

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MARYLAND**

STAR SCIENTIFIC, INC.,

Plaintiff,

v.

R.J. REYNOLDS TOBACCO COMPANY, et al.,

Defendants.

Civil Action No. MJG-01-CV-1504  
(Consolidated with MJG-02-2504)

Judge Marvin J. Garbis

**STAR SCIENTIFIC'S RENEWED MOTION FOR JUDGMENT AS A  
MATTER OF LAW AND, IN THE ALTERNATIVE, FOR A NEW TRIAL**

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**TABLE OF CONTENTS**

I. Introduction ..... 1

II. Summary Of Proceedings..... 1

III. Legal Standards For JMOL And New Trial..... 2

IV. Summary Of Grounds Entitling Star Scientific To Judgment  
As A Matter Of Law Or A New Trial..... 3

V. The Jury’s Non-Infringement Findings Were At Odds With The Overwhelming  
Weight Of The Evidence And Resulted From Clear Errors Of Law ..... 8

A. The Verdict of Non-Infringement Was Against the Overwhelming Weight  
of Evidence and Internally Inconsistent with the Jury’s Findings on Validity..... 10

1. As admitted by RJR’s own witnesses, at least one RJR grower infringed. .... 10

2. The jury’s non-infringement finding on the section 271(g) issues was also  
irrational. .... 13

B. The Court Erred by Allowing RJR to Argue that the Asserted Claims Require  
Distinguishing Between “Conventional” and “Unconventional” Airflow Volumes ..... 13

C. The Court Erred by Allowing RJR to Urge the Jury to Make an Improper  
Comparison Between the “Peele Method” and the Patented Method..... 16

D. The Court Erroneously Concluded that the Patents-in-Suit Could Not Claim  
Priority to the Filing Date of the September 15, 1998 Provisional..... 20

E. The Court Erred by Refusing to Instruct the Jury that “Practicing the Prior Art”  
Is Not a Valid Defense to Patent Infringement ..... 21

F. The Court Erred by Precluding Star Scientific from Calling Mr. Borschke  
to Testify Regarding Various Issues Presented to the Jury ..... 23

G. The Court Erred by Excluding Dr. Lee’s Deposition Testimony Explaining  
that His Detection Limit Was Substantially Lower than 0.05 ppm ..... 24

VI. The Jury’s Invalidity Findings Were Against The Overwhelming Weight Of The  
Evidence And Were Prompted By Clear Error By This Court ..... 26

A. Anticipation and Obviousness ..... 26

1. The Court erred by permitting RJR to re-argue inequitable conduct, in  
contravention of the Federal Circuit’s mandate. .... 28

2.	The verdict on anticipation and obviousness was against the overwhelming weight of the evidence. ....	32
3.	The jury’s verdict was internally inconsistent.....	39
4.	The Court erred by allowing RJR to present previously-undisclosed expert testimony through Inger Wahlberg. ....	40
B.	RJR Was Erroneously Permitted to Present a Definiteness Defense that It Already Lost on Appeal.....	42
C.	The Court’s Best Mode Instruction Ignored Clear Federal Circuit Precedent Requiring Deliberate Concealment.....	46
VII.	The Court Erred By Seating An Alternate Juror On The Last Day Of Trial Based Only On A Professed “Scheduling Issue” For The Excused Juror.....	48
VIII.	Conclusion.....	49

**TABLE OF AUTHORITIES**

**Cases**

*Abbott Labs. v. Sandoz, Inc.*,  
544 F.3d 1341 (Fed. Cir. 2008).....36

*Alliance for Telecomms. Indus. Solutions, Inc. v. Hall*,  
Civil No. CCB-05-440, 2007 WL 3224589 (D. Md. 2007).....2

*AllVoice Computing PLC v. Nuance Commc 'n, Inc.*,  
504 F.3d 1236 (Fed. Cir. 2007).....47

*Bio-Technology General Corp. v. Genentech, Inc.*,  
80 F.3d 1553 (Fed. Cir. 1996).....17

*Blanchard v. Putnam*,  
75 U.S. 420 (1869) .....17

*Buckley v. Mukasey*, 538 F.3d 306, 317 (4th Cir. 2008) .....2

*Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*,  
381 F.3d 1371 (Fed. Cir. 2004).....36

*Carter v. Rogers*,  
805 F.2d 1153 (4th Cir. 1986).....40

*Chemcast Corp. v. Arco Indus. Corp.*,  
913 F.2d 923 (Fed. Cir. 1990).....47

*City of Cleveland v. Peter Kiewit Sons' Co.*,  
624 F.2d 749 (6th Cir. 1980).....27

*Contech Stormwater Solutions, Inc. v. Baysaver Techs., Inc.*,  
534 F. Supp. 2d 616 (D. Md. 2008).....47

*Cook v. Sandusky Tool Co.*,  
4 S. Ct. 4 (1884) .....32

*Cordis Corp. v. Boston Scientific Corp.*,  
561 F.3d 1319 (Fed. Cir. 2009).....46

*Custer v. Terex Corp.*,  
196 F. App'x 733 (11th Cir. 2006).....40

*CytoLogix v. Ventana Med. Sys., Inc.*,  
424 F.3d 1168 (Fed. Cir. 2005).....14

*DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*,  
567 F.3d 1314 (Fed. Cir. 2009).....36

*East Tennessee Natural Gas Co. v. Thomas*,  
298 F. App’x 261 (4th Cir. 2008).....42

*Eisai Co. v. Dr. Reddy’s Labs., Ltd.*,  
533 F.3d 1353 (Fed. Cir. 2008).....38

*Exxon Research and Engineering Co. v. U.S.*,  
265 F.3d 1371 (Fed. Cir. 2001).....46

*Francis v. Clark Equipment Co.*, 993 F.2d 545 (6th Cir. 1993) ..... 19, 20, 24

*Girdler Corp. v. Abbotts Dairies*,  
24 F. Supp. 551 (D. Pa. 1938).....32

*Graham v. John Deere Co.*,  
383 U.S. 1 (1966) .....38

*Gumbro Lundia AB v. Baxter Healthcare Corp.*,  
110 F.3d 1573 (Fed. Cir. 1997).....38

*High Concrete Structures, Inc. v. New Enterprise Stone & Lime Co.*,  
377 F.3d 1379 (Fed. Cir. 2004).....46, 47

*Hundley v. District of Columbia*,  
494 F.3d 1097 (D.C. Cir. 2007) .....40

*In re Robertson*,  
169 F.3d 743 (Fed. Cir. 1999).....33, 34

*Innogenetics, N.V. v. Abbott Labs.*,  
512 F.3d 1363 (Fed. Cir. 2008).....2

*Int’l Data Prod. Corp. v. Dynamic Decisions, Inc.*,  
215 F.3d 1319, 2000 WL 560059 (4th Cir. 2000).....40

*Johnson v. ABLT Trucking Co.*,  
412 F.3d 1138 (10th Cir. 2005).....40

*Koufakis v. Carvel*,  
425 F.2d 892 (2d Cir. 1970).....31

*Kozlowski v. Hampton Sch. Bd.*,  
77 F. App’x 133 (4th Cir. 2003).....49

*KSR Int’l Co. v. Teleflex Inc.*,  
550 U.S. 398 (2007) ..... 36

*Ladnier v. Murray*,  
769 F.2d 195 (4th Cir. 1985)..... 40

*Lisle Corp. v. A.J. Mfg. Co.*,  
398 F.3d 1306 (Fed. Cir. 2005)..... 40

*Lucent Tech. v. Extreme Networks, Inc.*,  
229 F.R.D. 459 (D. Del. 2005)..... 28

*Maier v. AT&T*,  
No. 94-C-7468, 1996 WL 18887 (N.D. Ill. Jan. 12, 1996)..... 48

*Markman v. Westview Instruments, Inc.*,  
52 F.3d 967 (Fed. Cir. 1995) (*en banc*), *aff’d*, 517 U.S. 370 (1996)..... 13

*Molina v. City of Oxnard*,  
173 F. App’x 577 (9th Cir. 2006)..... 40

*O’Rear v. Fruehauf Corp.*,  
554 F.2d 1304 (5th Cir. 1977)..... 27

*O2 Micro Int’l Ltd. v. Beyond Innovation Technology Co.*,  
521 F.3d 1351 (Fed. Cir. 2008)..... 13, 14

*Personalized Media Communications, L.L.C. v. Int’l Trade Comm’n*,  
161 F.3d 696 (Fed. Cir. 1998)..... 46

*Potomac Elec. Power Co. v. Electric Motor Supply, Inc.*,  
192 F.R.D. 511 (D. Md. 2000)..... 25

*Praxair, Inc. v. ATMI, Inc.*,  
543 F.3d 1306 (Fed. Cir. 2008)..... 46

*S. Atl. Ltd. P’ship of Tenn. v. Riese*,  
356 F.3d 576 (4th Cir. 2004)..... 44

*Saleeby v. Kingsway Tankers, Inc.*,  
531 F.Supp. 879 (S.D.N.Y. 1981)..... 10

*Sanofi-Synthelabo v. Apotex, Inc.*,  
550 F.3d 1075 (Fed. Cir. 2008)..... 36

*Southern States Rack & Fixture, Inc. v. Sherwin-Williams Co.*,  
318 F.3d 592 (4th Cir. 2003)..... 41

<i>Sprague v. Ticonic Nat’l Bank</i> , 307 U.S. 161 (1939) .....	28
<i>Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.</i> , 537 F.3d 1357 (Fed. Cir. 2008).....	1, 8, 30
<i>Sundance, Inc. v. DeMonte Fabricating Ltd.</i> , 550 F.3d 1356 (Fed. Cir. 2008).....	13
<i>Tate Access Floors, Inc. v. Interface Architectural Res., Inc.</i> , 279 F.3d 1357 (Fed. Cir. 2002).....	17, 22
<i>Tec Air, Inc. v. Denso Mfg. Michigan Inc.</i> , 192 F.3d 1353 (Fed. Cir. 1999).....	38
<i>TLT-Babcock, Inc. v. Emerson Elec. Co.</i> , 33 F.3d 397 (4th Cir. 1994).....	41
<i>Transclean Corp. v. Bridgewood Servs., Inc.</i> , 290 F.3d 1364 (Fed. Cir. 2002).....	33, 34
<i>Tucker v. Ohtsu Tire &amp; Rubber Co.</i> , 49 F. Supp. 2d 456 (D. Md. 1999).....	25
<i>U.S. Philips Corp. v. Iwasaki Electric Co., Ltd.</i> , 607 F. Supp. 2d 470 (S.D. N.Y. 2009) .....	38
<i>United States v. Bell</i> , 5 F.3d 64 (4th Cir. 1993) .....	28, 43
<i>United States v. Perkins</i> , 470 F.3d 150 (4th Cir. 2006).....	41
<i>United States v. Varner</i> , 748 F.2d 925 (4th Cir. 1984).....	18
<i>Warner v. Rossignol</i> , 538 F.2d 910 (1st Cir. 1976).....	18
 <b>Statutes</b>	
35 U.S.C. § 271(g).....	13
35 U.S.C. §102(e).....	19
35 U.S.C. §102(g).....	19

**Rules**

Federal Rule of Civil Procedure 26 ..... 25, 41  
Federal Rule of Civil Procedure 47 ..... 6, 48  
Federal Rule of Evidence 701 ..... 41

**I. INTRODUCTION**

Plaintiff Star Scientific, Inc. (“Star Scientific”) hereby renews its motion for judgment as a matter of law (“JMOL”) pursuant to Federal Rule of Civil Procedure 50(b), and in the alternative moves for a new trial pursuant to Federal Rule of Civil Procedure 59(a). In support of its renewed motion for JMOL, Star Scientific incorporates by reference its Motion for Judgment as a Matter of Law (Dkt. No. 1065). With respect to Star Scientific’s alternative motion for a new trial, the basis for the requested relief is detailed below.

**II. SUMMARY OF PROCEEDINGS**

Star Scientific initiated this consolidated action for patent infringement against Defendants R.J. Reynolds Tobacco Company (“RJR”) more than eight years ago, seeking damages arising from RJR’s willful infringement of U.S. Patent No. 6,202,649 (“the ‘649 patent”), issued March 20, 2001, and related U.S. Patent No. 6,425,401 (“the ‘401 patent”), issued July 30, 2002 (collectively, “the patents-in-suit”).

The case has been to the U.S. Court of Appeals for the Federal Circuit on one previous occasion. On August 25, 2008, the Federal Circuit reversed this Court’s decisions on inequitable conduct and definiteness, and vacated the Court’s grant of partial summary judgment on the priority date issue as procedurally improper. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357 (Fed. Cir. 2008). Following remand, the Court ruled on a series of motions *in limine* that thereafter controlled the subsequent trial. The Court also announced *sua sponte* that it was going to bifurcate the trial into two phases – the first phase to cover the issues of direct infringement by RJR and its contract farmers and RJR’s invalidity defenses; and the second phase to cover the issues of inducement of infringement by RJR (even though neither party had ever requested that inducement be bifurcated), willful infringement, and damages. The Court’s expressed rationale for bifurcation was twofold, namely, to prevent the jury

from hearing evidence of RJR's specific intent to infringe, and to prevent the jury from learning in any detail that the patents-in-suit offered substantial health benefits.

The trial began with jury selection on May 18, 2009 and lasted more than four weeks. On June 16, 2009, the jury rendered a verdict finding that neither RJR nor any of its contract farmers infringed the patents-in-suit in either 2001 or 2002, and that both patents were invalid due to anticipation, obviousness, indefiniteness, and failure to disclose the best mode. Judgment on the verdict has not yet been entered.

### **III. LEGAL STANDARDS FOR JMOL AND NEW TRIAL**

The standards for a grant of judgment as a matter of law are set forth in Star Scientific's previously-filed motion (Dkt. No. 1065). In addition, after a jury trial, a district court may grant a motion for a new trial "for any reason for which a new trial has heretofore been granted in an action at law in federal court." Fed. R. Civ. P. 59(a). Under controlling Fourth Circuit precedent,<sup>1</sup> motions for a new trial may be granted where the district court judge is of the opinion that the verdict (i) "is against the clear weight of the evidence," (ii) "is based upon evidence which is false," or (iii) "will result in a miscarriage of justice." *Buckley v. Mukasey*, 538 F.3d 306, 317, 321 (4th Cir. 2008) (granting new trial); *Alliance for Telecomms. Indus. Solutions, Inc. v. Hall*, Civil No. CCB-05-440, 2007 WL 3224589, \*4, \*17 (D. Md. 2007) (granting-in-part motion for a new trial).

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<sup>1</sup> In a patent case, regional circuit law governs motions for a new trial. *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1372 (Fed. Cir. 2008).

**IV. SUMMARY OF GROUNDS ENTITLING STAR SCIENTIFIC TO JUDGMENT AS A MATTER OF LAW OR A NEW TRIAL**

In its trial and pretrial rulings, the Court committed a series of legal errors that irrevocably affected the outcome of this case. These errors are explained below, or are summarized in Star Scientific's previously-filed motion for JMOL, but include without limitation the following:

- The Court disregarded the decision of the Federal Circuit by allowing RJR to retry inequitable conduct and make a focal point of trial the already decided issue of whether Star Scientific had improperly withheld material information from the Patent Office, specifically including the Burton letter (DTX 53).<sup>2</sup>
- The Court further disregarded the Federal Circuit's mandate by allowing RJR to retry claim construction issues previously resolved by the Federal Circuit or otherwise controlled by the claim construction approved by the Federal Circuit.<sup>3</sup>

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<sup>2</sup> See, e.g., Tr. at 678:13-686:2 (overruling Star Scientific's objection, and permitting RJR's counsel to read substantial portions of the Burton letter into the record while questioning the witness on its contents), 687:19-22, 689:20-700:20 (overruling Star Scientific's objection to RJR's efforts to retry inequitable conduct, and allowing further questioning on the Burton letter in connection with Williams' provisional application), 3688:4-3692:17 (overruling Star Scientific's objection to RJR's questions raising inequitable conduct, and permitting further questioning on the Burton letter), 3693:8-3695:6, 3705:2-4, 3886:17-3887:2 (denying Star Scientific's Motion *in Limine* to Preclude RJR from Arguing in Closing that Star Scientific Failed to Disclose the Burton letter or Made Misstatements to the Patent Office (Dkt. No. 1063)), 3978:16-24, 4009:9-12, 4013:15-4014:2, 4018:25-4019:2, 4021:12-20. The Court also admitted, over numerous objections, portions of Dr. Burton's video deposition testimony discussing the Burton letter and its contents. See *id.* at 2691:1-2696:9, 2756:13-2758:8.

<sup>3</sup> See, e.g., Pretrial Order re: Documents 599 & 737 [Airflow] (Dkt. No. 929); Tr. at 234:19-299:6 (Star Scientific's objections to RJR's opening slides), 448:13-449:20, 452:3-459:25 (Star Scientific's motion to strike large portions of RJR's opening statement), 463:1-463:3 (denying same), 1761:25-1764:11, 3061:7-3063:7, 3386:4-22 (overruling Star Scientific's objection to Dr. Otten testifying to his understanding of the term "controlled environment"), 3386:25-3396:19, 3682:24-3683:19, 3993:21-3998:9.

- The Court permitted RJR to present evidence and argue to the jury that the primary issue in dispute was whether RJR farmers were practicing the “Peele process” rather than Star Scientific’s patented process, and that if the jury found that RJR farmers were “practicing Peele,” they could not find infringement.<sup>4</sup>
- The Court improperly denied Star Scientific its September 15, 1998 priority date based on the provisional patent application, thereby allowing RJR improperly to argue that “Peele was first.”<sup>5</sup>

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<sup>4</sup> See, e.g., Tr. at 213:14-214:13, 243:21-245:6, 281:13-282:11, 293:24-294:4, 415:23-416:22 (RJR’s opening statement regarding the “Peele process”), 432:5-8, 435:10-436:1, 446:1-16, 452:3-459:25 (denying Star Scientific’s motion to strike portions of RJR’s opening statement), 460:16-463:24 (denying Star Scientific’s request for a proper curative instruction); Hearing Exhibits 1-3; Tr. at 869:9-870:19, 1016:1-1018:8, 1026:15-22, 1402:3-1409:24, 1484:16-1485:6, 1585:18-1586:4, 1597:1-1599:9, 1610:1-1613:8, 1767:18-1769:23, 1951:16-1953:20 (overruling Star Scientific’s request for a limiting instruction), 2115:11-2116:19, 2149:13-2151:20 (sustaining RJR’s objections to Star Scientific’s questioning of Dr. Peele regarding differences between the Peele patent and the claims of the patents-in-suit), 2283:3-2284:17 (overruling Star Scientific’s objection to the comparison of the accused process to Star Scientific’s commercial embodiment), 2918:2-2920:2 (denying Star Scientific’s request for a limiting instruction regarding the Peele method and patent), 3072:4-19, 3443:1-3448:3, 3698:13-20 (sustaining RJR’s objection to Star Scientific’s use of the Peele patent prosecution to distinguish from the asserted patents), 3885:20-3886:16 (Star Scientific’s objection to failure to give a practicing prior art jury instruction), 3972:2-4027:10 (RJR’s closing argument regarding the Peele method and patent); Star Scientific’s Motion *in Limine* to Exclude Evidence of the “Peele Method” and to Bifurcate Willfulness Evidence (Dkt. No. 733); Second Procedural Order Denying Motions *in Limine* (Dkt. No. 870); Star Scientific’s Objections to Lee Cross-Examination (Dkt. No. 985); RJR’s Response (Dkt. No. 988).

<sup>5</sup> See, e.g., Tr. at 418:4-429:14, 446:12-16, 971:4-981:10, 1933:24-1935:7, 1951:16-1953:20 (overruling Star Scientific’s request for a limiting instruction), 1960:3-1963:3, 2115:7-2116:17, 2297:17-2298:5, 443:1-3448:3, 3885:20-3886:16 (Star Scientific’s objection to prior art jury instruction), 4007:20-4010:5 (RJR closing argument re Peele timeline); Pretrial Order re: Document 746 [Filing Date] (Dkt. No. 923); RJR’s Motion *in Limine* No. 11 to Preclude Star from Introducing Any Evidence or Argument of Conception or Reduction to Practice Prior to the Sept. 15, 1999 Filing Date of the Patents-in-Suit (Dkt. No. 938).

- The Court denied Star Scientific the right to call RJR's Chief Patent Counsel, August Borschke, as a witness and/or to introduce the Lione opinion letter to establish critical facts and admissions bearing on issues of infringement and validity.<sup>6</sup>
- The Court permitted RJR to introduce evidence and argument directly at odds with the plain language and structure of the claims, including evidence and argument that the "controlled environment" could be properly construed to require some numeric level of airflow, including airflows substantially at odds with levels described in the patents.<sup>7</sup>
- The Court repeatedly rejected favorable evidence proffered by Star Scientific, while accepting parallel unfavorable evidence proffered by RJR on the identical issues.<sup>8</sup>
- After Star Scientific's lead expert, Dr. Lee, had completed his *de bene esse* testimony, the Court allowed RJR to name a new expert, limited Star Scientific's right to respond to that

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<sup>6</sup> See Tr. at 1005:12-1023:8, 1042:5-1046:23 (excluding Borschke presentation, PTX 276, from evidence), 1400:12-1402:2 (granting RJR's motion *in limine* to preclude Star Scientific from calling Mr. Borschke, and excluding the Lione opinion letter).

<sup>7</sup> See, e.g., Pretrial Order re: Documents 599 & 737 [Airflow] (Dkt. No. 929); Tr. at 234:19-299:6 (Star Scientific's objections to RJR's opening slides), 246:24-247:17, 435:10-438:9, 452:3-459:25 (Star Scientific's motion to strike large portions of RJR's opening statement), 463:1-3 (denying same), 733:17-22, 735:22-738:12, 1280:2-8, 1282:4-1284:5, 1291:8-1293:14, 1296:6-1298:5, 1303:12-1304:12, 2283:3-17, 2290:17-21, 2313:6-12, 2599:2-2599:5, 2606:17-2607:4, 3072:20-3074:18, 3386:4-3396:19, 3465:7-3472:10, 3608:22-3611:1, 3617:21-3618:1, 3673:10-19, 3684:14-3685:12, 3991:7-3993:20, 4022:1-10.

<sup>8</sup> See, e.g., Tr. at 3213:12-3214:5, 3370:10-17 (excluding Edwards deposition rebuttal testimony); see also Dkt. No. 1036 (Star Scientific's Notice of Anticipated Witnesses and Exhibits for Wednesday, June 10, 2009); June 10, 2009 Order re Edwards Deposition Testimony.

expert, and at trial allowed a further and previously unidentified expert (Dr. Wahlberg) to give testimony without complying with the requirements of Rule 26.<sup>9</sup>

- The Court gave erroneous jury instructions, including failing to give a “practicing the prior art” instruction and misstating of the law as to best mode.<sup>10</sup>
- The Court dismissed a sitting juror on grounds that she had “volunteered” to be displaced by an alternate, in contravention of the clear requirements of Federal Rule of Civil Procedure 47.<sup>11</sup>
- The Court excluded all evidence tending to show that Jonnie Williams and/or Star Scientific caused a profound effect on the tobacco industry, while permitting RJR witnesses to testify at length regarding Dr. Peele’s supposedly corresponding contribution.<sup>12</sup>

The separate and cumulative impact of these errors was profound, and led to a runaway jury whose verdict was completely at odds with the overwhelming weight of the evidence. Indeed, the jury

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<sup>9</sup> See, e.g., Star Scientific’s Motion *in Limine* to Exclude New Expert Testimony, 2-5 (Dkt. No. 999); Tr. at 421:17-20, 422:10-15, 1769:24-1770:22, 2441:8-2446:5, 2584:15-2588:23, 2592:8-2594:10, 2597:8-2599:7, 2608:6-2609:2, 2610:6-2613:20.

<sup>10</sup> See Tr. at 3885:20-3886:3; Star Scientific’s Supplementation of Record Regarding Objections to Jury Instructions (Dkt. No. 1077, Ex. A at Email from F. Rasheed to Counsel, June 14, 2009, 2:26 PM, Email from R. McMillan to F. Rasheed, June 14, 2009, 3:29 PM, Email from F. Rasheed to Counsel, June 14, 2009, 9:06 PM, Email from F. Rasheed to Counsel, June 15, 2009, 12:05 AM, Email from R. McMillan to F. Rasheed, June 15, 2009, 7:15 AM); *cf.* Tr. at 3882:12-3884:11 (allowing parties to supplement record with objections *nunc pro tunc*).

<sup>11</sup> See Tr. 4055:6-11 (overruling Star Scientific’s objection to juror dismissal); Star Scientific’s Objection to Seating of Alternate Juror (Dkt. No. 1075).

<sup>12</sup> Compare Tr. at 313:6-315:3, 499:14-500:1, 671:13-672:18 (sustaining RJR’s motion to strike testimony on Star Scientific’s nitrosamine laboratory and excluding PTX 554, 555, and 556), 675:19-676:11 (sustaining RJR’s objection to PTX 511 and limiting testimony to 2002 activities), *and* 889:18-24 (sustaining RJR’s objection to testimony on contribution of Mr. Williams’ invention to society) *with* Tr. at 2133:9-2142:17, 2145:6-2146:5, 3419:23-3420:12, *and* 3475:14-3476:11.

ruled in RJR's favor on issues that had been effectively conceded. Even RJR's experts conceded that at least seven RJR farmers infringed, and this analysis was confirmed in specific RJR trial exhibits. Tr. at 2892:9-2893:3, 3119:7-3120:4, 3128:9-16; DTX 2898, slide 49; DTX 2318M. There was no evidence whatsoever in the record from which any reasonable juror could have concluded that the tobacco purchased from RJR's contract farmers was a "trivial and non-essential component" of cigarettes. And the only two grounds on which RJR ultimately claimed anticipation were both conceded by RJR's own witnesses not to have included all elements of the Claim at Issue.

For the reasons set forth in Star Scientific's motion for JMOL, most of these errors in the jury verdict should be corrected now as a matter of law. Alternatively, the errors committed by the Court, coupled with the irrational and runaway nature of the jury verdict, entitle Star Scientific to a new trial. The fact that the jury found adversely to Star Scientific on every issue, despite the overwhelming contrary weight of the evidence, is a telling indicator of a failed process. Indeed, the findings of non-infringement and invalidity (by anticipation and obviousness) are directly at odds with one another. RJR argued that it did not infringe because it was only "practicing the prior art" (which, according to RJR, was incorporated in the claim construction); but if infringement of Star Scientific's invention could be avoided on the basis that it was different from the prior art, then the invention could not also have been anticipated.<sup>13</sup> No reasonable jury could therefore have ruled in RJR's favor on both issues.

The jury made ten specific findings in RJR's favor, but only five of those findings are case dispositive—namely, findings that not a single one of RJR's contract farmers infringed, and findings on the four separate grounds of invalidity. Many of the errors committed by the Court, or improper

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<sup>13</sup> The jury's flawed finding on anticipation necessarily infected its finding of obviousness as well, since once the jury found that a single prior art reference disclosed all of the elements of the Claim at Issue, obviousness would have been a foregone conclusion.

arguments made by RJR, impacted the jury in multiple ways, as to both infringement and validity. For simplicity purposes, however, we discuss separately below the grounds for vacating each of the jury's findings, addressing non-infringement in Part V and validity in Part VI.

**V. THE JURY'S NON-INFRINGEMENT FINDINGS WERE AT ODDS WITH THE OVERWHELMING WEIGHT OF THE EVIDENCE AND RESULTED FROM CLEAR ERRORS OF LAW**

RJR from the outset thumbed its nose at the Federal Circuit's ruling in this case, and during the course of trial (and before) obtained this Court's blessing to do so. On infringement issues, RJR framed the case as a contest between practicing "conventional" curing and "unconventional" curing. The argument focused principally on the issue of airflow, with RJR asserting throughout the trial that there must be some numeric dividing line between "conventional airflow" and "unconventional airflow." According to RJR, its growers could infringe only if they used "unconventional airflow" of something well in excess of 25,455 cfm. *See, e.g.*, Tr. at 435:10-436:1, 437:21-438:9, 3993:5-20, 4022:1-6; DTX 2550, slide 63.

This contention that the claims required a particular *volume* of airflow that was "unconventional" was rejected by the Federal Circuit,<sup>14</sup> and is clearly at odds with the structure and wording of the claims themselves. The requisite airflow is defined solely by the claim element "airflow sufficient to substantially prevent an anaerobic condition," which the Federal Circuit expressly approved. This Court

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<sup>14</sup> In its appellate brief, RJR argued as an alternative grounds for affirmance that the "controlled environment" limitation of the "claimed invention" required "unconventional airflow," and therefore was indefinite. *See* Br. of Defendants-Appellees at 35-37, 67-68. The Federal Circuit's decision necessarily rejected those arguments. *Star Scientific*, 537 F.3d at 1371-73. Indeed, the Federal Circuit specifically noted that the construction of "controlled environment" adopted by the Court was "not disputed," *id.* at 1364, and it was therefore too late, in the second trial, for RJR to challenge a construction previously accepted by it and the Federal Circuit that formed the basis for the Court's holding.

simply ignored that mandate, and then compounded the error by allowing extensive evidence on the volumetric flow in prior art direct-fired barns, even though such airflow in direct-fired barns is completely irrelevant to any proper application of the claims.

These errors in turn set up RJR's next specious contention—namely, that if RJR's retrofit barns used less airflow than something in the range of 25,455 cfm to 28,000 cfm (or more), then they were using “conventional” airflow that could not infringe. Again, to permit this argument required the Court to abdicate its own responsibility for claim construction, and to ignore the clear guidance in the patents themselves, which described volumes below these levels as plainly within the patented method.

These compounding errors ultimately permitted RJR to frame the infringement issue in terms of whether RJR growers used “conventional airflow”—which was equated with the Peele method—or “unconventional airflow” which was asserted to be required by the patents. This “defense”—which the jury was told was a “total defense” (Tr. at 435:14-22)—was buttressed with the further argument that “Peele was first,” even though, as RJR ultimately admitted, that issue was completely irrelevant if Peele was not anticipatory (as RJR conceded it was not). The “Peele was first” argument was then in turn allowed further traction by another clear error, namely, this Court's ruling that the patents-in-suit were not entitled to their claimed priority date of September 15, 1998, and thus Williams was “second” to Peele. A series of other errors barring Star Scientific from introducing admissions by RJR of its growers' infringement further compromised the process.

Aided or compelled by these multiple legal errors, the jury proceeded to find non-infringement by every single RJR grower. It did so in defiance of the overwhelming weight of contrary evidence. Even RJR had conceded that some farmers would infringe. For all of these reasons, Star Scientific is entitled to a ruling that no reasonable jury could have reached a verdict of non-infringement, or alternatively, to a new trial on this issue.

**A. The Verdict of Non-infringement Was Against the Overwhelming Weight of Evidence and Internally Inconsistent with the Jury's Findings on Validity**

Before addressing the many legal errors that led to the jury's runaway verdict, it is useful to focus on what the evidence demonstrated on infringement. Three things are evident: first, no reasonable jury could have reached the conclusion that not a single RJR farmer infringed; second, no reasonable jury could have reached the determination that tobacco purchased by RJR became a trivial and non-essential part of cigarettes (or was materially changed by RJR in the manufacturing process); and third, the verdicts of non-infringement by RJR farmers can not in any sense be squared with the jury's finding of anticipation under RJR's theory of the case.

Indeed, it is fair to say that the evidence of infringement by at least one RJR grower was so overwhelming that JMOL would be mandated wholly apart from the multiple errors that influenced the verdict, as discussed below. But the presence of those errors underscores and helps explain the unfairness of the process, and Star Scientific's right to appropriate relief. *See, e.g., Saleeby v. Kingsway Tankers, Inc.*, 531 F. Supp. 879, 884, 893 (S.D.N.Y. 1981) (granting new trial on damages where "run-away" jury "drastically erred in its evaluation of the evidence").

**1. As admitted by RJR's own witnesses, at least one RJR grower infringed.**

The first question the jury was required to answer was whether "one or more" RJR growers infringed. For both 2001 and 2002, this issue was largely conceded with respect to three of the four elements of the Claim at Issue. In particular:

- It was conceded that all retrofits maintained "air free of combustion exhaust gases;"<sup>15</sup>

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<sup>15</sup> Tr. at 1263:17-1264:10, 1491:1-1492:8, 1493:20-1495:16, 1498:14-1502:5, 2096:4-23, 2300:8-10, 3487:19-3489:7, 3601:10-17.

- The evidence, presented by Dr. Lee, that the retrofits provided “airflow sufficient to substantially prevent an anaerobic condition” was un rebutted, and in fact confirmed by RJR’s own testing (which this Court improperly excluded);<sup>16</sup>
- The fact that there was “substantial prevention of at least one” TSNA by at least one RJR grower in each year was also compelled, both by the un rebutted demonstration that anaerobic conditions had been substantially prevented by most growers, and by the TSNA test data from both Dr. Lee and RJR which, although debated with respect to the extent of infringement, were ultimately conceded to prove at least some infringement.<sup>17</sup>

For 2002, for example, Star Scientific had done detailed infringement testing on 57 growers, and although RJR contested Star Scientific’s ability to extrapolate from those tests to reach broader conclusions regarding all farmers, no one seriously suggested that Star’s testing failed to establish some infringement by some farmers. Indeed, after mustering all manner of attacks on Dr. Lee’s methodology, measurement error, pilot study, etc., Dr. Stark himself put up a list of seven farmers which, if all those “mistakes” were acknowledged, would still have infringed.<sup>18</sup> RJR thereby essentially conceded that the jury’s response to the first special verdict form question for 2002 had to be “yes.”

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<sup>16</sup> Tr. at 1492:9-1495:9; PTX 373 at App. D; Star Scientific’s Proffer Regarding the Expected Testimony of August J. Borschke, 1-2 (Dkt. No. 950); *see also* Tr. at 1013:18-1016:23.

<sup>17</sup> Tr. at 1488:4-25, 1530:2-1539:23, 1540:7-1542:25, 2892:9-2893:3, 3119:7-3120:4, 3128:9-16; PTX 278; PTX 313, PTX 314, PTX 411A, PTX 716; DTX 2318M, DTX 2898 slide 49.

<sup>18</sup> These farmers were specifically named: Barnes, Brown, Thomas, Adcock, Harden, Hill, and Rouse. *See* Tr. at 2892:9-2893:3, 3119:7-3120:4, 3128:9-16; DTX 2318M, DTX 2898 slide 49.

Similarly, RJR offered no rebuttal whatever to the proposition that at least one RJR grower infringed in 2001. It is undisputed that average TSNA levels for 2000-2001 were *lower* than for 2002.<sup>19</sup> Perhaps for this reason, Dr. Stark barely mentioned 2001 in his testimony, and when he did, confined his opinions to what could be determined from a “statistics standpoint.” Tr. at 3122:11-3123:7. But statistics weren’t required to prove that at least one RJR grower infringed, because Star Scientific’s proof of infringement in that year relied on 2000-2001 data that was essentially a complete census of all RJR farmers. Rather than respond to this analysis, Dr. Stark himself admitted that he had made essentially no investigation of 2001 in arriving at his opinions. Indeed, as far as he knew, “the TSNA data in 2001 was perfectly representative of the population of Reynolds contract farmers.” Tr. at 3204:2-6.

In the face of these uncontested facts and admissions, there is only one conceivable explanation for the jury’s verdict of non-infringement by every single RJR grower: the jury must have accepted RJR’s assertion that its farmers used “conventional airflow” as RJR defined that term and that this excluded the possibility of infringement. This is the only way to interpret the otherwise irrational verdict. Since this was not a proper basis for a finding of non-infringement, as discussed in Parts B-E, *infra*, the jury’s verdict of non-infringement must be overturned as a matter of law, or a new trial granted.

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<sup>19</sup> With respect to 2001, there is no dispute that the RJR growers achieved lower TSNA results in 2000-2001 (the two years on which Dr. Lee based his 2001 infringement findings) than in 2002. This is easily seen by comparing the database of test results. For Evans farmers in 2000-2001, for example, 55% of the test results showed all TSNA values below the 0.15 ppm detection limit, whereas in 2002—utilizing the same 0.15 ppm cut-off—only 42% showed all values below that cut-off. *Compare* PTX 716, Tab 6 *and* Tab 9 *with* PTX 716, Tab 14.

**2. The jury's non-infringement finding on the section 271(g) issues was also irrational.**

Evidencing a complete disregard for the real evidence of record, the jury also found that tobacco that represents 50% of a cigarette is merely a “trivial and non-essential component” of that cigarette. This is a specious finding on its face, but reflects the tenor of the jury’s verdict. The jury similarly found that the tobacco had been materially changed by some RJR process, but no such process was ever identified that could support the jury’s finding. While the 35 U.S.C. § 271(g) findings are not case-dispositive (since inducement has yet to be tried), the jury’s findings are telling in their disregard for the evidence.

**B. The Court Erred by Allowing RJR to Argue that the Asserted Claims Require Distinguishing Between “Conventional” and “Unconventional” Airflow Volumes**

As discussed above, the verdict of non-infringement apparently depended upon RJR’s improper interpretation of the Court’s construction of the “controlled environment” claim element requiring controlling conditions “in a manner different from conventional curing in order to substantially prevent the formation of at least one TSNA,” which RJR translated as requiring “unconventional” airflow volumes. This was the focal point of most of RJR’s evidence, and is the only explanation for a jury verdict that was in all other respects totally at odds with the evidence.

The purpose of claim construction is to determine the meaning and scope of the claims asserted to be infringed. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*), *aff’d*, 517 U.S. 370 (1996). “When the parties raise an actual dispute regarding the proper scope of these claims, the court, not the jury, must resolve that dispute.” *O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360, 1363 (Fed. Cir. 2008) (vacating jury verdict because parties’ arguments regarding meaning and legal significance of claim term were improperly submitted to the jury); *see also Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1364 n. 6 (Fed. Cir. 2008) (it is improper to

allow a witness to testify before the jury about claim construction); *CytoLogix v. Ventana Med. Sys., Inc.*, 424 F.3d 1168, 1172 (Fed. Cir. 2005) (holding it was improper for the district court to allow the parties to present expert witness testimony to the jury regarding claim construction, and to allow counsel to argue conflicting claim constructions to jury).

Here, the Court erroneously permitted RJR to repeatedly redefine the plain terms of the Claim at Issue. Throughout the trial, RJR defined the “controlled environment” limitation to require “unconventional airflow.” *See, e.g.*, Tr. at 435:10-436:1 (“[Controlled environment] has been defined in a way that you have to consider the difference between what is conventional airflow and unconventional airflow.”). This was put to the jury as “a total defense to this infringement charge.” *Id.*; *see also* Tr. at 3992:23-25 (“Star cannot show an unconventional number for airflow. And without that, they cannot prove their case for infringement.”).

Allowing RJR to make this claim construction argument usurped this Court’s role, and was contrary to clear Federal Circuit precedent, including its ruling in this very dispute. This Court, however, sidestepped the ruling of the Federal Circuit and disregarded its own obligation to construe the claims for the jury in a reasonable manner. Instead, it permitted RJR to resuscitate the very arguments that it had made and lost earlier. When the infringement evidence so clearly favors one party as it does here, a Court’s failure to ensure proper claim construction requires a new trial. *See O2 Micro*, 521 F.3d at 1363, n.4; *see also CytoLogix Corp.*, 424 F.3d at 1173-1174.

Most egregious was the Court’s willingness to permit the contention that “unconventional airflow” required a volumetric flow of at least 25,455 cfm.<sup>20</sup> No one of reasonable skill in the art could

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<sup>20</sup> *See* Pretrial Order re: Documents 599 & 737 [Airflow] (Dkt. No. 929); Tr. at 234:19-299:6 (Star Scientific’s objections to RJR’s opening slides), 246:24-249:9, 435:10-438:9, 452:3-459:25 (Star

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possibly have read these claims as requiring in excess of 25,455 cfm. This is true for at least three compelling reasons. First, the patents themselves explain that the claimed method can be practiced with airflow less than this figure (*e.g.*, 25,000 cfm in Example 7). Second, every witness at trial conceded that there is no single “number” that defines conventional airflow, since airflow changes throughout even a given cure.<sup>21</sup> Third, the “amount” of airflow required by the claims is specifically explained—in non-numeric terms—in the claims themselves, *i.e.*, as an “airflow sufficient to substantially prevent an anaerobic condition.”<sup>22</sup>

Given the green light by the Court, however, RJR repeatedly argued to the jury that the asserted claims must be understood as requiring particular values for temperature, airflow and humidity, as the following testimony by Dr. Otten illustrates:

Q. Okay. And in a manner different from conventional curing, is that referring to numbers or something else?

A. Well, it has to, this is the process. And in the process, you have to know the numbers.

Q. So is it referring to numbers from the perspective of one ordinary skill in the art?

A. Right. You need to know the numbers. (Tr. at 3389:6-12).

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Q. Okay. And how about airflow?

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Scientific’s motion to strike large portions of RJR’s opening statement), 463:1-3 (denying same), 733:17-22, 735:22-738:12, 1280:2-8, 1282:4-1284:5, 1291:8-1293:14, 1296:6-1298:5, 1303:12-1304:12, 2283:3-17, 2290:17-21, 2313:6-12, 2599:2-5, 2606:17-2607:4, 3072:20-3074:18, 3386:4-3396:19, 3465:7-3472:10, 3608:22-3611:1, 3617:21-3618:1, 3673:10-19, 3684:14-3685:12, 3990:20-3993:20, 4021:21-4022:10; DTX 2550 slides 59 and 63.

<sup>21</sup> *See, e.g.*, Tr. at 738:2-10, 1282:20-1283:12, 1284:6-12, 1399:14-20, 1910:16-1911:7, 3616:24-3618:1.

<sup>22</sup> RJR’s tobacco barn furnace designer (George Varsos) confirmed that, in the context of tobacco curing, “airflow” is not simply a volumetric flow, but necessarily takes into account the oxygen content. *See* Tr. 2529:3-15, 2536:4-19; *see also* Tr. at 2439:24-2440:18, 2522:4-2528:21.

A. Same thing applies for airflow. It has to be a number that is different from conventional curing.

Q. So one of ordinary skill in the art would understand in a manner different from conventional curing to be referring to airflow in terms of a number that is different from the airflows used in conventional curing processes?

A. Yes. (Tr. at 3390:21-3391:3).

The issue of the meaning of the claims was an issue for the Court, not an issue as to which the Court should have permitted expert testimony (particularly from Dr. Otten, who by his own admission was not one of skill in the art).<sup>23</sup> *See* Tr. at 3385:25-3386:22.<sup>24</sup> The Court erred in disregarding the Federal Circuit’s mandate, its own claim construction, and the plain language and structure of the claims, and this error clearly infected the jury’s improper verdict.

**C. The Court Erred by Allowing RJR to Urge the Jury to Make an Improper Comparison Between the “Peele Method” and the Patented Method**

The Court’s errors in permitting the case to be framed around “unconventional airflow” were exacerbated by a series of related errors built on similarly fundamental misconceptions of law. RJR argued throughout the trial that it was a “total defense” if RJR was practicing its own (patented) Peele method. Since the Peele patent disclaims the need for unconventional airflow, RJR claimed that its own farmers—who were “just practicing Peele—never used such “unconventional airflow,” defined as something above the range of 25,455-28,000 cfm. Defined in these terms according to RJR, the case simply boiled down to whether RJR’s farmers were practicing the so-called “Peele process” or Jonnie Williams’ patented process:

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<sup>23</sup> Dr. Otten was not one skilled in the art even under the agreed definition set forth in the jury instructions (Tr. at 3906:9-3907:6), both because he does not have the requisite tobacco curing experience and because he has not studied the formation of TSNAs. Tr. at 3614:10-3615:25; 3621:23-3622:21.

<sup>24</sup> In further support, Star Scientific incorporates by reference its papers concerning these claim construction issues. Star Scientific’s Opp’n to RJR’s Motion *in Limine* No. 2 re Airflow (Dkt. No. 628); Star Scientific’s Motion *in Limine* re Dr. Lambert Otten and DTX 2550 (Dkt. No. 1054).

You're going to have to decide whether Reynolds is following the process of Dr. Peele or following the process of Mr. Williams. We believe the evidence will show you that it is Dr. Peele's process that is the process that is being used. . . And Star has the burden of proving that the Reynolds farmers used the process of Mr. Williams and not the process of David Peele. We believe the evidence will show you, just based on the test data that Star collected, that there is no question that it is Dr. David Peele's process that Reynolds is following . . . . (Tr. at 415:23-416:22).

Dr. Peele's work is both front and center on the infringement side of this case and the invalidity side of this case, because his work precedes the work of Mr. Williams and his patent application was filed before the operative patent application was filed by Mr. Williams. (Tr. at 446:12-16).

The "Peele versus Williams" choice was a central theme of RJR's examination of witness after witness, and RJR continued to pursue this theme right up through closing:

[Peele's] moment of inspiration for the invention, for a recipe to reduce TSNAs, was based on years of very well documented scientific research. The evidence shows you get excellent results, and those are the results that Reynolds is getting today. Now, again, Mr. McMillan suggested that I was going to come here and say that Dr. Peele's method is the same. It is different. That is what this whole case is about, the difference that exists between Dr. Peele's work, Dr. Peele's invention, Dr. Peele's process, and what Mr. Williams claims to be his invention. And that at its core is the reason Reynolds doesn't infringe, because it followed that process, not a different process. (Tr. at 3980:18-3981:5)

Under the law, however, the comparison that RJR consistently urged the jury to make is irrelevant to the issue of infringement. The only proper comparison is between the elements of the asserted patent claims and the curing process practiced by RJR's farmers. *Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1366 (Fed. Cir. 2002) (infringement is properly determined only "by construing the claims and comparing them to the accused device"). Practicing one's own patent or method is not a defense to the charge of infringing someone else's patent. *Bio-Technology General Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1559 (Fed. Cir. 1996); *see also Blanchard v. Putnam*, 75 U.S. 420, 425-26 (1869).

The Court ultimately referred to this principle in a jury instruction, but in the process left the underlying confusion regarding "unconventional airflow" in place, and, in any event then continued to

allow RJR counsel to argue in disregard of the new instruction.<sup>25</sup> The belated jury instruction was further compromised by the fact that it conflicted with the Court's earlier instructions on the same issue, which could only have confused the jury.<sup>26</sup> The Court's unwillingness to give a correct instruction at the proper time was surprising, since well before the final jury instruction, the Court had asserted that the legal principle described above was "perfectly obvious" (Tr. at 2919:16-17).<sup>27</sup>

In any case, by the time of the eventual jury instructions, the damage had already been done. The Court's unwillingness to insist on proper claim construction throughout the trial resulted in a series of errors concerning admissibility of evidence which could not be corrected *post hoc*. For example, the Court struck nearly one hour of Dr. Lee's rebuttal testimony (given on cross-examination) as to why RJR farmers were not just practicing Peele, and did so on the basis that the testimony was irrelevant. But when RJR's experts presented the exact flip side of the coin (*i.e.*, by contending that RJR growers were "just practicing Peele"), the testimony was fully allowed. Tr. at 3443:1-3448:3. Star Scientific

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<sup>25</sup> See *Warner v. Rossignol*, 538 F.2d 910, 912-913 (1st Cir. 1976) (ordering new trial where jury instructions were unable to counterbalance prejudicial remarks of trial counsel).

<sup>26</sup> The Court's ultimate jury instruction was the third instruction on the subject. Taken together, the three were inconsistent and misleading. See Tr. at 1585:18-1586:4, 1597:1-1599:7, 3908:24-3909:22; see also *id.* at 455:4-459:25, 460:16-464:8, Hearing Exs. 1-3. Cf. *United States v. Varner*, 748 F.2d 925, 927 (4th Cir. 1984) ("Where two instructions are in conflict, and one is an incorrect statement of law and is clearly prejudicial, the charge constitutes reversible error, since the jury 'might have followed the erroneous instruction.'").

<sup>27</sup> The Court continued to assert that the evidence was relevant to "copying." Tr. at 3072:4-19. Star Scientific never contended, however, that Dr. Peele copied from Mr. Williams the idea of curing tobacco with a heat exchanger instead of a direct-fired burner. Rather, as Dr. Peele confirmed at trial, what RJR copied was the idea of *using increased airflow* to substantially prevent anaerobic conditions – something RJR adopted in 2000 *after* it learned that the Peele process did not achieve sufficiently-low TSNA levels. *Id.* at 2204:6-2208:22 (Dr. Peele discussing VCU2K design changes), 2282:3-2283:6 (Dr. Peele testifying about Star barn he saw in June of 1999 with a "big fan"). Since RJR repeatedly emphasized that the Peele process did not rely on airflow in any way, it was inappropriate to use the alleged copying as a way of shoe-horning RJR's improper comparison into the case.

was thus deprived of its best proof for why RJR growers were not “just practicing Peele,” and that proof not only was lost completely but was replaced by contrary RJR testimony that the Court allowed.<sup>28</sup>

RJR exacerbated the confusion by affirmatively misleading the Court regarding the issues in dispute. RJR continuously represented to the Court that it was contending that the Peele patent application (or “invention”) anticipated Williams under Sections 102(e) and 102(g). Based on that representation, the Court refused to limit testimony on the Peele issue. Tr. at 243:21-245:6, 281:13-282:9, 446:12-16; 455:4-459:25, 460:16-464:8, Hearing Exs. 1-3; *see also* Dkt. No. 1065. But after instructions were approved—and given to the jury—RJR counsel in his closing (and after Star’s closing argument) withdrew the 102(e) and (g) defenses.<sup>29</sup> This obviously reflected the complete disingenuousness with which RJR counsel had argued to the Court—only several hours earlier—that Section 102(e) and 102(g) remained central to the case. And the confusion and prejudice resulting from this kind of unfettered theory shifting is exactly the type of conduct that warrants a new trial. *Francis v. Clark Equip. Co.*, 993 F.2d 545, 551 (6th Cir. 1993) (holding that the court’s limiting instruction to the

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<sup>28</sup> The jury’s consideration of infringement was also prejudiced by RJR’s introduction of inequitable conduct evidence. For example, RJR used the Burton letter to suggest that RJR couldn’t infringe, because it was simply practicing the prior art or otherwise achieving the same level of TSNAs achieved by “older” methods used previously in the United States. *See, e.g.*, Dkt. No. 1064 at 3; Tr. at 3984:20-25, 3989:23-3990:8, 4017:5-9.

<sup>29</sup> RJR argued that Peele’s process and Williams’ invention were different, and therefore RJR did not infringe:

But big difference, Dr. Peele is saying use a heat exchanger with conventional temperature, humidity, and airflow and you will get low TSNAs. Mr. Williams’ method calls for unconventional temperature, humidity, and airflow, because they’re trying to deal with different goals. He wants to deal with the microbes. Dr. Peele is really only interested in dealing with the NOx. (Tr. at 3985:10-16).

Our position has been clear from day one that Dr. Peele’s process is different than the Star patents, and that’s why we don’t infringe. And you can’t be doing both. (Tr. at 4030:9-12).

jury “could not effectively eliminate the prejudice and confusion” caused by allowing a theory to be presented at trial and then abandoned midway through the trial).

It should not be surprising that the jury was confused by the Peele issue as it was presented to them. The evidence on the issue dominated the trial. It was Peele versus Williams from the outset, based on a set of playing rules that made no sense and was inconsistent with the patent claims and the proof at trial.<sup>30</sup> The jury verdict was unavoidably tainted in the process.

**D. The Court Erroneously Concluded that the Patents-in-Suit Could Not Claim Priority to the Filing Date of the September 15, 1998 Provisional**

The insidiousness of the errors committed by the Court was that they were cumulative. The jury was permitted to hear that the issue in the case was whether RJR growers were practicing “conventional” or “unconventional” airflow. This was augmented by the suggestion that the reason they should find that growers were only using “conventional” airflow is that they were “just practicing Peele.” This was then further exacerbated by RJR’s improper emphasis on the proposition that “Peele was first.” And once again, RJR’s ability to argue that “Peele was first” was the direct product of clear error by the Court. It was also the product of misconduct by RJR’s counsel—who argued a 102(e) and 102(g) defense throughout the case in order to justify its proof that “Peele was first,” and then withdrew this defense during closing—without prior notice—in order to argue that “Peele was different.”<sup>31</sup>

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<sup>30</sup> The Court further obscured the distinction between Peele and Williams by making the perplexing ruling that as to patents whose sole purpose was to improve health and safety, Star Scientific would not be allowed to explain the health and safety benefits of its invention to the jury. Second Procedural Order (Dkt. No. 870). Indeed, when Mr. Williams testified that he recently had discovered a new method to bring TSNAs below “substantial prevention” to a level of virtually zero, the Court cut him off and declared before the jury such testimony was “bizarre.” Tr. at 661:25-662:11.

<sup>31</sup> In *Francis v. Clark Equipment Co.*, the Sixth Circuit affirmed a grant of a new trial where one party first presented and then abandoned a key case theory during the trial, which prejudiced the other

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The “Peele was first” defense received much air time during trial, even though—as ultimately conceded—that proposition was irrelevant, since Peele was “different.” But the proposition was given life in the first place by this Court’s order giving Peele ostensible priority. At the beginning of trial, the Court reaffirmed its earlier order denying Star Scientific the right to claim priority to September 15, 1998, the filing date of the provisional application. Pretrial Order re: Document 746 [Filing Date] (Dkt. No. 923). For the reasons set forth in Star Scientific’s opposition brief on the issue (Dkt. No. 685), incorporated herein by reference, the Court’s priority date decision rests on an erroneous legal analysis and involves the resolution of factual issues that should have been presented to the jury.<sup>32</sup>

The adverse priority ruling had major implications for trial, because it promoted the “Peele was first” issue into a major contention. It remained a theme through RJR’s closing argument: “the idea that somehow Jonnie was first when you look at the timeline...is just dispelled by the documentation and all the testimony that shows to the contrary. And again...the effective date of Mr. Williams’ patent is not until September 15, 1999.” Tr. at 4009:17-22. Under these circumstances, a new trial is required.

**E. The Court Erred by Refusing to Instruct the Jury that “Practicing the Prior Art” Is Not a Valid Defense to Patent Infringement**

As discussed above, the cornerstone of RJR’s defense in this case was the establishment of a false dichotomy between using “conventional” airflow found in the prior art and using “unconventional” airflow. After allowing RJR to present this legally—and factually—flawed argument to the jury

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party and prevented it from adequately challenging the defense. 993 F.2d at 548, 552. The Court further concluded that “no curative instruction would suffice to correct the prejudice.” *Id.* at 551.

<sup>32</sup> As further evidence of the Court’s erroneous decision, even RJR’s outside counsel, Mr. Lione of the Brinks Hofer firm, concluded that the September 15, 1998 provisional application disclosed the invention claimed in the ‘649 patent. PTX 373 at 52642 0051. This is evidence that Star Scientific should have been permitted to present to the jury on the priority date issue.

repeatedly over the course of four weeks, the Court refused to give a jury instruction to explain to the jury that “practicing the prior art” is not a defense to patent infringement. *See, e.g., Tate Access Floors*, 279 F.3d at 1365. According to the Court, such an instruction was unnecessary “in light of the Claim at Issue’s construction to exclude conventional curing.” Email from F. Rasheed to Counsel, June 15, 2009 12:05 AM (Dkt. No. 1077, Ex. A). Ironically, the Court’s observation regarding the scope of the asserted claims is precisely why the “practicing the prior art” instruction was necessary. “Conventional airflow”—which RJR described as airflow found in prior art *direct-fired* barns—was completely irrelevant to the issue of infringement, because direct-fired barns used combustion exhaust gases that created anaerobic conditions irrespective of airflow volumes.

The confusion arising from the lack of any instruction on this important point of law helps explain how the jury could simultaneously find that the patents-in-suit were both anticipated by the prior art and not infringed.<sup>33</sup> On the key point of whether RJR could defend this case on the basis that RJR growers were “just practicing the prior art,” the Court’s unwillingness to give a proper instruction was

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<sup>33</sup> If there was any uncertainty here, the Court was obligated to alter its construction of the claims to clarify them, as requested in Star Scientific’s JMOL motion. Dkt. No. 1065 at 12-13. The patent claims themselves required only “controlling” one of three conditions. The addition of the phrasing “in a manner different from conventional curing in order to substantially prevent” TSNAAs was designed solely to make clear that the control was directed to lowering TSNAAs rather than merely obtaining good quality tobacco. This tracks the structure of the claims. The definition of “what” defines a “controlled environment” is set forth in the claims, *i.e.*, it “comprises” air free of combustion exhaust gases and airflow sufficient to substantially prevent an anaerobic condition. “How” this is accomplished is set forth separately, *i.e.*, by “controlling” one or more of airflow, humidity or temperature. The Court’s rulings at trial regarding how the claims might be construed simply ignored this structure. *See* Tr. at 457:16-458:5, 1761:25-1765:25, 3058:22-3059:19. The “in a manner different” phrasing was never intended to define “what” the level of airflow should be (and certainly wasn’t intended to define it as “unconventional airflow”), which would be completely at odds with the remaining structure of the claims (and, in particular, the “airflow sufficient...” clause). To the extent that the Court nevertheless chose to utilize its own construction as a way of introducing irrelevant issues into the case, that construction should have been revised or eliminated, in favor of the plain language of the claims themselves.

clear error that must have misled the jury, particularly given the overwhelming evidence of infringement in this record.

**F. The Court Erred by Precluding Star Scientific from Calling Mr. Borschke to Testify Regarding Various Issues Presented to the Jury**

The jury's finding of non-infringement was also aided by the Court's refusal to permit Star Scientific to introduce clearly relevant evidence in support of its infringement contentions. During trial, the Court granted RJR's motion *in limine* to preclude Star Scientific from calling Mr. Borschke from testifying during the first phase of the trial despite Star Scientific's showing that Mr. Borschke had information directly relevant to the infringement and validity issues in the case. *See* Tr. at 1400:12-1402:2; *see also* Star Scientific's Proffer, 1-2 (Dkt. No. 950).

As to infringement, the proffered Borschke testimony, and the underlying Lione opinion on which it would in part have been based, was relevant not only as an admission of infringement,<sup>34</sup> but because the Lione opinion had as an attachment detailed print-outs of oxygen testing performed by RJR consultants. That testing showed beyond doubt that RJR's retrofit barns were substantially preventing anaerobic conditions within the barns. *See* Tr. at 1013:18-1016:23; PTX 373 at App. D. This crucial evidence would have formed a fundamental basis for an infringement finding.<sup>35</sup>

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<sup>34</sup> The Court apparently based its exclusion ruling on its earlier bifurcation order, which was also clear error. Bifurcating inducement, when coupled with the exclusion of Mr. Borschke, deprived Star Scientific of its right to prove RJR's specific intent to infringe. The bifurcation of inducement was particularly in error, because it had been requested by no one.

<sup>35</sup> In addition, as reflected in Star Scientific's proffer (Dkt. No. 950), Mr. Borschke was expected to refute the Peele versus Williams argument, address the claim requirements as understood by RJR, verify that RJR's own test data proved its barns met the "sufficient airflow to substantially prevent an anaerobic condition" element, address facts relevant to validity defenses, and enable Star Scientific to introduce into evidence PTX 276, a presentation to Mr. Schindler containing an admission "that the microbial mediated process" does indeed have what he describes as secondary "significance in forming TSNAs." *See* Tr. at 1013:18-1016:23.

By refusing to allow Star Scientific to call Mr. Borschke and introduce the infringement evidence that he would have sponsored, the Court undermined Star Scientific's position on crucial issues bearing directly on RJR's infringement. The Court lacked any compelling justification for excluding this evidence.

**G. The Court Erred by Excluding Dr. Lee's Deposition Testimony Explaining that His Detection Limit Was Substantially Lower than 0.05 ppm**

Finally, RJR's attack on Star Scientific's infringement case was based in important respects on the clearly-erroneous proposition that Dr. Lee's limit of detection was 0.05 ppm. In particular, the jury was permitted to hear from a number of expert witnesses (*i.e.*, Drs. Higby, Stark and Otten) who testified—contrary to the facts known to each of them—that Dr. Lee, Star Scientific's primary technical expert, used instrumentation with a detection limit of 0.05 ppm during his 2002 testing of the TSNA levels achieved by RJR's contract farmers. However, Star Scientific was deprived of its countervailing right to cross-examine these witnesses to put the full facts before the jury. *See Francis*, 993 F.2d at 550 (“Refusal to permit cross-examination of a witness concerning matters testified to on direct examination constitutes prejudicial error.”).

The detection limit issue was important, because RJR argued that even if Dr. Lee's test results were otherwise reliable, they could not be relied upon here because of detection limit deficiencies. Because there is test error in any methodology, RJR argued that Dr. Lee—to account for that error—should have set his detection limit below 0.05 ppm. But, as RJR's experts knew, he had done just that.

RJR's experts premised their assertion that Dr. Lee used a higher 0.05 ppm detection limit in his expert report. These experts knew, however, that after submission of that report, Dr. Lee had given deposition testimony in which he explained that 0.05 ppm was his limit of quantitation, not his detection limit. In essence, while all parties in this case have tended to use “detection limit” as a simple shorthand, Dr. Lee explained that this shorthand had a more precise underlying definition:

Q. Okay. Now, what was the level of detection of the method used?

A. In 2002?

Q. Yes, sir.

A. Approximately .05 ppm.

Q. For each of the four nitrosamines?

A. They varied a little -- they varied somewhat but the -- that's the limit of quantitation. The level of detection was probably, I don't know, on the order of a fourth of that or something.

Q. Okay. So the numbers in your report are actually -- I think you said a fourth, .05, that's the limit of quantification from --

A. That was our -- that was our -- and there is -- there is some differences in between the various nitrosamines. I don't remember what they are.

Q. What would you need to consult to find out what the -- precisely what the limit of quantification was for each of the four nitrosamines?

A. I would have to consult the laboratory data that should have been provided you guys in a box full of stuff.

Deposition of Dr. Lee, March 17, 2007, at 101:18-102:17. *See also* Star Scientific's Opp'n to RJR's Motions *In Limine* Nos. 15-18 (Dkt. No. 1031). Under the Federal Rules of Civil Procedure, this testimony operated automatically as a supplementation of Dr. Lee's report. Fed. R. Civ. P. 26(e)(1)(A) advisory committee's notes (1993); *Potomac Elec. Power Co. v. Electric Motor Supply, Inc.*, 192 F.R.D. 511, 514 (D. Md. 2000); *Tucker v. Ohtsu Tire & Rubber Co.*, 49 F. Supp. 2d 456, 460 (D. Md. 1999) (expert deposition testimony "was a form of supplementation permitted by Rule 26(e)(1)").

Having permitted RJR's experts to opine based on the expert report, the Court refused to permit cross-examination on the basis of the deposition—even though the experts were aware of and had read the deposition, and in fact had been prompted as a result to make their own analysis which confirmed that Dr. Lee's detection limit was lower than 0.05 ppm. Tr. at 3213:12-3214:5 (the Court *sua sponte* "sustained an objection" to Star Scientific impeaching Dr. Stark with Dr. Lee's deposition testimony, rejecting counsel's argument that RJR opened the door by questioning Dr. Stark about Dr. Lee's expert report). This was clear error, and highly prejudicial. It permitted the jury to view the detection limit as a "battle of experts" in which Dr. Lee had allegedly taken inconsistent positions, without allowing the

jury to hear that Dr. Lee had been fully consistent—and that RJR’s experts knew this. This clear error must necessarily have confused the jury and tainted their consideration of Dr. Lee’s testimony on infringement.<sup>36</sup>

**VI. THE JURY’S INVALIDITY FINDINGS WERE AGAINST THE OVERWHELMING WEIGHT OF THE EVIDENCE AND WERE PROMPTED BY CLEAR ERROR BY THIS COURT**

As with infringement, the jury’s findings on invalidity can not be sustained. Once again, the jury was misled by this Court’s unwillingness to follow the mandate of the Federal Circuit. In other respects, the Court simply ignored the precedents of the appellate court. The jury in any case ignored the clear weight of the evidence in reaching its findings with respect to anticipation, obviousness, best mode and definiteness. Each finding, and the errors associated with each, are discussed below.

**A. Anticipation and Obviousness**

A series of errors by the Court and jury require JMOL or a new trial. With respect to anticipation and obviousness, these errors are of three basic types. First, the Court erred by permitting RJR to re-argue inequitable conduct, in contravention of the Federal Circuit’s precedents. This necessarily prejudiced the jury’s consideration of at least anticipation and obviousness. Second, RJR’s proof on both issues was exceedingly narrow, and under clearly articulated Federal Circuit precedent, no reasonable jury could have found for RJR on these issues under a clear and convincing standard of evidence. Third, the Court made additional errors that further prejudiced a fair adjudication of these two issues. Each of these errors is discussed below.

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<sup>36</sup> The ruling was particularly prejudicial because Dr. Lee, due to his heart transplant, was unavailable to appear live in Court to provide direct rebuttal.

RJR's case on anticipation and obviousness was very limited. Not a single printed publication was relied on for anticipation. Instead, RJR relied on only two alleged "public uses," each of which were ultimately conceded on the evidence of record not to anticipate. Similarly, on obviousness, RJR relied solely on a single proposed combination of two references, which for a variety of reasons could not as a matter of law form a basis for any legitimate obviousness finding.

Because it lacked a real case on anticipation and obviousness, RJR sought instead to confuse the issue by focusing on whether Star Scientific withheld material information from the Patent Office. The information—*i.e.*, the Burton letter—was not prior art, however, and was therefore not relevant to the anticipation or obviousness inquiry. But RJR suggested repeatedly that the Patent Office would never have allowed the patents if it had known the facts in the Burton letter "concealed" by Star Scientific. By repeatedly referencing the Burton letter, and purporting to focus its anticipation and obviousness attacks on information contained in that letter, RJR succeeded in seriously misleading the jury.

This was not harmless error. RJR's proof of anticipation and obviousness should have failed on its face—and is the subject of Star Scientific's JMOL motion. But given the paucity of that proof, the Court's error in allowing RJR to argue that the Patent Office was denied key information as the result of intentional acts by Star Scientific must be deemed prejudicial. *Cf. City of Cleveland v. Peter Kiewit Sons' Co.*, 624 F.2d 749, 758-760 (6th Cir. 1980) (requiring a new trial on all issues based on "spillover" from "pervasive" "misconduct" in the form of prejudicial comments from counsel on improper and irrelevant issue); *O'Rear v. Fruehauf Corp.*, 554 F.2d 1304, 1308-09 (5th Cir. 1977) (ruling that plaintiff's "substantial right to a fair trial by an impartial jury was violated by [opposing] counsel's repeated subjection of the jury to prejudicial information").

**1. The Court erred by permitting RJR to re-argue inequitable conduct, in contravention of the Federal Circuit’s mandate.**

“Few legal precepts are as firmly established as the doctrine that a mandate of a higher court is ‘controlling as to matters within its compass.’” *United States v. Bell*, 5 F.3d 64, 66 (4th Cir. 1993) (citing *Sprague v. Ticonic Nat’l Bank*, 307 U.S. 161, 168 (1939)). Yet despite the mandate issued by the Federal Circuit rejecting RJR’s inequitable conduct and indefiniteness defenses, this Court improperly permitted RJR to argue both defenses to the jury at trial. *See Lucent Tech. v. Extreme Networks, Inc.*, 229 F.R.D. 459, 461 (D. Del. 2005) (granting a motion for a new trial to patentee after an adverse jury verdict where defendant had repeatedly referred to counterclaims and affirmative defenses that were not at issue in that trial).

RJR’s introduction of the Burton letter started from the outset of the case. It was first used in cross-examination of Mr. Williams. Initially, the questioning was seemingly directed at an inventorship issue, even though RJR was not presenting an inventorship issue in the case. But it soon became apparent that this was just a cover for injecting inequitable conduct into the trial. Though Star Scientific’s counsel again objected (Tr. at 691:5-24), the Court pronounced that the issue of why part of the Burton letter was not before the Patent Office was “a fact” and since the patent listed things that were before the Patent Office, it was only fair to bring out what had not been provided. According to the Court: “we’re not talking about the inequitable conduct; we’re talking about the Patent Office [and] if can see it.” *Id.* at 691:15-24.

From that point forward it was a runaway train. RJR introduced the Burton letter eight different times with a variety of witnesses. It featured the letter in opening and closing. Eventually, Star Scientific filed a specific motion *in limine* on the issue, which also was denied. Dkt. No. 1063; Tr. at 3886:17-3887:2. Ultimately, RJR’s counsel—over Star Scientific’s objection—put before the jury the

exact same inequitable conduct arguments that were previously and unambiguously rejected by the Federal Circuit:

Q. They never told the Patent Office what Dr. Burton was telling Star's patent lawyer about the old flue curing process?

A. They did not.

Q. And so the Patent Office got information from Star's patent lawyer that was contrary to the information that Dr. Burton, their own technical advisor had provided this patent attorney, right?

A. That's true.

Q. And in all those binders, did Star ever tell the Patent Office that if you use the old flue curing process where you separate combustion exhaust gases, you can sometimes get very low and even non detectable levels of TSNAs?

A. The answer is no. (Tr. at 3686:4-3692:17 (Otten re-direct)).<sup>37</sup>

In closing argument, RJR's counsel then projected onto a six-foot high screen a slide that showed a man in silhouette holding a document behind his back, with the title "Star Failed to Disclose the Burton Letter to the PTO as Required." RJR Closing, Slide 117;<sup>38</sup> *see also* Tr. at 4021:12-20 (Mr. Kaplan: "So for all the stacks and stacks of paper the Patent Office had, they didn't have [the Burton letter]. And so, you know, it's one thing to come in and say you disclosed everything, but it is another to say you kind of are holding a key document behind your back.>").<sup>39</sup>

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<sup>37</sup> When Star Scientific's counsel continued to object to RJR's improper arguments, the Court warned that it would be grounds for a mistrial if counsel informed the jury of the Federal Circuit's decision on the issue. Tr. at 3688:15-3689:10.

<sup>38</sup> Star Scientific has repeatedly requested that RJR's counsel provide a copy of the slides used in closing to ensure a complete record for post-trial briefing and appeal, but thus far those requests have been ignored.

<sup>39</sup> This error was compounded by the Court's unwillingness to permit testimony by Mr. Borschke, who signed or approved submissions to the PTO regarding the patentability of much broader claims directed to the Peele process. *Supra* at p. 23-24. This testimony—describing RJR's actions in support of the Peele application before the Patent Office—would have constituted an important admission that RJR did not truly believe that Wiernik, Hassel Brown, or any of the other known reference presented grounds for non-patentability, either for anticipation or obviousness. *A fortiori*, RJR's position that the Peele claims were not anticipated or rendered obvious by any of these references constituted an admission that the substantially-narrower Williams claims also could be distinguished

(continued...)

RJR exacerbated the problem further—again in contravention of the Federal Circuit mandate—by repeatedly attempting to compare the Burton letter with what was stated in Mr. Williams’ provisional patent application. *See* Tr. at 690:1-694:12, 2297:17-2298:13, 3686:6-3692:17. RJR contended that the reference to older curing technologies producing “high” TSNAs must also have misled the Patent Office, but the Federal Circuit’s mandate barred such evidence or argument.<sup>40</sup> *Star Scientific*, 537 F.3d at 1367-71.

Again, this was not harmless error. Quite the contrary, RJR attempted to tie its inequitable conduct allegations directly to the issues of anticipation and obviousness. Indeed, at one point, RJR argued that since the issue of anticipation depended upon what was before the Patent Office, it was only fair to bring out that the Burton letter was not disclosed. *See* Dkt. No. 1064. But the Burton letter was *not prior art*—it was neither public, nor written prior to Mr. Williams’ invention. No one has ever seriously contended otherwise. Thus, in connection with the issues of *anticipation and obviousness*, there was no possible relevance of the Burton letter to either inquiry. That is not what the jury was told, however. The jury was repeatedly advised that it should not be swayed by the fact that the Patent Office had references such as Wiernik before it because other “references” like the Burton letter were hidden.

In closing, RJR’s counsel particularly stressed the point on the issue of obviousness:

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(continued)

over the same prior art. This was evidence that the jury should have been permitted to hear.

<sup>40</sup> Just as it did during the inequitable conduct trial, RJR also questioned Mr. Williams about differences between the language used in the 1998 provisional application and the 1999 utility application to suggest that Star Scientific was attempting to mislead the patent examiner. Tr. at 689:20-700:20. But given the Court’s ruling that Star Scientific could not claim priority to the provisional application, as well as the fact that provisional applications are not even examined by the Patent Office, such evidence had no relevance whatsoever to the infringement and validity issues being tried. The only purpose for such evidence was to inject the specter of inequitable conduct into the trial, in direct contravention of the Federal Circuit’s rejection of that defense.

[O]n obviousness, you know, the patent system you're supposed to have claims that are not obvious . . . Tohno was a reference that the Patent Office did not have in front of it, so it was never considered by the Patent Office. And in that respect is similar to the fact that the Burton letter was something that the Patent Office did not have. (Tr. at 4018:10-4019:2).

The Court's treatment of the Burton letter and inequitable conduct issues put Star Scientific in an impossible position. It could not respond to RJR's evidence without retrying inequitable conduct. More specifically, the available witnesses that Star Scientific could have used—as Star Scientific in fact had done in the inequitable conduct trial—were primarily lawyers whose only relevant testimony was to explain why they did or did not submit various things to the Patent Office. Such testimony would have been completely out of place in this trial, and it would have been highly prejudicial for Star Scientific to even attempt to introduce such testimony, since it would necessarily have been understood by the jury as an acknowledgement that the testimony was somehow relevant. *See Koufakis v. Carvel*, 425 F.2d 892, 901 (2d Cir. 1970) (“As the trial judge never did make clear that this aspect of [trial counsel's] argument was grossly improper, it is likely that both the jury and [trial counsel] considered his failure to intervene as tacit approval of the line of argument.”).

In short, in searching for a reason for the runaway nature of the jury verdict, this Court should presume that RJR's incessant use of inequitable conduct evidence played a major role in that outcome. This error was necessarily a key aspect of the jury's consideration of anticipation and obviousness (and other issues as well—*see supra* note 28). In particular, the jury was effectively told that if the Patent Office had known about the Burton letter, it would certainly have concluded that the Williams invention was either anticipated or, at minimum, obvious. There is no way this improper evidence could not have affected the jury's deliberations on these issues, given the verdict and the overwhelming weight of evidence favoring a finding of no invalidity.

**2. The verdict on anticipation and obviousness was against the overwhelming weight of the evidence.**

Because RJR's proof on anticipation and obviousness was so compact—relying on only a handful of references or uses—it can easily be examined for sufficiency. As a matter of law, it fails on both issues.

**a. RJR's Evidence of Alleged Anticipation Was Insufficient as a Matter of Law to Support the Jury's Verdict**

At the beginning of trial, RJR argued that the patents-in-suit were invalid for anticipation in view of three alleged prior art references: (1) the Peele patent application, (2) the indirect-fired curing process used by Hassel Brown,<sup>41</sup> and (3) the “quick drying” experiments performed by Dr. Burton and others at Spindletop Farm. Tr. at 445:4-446:16; RJR Opening Slide No. 27. By the end of trial, RJR abandoned the Peele patent application, arguing in no uncertain terms that “Dr. Peele's process is different than the Star patents, and that's why we don't infringe.” Tr. at 4030:9-11. Of course, if the Peele process does not infringe, it also cannot anticipate. *Cook v. Sandusky Tool Co.*, 4 S. Ct. 4 (1884); *Girdler Corp. v. Abbotts Dairies*, 24 F. Supp. 551, 555 n.2 (D. Pa. 1938) (“If the . . . process would not infringe these claims . . . it does not anticipate.”).

As for Hassel Brown and Spindletop, the evidence of record requires JMOL in favor of Star Scientific. To support its anticipation defense based on Mr. Brown, RJR produced a single sample for Mr. Brown from 1996 and multiple samples from 1998 (after the date of Williams' provisional application). But Mr. Brown insisted that these samples were cured using conventional indirect-fired

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<sup>41</sup> RJR also introduced test results for a Mr. Hicks (Tr. at 3439:25-3440:19), but did not purport to establish that Mr. Hicks' stick barn anticipated all the elements of the Claim at Issue. Indeed, the patents themselves specifically disclaim and distinguish stick barns. But, in any event, the same data infirmities regarding RJR's TSNA data that infect the Brown contentions doom Mr. Hicks as well.

processes, and it was conceded at trial that such processes typically produce TSNAs of 1-2 ppm—well above the patent threshold. The 1-2 ppm parameter for prior art indirect-fired curing was accepted by all RJR scientists and RJR’s Chairman of the Board. *See* PTX 132, 160, 161, 163. It was confirmed at trial by Dr. Peele, Dr. Otten, and every other witness who discussed the issue. *See* Tr. at 1167:11-1169:25, 1561:10-1564:12, 2141:17-2142:3, 2178:11-2179:10, 2191:9-14, 2202:9-2203:9, 2273:1-2275:15, 3483:15-19. And importantly, the underlying RJR testing data on which this conclusion was based directly relied on a significant number of samples from Hassel Brown. *Id.*; *see also* PTX 88, PTX 411A at 75-76, 85.

Thus, RJR’s selection at trial of a small and isolated subset of Hassel Brown samples purporting to have “undetectable” TSNAs would show—at best—that Mr. Brown achieved low TSNAs accidentally or on occasion—a finding that would not establish anticipation under well-established case law regarding principles of inherency. *Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1373 (Fed. Cir. 2002); *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999).

The inherency issue need not even be reached on this record, however, because although RJR’s results show TSNA levels down to “zero” in some cases, the evidence showed beyond dispute that these “zeros” meant nothing—for two independent reasons. First, RJR’s detection limit in the relevant time period was somewhere between 0.2 and 0.4 ppm—four to eight times the levels (*e.g.*, 0.05 ppm) necessary to prove “substantial prevention.”<sup>42</sup> While Dr. Peele asserted that he understood the detection limit was 0.15 ppm in 1996 (Tr. at 1932:17-1933:2), he later admitted that this was without foundation

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<sup>42</sup> Dr. Lee testified that he could assume a detection limit of 0.2 ppm or higher based on his review of RJR’s data. Tr. at 1567:10-14.

(Tr. at 2165:16-2167:6).<sup>43</sup> Moreover, even RJR's lead technical expert, Dr. Otten, testified that one sample "tells me nothing." Tr. at 3515:23-3516:4. RJR thus offered no serious proof—much less clear and convincing proof—that Mr. Brown achieved "substantial prevention" of TSNAs even occasionally. *See Transclean*, 290 F.3d at 1373; *Robertson*, 169 F.3d at 745.

Moreover, Dr. Lee examined Hassel Brown's sampling data in detail and concluded that they demonstrated total TSNAs well above 1 ppm. This conclusion likewise was based directly on RJR's 1998 testing, and in that testing, RJR gathered more samples from Hassel Brown than any other farmer. On this record, no reasonable jury could have found that Hassel Brown's prior art process anticipated the patents-in-suit.

RJR's anticipation defense fares no better with respect to Dr. Burton's Spindletop work. Most clearly, the 24-hour "quick drying" process failed to satisfy the requirement of the Claim at Issue of drying the tobacco for a period of at least 48 hours. *See* Tr. at 2614:14-2615:24, 2652:17-2656:13. This is not merely a technical distinction. Dr. Burton was trying to halt all microbial activity as fast as possible, and there is nothing in this record that would even remotely suggest that "quick drying" would have worked if conducted over the longer time frame defined in the Claim at Issue.<sup>44</sup>

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<sup>43</sup> To the extent the detection limit issue is significant, the Court further erred in excluding the rebuttal testimony of Mr. Edwards. Dkt. No. 1036; June 10, 2009 Order; Tr. at 3370:10-17. Mr. Edwards was the person at RJR who conducted the TSNA testing. His deposition testimony, offered in rebuttal, confirmed that RJR did not utilize a particular limit of detection in 1996. Dep. at 20:6-8.

<sup>44</sup> RJR also failed to make the required showing that the Spindletop work was public. Rather, the evidence showed that the research was conducted under contract with Swedish Match, and that the results were publicized only generally, and not in the level of detail that suggested overlap with the Williams patent claims. *See* Tr. at 2619:9-2624:13, 2626:8-2627:25. In particular, the October 1997 Burton declaration and attached data from 1993 and 1994 (DTX 308 (RJR's summary chart), DTX 313, DTX 2550 at 34-37) did not enter the public domain until well after September 15, 1999, which is the latest effective filing date to which the patents-in-suit could be entitled.

RJR attempted to argue that this limitation was somehow met because the tobacco was air cured for 5 days before being subjected to the quick drying process (Tr. at 4017:22-4018:5), but the argument was not supported by a single witness and is contradicted by the claim language. The 48-hour minimum time period refers to the time the tobacco is treated in the claimed “controlled environment,” which includes, among other things, “airflow sufficient to substantially prevent an anaerobic condition.” PTX 10, claims 4 and 12. However, the record is clear that the “air curing” performed prior to the quick drying process did not involve any forced airflow at all, but instead simply involved hanging the tobacco in an open barn.<sup>45</sup> Tr. at 3248:12-21.

Lastly, while RJR attempted to “cherry-pick” the TSNA results, the published results of Dr. Burton’s work confirm that the quick drying experiment did not achieve “substantial prevention” of TSNAs. PTX 449 at 55-56.

On this record, no reasonable jury could have found anticipation by clear and convincing evidence with respect to either Hassel Brown or Spindletop.

**b. RJR’s Evidence of Alleged Obviousness Was Insufficient as a Matter of Law to Support the Jury’s Verdict**

RJR urged the jury to find the patents-in-suit invalid as obvious over the combination of the Wiernik article and a Japanese patent application filed by Tohno. As noted earlier, the jury’s consideration of obviousness was prejudiced by RJR’s improper assertion that the Patent Office lacked important information relevant to the obviousness inquiry (*i.e.*, the Burton letter). RJR also relied on

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<sup>45</sup> Moreover, the tobacco that was cured for 5 days and then quick-dried (EOY+5) did not fall within the requirements of the claims for a further reason. The Claim at Issue recites, in pertinent part, “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.” PTX 10, claim 4 (emphasis added). Tobacco that had begun the curing process (*i.e.*, was five days into the curing process) was not “uncured.”

improper expert testimony from Dr. Wahlberg to the effect that a person of ordinary skill in the art would understand the Wiernik article as teaching the avoidance of anaerobic conditions to reduce TSNA's. Tr. at 2604:24-2065:2. RJR then compounded these errors by offering testimony by Dr. Otten to the effect that Tohno taught the introduction of airflow to a curing environment to avoid oxygen deficiencies, and that the combination of Wiernik and Tohno disclose each and every limitation of the asserted claims. Tr. at 3428:21-3435:8.

Under the standards enunciated by the Supreme Court in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), as they have come to be understood by the lower courts, however, RJR offered no evidence that one skilled in the art would have been motivated to combine the two references or predictably have understood such combination as likely to work, and this omission is particularly glaring given the unpredictability of tobacco curing and TSNA formation in the first place. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1326 (Fed. Cir. 2009). The record instead demonstrated: 1) that the references teach away from each other; 2) that the references concern different types of tobacco and different curing methods that one skilled in the art would have no reason to combine; and 3) that neither reference nor their combination discloses or suggests the subject matter of the claims as a whole.<sup>46</sup> Merely recognizing a goal to be achieved or the problem to be solved doesn't render a solution obvious. *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1352 (Fed. Cir. 2008) (“[K]nowledge of the goal does not render its achievement obvious”); *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 381 F.3d 1371, 1377 (Fed. Cir. 2004) (“Recognition of a need does not render obvious

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<sup>46</sup> Obviousness applies to the whole claim. See *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1086 (Fed. Cir. 2008) (“The determination for obviousness is made with respect to the subject matter as a whole, not separate pieces of the claim”).

the achievement that meets that need . . . Recognition of an unsolved problem does not render the solution obvious.”).

Neither Wiernik nor Tohno involved curing Virginia flue-cured tobacco. Wiernik relates to the quick-drying of burley tobacco, whereas Tohno relates to an unspecified Japanese curing method used to cure “domestic” Japanese tobacco.<sup>47</sup> Perhaps not surprisingly, therefore, Wiernik and Tohno teach away from the Williams invention, and from each other. Both Williams and Wiernik identify high humidity as one of the conditions favoring TSNA formation, yet Tohno teaches spraying the tobacco with hot water to avoid drying out the tobacco with the air being used to control odors. *Compare* PTX 449 at 54 *with* DTX 2663 at 1, 3-4. RJR failed to present any evidence as to why a person of ordinary skill would be expected to combine these contradictory teachings, and likewise failed to present any evidence whatsoever that doing so would achieve substantial prevention of TSNA. To the contrary, according to the teaching in Wiernik regarding humidity, it is likely that spraying hot water on tobacco during curing, as taught by Tohno, would actually *increase* TSNA.

Moreover, the Wiernik mention of “anoxia” was not at issue in the experiments undertaken. Dr. Wahlberg herself admitted that the hypothesis she was trying to test in Wiernik had “nothing to do with anaerobic conditions.” Tr. at 2625:1-2626:5. And Dr. Wahlberg further acknowledged that she didn’t describe the desirability of avoiding anaerobic conditions when she presented her work to scientists at RJR. *Id.* at 2626:6-2627:25; DTX 32. Thus, nothing in Wiernik suggested that an altered curing process with increased airflow was a solution to TSNA, a subject as to which Tohno is also completely

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<sup>47</sup> Tohno deals with a peculiar (and unidentified) type of Japanese “domestic” tobacco, which under cold curing conditions, released a very bad odor. Apparently recognizing that the tobacco was in effect rotting, Tohno teaches adding enough oxygen to prevent rotting, but goes no further, and clearly teaches nothing regarding TSNA.

silent. No one of skill in the art would have predicted success from the combination of two such disparate references. *See, e.g., U.S. Philips Corp. v. Iwasaki Electric Co., Ltd.*, 607 F. Supp. 2d 470, 479 (S.D. N.Y. 2009) (no obviousness based on purported combination of “fundamentally different” references); *see also Tec Air, Inc. v. Denso Mfg. Michigan Inc.*, 192 F.3d 1353, 1359-1360 (Fed. Cir. 1999) (references that teach away from one another cannot be combined).

RJR’s proffered combination of references therefore fails *ab initio*, but in addition was contradicted by a series of secondary considerations, all of which pointed away from obviousness.<sup>48</sup> In

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<sup>48</sup> Obviousness is ultimately a legal question grounded upon factual determinations, which include objective indicia of nonobviousness. *See Eisai Co. v. Dr. Reddy’s Labs., Ltd.*, 533 F.3d 1353, 1356 (Fed. Cir. 2008). “These objective indicia may often be the most probative and cogent evidence of nonobviousness in the record.” *Gumbro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579 (Fed. Cir. 1997) (quotation omitted). Such indicia or “secondary considerations” include commercial success, long-felt but unsolved needs, failure of others to achieve the invention, skepticism of the invention’s advantages, unexpected results, and industry acceptance. *See Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). The objective indicia of non-obviousness are simply overwhelming in this record.

(1) Commercial success. The patented invention was successful in the marketplace, with Brown & Williamson (the then third-largest tobacco company) licensing the invention of the patents-in-suit for millions of dollars (in capital and loans). *See* PTX 207, 208, 306; Tr. at 485:2-22, 489:17-490:4, 668:6-670:8, 767:7-22.

(2) Long-felt but unsolved need. The scientific literature conclusively documents the long-felt but unsolved need. Specifically, the literature reflects widespread knowledge that TSNA’s are the most powerful and abundant carcinogens in tobacco. *See, e.g.*, PTX 732, Tabs 108, 110, 111, 113, 122, 126, 128, 129, 133, 134, 135, 146, 147. The tobacco industry had therefore long recognized that something needed to be done to solve the TSNA problem. *See, e.g.*, PTX 732, Tabs 114, 150, 188 (at 10); Tr. at 402:16-21, 724:12-725:16, 880:1-17, 900:5-907:2.

(3) Failure of others. For decades, the tobacco industry extensively studied the formation of TSNA’s in tobacco (*e.g.*, PTX 732, Tabs 103, 106, 109, 115, 116, 136, 142, 153, 155, 166, 167, 168, 169, 179, 189, 190, 191, 192) and tried to reduce or eliminate TSNA’s by various methods (*e.g.*, PTX 732, Tabs 108, 159, 162, 163, 164, 165, 171). RJR had its own Nitrosamine Task Force that worked for five years and was ultimately disbanded due to its lack of success. Tr. at 900:5-907:2. The literature specifically taught away from increased airflow (*e.g.*, PTX 732, Tabs 176, 196) and also made clear that “the interaction of chemical composition with temperature, time, and airflow is very complex and not

(continued...)

short, RJR's proof of obviousness did not present a close question, and the jury's verdict must be overturned.

**3. The jury's verdict was internally inconsistent.**

As discussed earlier, the jury's verdict of non-infringement seems to have been based on the misperception that one could only practice the Williams patents by using "unconventional" airflow. But by that measure, the verdict is internally inconsistent. If the Williams' patents require "unconventional" airflow, it would then have been impossible on this record to have the patents found invalid as anticipated or obvious, because by definition the patents required practices not found in the prior art. The only prior art that was urged to be "unconventional" was Spindletop,<sup>49</sup> which for reasons discussed above could not possibly have been the basis for a finding of anticipation or obviousness. All other prior art—*e.g.*, Hassel Brown—was the epitome of "conventional" and so admitted by RJR and its witnesses. *See, e.g.*, Tr. at 1994:5-7, 4017:5-9.

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(continued)

completely understood," (PTX 732, Tab 178), and thus it would not have been obvious to increase the airflow in tobacco curing barns.

When Mr. Williams told Dr. Burton that he needed to figure out how to eliminate TSNA's from tobacco, the response from Dr. Burton (a TSNA researcher at the University of Kentucky) was "good luck" because the tobacco industry has "been trying to do this for thirty years." Tr. at 478:22-479:19; *see also* Tr. at 880:1-7.

(4) Unexpected results. Mr. Williams' success in solving the TSNA problem was entirely unexpected to everyone in the industry. *See, e.g.*, Tr. at 483:22-484:22, 879:19-880:20.

(5) Industry acceptance. Brown & Williamson licensed the invention for millions, as discussed above. RJR and the rest of the U.S. tobacco industry switched to specially-designed indirect-fired furnaces in 2000-2001 for the very purpose of practicing the Williams' invention. Moreover, once RJR came to understand that Mr. Williams' invention involved increased airflow, RJR copied that feature in its retrofits.

<sup>49</sup> *See* Tr. at 2598:25-2599:5, 2606:17-2607:4.

Accordingly, the verdict simply doesn't add up. If Hassel Brown (or any other prior art curing process) anticipated, then RJR's farmers infringed—contrary to the jury's finding. This follows simply from established law that “that which infringes, if later, anticipates, if earlier.” *Lisle Corp. v. A.J. Mfg. Co.*, 398 F.3d 1306, 1315 (Fed. Cir. 2005).

When verdicts contain inconsistencies, a new trial must be granted. Indeed, “[t]he Seventh Amendment right to a jury trial does not permit entry of a judgment when a jury's verdict is internally inconsistent.” *Johnson v. ABLT Trucking Co.*, 412 F.3d 1138, 1139 (10th Cir. 2005); *see also Ladnier v. Murray*, 769 F.2d 195, 198 n.3 (4th Cir. 1985) (noting entry of judgment on an inconsistent special verdict “may be an error of constitutional magnitude, infringing the seventh amendment right to a jury trial”). As the Fourth Circuit has recognized, “[i]t is well settled that a court may set aside a jury verdict where it is impossible to reconcile the jury's findings.” *Int'l Data Prod. Corp. v. Dynamic Decisions, Inc.*, 215 F.3d 1319, 2000 WL 560059, at \*3 (4th Cir. 2000) (unpublished). Thus, where, as here, a jury's verdict cannot be harmonized on a “fair reading,” the district court is obligated to grant a new trial. *See, e.g., Hundley v. District of Columbia*, 494 F.3d 1097, 1102-04 (D.C. Cir. 2007) (reversing judgment and remanding for a new trial where the jury verdict was internally inconsistent); *Custer v. Terex Corp.*, 196 F. App'x 733, 739 (11th Cir. 2006) (same); *Molina v. City of Oxnard*, 173 F. App'x 577, 581 (9th Cir. 2006) (same); *Carter v. Rogers*, 805 F.2d 1153, 1158-1159 (4th Cir. 1986) (same).

**4. The Court erred by allowing RJR to present previously-undisclosed expert testimony through Inger Wahlberg.**

The issues of anticipation and obviousness were further compromised by the inappropriate testimony of previously undisclosed “experts.” During opening statements, RJR's counsel told the jury that it would be presenting the testimony of Dr. Inger Wahlberg, whom counsel described as being “generally regarded as [one] of the foremost authorities on the issue of TSNAs and TSNA formation.” Tr. at 421:17-20. Even though Dr. Wahlberg was only identified as a fact witness, had never provided a

Rule 26(a)(2) disclosure, and had never even been deposed in the case, RJR's counsel indicated that Dr. Wahlberg would testify regarding her opinion as to the mechanism of TSNA formation in tobacco. Tr. at 422:10-15. Consequently, Star Scientific moved to preclude RJR from introducing expert testimony through Dr. Wahlberg. Dkt. 999 at 2-5.<sup>50</sup>

Dr. Wahlberg was nonetheless permitted to testify concerning her expert opinions on the mechanisms underlying TSNA formation and what was understood in the art at the time. She claimed for example that anaerobic conditions caused TSNAs, and RJR used this testimony to later argue the Williams invention would have been obvious. While framing her answers in terms of what her colleagues at Swedish Match "knew," her testimony was blatantly that of an expert. She opined on what the research documents "meant," what she "understood" by virtue of her expertise in the area, and whether methods used were "conventional" or "unconventional." Tr. at 2585:6-2609:2.

The admissibility of opinion testimony by a lay witness is governed by Federal Rule of Evidence 701, which permits such testimony only when it is "not based on scientific, technical or other specialized knowledge within the scope of Rule 702." *See United States v. Perkins*, 470 F.3d 150, 156 (4th Cir. 2006) ("Rule 701 forbids the admission of expert testimony dressed in lay witness clothing."). Under Rule 701(a), a lay opinion must be "rationally based on the perception of the witness." *See TLT-Babcock, Inc. v. Emerson Elec. Co.*, 33 F.3d 397, 400 (4th Cir. 1994) (affirming district court's exclusion of lay opinion testimony that was not based on a witness's own perceptions but rather on

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<sup>50</sup> Allowing RJR to introduce at trial previously-undisclosed expert opinions from Dr. Wahlberg was incompletely inappropriate under the Federal Rules and Fourth Circuit law. *See Southern States Rack & Fixture, Inc. v. Sherwin-Williams Co.*, 318 F.3d 592, 598-99 (4th Cir. 2003) (agreeing with district court that "the ability to simply cross-examine an expert concerning a new opinion at trial is not the ability to cure" and the "rules of expert disclosure are designed to allow an opponent to examine an expert opinion for flaws and to develop counter-testimony through that party's own experts").

reports of others). Dr. Wahlberg's testimony was well outside the limited scope of lay opinion testimony permitted by the Federal Rules of Evidence, and thus should have been excluded.<sup>51</sup>

\* \* \* \* \*

In summary, the jury's verdict on anticipation and obviousness was at odds with clear and undisputed evidence. RJR's proof failed as a matter of law and JMOL on both issues should have been awarded to Star Scientific. Alternatively, and in light of the weight of evidence that so compelled a finding of validity, the errors of the Court must be deemed to have affected the verdict, requiring a new trial. *E.g., East Tennessee Natural Gas Co. v. Thomas*, 298 F. App'x 261, 264 (4th Cir. 2008) (unpublished) (affirming grant of new trial where weight of evidence was insufficient to support the verdict).

**B. RJR Was Erroneously Permitted to Present a Definiteness Defense that It Already Lost on Appeal**

The Court's disregard of the Federal Circuit's mandate unquestionably affected the jury's determinations of infringement, anticipation and obviousness, as discussed above. In addition, however, it directly affected the jury's consideration of definiteness.

The sum and substance of RJR's indefiniteness defense at trial, as explained by its counsel during closing argument, was that the "controlled environment" element of the asserted claims failed to specify any numbers that would permit someone to ascertain the dividing line between "conventional" and "unconventional" temperature, airflow and humidity:

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<sup>51</sup> Dr. Wahlberg was permitted to testify about various scientific studies that she was not personally involved in and/or that clearly were not prior art, including the conclusions that supposedly could be drawn from those studies. *See, e.g.,* Tr. at 2584:7-2588:17 (testifying about study conducted in Poland in 1990 by Dr. Wahlberg's colleagues), 2597:4-2599:7 (testifying about an unpublished study conducted in the early 1990s that allegedly supported Dr. Peele's NOx theory).

Star to this day has never explained what the farmers are supposed to do differently with respect to airflow, temperature or humidity to try and tell a farmer what they're supposed to do differently if what they're trying to do is to get good quality tobacco. That is a missing answer that we have never heard from Star. (Tr. at 3994:15-20).

So from reading the patent, there's no evidence, any evidence that anybody presented that a person skilled in the art actually understands what the invention is in terms of Star's temperature range, Star's humidity range, or the airflow rate. (Tr. at 3996:4-8).

And the patent system is supposed to have rules. After all, that is about science and technology, things that people are supposed to be able to break down, figure out, and understand. And if Star's own technical expert Mr. Sturgill doesn't know where to draw the line between conventional airflow of the prior art and unconventional airflow of the claimed controlled environment, how can it be fair to expect the farmers or anybody else to figure that out? I mean, this is about rules. The Patent Office has rules, and this kind of stuff doesn't follow those rules. (Tr. at 3997:15-25).

RJR's argument at trial was precisely the same argument that RJR made to the Federal Circuit as an alternative ground for affirming this Court's grant of summary judgment. *See* RJR's Appeal Br. at 35-37, 67-68. Once again, the overlap between RJR's losing argument before the Federal Circuit and its renewed argument before the jury was exact. To read RJR's appeal brief is to paraphrase the arguments made repeatedly to the jury.<sup>52</sup>

These arguments were barred by the mandate of the Federal Circuit's ruling. The issue on appeal was whether "controlled environment" was indefinite, an issue that both this Court and the Federal Circuit concluded must turn on "anaerobic conditions." In reversing this Court's decision, the Federal Circuit necessarily rejected RJR's argument regarding the "controlled environment" limitation. Accordingly, this Court erred by permitting RJR to raise that failed argument again at trial. *Bell*, 5 F.3d at 66 ("[The mandate rule] compels compliance on remand with the dictates of a superior court and

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<sup>52</sup> As signaled in the section headings of its appeal brief, RJR aggressively pressed its argument of indefiniteness based on the "controlled environment" limitation: "One Of Ordinary Skill In The Art Cannot Distinguish The Alleged Invention's Unconventional 'Controlled Environment' From The Conventional Conditions Of The Prior Art" (*id.* at 35 (heading in Statement of Facts)).

forecloses relitigation of issues expressly or impliedly decided by the appellate court”); *S. Atl. Ltd. P’ship of Tenn. v. Riese*, 356 F.3d 576, 584 (4th Cir. 2004) (noting that a lower court “may not alter rulings impliedly made by the appellate court”).

In permitting the testimony, this Court asserted that one of ordinary skill in the art could nevertheless have construed the claim term “controlled environment” to require numeric limitations. But this is expressly excluded by, and contrary to, the wording and structure of the claims. The claims speak unequivocally to the two elements that “comprise” the controlled environment—“air free of combustion exhaust gases” and an “airflow sufficient to substantially prevent an anaerobic condition.” The level of airflow in this controlled environment has therefore been specifically defined—*i.e.*, it is “airflow sufficient to substantially prevent an anaerobic condition.” It was precisely this limitation that the Federal Circuit found to be definite. There is nothing in the patents that would permit a departure from this structure or require airflow to be defined “by the numbers.” PTX 10 at 6:34-55, 11:39-41. Rather, curing is “more an art than a science,” and accordingly, even in conventional curing, there is no “set of numbers” that defines how a farmer should cure. *Id.* at 6:34-55; *see also* Tr. at 1282:20-1283:12, 3612:23-3614:6.

RJR argued that the third element of the Claim at Issue—controlling conditions “in a manner different from conventional curing”—was a back door requirement for numeric limitations, but again, this would completely undercut the structure of the claims. Rather, this element of the claim was simply alerting the practitioner to three conditions (airflow, temperature and humidity) that could be controlled to prevent TSNAs. The evidence at trial demonstrated that one of skill in the art would readily understand that in order to reduce TSNAs, he should consider some combination of reduced humidity (since humidity favors microbial activity), increased airflow (since greater airflow discourages microbial

activity), and higher temperatures (since microbes optimally flourish in temperature ranges well known in the art but die or deactivate at temperatures approaching 160° Fahrenheit). Tr. at 3584:11-3589:2.

Airflow volumes in this structure, however, remain subject to a single requirement, namely that the airflow be sufficient to substantially prevent an anaerobic condition. What the controlled environment “comprises,” in other words, remains the same. It has two attributes—namely, air free of combustion exhaust gases and sufficient oxygen—both designed to substantially prevent the causes of microbial activity. As to airflow, this generally requires control in a manner different from conventional direct-fired curing, in order to avoid the oxygen deficiencies present in the direct-fired environment.<sup>53</sup> But the proof at trial demonstrated that moving from conventional direct-fired equipment to the retrofit units necessarily altered control of humidity and temperature as well. Tr. at 1260:13-1262:10, 1263:17-1264:10, 1369:17-1373:14. As the patents teach, these are straightforward comparisons easily understood by one of ordinary skill in the art.

In sum, the supposed indefiniteness of the Claim at Issue is belied not only by the Federal Circuit’s earlier mandate, but by the Court’s own construction of the claims, the structure of the claims, and the explanation of terms provided in the specification. There are no “numeric” absolutes required by the patents. As taught by the patents, the amount of airflow required is an “airflow sufficient to substantially prevent an anaerobic condition,” which can vary from barn to barn. The Federal Circuit

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<sup>53</sup> RJR’s reliance on controlling conditions “in a manner different from conventional curing” was also misplaced because this clause is directed to distinguishing direct-fired curing methods. The patents contain a specific definition of “conventional curing”: “tobacco that has been ‘conventionally cured’ is tobacco that has been air cured, or flue-cured, without the controlled conditions described herein, according to conventional methods *commonly* and commercially used in the U.S.” PTX 10 at 6:14-18 (emphasis added). For flue-cured tobacco at the time of the invention, this meant direct-fired barns, as virtually all witnesses conceded. *See* Tr. at 661:11-13, 734:22-735:1, 738:18-22, 1248:2-1249:5, 1278:3-14, 1978:2-25, 3618:4-25. Equally obvious would have been distinctions with older indirect-fired barns, which had 30-40% less airflow than RJR’s retrofits. Tr. at 1275:13-19, 1280:15-19.

has already determined this claim element to be definite. RJR was bound by that ruling. This Court incorrectly allowed RJR to resuscitate its argument, but RJR still failed to produce any evidence on which a reasonable jury could have found indefiniteness. JMOL on this issue is therefore appropriate. Alternatively, at a minimum the jury's deliberations were improperly affected by improper claim construction and disregard of the Federal Circuit's ruling, and a new trial must be granted.<sup>54</sup>

**C. The Court's Best Mode Instruction Ignored Clear Federal Circuit Precedent Requiring Deliberate Concealment**

The jury's verdict that the patents-in-suit are invalid due to violation of the best mode requirement was based on a flawed instruction that failed to properly inform the jury that "[i]nvalidation based on a best mode violation requires that the inventor knew of *and intentionally concealed* a better mode than was disclosed." *High Concrete Structures, Inc. v. New Enterprise Stone & Lime Co.*, 377 F.3d 1379, 1383 (Fed. Cir. 2004) (emphasis added). It was also against the overwhelming weight of the evidence, which demonstrated without contradiction that Mr. Williams believed that Example 7 of the patents accurately described his best mode. Tr. at 526:25-530:22, 645:25-646:22, 743:3-747:25.

In refusing to include any reference to concealment in its best mode instruction, the Court stated that it "does not understand Federal Circuit precedent, including *High Concrete*, to hold that intentional

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<sup>54</sup> As RJR's counsel was forced to concede at trial, "there is an argument to be made that indefiniteness is actually a question of law for the Court." Tr. at 1763:17-22. In fact, there is no argument: indefiniteness is a question of law for the Court, and it was error to allow RJR to argue indefiniteness to the jury. *Cordis Corp. v. Boston Scientific Corp.*, 561 F.3d 1319 (Fed. Cir. 2009) ; *Exxon Research & Engineering Co. v. U.S.*, 265 F.3d 1371, 1376 (Fed. Cir. 2001) ("determination of claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims"). Determining indefiniteness does not involve fact-finding by a jury. See *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1321 (Fed. Cir. 2008) (rejecting defendant's argument that patent was indefinite based on expert's testimony "since indefiniteness is a legal rather than a factual question"); *Exxon Research*, 265 F.3d at 1376. Consequently, the judgment as a matter of law for Star Scientific on this issue is appropriate.

concealment is required to prove a best mode violation.” Email from F. Rasheed to R. McMillan, June 14, 2009 9:06 PM (Dkt. No. 1077, Ex. A). The Court opted instead to use a model instruction proposed by the National Jury Instruction Project which, while released for comment in 2008, cites no Federal Circuit decision more recent than 2002. *Id.*

The Court’s professed reading of Federal Circuit precedent cannot be reconciled with the unequivocal statement in *High Concrete* quoted above, which specifically requires a determination that the inventor “intentionally concealed” his best mode. Nor is *High Concrete* the only (or even the most recent) decision by the Federal Circuit recognizing an intent element of a best mode violation. *See AllVoice Computing PLC v. Nuance Commc’ns, Inc.*, 504 F.3d 1236, 1246-1247 (Fed. Cir. 2007) (“[T]he second part of the analysis [asks] . . . has the inventor ‘concealed’ his preferred mode” and whether this concealment was “deliberate.”)<sup>55</sup> (quoting *Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 928 (Fed. Cir. 1990)). The best mode instruction given to the jury is even inconsistent with this Court’s own precedent holding that a best mode violation requires evidence that “(1) the inventor knew of a better mode than was disclosed, and (2) *the inventor concealed that better mode.*” *Contech Stormwater Solutions, Inc. v. Baysaver Techs., Inc.*, 534 F. Supp. 2d 616, 628 (D. Md. 2008) (granting summary judgment to patentee where the evidence did “not demonstrate any subjective intent on the part of the inventors to intentionally conceal a better mode”) (emphasis added).

The Court’s erroneous best mode instruction was severely prejudicial. Mr. Williams testified clearly that Example 7 disclosed his best mode, as he intended and believed. Tr. at 526:25-528:25, 742:22-747:25; *see also* 3519:24-3520:15 (Dr. Otten confirming measured airflow in a StarCure barn to

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<sup>55</sup> The Federal Circuit noted that the patent-in-suit could be found invalid only for “*deliberate* concealment of the best mode – a requirement of 35 U.S.C. § 112, ¶ 1.” *Id.* at 1246 (emphasis added).

be 25,100 cfm), 3612:1-15(same). Given the total lack of evidence that Mr. Williams concealed (much less intended to conceal) any other alleged best mode for practicing his invention, no reasonable jury could have found a best mode violation based on a proper statement of the law.

**VII. THE COURT ERRED BY SEATING AN ALTERNATE JUROR ON THE LAST DAY OF TRIAL BASED ONLY ON A PROFESSED “SCHEDULING ISSUE” FOR THE EXCUSED JUROR**

When the jury was originally selected, there were twelve jurors and two alternates, and the Court’s stated plan was to excuse the two alternates prior to deliberations if they were not needed. Tr. at 374:3-7.<sup>56</sup> Nevertheless, just prior to the case being given to the jury, the Court replaced one of the original twelve (Juror No. 152) with an alternate (Juror No. 236) without advising the parties in advance that the Court intended to deviate from the stated plan to dismiss the designated alternate. Tr. at 4054:4-9. The Court indicated that Juror No. 152 had “volunteered” to be the alternate and that the Court decided to “honor the request.” *Id.* Star Scientific timely objected to this last-minute replacement. Tr. at 4055:6-11.

Federal Rule of Civil Procedure 47(c) dictates that “[d]uring trial or deliberation, the court may excuse a juror for good cause.” According to the Advisory Committee Notes accompanying the 1991 Amendment that added subsection (c), “sickness, family emergency or juror misconduct that might occasion a mistrial are examples of appropriate grounds for excusing a juror.” Thus, the drafters plainly contemplated that a court would demand a showing of more than mere inconvenience before a juror would be excused during trial.

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<sup>56</sup> It was prejudicial error for the Court to seat the two alternate jurors, *see Maier v. AT&T*, No. 94-C-7468, 1996 WL 18887, at \*4 (N.D. Ill. Jan. 12, 1996) (“[T]he institution of the alternate juror was abolished in federal civil cases effective December 1, 1991.”) (unpublished), which compounded the error under Rule 47 of allowing an original juror to “volunteer” to be replaced by an alternate juror.

Although body language can be an imperfect indicator of attitudes and beliefs, during the trial Juror No. 152 (the excused juror) appeared to react favorably to Star Scientific's witnesses and arguments, whereas Juror No. 236 (the second alternate) appeared to be almost hostile to Star Scientific's case. Thus, Star Scientific believes it was prejudicial to replace Juror No. 152 with Juror No. 236 in the absence of any showing of "good cause."

#### **VIII. CONCLUSION**

Judgment as a matter of law or a new trial is warranted because no reasonable jury could have reached the verdict reached by this jury on the evidence presented at trial. This case is unusual for the number and scope of the errors permeating the trial record, and the sheer volume of errors justifies a new trial in and of itself. *Cf. Kozlowski v. Hampton Sch. Bd.*, 77 F. App'x 133, 154 (4th Cir. 2003) (recognizing that "the collective force of multiple errors can, in some instances, warrant reversal even when one or two of the errors standing alone would not"). Taken individually or collectively, there are errors infecting each and every one of the jury's subsidiary findings, as detailed in the following table:

Jury Finding	Associated Error(s)
Non-infringement	Disregard of Federal Circuit mandate; presentation of claim construction issues to jury; permitting “Peele versus Williams” comparison; erroneous priority date decision; failure to give “practicing the prior art” instruction; preclusion of Borschke testimony; improper inequitable conduct argument, including presentation of the Burton letter; exclusion of Lee deposition testimony regarding detection limit; inconsistent jury findings; verdict inconsistent with overwhelming weight of evidence.
Anticipation	Disregard of Federal Circuit mandate; presentation of inequitable conduct evidence to the jury; presentation of claim construction issues to jury; permitting “Peele versus Williams” comparison; erroneous priority date decision; preclusion of Borschke testimony; improper inequitable conduct argument, including presentation of the Burton letter; inconsistent jury findings; verdict inconsistent with overwhelming weight of evidence.
Obviousness	Disregard of Federal Circuit mandate; presentation of inequitable conduct evidence to the jury; insufficient evidence of motivation to combine, teaching away, lack of other indicia of obviousness, and conflict with secondary considerations; improper expert testimony from fact witness; preclusion of Borschke testimony; improper inequitable conduct argument, including presentation of the Burton letter; erroneous priority date decision; inconsistent jury findings; verdict inconsistent with overwhelming weight of evidence.
Definiteness	Mandate doctrine; improper presentation of claim construction issues to jury; improper claim construction arguments; verdict inconsistent with overwhelming weight of evidence.
Best Mode	Erroneous jury instruction; improper presentation of claim construction issues to jury; verdict inconsistent with overwhelming weight of evidence.

For the foregoing reasons, as well as those set forth in its renewed Motion for Judgment as a Matter of Law, Star Scientific respectfully requests that the Court vacate the jury’s verdict in all respects, and grant judgment that RJR has infringed the patents-in-suit, and that the patents are not invalid for anticipation, obviousness, indefiniteness, or best mode violation. In the alternative, Star Scientific requests that the Court grant a new trial on Star Scientific’s patent infringement claim against RJR.

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Respectfully submitted,

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on this 7th day of July, 2009, I caused a true and correct copy of the foregoing to be served on the persons, and in the manner, indicated below.

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