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

STAR SCIENTIFIC INC,
Plaintiff.
v.
R.J. REYNOLDS TOBACCO COMPANY,
Defendant.

Dec. 4, 2003.

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REPORT AND RECOMMENDATION REGARDING STAR SCIENTIFIC, INC.'S MOTION FOR CLAIM CONSTRUCTION AND SUMMARY JUDGMENT THAT THE CLAIMS OF THE PATENTS-IN-SUIT SATISFY THE DEFINITENESS REQUIREMENT OF 35 U.S.C. s. 112**, SECOND PARAGRAPH**

PHILIP G. HAMPTON, II, Special Master.

This action was referred to me pursuant to the Order of Reference dated September 15, 2003 (Docket No. 382) and Rule 53 of the Federal Rules of Civil Procedure. Plaintiff, Star Scientific, Inc. ("Star"), moves this Court (Docket No. 270) for an order construing the claims of the patents-in-suit and an order granting summary judgment that the claims of the patents-in-suit satisfy the definiteness requirement under 35 U.S.C. s. 112, second paragraph. Defendant, R.J. Reynolds Tobacco Company ("RJR"), opposes Star's motion for claim construction and summary judgment (Docket No. 306). Star filed a reply memorandum (Docket No. 331). After reviewing these pleadings, I respectfully recommend that the Court enter an order construing the claims of the patents-in-suit as recommended herein and deny Star's motion for summary judgment that the asserted claims of the patents-in-suit are definite under 35 U.S.C. s. 112, second paragraph.

I. *BACKGROUND*

This patent infringement action involves two patents owned by Star, United States Patent Numbers 6,202,649 ("the '649 patent") and 6,425,401 ("the ' 401 patent"), collectively referred to hereinafter as "the patents-in-suit." Star is the exclusive licensee of the '649 and '401 patents. FN1 The patents-in-suit arise from a common parent application, share the same specification (*i.e.,* they share a common written description), have common figures and are identically entitled "Method of Treating Tobacco to Reduce Nitrosamine Content, and Products Produced Thereby." These patents describe and claim methods of preventing the formation of tobacco-specific nitrosamines ("TSNAs") in tobacco plants during the curing

process, including N'-nitrosonornictotine ("NNN"), 4-(N-nitrosomethylamino)-1-(3-pyridyl)-1-butanone ("NNK"), N'-nitrosoanatabine ("NAT"), and N'-nitrosoanabasine ("NAB").

FN1. The named inventor of the patents-in-suit is Jonnie R. Williams. The original assignee of the patents-in-suit, Regent Court Technologies, granted Star an exclusive license, including the right to bring legal action to enforce the patents-in-suit.

Application Serial No. 09/397,018, ("the '018 application"), which became the '649 patent was filed on September 15, 1999, as a continuation-in-part of Application Serial No. 08/9 98,043 ("the '043 application) FN2. The ' 018 application also claims priority to a provisional application, Application Serial No. 60/100,372 ("the '372 application") that was filed on September 15, 1998. The ' 649 patent issued on March 20, 2001.

FN2. The '043 application was filed on December 2, 1997, as a continuation-in-part of Application Serial No. 08/879,905 (filed June 20, 1997), which was a continuation-in-part of Application Serial No. 08/757,104 (filed December 2, 1996).

In 1999, RJR contracted with certain farmers to purchase low TSNA tobacco cured in barns retrofitted with heat exchangers purchased from Vancon-Varsos, a Greek company, and assembled and installed in the farmers' barns by Evans Machinery and Metal Fabrication, a U.S. company ("the heat exchanger technology"). In November 1999, Reynolds spent over $11,000,000 to purchase 2,050 heat exchangers and retrofit hundreds of curing barns with the heat exchanger technology. Moreover, RJR contracted with additional farmers to purchase low TSNA tobacco cured in barns having heat exchanger technology for the 2000 curing season.FN3 In early 2001, RJR replaced many of the contracts for the 2000 curing season with new contracts for the purchase of low TSNA tobacco cured using the heat exchanger technology during the 2001 through 2005 curing seasons.

FN3. RJR also contracted with other farmers to purchase tobacco cured in barns equipped with the same heat exchangers selected by RJR, but owned by the farmers themselves.

On May 23, 2001, Star sued RJR for infringement of the '649 patent ("the 01-1504 case"). Star alleged that RJR has infringed or has induced infringement of claims 4, 12 and 20 of the '649 patent by contracting with tobacco farmers to purchase low-TSNA tobacco cured using a certain type of heat exchanger technology in lieu of direct fire heaters. RJR counter-claimed for a declaratory judgment that the '649 patent is invalid and not infringed by RJR. Claims 4, 12 and 20 of the '649 patent state:

4. A process of substantially preventing the formation of at least one nitrosamine in a harvested tobacco plant, the process comprising:

drying at least a portion of the plant, while said portion is uncured, yellow, and in a state susceptible to having the formation of nitrosamines arrested, in a controlled environment and for a time sufficient to substantially prevent the formation of said at least one nitrosamine;

wherein said controlled environment comprises air free of combustion exhaust gases and an airflow sufficient to substantially prevent an anaerobic condition around the vicinity of said plant portion;

and wherein said controlled environment is provided by controlling at least one of humidity, temperature, and airflow.

* * *

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

* * *

20. A process of substantially preventing the formation of at least one nitrosamine in a harvested tobacco plant, the process comprising:
drying at least a portion of the plant, while said portion is uncured, yellow and in a state susceptible to having the formation of nitrosamines arrested, in a controlled environment and for a time sufficient to substantially prevent the formation of said at least one nitrosamine;

wherein said controlled environment comprises a flow of air sufficient to avoid an anaerobic condition around the vicinity of said plant portion; and wherein said controlled environment is provided by controlling at least one of humidity, temperature and airflow.

On September 25, 2000, Application Serial No. 09/668,144 was filed as a continuation of the '018 application. This application issued as the '401 patent on July 30, 2003. On that date, Star sued RJR for infringement of claim 41 of the '401 patent,FN4 alleging that RJR's contract with tobacco farmers directly infringed, or induced others to infringe, the patented process for curing tobacco disclosed in the ' 401 patent ("the 02-2504 case"). RJR counter-claimed for a declaratory judgment of invalidity, non-infringement, and unenforceability of the ' 401 patent. Claim 41 of the ' 401 patent reads:

FN4. Star states that for purposes of this litigation, the only material difference between claim 41 of the '401 patent and the other asserted claims is that claim 41 is limited to "Virginia flue tobacco" and the other claims are not so limited.

41. A process of substantially preventing the formation of at least one nitrosamine in a Virginia flue tobacco plant by treating the tobacco plant after the yellowing stage, the process comprising:
drying at least a portion of a Virginia flue tobacco plant, while said portion is uncured, yellow, and in a state susceptible to having the formation of nitrosamines arrested, in a controlled environment and for a time sufficient to substantially prevent the formation of said at least one nitrosamine;

wherein said controlled environment comprises air free of combustion exhaust gases and an airflow sufficient to substantially prevent an anaerobic condition around the vicinity of said plant portion;

wherein said controlled environment is provided by controlling at least one of humidity, temperature, and airflow.

On August 27, 2002, this Court ordered the consolidation of the 02-2504 case with the 01-1504 case.

II. ***DISCUSSION***

Star moves this Court for an order construing the four asserted claims of the patents-in-suit. In its memorandum supporting its motion, Star set forth how it believes the claims should be construed, *i.e.*, it provided a specific claim construction *vis-a-vis* four claim terms that it believed are at issue. Star also moved the Court for summary judgment that the claims, as construed, are definite as required by 35 U.S.C. s. 112, second paragraph.FN5 In response to Star's motion, RJR did not suggest a different claim construction. FN6 Instead, RJR repeatedly asserted that the claims of the patents-in-suit are "fatally vague and indefinite" (RJR Br., pp. 2, 24).FN7

FN5. Star stated that while the background information in its opening brief is well supported, much of it was irrelevant to a decision on its motion (St. Br., p. 2, note 1). Although RJR agreed, it devoted nine pages of

its brief discussing Star's admitted irrelevant background information (RJR Br., pp. 39-47).

FN6. RJR also asserted that "the factual underpinnings of Star's motion [were] fraught with misstatements, glaring deficiencies and improper inferences that compel its denial." (RJR Br., p. 2).

FN7. St. Br. refers to Star Scientific, Inc.'s Memorandum in Support of Its Motion for Summary Judgment on Claim Construction and Definiteness. RJR. Br. refers to Defendant's Memorandum in Opposition to Star Scientific, Inc.'s Memorandum in Support of Its Motion for Summary Judgment on Claim Construction and Definiteness. St.R.Br. refers to Scientific, Inc.'s Reply of Its Motion for Summary Judgment on Claim Construction and Definiteness.

In its response to RJR's opposition to its motion, Star asserted that by not proposing its own construction of the claims at issue, RJR "by law defaults" on the issue of indefiniteness. Star correctly notes that RJR is arguing that " *undefined* claims" are *indefinite* (St. R. Br., p. 1). However, Star does not cite any support for its contention that the Court must grant it the proposed summary relief it is seeking regarding definiteness, and the Special Master can find none. Instead, as Star asserted, the claims must be construed "before definiteness can be assessed." *Id*. Therefore, the claims at issue will first be construed without the benefit of a proposed construction by RJR. Then, the definiteness of the claims, as construed, will be assessed taking into consideration RJR's arguments regarding vagueness and indefiniteness.

A. *Construction of the Asserted Claims*

The claim language "defines the bounds of claim scope." York Products Inc. v. Central Tractor Farm & Family Center, 99 F.3d 1568, 1572 (Fed.Cir.1996). The meaning of claim terms is a matter of law and, therefore, a matter for a court to decide. *See* Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed.Cir.1995), *en banc, aff'd* 517 U.S. 370 (1996). When construing the claims of a patent, a "court should look first to the intrinsic evidence of record, *i.e.,* the patent itself, including the claims, the specification and, if in evidence, the prosecution history." *Vitronics Corp v. Conceptronic, Inc.,* 90 F.3d 1579, 1582 (Fed.Cir.1996).FN8 If such intrinsic evidence allows the Court to resolve all ambiguities in construing the claim, the Court should look at no other evidence. Personalized Media Communications, LLC v. International Trade Commission, 161 F.3d 696, 706 (Fed.Cir.1998).

FN8. The starting point for claim interpretation is the language of the claims. Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1201-02 (Fed.Cir.2002); *see also* Buckley v. Airshield Corp., 116 F.Supp.2d 658, 665 (D.Md.2000) (citing Renishaw PLC v. Marposs Sociat a per Azioni, 158 F.3d 1243, 1248 (Fed.Cir.1998)) ("The language of the claim itself is of the utmost importance in interpreting a claim.").

When the intrinsic evidence is insufficient to establish the clear meaning of an asserted claim, the Court should turn to extrinsic evidence, *i.e.,* expert testimony, inventor testimony, treatises and prior art not cited in the prosecution history. Zodiac Pool Care, Inc. v. Hoffinger Indus., 206 F.3d 1408, 1414 (Fed.Cir.2000). Extrinsic evidence may always be consulted, however, to assist in understanding the underlying technology. Interactive Gift Express, Inc. v. CompuServe, Inc., 256 F.3d 1323, 1332 (Fed.Cir.2001). Moreover, technically extrinsic evidence, "dictionaries, encyclopedias and treatises are particularly useful resources to assist the court in determining the ordinary and customary meaning of claim terms," Texas Digital Sys, Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202.

Claim language ordinarily should be given its plain meaning; however, the patentee always retains the right to be his own lexicographer. *Vitronics Corp.,* 90 F.3d at 1582. Similarly, the presumption in favor of a

dictionary definition will be overcome where the patentee, acting as his or her own lexicographer, explicitly defines the term differently from its ordinary meaning. Texas Digital Sys., 308 F.3d at 1204. Where the patentee has defined a term in the patent specification differently from the ordinary meaning found in a dictionary, or in a way different from how the term is used in the art, the patentee's definition governs. Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 990 (Fed.Cir.1999) (the patentee "has chosen to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term."). However, to overcome the plain meaning of a claim term, the patentee must have demonstrated his intent to act as his own lexicographer and set forth a definition of the disputed claim term in either the specification or prosecution history. *See, e.g .,* Johnson Worldwide Assocs. v. Zebco Corp., 175 F.3d 985, 990 (Fed.Cir.1999); Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed.Cir.2001).

In addition, a claim term will not have its ordinary meaning if the intrinsic evidence shows that the patentee distinguished that term from prior art. *See, e.g.,* Spectrum Int'l, Inc. v. Sterilite Corp., 164 F.3d 1372, 1378 (Fed.Cir.1998), where the narrowing ordinary meaning of a claim term was limited based on the patentee's statements in intrinsic evidence that distinguished the claimed invention from prior art, and Scimed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1343-44 (Fed.Cir.2001), where the meaning of a claim term was narrowed based in part on statements in the specification indicating that "all embodiments" of the claimed invention used a particular structure.

In its memorandum in support of its motion, Star asserted that only the following four claim limitations needed to be construed by the Court FN9: (1) "airflow sufficient to substantially prevent [avoid] an anaerobic condition" FN10; (2) "air free of combustion exhaust gases"; (3) "controlled environment"; and (4) "substantially prevent the formation of at least one nitrosamine" (St.Br., pp. 23-24). Since RJR did not assert that there were other claim limitations at issue, the Special Master will only construe the four claim limitations set out above.FN11

FN9. At the time it filed this motion, Star believed these claim terms were the only ones disputed by RJR.

FN10. Claim 4 of the '649 patent and claim 41 of the '401 patent contain the term "airflow sufficient to substantially prevent an anaerobic condition." Claim 20 of the '649 patent contains the term "airflow sufficient to substantially avoid an anaerobic condition."

FN11. RJR discussed the terms "air flow sufficient" and "anaerobic condition" separately in its opposition paper.

1. " *Anaerobic Condition* "

Star proposes that the term "anaerobic condition" be construed to mean "an oxygen deficient condition (such as is created by an atmosphere of combustion exhaust gases or a lack of aeration) which promotes microbial nitrate reductase activity" FN12 (St.Br., pp. 24, 28). Star contends that in light of the specification, statements made during the prosecution of the ' 649 patent and the ordinary meaning of "deficient," *i.e.,* "not up to a normal standard or complement," FN13 "oxygen deficient" does not mean a total absence of oxygen, but only the lack of oxygen which will stimulate microbial nitrate-reductase activity. To support its position, Star points to column 1, lines 54-56 and column 7, lines 43-45 of the ' 649 patent where "anaerobic" is defined as "oxygen deficient":

FN12. Microbial nitrate-reductase activity refers to a process occurring during the curing of tobacco leaves wherein microbes in and on the tobacco leaves produce an enzyme (nitrate reductase) that reduces the nitrate in the tobacco leaves to nitrite.

FN13. Merriam-Webster's Collegiate Dictionary 302 (10th ed., 1997) (St.Br., Ex. 23).

accumulate during the death of the plant cell [referring to nitrites] and are formed during curing by the reduction of nitrates under conditions approaching an anaerobic (oxygen deficient FN14 environment.
FN14. The Federal Circuit has recognized that words within a parenthetical following a phrase serve to define that phrase. Abbott Laboratories v. Novopharm Limited, 323 F.3d 1324, 1330 (Fed.Cir.2003) (St. R. Br., p. 6).

* * *

which are formed [referring to TSNAs] during the curing process by reduction of nitrates to nitrites under conditions approaching an anaerobic (i.e., oxygen deficient) environment.
Star points out that column 7, lines 43-45 of the '649 patent teaches how an anaerobic environment is created:
In one conventional curing technique, the combustion exhaust gases pass through the tobacco, thereby creating a condition approaching an anaerobic environment.

Moreover, during the prosecution of the '649 patent, Star further defined "anaerobic" by again setting out how an anaerobic environment is created:
Anaerobic conditions can result, *e.g.,* from the *presence of combustion exhaust gases* inside the curing barn or from the *release of carbon dioxide* by the plant during cure. Such anaerobic conditions are believed to contribute to nitrosamine formation by microbial action. (emphases added by Star, St. Br., p. 27) (St.Br., Ex. 3, p. 5).

RJR states that "[a]ny standard or scientific dictionary will define 'anaerobic' as the absence of free oxygen," citing to WEBSTER'S Ninth New Collegiate Dictionary 82 (1983) and Hackh's Chemical Dictionary 54 (3d ed. 1944) (RJR Br., pp. 19-20). Moreover RJR contends that while Star chose to define the term "anaerobic" as "oxygen deficient" in its proposed claim construction, "there are many different informal references to 'anaerobic' in the specification" FN15 (RJR Br., p. 20). RJR's arguments are not persuasive. In the present case, the term "anaerobic" was defined as meaning "oxygen deficient" in the specification by including "oxygen deficient" within the parenthetical after the term "anaerobic." Accordingly, based on *Abbott* and *Johnson,* the term "anaerobic," as defined by Mr. Williams means "oxygen deficient."

FN15. RJR does not explain what it means by "informally in the specification."

Nowhere in the specification is a numerically specific oxygen level used to define "anaerobic." Star contends, however, that such numerical specificity is not required, particularly since the level of oxygen defining an anaerobic environment will vary depending on the particular microbe and the environmental conditions. Star relies (St.Br., pp. 24-25) on Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565 (Fed.Cir.1986) for the proposition that it is not practicable to determine the level of oxygen corresponding to the anaerobic environment for each of the thousands of microbes in the many possible curing conditions. In *Orthokinetics,* the Federal Circuit found that the phrase "so dimensioned" was as accurate as the subject matter (automobiles) permitted, since automobiles come in various sizes. The Court continued,

[a]s long as those of ordinary skill in the art realized that the dimensions could be easily obtained [35 U.S.C.] s. 112, 2d para. requires nothing more. The patent law does not require that all possible lengths corresponding to the spaces in hundreds of different automobiles be listed in the patent, let alone that they

be listed in the claims. Orthokinetics, 806 F.2d at 1576.

The requirements of definiteness do not demand a level of precision beyond what is scientifically practicable. Exxon Research and Engineering Co. v. United States, 265 F.3d 1371, 1381 (Fed.Cir.2001). Since both Star and RJR have measured the oxygen levels of direct-fired environments and correlated particular oxygen levels with increased TSNAs, Star correctly asserted that anyone skilled in the art could do the same (St.Br., p. 43).

RJR asserted that extrinsic evidence belies Star's reliance on *Orthokinetics*. In his report, Star's expert, Dr. Richard J. Lee, stated that it was not possible to precisely measure the amount of oxygen that is in contact with the leaves of the tobacco plants, thereby making it impossible for one skilled in the art to "easily obtain" that information (RJR Br., pp. 37-38). However, since the specification clearly set out the meaning of "anaerobic," in this case extrinsic evidence is irrelevant "and cannot serve to inject ambiguity where none exists." Personalized Media Communications v. International Trade Commission, 161 F.3d 696, 706 (Fed.Cir.1998).

The specification defines "anaerobic condition" to mean "oxygen deficient" and further provides examples of anaerobic conditions, *e.g.,* the presence of combustion exhaust gases inside the curing barn or the build-up of carbon dioxide from the curing process itself.FN16 Moreover, in its responses to Interrogatories Nos. 26 and 28, RJR stated that an "anaerobic condition" means "a condition where microbes reduce nitrates to nitrites," and "airflow sufficient to substantially prevent an anaerobic condition" means "the movement of a volume of air per unit time, is enough, by itself, to no longer have a condition in which microbes reduce nitrates to nitrites" (St.Br., Ex. 25, pp. 4-5). These definitions are consistent with Star's proposed claim construction and the plain language of the specification of the ' 649 patent. Since RJR and the intrinsic evidence agree, there is no ambiguity as to the meaning of "anaerobic condition" and the court should not consult extrinsic evidence to construe this claim term.

FN16. The specification of the patents-in-suit does not recite "lack of aeration," as proposed by Star as an example of an oxygen deficient condition.

In light of the foregoing, I respectfully recommend that the claim term "anaerobic condition" be construed to mean "an oxygen deficient condition (such as is created by an atmosphere of combustion exhaust gases or from the release of carbon dioxide by the plant during cure) which promotes microbial nitrate reductase activity."

2. " *Air Free of Combustion Exhaust Gases* "

Star proposes that the term "free of combustion exhaust gases" be construed to mean "combustion exhaust gases are not permitted to enter the curing atmosphere during curing" (St.Br., pp. 28, 30). Star contends that the words "air free of combustion exhaust gas" should be given their ordinary meaning and relies on the prosecution history of the '649 patent to support its proposed claim construction. Star refers to the following statement made in an amendment during prosecution of the '649 patent: FN17

FN17. JR contends that Star's proposed interpretation is inconsistent with this argument, since that at the time this argument was made, "Star said nothing about poorly designed or maintained heat exchangers." (RJR Br., p. 38).

It will be understood, of course, that the curing air contains quantities of water vapor and other compounds present in ambient air which may be considered combustion products. Rather, the limitation "free of combustion products" is meant only to distinguish direct-fired heating in which combustion gases are

readily exhausted into the curing air. (St. Br., Ex. 3, August 9, 2000 Amendment and Response, p. 6). Star also relies on the Examiner Summary of an interview:

Examiner Colaianni indicated that the language "substantially free of combustion exhaust gases" did not necessarily remove the use of a direct fired burner. It was agreed to remove the word 'substantially' from claims 53 and 58 before the language "free of combustion exhaust gases." (St.Br., Ex. 3).

Star further asserts that "free of combustion exhaust gases" distinguishes its indirect-fired heating environment from those heating environments, including other indirect-fired heating environments, in which combustion exhaust gases are permitted to leak into the curing air (St.Br., p. 28). RJR takes exception to Star's attempt to distinguish indirect-fired heating environments that leak combustion gases into the curing atmosphere" (RJR Br., p. 38, *see also* footnote 17 herein). RJR contends that Star's proposed limitation is inconsistent with the arguments made by Star during the prosecution of the ' 649 patent and, more importantly, such a limitation has no support in the specification of the '649 patent. In responding to RJR's argument, Star argued that the doctrine of claim differentiation FN18 supports its proposed construction of the claim term. However, Star does not offer any intrinsic evidence that the term "free of combustion exhaust gases" should exclude indirect-fired heating environments in which combustion exhaust gases leak into the curing air.

FN18. Star states that "Mr. Williams argued before the United States Patent and Trademark Office ('PTO') that both 'free of combustion exhaust gases' and 'substantially free of combustion exhaust gases' distinguished over direct-fired heating." (St.R.Br., a 7).

RJR's exception to Star's proposed claim construction is well-founded. The specification and prosecution histories of the patents-in-suit support Star's proposed construction of the term "free of combustion exhaust gases" to exclude combustion gases from direct-fired heating environments. However, such intrinsic evidence also supports RJR's contention that the term "free of combustion gases" includes combustion gases from indirect-fired heating environment that leak into the curing environment. Therefore, I respectfully recommend that the Court construe the term "free of combustion exhaust gases" to mean "air that does not contain the combustion exhaust gases from a direct-fired heating environment."

3. " *Controlled Environment* "

Star proposes that the term "controlled environment" be construed to mean "controlling one or more of the conditions in the curing barn (as listed at col, 5, line 66 through col. 6, line 4 of the '649 patent) in a way different from conventional curing in order to substantially prevent the formation of nitrosamines" (St.Br., p. 30). The conditions listed at col. 5, line 66 through col. 6, line 4 of the '649 patent are humidity, rate of temperature change, temperature, time of treatment of the tobacco, airflow, CO level, CO_2 level, O_2 level and arrangement of the tobacco leaves. Star premises its proposed claim construction on the specification of the patents-in-suit. Star points to parts of the specification that differentiate the "controlled environment" of the asserted claims from the environment present when conventional prior art curing techniques are utilized (St.Br., pp. 32-33):

Conventional curing has been developed over time without any appreciation for subjecting tobacco to a controlled environment for the purpose of eliminating or reducing TSNAs. Accordingly, such conventional curing techniques do not provide suitable conditions (*e.g.* adequate oxygen flow) and fail to prevent an anaerobic condition in the vicinity of the tobacco leaves. Col. 7, lines 61-67.

In this disclosure, tobacco that has been "conventionally cured" is tobacco that has been air-cured or flue-cured, without the controlled conditions described herein, according to conventional methods commonly and commercially used in the U.S. Col., 6, lines 14-18.

RJR objects to Star's proposed claim construction, asserting that it is indefinite and is not supported by the specification of the '649 patent. According to RJR, Star's proposed claim construction should not be accepted by the Court, since the specification of the patents-in-suit fail to inform the public of "where conventional curing techniques end and potential infringing techniques begin." (RJR Br., p. 26). RJR contends that such indefiniteness is exacerbated by the fact that while the specification of the '372 provisional application described the prior art as being directed to a flue-curing process as utilizing a "controlled environment" (RJR Br., p. 10; Ex. 5, pp. 12-13), the specification of the '018 application is directed to a "somewhat controlled environment" (RJR Br., pp. 13-14, Ex. 7, p. 15).FN19 RJR's argument is not persuasive. As Star points out (St. R. Br., pp. 16-17):

FN19. RJR contends that if Star is entitled to its provisional priority date, then the term "controlled environment" is indefinite because "the term cannot simultaneously cover both the prior art process and the invention." (RJR Br., p. 31). Since Star does not rebut this contention the term "controlled environment" cannot claim priority to the ' 372 provisional application.

A person skilled in the art would readily understand the difference between how conditions must be controlled if the purpose is merely to produce good quality tobacco and how conditions must be controlled if the purpose is substantially preventing TSNAs. Controlling microbial activity that causes TSNAs is different from controlling tobacco color and texture. The patents themselves explain the controls, and the conditions that can be controlled are specifically listed.
The specification defines the parameters for airflow,FN20 humidity, FN21 and temperature FN22 both for the invention and for conventional methods of curing tobacco (St. R. Br., p. 17, n. 22). The specification of the ' 649 patent enumerates the differences between the invention and traditional tobacco curing conditions, disclosing that Star's invention utilizes airflow that is ten percent greater than the airflow used in conventional curing methods, humidity that is lower than that of conventional curing methods and temperatures that are higher than those used in conventional curing methods. Since the specification of the patents-in-suit distinguishes the "different controls," Star's proposed claim construction reciting "in a way different from conventional curing" is supported by the specification.

FN20. At col. 11, lines 43-45, the specification states that "the minimum airflow is preferably about ten percent higher than the flow of flue gas commonly used in the prior art."

FN21. At col. 11, lines 57-63, the specification states that "the heated or unheated air flow comprises dehumidified air with a humidity level of less than about 85%, more preferably less than about 60%, most preferable less than about 50%." At col. 8, lines 44-47, the specification describes the humidity of a typical flue-curing process at approximately 85%. At col. 7, lines 58-61, the specification states that in one conventional curing technique, the humidity is often high.

FN22. At col. 12, lines 3-13, the specification states, "[t]he temperature within the curing barn of the present invention may range from ambient (*i.e.,* outside) temperature to as high as about 250 (deg.) F or more, without charing the tobacco product. If heated air (*i.e.,* convective heat) is used to accelerate the drying of the tobacco product, suitable temperatures may range anywhere from about 100 (deg.) F to about 250 (deg.) F, more preferable from about 106 (deg.) F to about 170 (deg.) F. However, the optimum temperature within the curing barn can be determined for each case, depending on the overall conditions of the environment and the tobacco product being treated." At col. 8, lines 18-26, the specification describes the temperature ranges for conventional flue-curing processes; the range is from 35-75 (deg.) C or 95-167 (deg.) F.

In order to control the environment, *i.e.*, the curing atmosphere, at least one condition must be controlled. In the case of curing tobacco, those conditions include the list of conditions at col. 5, line 66 through col. 6, line 4 of the '649 patent. Star seeks to support its claim construction regarding specific conditions controlled by its claimed process by referring to the portions of the specification that set out the conditions controlled within its "controlled environment" (St.Br., pp. 33-34):

For purposes of the invention, the phrase "controlling the conditions" means determining and selecting an appropriate humidity, rate of temperature change, temperature, time of treatment of the tobacco, airflow, CO level, CO_2 level, O_2 level, and arrangement of the tobacco leaves to prevent or reduce the formation of at least one TSNA. Col. 5, line 66 to col. 6, line 4.

[This invention involves] subjecting the tobacco to a controlled environment capable of providing a reduction in the amount of nitrosamines, for a time sufficient to ... substantially prevent the formation of at least one nitrosamine, wherein said controlled environment is provided by controlling at least one of humidity, rate of temperature change, temperature, airflow, CO level, CO_2 level, O_2 level, and arrangement of leaves. Col. 7, lines 10-18.

RJR contends that the claim cannot be construed to cover all of the conditions set out by Star, since Star surrendered some of that subject matter during prosecution of the '649 patent. RJR points out that Star amended the definition of "controlled environment" from "controlling at least one of humidity, rate of temperature change, temperature, airflow, CO level, CO_2 level, O_2 level and arrangement of leaves" to "controlling at least one of humidity, temperature and airflow." Star did not seriously challenge RJR's contention that it surrendered the subject matter relating to the rate of temperature change, temperature, airflow, CO level, CO_2 level, O_2 level and arrangement of leaves.FN23 Consequently, the claim term "controlled environment" does not include all of the parameters listed at col. 5, line 66 through col. 6, line 4 of the ' 649 patent; instead, the claim term "controlled environment," is limited to "humidity, temperature and airflow."

FN23. In its reply brief, Star contends that "towards the end of its brief [referring to RJR's brief] "RJR includes a *one-sentence* 'argument that Star Scientific 'surrendered' certain subject matter by pursuing particular versions of its claims but not others before the PTO (a very normal process), but RJR cites no case law, making its theory opaque." (emphasis in original) (St.R.Br., p. 24, n. 35). Since Star cannot provide an exact reference to RJR's brief and RJR discusses the sunender of subject matter during prosecution of the '649 patent on pages 17-18 (not "towards the end of its brief"), Star's comments in footnote 35 have not been considered in connection with this issue.

Accordingly, I respectfully recommend that the claim term "controlled environment" be construed to mean "controlling one or more of humidity, temperature and airflow in the curing barn, in a manner different from conventional curing, in order to substantially prevent the formation of TSNAs."

4. " *Substantially Prevent the Formation of ... at Least One Nitrosamine* "

Star proposes that the term "substantially prevent the formation of ... at least one nitrosamine" be construed to mean "prevention that is substantially or essentially or virtually achieved (typically 0.05 g/g for NNN, 0.10 g/g for NAT plus NAB FN24 and 0.05 g/g for NNK)" (St.Br., p. 35). Star asserts that "substantially" and "preventing" FN25 should be given their ordinary meanings. Moreover, Star asserts that while "substantial prevention" does not require total prevention, the term means that total prevention is being approached (St.Br., p. 36). Star refers to col. 15, line 64 to col. 16, line 1 of the ' 649 patent for teachings of specific TSNA levels that meet this claim limitation:

FN24. Star stated that the parties agree that NAT and NAB levels must be combined in order to determine whether NAT and NAB have been "substantially prevented."

FN25. Star pointed out that "preventing" is different from reducing, since "reducing" is a relative term while "preventing" is an absolute term.

the NNN level of the tobacco product according to the present invention is typically less than about 0.05 g/g, the combined NAT and NAB level is typically less than about 0.10 g/g, and the NNK level is typically less than about 0.05 g/g.
RJR contended that the "substantially prevent" claim limitation cannot be given any meaning. Alternatively, RJR contended that if the "substantially prevent" claim limitation has any meaning, it means "non-detectable amounts of TSNAs," as shown in Figure 7 of the specification of the patents-in-suit (RJR Br., p. 23, n. 5).FN26 RJR's contentions are based, in part, on the fact that during prosecution of the ' 649 patent, the claims were narrowed to cover "preventing" the formation of TSNAs rather than both "preventing" the formation of TSNAs and "reducing" the level of already formed TSNAs.

FN26. RJR contended that Star conceded that "substantially reduce" means something higher than "substantially prevent" (RJR Br., pp. 11 and 24). However, Star denied that it made such a concession (St .R.Br., p. 13) and the Special Master found none. Star pointed out that RJR consistently tried to read the word "substantially" out of the claim limitation "substantially prevent," stating that " 'prevent' means to 'keep from happening' and that 'substantially prevent' also means to "keep ... from happening.' " (St. R. Br., p. 14).

RJR's proposed alternative definition of the limitation "substantially prevent the formation of ... at least one nitrosamine" does not comport with the definition of the term as discerned from the specification of the '649 patent (col. 7, lines 5-7). Detectable amounts of each of TSNAs is set out in the specification at col. 15, line 64 to col. 16, line 1 of the '649 patent:

less than about 0.05 g/g for NNN, less than about 0 .10 g/g for NAT plus NAB, and less than about 0.05 g/g for NNK.

The specification of the '649 patent (col. 7, lines 9-15) discloses that the invention encompasses both the substantially prevention of TSNA, or in the context of any already formed TSNA, a substantial reduction in TSNA. These substantial changes in the TSNA levels result from "subjecting the tobacco to a controlled environment capable of providing a reduction in the amount of nitrosamines, for a time sufficient to reduce the amount, or substantially prevent the formation, of at least one nitrosamine." Since the invention encompasses both "substantially prevent" and "substantially reduce," and the specification does not differentiate between the TSNA levels for the different activities, TSNA levels provided in the specification apply equally to both "substantially prevent" and "substantially reduce."

Accordingly, I respectfully recommend that the term "substantially prevent the formation of ... at least one nitrosamine" means that "the level of at least one of the nitrosamines falls within the following ranges: less than about 0.05 g/g for NNN, less than about 0.10 g/g for NAT plus NAB, and less than about 0.05 g/g for NNK."

B. ***Definiteness of the Asserted Claims***

35 U.S.C. s. 112, second paragraph requires that "the specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." "The amount of detail required to be included in the claims depends on the particular invention

and the prior art, and is not to be viewed in the abstract but in conjunction with whether the specification is in compliance with the first paragraph of s. 112." Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 624 (Fed.Cir.1985). If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, s. 112 demands no more. Personalized Media, 161 F.3d at 705, *quoting Miles Lab., Inc. v. Shandon, Inc.,* 997 F.2d 873, 875 (Fed.Cir.1993). "The primary purpose of this deflniteness requirement is to permit a potential competitor to determine what actions will violate the monopoly given to the inventor because of his patent." Morton Intern., Inc. v. Cardinal Chemical Co., 5 F.3d 1464, 1470 (Fed.Cir .1993).

Star moves for summary judgment that the claims of the patents-in-suit are definite under 35 U.S.C. s. 112, second paragraph. Determining whether a patent claim is invalid for failure to meet the deflniteness requirement of 35 U.S.C. s. 112, second paragraph, is a legal conclusion based upon the Court's construction of the patent claims and therefore is a question of law. All Dental Prodx, LLC v. Advantage Dental Prods., Inc., 309 F.3d 774, 778 (Fed.Cir.2002). After construing the claims, the Court can then determine whether the claims, as construed, are definite and comply with the statute. *Id.*

Disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). Summary judgment will not lie if the dispute about a material fact is "genuine," that is, the evidence is such that a reasonable jury could return a verdict for the nonmoving party. *Id.* However, the moving party is entitled to a judgment as a matter of law if the nonmoving party fails to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof. Celotex v. Catrett, 477 U.S. 317, 322 (1986). A party opposing a properly supported motion for summary judgment "may not rest upon the mere allegations or denials of his pleading, but ... must set forth specific facts showing that there is a genuine issue for trial." Anderson, 477 U.S. at 248, quoting First National Bank of Arizona v. Cities Service Co., 391 U.S. 253, 288-89 (1968). In other words, the nonmoving party must go beyond the pleadings and by her own affidavits, depositions, answers to interrogatories, and admissions of record designate specific facts showing that there is a genuine issue for trial. Celotex, 477 U.S. at 324.

RJR contends that throughout this litigation, Star attached "many different, inconsistent, and contradictory interpretations" to these claim terms, and this "multiplicity of interpretations" is evidence that the claims are indefinite, based on Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1342 (Fed.Cir.2003) FN27 and Candela Laser Corp. v. Cynosure, Inc., 862 F.Supp. 632, 642-43 (D.Mass.1994) FN28 (RJR Br., pp. 1 and 6). As evidence of Star's "multiplicity of interpretations," RJR lists statements (1) in Star's brief in support of this motion, (2) in responses to interrogatories and (3) in Star's expert witness reports (RJR Br., pp. 6-9). Star responds that "RJR focuses on the notion that if a single concept is described using two different sets of words, it is two entirely different concepts and if a single claim element has more than one aspect, it is dissected into conflicting sub-elements" (St. R. Br., p. 2).FN29

FN27. In *Amgen,* the Court found the claims indefinite under s. 112, para. 2 because those of ordinary skill in the art would have been faced with a "conundrum" as to claims requiring "glycosylation which differs from that of human urinary erythropoietin." The Court found that this claim language presupposes that the glycosylation of urinary erythropoietin is a fixed, identifiable marker when, in reality, it is not, there being many heterogeneous urinary erythropoietins. The Court found that the specification failed to disclose a standard by which the "difference" could be measured. *Id.* at 1341. The Court findings were based on the specification's failure to disclose a standard which led to a "multiplicity of different meanings."

FN28. In *Candela,* the plaintiff did not refute the defendant's argument that "the parties' greatly contrasting interpretations of the patent, particularly regarding the definitions of 'saturation' and 'regeneration medium' demonstrate that the claims are indefinite ." However, the Court found that "the inventors themselves were vague as to how the regeneration medium worked" and "a person reasonable skilled in the art would not be

certain as to the scope and meaning of the claims." Candela, 862 F. Supp at 642-43. The Court's finding was based on the vagueness of the specification, not on a "multiplicity of different meanings."

FN29. Star analogizes to Mr. Williams's sweater having red, blue, and green checks, and RJR viewing three different statements by Mr. Williams, *i.e.*, (1) "My sweater has red checks," (2) "My sweater has blue checks," and (3) "My sweater has green checks," as describing three different sweaters. *Id*.

Based upon its proposed claim construction, Star discusses each of the claim limitations in dispute and concludes that those skilled in the art FN30 would know and understand the meaning of each claim limitation. However, since the definiteness requirement of 35 U.S.C. s. 112, second paragraph, is based upon the Court's construction of the patent claims, the following analysis will be based on the construction of the claims as recommended hereinabove.

FN30. Star appears to be assuming, but does not expressly state, that RJR and Star are "those skilled in the art," and not tobacco farmers.

1. " *Anaerobic Condition* "

As discussed above, the Special Master recommended that the claim term "anaerobic condition" be construed to mean "an oxygen deficient condition (such as is created by an atmosphere of combustion exhaust gases or from the release of carbon dioxide by the plant during cure) which promotes microbial nitrate reductase activity." The parties disagree as to whether the specification "reasonably apprise[s] those skilled in the art" of the meaning of the term "anaerobic condition." Personalized Media, 161 F.3d at 705.

Star asserted that those skilled in the art would know that even conditions that are only slightly oxygen deprived may qualify as "anaerobic," thereby not needing a specific mathematical definition to define the limitation. (St.Br., p. 43). Star relied on the studies conducted by Dr. Lee that ambient air contains an oxygen level of 20.9%, and reduction of oxygen levels to below 20.5% and sometimes below 20% by combustion exhaust gases increases TSNAs. (St.Br., pp. 43-44). RJR contended that the specification of the patents-in-suit fail to inform "anyone" FN31 how to determine whether an anaerobic condition is present or whether it has been avoided. (RJR Br., p. 36). According to RJR, one of Star's experts, Dr. Timothy Nelson, testified that "the meaning of the term varies with the precise make-up of the microbial population that is present on any given day." FN32(RJR Br., p. 37). Moreover, RJR asserted that the RJ Lee Group's report stated that "it is not possible to measure precisely the oxygen that is actually in contact with the leaves." FN33 Star's rebuttal continued to argue that the specification clearly defined the term "anaerobic" as "oxygen deficient," and that the points inconsistency found by RJR were merely different aspects of the term "anaerobic" as that term was used to define the invention set forth in the specification (the ' 649 patent, col. 7, lines 56-57; col. 8, lines 3-6).

FN31. The standard is "those skilled in the art," not "anyone."

FN32. Dr. Nelson also testified, according to RJR, that "whether oxygen levels of 10% or 15% are 'anaerobic' depends on the nature of the microbial population on the tobacco leaf." (RJR Br., p. 20).

FN33. The claims do not require that the prevention of an anaerobic condition be at the leaf surface, only "around the vicinity of said plant portion." (claims 4 and 20 of the '649 patent and claim 41 of the ' 401 patent). RJR stated that the RJ Lee Group's opinion belied Star's reliance on *Orthokinetics* regarding whether

a precise oxygen level needed to be disclosed.

The patents-in-suit teach that the reduction of nitrates to nitrites under an anaerobic condition on the surface of the leaf is responsible for the formation of TSNAs during the curing process. The testimony of Star's experts, Dr. Nelson and Dr. Lee, conclusively point out that those skilled in the art may be unable to determine what specifically constitutes an anaerobic condition sufficient to facilitate the formation of TSNA by microbes on the surface of the tobacco leaf. As pointed out by RJR, the specification does not appear to provide sufficient guidance as to what constitutes an anaerobic condition. Star countered that one can determine whether an anaerobic condition has been prevented (St. R. Br., p. 21) by measuring the levels of nitrites or the nitrate reductase enzyme. However, measuring nitrites or the nitrate reductase enzyme levels after a patent-in-suit has been infringed defeats the primary purpose of definiteness, *i.e.,* "permitting a potential competitor to determine what actions will violate the monopoly given to the inventor because of his patent." Morton, 5 F.3d at 1470. Since, according to Dr. Lee, it is not possible for one of ordinary skill in the art to determine on any given day whether he is infringing the patents-in-suit unless he does what is not possible *i.e.,* continually monitor the oxygen levels at the surface of the leaf regarding the definiteness of the limitation "anaerobic condition," FN34 a genuine issue of fact exist in connection with the limitation "anaerobic condition."

FN34. Star also suggested that "one could examine oxygen levels to determine any variance from normal ambient (*i.e.,* aerobic) levels that might trigger microbial activity" (St. R. Br., pp. 21-22). However, according to Dr. Nelson, the oxygen level at the surface of the leaf "varies with the precise make-up of the microbial population that is present on any given day."

2. " *Air Free of Combustion Exhaust Gases* "

As discussed above, the Special Master recommended that the Court construe the term "air free of combustion exhaust gases" to mean "air that does not contain the definition exhaust gases from a direct-fired heating environment." This construction of "free of combustion exhaust gases" excludes exhaust gases for indirect-fired heating environments that leak into the curing environment, since neither the specification nor the prosecution history provide any support for its inclusion. Since RJR's opposition is directed to the exclusion of indirect-fired heating environments and the recommended claim construction does not contain indirect-fired heating environments, no genuine issue of fact remains regarding this claim limitation.

3. " *Controlled Environment* "

As set out above, I have recommended that the claim term "controlled environment" be construed to mean "controlling one or more of humidity, temperature and airflow in the curing barn, in a manner different from conventional curing, in order to substantially prevent the formation of TSNAs." Star stated that "any farmer experienced in curing tobacco" can distinguish conventional curing methods from the teachings of the present invention using "new equipment (or the use of old equipment in a new way)." (St.Br., p. 45). Conversely, with respect to the claim limitation "controlled environment" and "controlling at least one of humidity, temperature, and airflow," RJR contended that "the claims and specification give little indication or guidance as to l)what these individual parameters should be, 2) how to control these parameters relative to each other, or 3) how these parameters could be set or controlled in a way different from conventional or prior art curing practices" FN35 (RJR Br., p. 25). To show there is a genuine issue of fact in the "controlled environment" claim limitation, RJR relied upon the testimony of Mr. James Sturgill. This Star expert testified that he could not advise someone how to "either practice the invention or avoid it with respect to the controlled environment" (RJR Br., Ex. 28, p. 229). Since Mr. Sturgill does not appear to be "reasonably apprised of the scope of the invention," there is a genuine issue of material fact as to whether those of ordinary skill in the art have been reasonably apprised of the scope of the invention. Personalized Media,

161 F.3d at 705.

FN35. RJR relied upon Union Pacific Resources Co. v. Chesapeake Energy Corp., 53 U.S.P.Q.2d 1669, 1673 (N.D.Tex.1999), *aff'd* 236 F.3d 684 (Fed.Cir.2001), for this contention. In *Union Pacific,* the Federal Circuit found that the patent did not define the means to "compare" the two sets of characterizing information, thereby affirming the district court's finding of indefiniteness. However, the Federal Circuit states, "Even if the written description does not enable the claims, the claim language may still be definite." *Id*. at 692, *citing* In re Hyatt, 708 F.2d 712, 714-15 (Fed.Cir.1983) and In re Miller, 441 F.2d 689, 693 (CCPA 1971).

Furthermore, Star's position in connection with this term is that one skilled in the art is "any farmer experienced in curing tobacco," whereas RJR's position is that Mr. Sturgill is one skilled in the art. This apparent disagreement as to who is the person skilled in the art, presents another genuine issue of material fact with regard to this limitation, since knowing the level of skill in the art is necessary to an analysis under s. 112. Chemcast Corp. v. Arco Industries Corp., 913 F.2d 923, 926 (Fed .Cir.1990). Since genuine issues of material fact exist regarding the defmiteness of this limitation, summary judgment is not appropriate in connection with those claims containing this limitation.

4. " *Substantially Prevent the Formation of ... at Least One Nitrosamine* "

I have recommended that the term "substantially prevent the formation of ... at least one nitrosamine" means that "the level of at least one of the nitrosamines falls within the following ranges: less than about 0.05 /g for NNN, less than about 0.10 g/g for NAT plus NAB, and less than about 0.05 g/g for NNK."

Star asserted that since typical levels of TSNAs are recited in the specification of the patents-in-suit, that guidance is sufficient to define "substantially prevent," relying on In re Marosi, 710 F.2d 799, 802 (Fed.Cir.1983).FN36 RJR disagreed, contending that Star's reliance on *In re Marosi* is misplaced because in that case, unlike the present case, the limitation at issue was explicitly defined in the specification to permit some impurities in the starting materials (RJR Br., p. 32). RJR also argued that Star promoted a different interpretation for the claim term "substantially prevent the formation of ... at least one nitrosamine" in violation of the Court's September 16, 2002, Order to Compel. RJR specifically pointed to statements allegedly made by Star's technical expert.FN37 In addition to its "red checks, blue checks, green checks" analogy, Star proffered a comparison chart showing that its statements regarding the claim term "substantially prevent the formation of said at least one nitrosamine" are accurate, correct and consistent (St. R. Br., p. 12). Star stated that in connection with the testimony of its technical experts quoted by RJR, it "has never asserted that the claim should be construed as incorporating this requirement." *Id* .

FN36. The *In re Marosi* court found that the specification provided a general guideline and examples sufficient to enable a person of ordinary skill in the art to determine whether a process uses a silicon dioxide source "essentially free of alkali metal." *Id*. at 803.

FN37. RJR referred to the RJ Lee Group Report which "adopted a 70% standard to reflect when a grower was typically achieving the results described in the patents" (RJR Br., Ex. 3, p. 34). RJR, however, did not point to the specification or the file history to support its contention that 70% described the "substantially prevent" claim limitation.

RJR's arguments are not persuasive in light of the recommended construction of the claim limitation. RJR did not present any evidence that one of ordinary skill in the art would find the detectable amounts of TNSAs set out at col. 15, line 64 to col. 16, line 3 to be indefinite. In light of the above, there are no genuine

issues of material fact regarding this claim limitation.

5. ***Definiteness of the Asserted Claims***

RJR raised genuine issues of material fact regarding the defmiteness of two of the four contested claim limitations, *i.e.*, "anaerobic condition" and "controlled environment." Since claims 4 and 20 of the '649 patent and claim 41 of the '401 patent contain the limitations "anaerobic condition" and "controlled environment," there is a genuine issue of material fact as to whether these claims are definite. Moreover, since claim 12 of the '649 patent depends from claim 4, as to that claim, too, there is a genuine issue of material fact regarding defmiteness. Consequently, I respectfully recommend that the Court deny Star's motion for summary judgment that the claims 4, 12 and 20 of the '649 patent and claim 41 of the '401 patent are definite under 35 U.S.C. s. 112, second paragraph.

III. ***CONCLUSION***

For the foregoing reasons, I respectfully recommend that the Court enter an order construing the claims of the patents-in-suit as recommended herein and deny Star's motion for summary judgment that the asserted claims of the patents-in-suit are definite under 35 U.S .C. s. 112, second paragraph.

D.Md.,2003.
Star Scientific Inc. v. R.J. Reynolds Tobacco Co.