*, 591 F.2d 693, 700 (C.C.P.A. 1979) (emphasis added); *see also In re Alton*, 76 F.3d 1168, 1172 (Fed. Cir. 1996).

Here, it is plain that Williams had possession of the invention at the time he filed the provisional. The claims of the patents-in-suit describe a “controlled environment compris[ing] air free from combustion exhaust gases and an airflow sufficient to substantially prevent an anaerobic condition,” and “controlling at least one of humidity, temperature and airflow,” for the purpose of “substantially preventing” the formation of TSNAs. A5846(20:18-33). The provisional contains the same basic elements. It states that Williams “discovered that subjecting tobacco leaf to a sufficiently high flow of heated or unheated air ... prevents the formation of, or reduces the amount, of carcinogenic substances (namely nitrosamines) in the tobacco product.” A5812. It discloses that this airflow should be “sufficient to

prevent an anaerobic condition.” A5831(claim 3). It describes a “hot air stream substantially free of combustion exhaust gases.” A5824. In a preferred embodiment, “the heated or unheated air is dehumidified air.” A5814. “[C]onventional curing techniques,” by contrast, “do not provide adequate oxygen flow and do not avoid an anaerobic condition ... [c]onsequently, TSNA[s] are formed.” A5817.

RJR next argues (at 70) that, whereas the provisional required “high” airflow, Star deleted that requirement from the non-provisional application, which permitted “low” airflow. This is simply incorrect. The patents continue to refer to the use of high airflow. A5839(6:7-9)(“it is possible to prevent or reduce the formation of TSNAs by simply setting a high airflow through the curing apparatus or barn”); A6015(6:11-13)(same). More importantly, nowhere did the provisional specify that “high” airflow is *required*. Rather, it specified in *relative* terms – appropriately for a result-based limitation – that there should be a “*sufficiently* high flow of heated or unheated air” “to reduce the amount of or substantially prevent formation of at least one nitrosamine.” A5814-A5815. The provisional expressly defined “sufficiently high flow of heated or unheated air” to mean “an amount of air adequate to eliminate or reduce the levels of TSNA in the tobacco product,” A5816, and, like the patent claims, further describes this as airflow sufficient to “avoid[] the establishment of an anaerobic condition,” A5831. This disclosure is fully supportive of the issued claims, which recite the use of airflow that “is suffi-

cient to avoid an anaerobic condition.” *E.g.*, A6022(20:18-19). Were there any doubt that the provisional discloses the subject matter claimed in the patents, it is dispelled by the repeated use of nearly identical terms to describe airflow. *Compare, e.g.*, A5824 (“The minimum flow of air is approximately ten percent higher than the flow of flue gas used in the prior art.”), *with* A6018(11:56-58) (“the minimum flow of air is preferably about ten percent higher than the flow of flue gas commonly used in the prior art”).

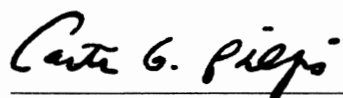
B. At a minimum, summary judgment for RJR was improper. Star Br. 63-64. RJR’s only response is a single sentence that is so cryptic, brief and unsupported by factual citation as to waive the argument. RJR Br. 71; *see SmithKline-Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1320 (Fed. Cir. 2006) (“When a party includes no developed argumentation on a point ... we treat the argument as waived under our well established rule.”). As we have explained, and RJR has failed to gainsay, granting summary judgment to RJR on the effective filing date required the district court improperly to resolve the disputed factual issue of whether the disclosure in the ‘372 provisional application satisfies the written description requirement with respect to the issued claims. Star Br. 63. This inquiry implicates the proper definition of one skilled in the art, and what the provisional discloses to such a person, both issues of fact. *Id.* Star presented evidence on

these questions, A4017-4018,A4046,A43001-A43005,A43511-43512, which RJR did not dispute, A44000-44004. Accordingly, summary judgment was improper.

### CONCLUSION

Each of the district court's decisions should be reversed.

Respectfully submitted,



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Dated: December 21, 2007

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I hereby certify that on this 21st day of December, 2007, two copies of the foregoing PLAINTIFF-APPELLANT STAR SCIENTIFIC, INC.'S OPENING BRIEF were served by sending same via FEDERAL EXPRESS, PRIORITY OVERNIGHT, postage prepaid, addressed to:

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I certify that the foregoing PLAINTIFF-APPELLANT STAR SCIENTIFIC, INC.'S REPLY BRIEF complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) and contains 6956 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b).

I further certify that this brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman, 14 point.

Date: December 21, 2007

  
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