

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MARYLAND

STAR SCIENTIFIC, INC.

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Plaintiff

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vs.

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CIVIL ACTION NO. MJG-01-1504

(Consolidated with MJG-02-2504)

R.J. REYNOLDS TOBACCO COMPANY,  
et al.

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Defendants

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MEMORANDUM AND ORDER  
RE: INDEFINITENESS

The Court has before it Defendants' Motion for Summary Judgment of Invalidity Based on Claim Indefiniteness [Paper 668], Plaintiff's Cross-Motion for Summary Judgment that all the Asserted Claims of the Patents-in-Suit are Not Indefinite [Paper 682], and the materials submitted relating thereto.

Plaintiff Star Scientific, Inc. ("Star") contends that Defendants R.J. Reynolds Tobacco Company, a North Carolina corporation and R.J. Reynolds Tobacco Company, a New Jersey corporation (collectively, "RJR"), infringed certain claims of United States Patent Nos. 6,202,649 ("the '649 Patent") and 6,425,401 ("the '401 Patent") (the "Patents-in-Suit") that relate to the curing of tobacco.

I. INTRODUCTION

Tobacco that is freshly harvested is not suitable for human

consumption but must be "cured" before it can be used in cigarettes and other products. Tobacco has, of course, been cured for centuries by various methods, including those involving types of drying processes in "barns."

By about the 1990's, the tobacco industry became aware of a possible problem in regard to the formation of nitrosamines<sup>1</sup> in the curing process. The nitrosamines that form in tobacco plants during the curing process are referred to as "tobacco specific nitrosamines" or "TSNAs." Some TSNAs were thought to be carcinogenic, so efforts were made to find ways to avoid TSNA formation in the curing process.

In September of 1998, Jonnie Williams ("Williams") filed a Provisional Application<sup>2</sup> and, a year later, a Non-Provisional Application.<sup>3</sup> These Applications led to the issuance of United States Patent Nos. 6,202,649 ("the '649 Patent") and 6,425,401 ("the '401 Patent") (the "Patents-in-Suit"). The Patents-in-Suit include claims relating to methods of curing tobacco claiming a tobacco curing process to prevent TSNA formation comprising drying in a controlled environment (controlling humidity,

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<sup>1</sup> Nitrosamines are chemical compounds that contain nitrogen and that form in a variety of organic materials (including plants).

<sup>2</sup> Application Serial No. 60/100,372.

<sup>3</sup> Application Serial No. 09/397,018.

temperature and/or airflow) with sufficient airflow to prevent an anaerobic condition.

As discussed herein, RJR asserts that the claims at issue are indefinite by virtue of the inclusion therein of the limitations that there be a "controlled environment" and "anaerobic condition."

By the instant cross-motions, each side seeks summary judgment with regard to RJR's indefiniteness defense.

## II. SUMMARY JUDGMENT STANDARD

In a patent case, as in any other type of case, a motion for summary judgment shall be granted if "there is no genuine issue of material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); e.g. Jamesbury Corp. v. Litton Indus. Prods., Inc., 839 F.2d 1544, 1548 (Fed. Cir. 1988), cert. denied, 488 U.S. 828 (1988).

The well-established principles pertinent to such motions can be distilled to a simple statement. The Court may look at the evidence presented in regard to the motion for summary judgment through the non-movant's rose colored glasses, but must view it realistically. After so doing, the essential question is whether a reasonable fact finder could return a verdict for the

non-movant or whether the movant would, at trial, be entitled to judgment as a matter of law. E.g., Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 251 (1986); Celotex Corp. v. Catrett, 477 U.S. 317, 327 (1986); Adickes v. S.H. Kress & Co., 398 U.S. 144, 158-59 (1970).

When parties file cross-motions for summary judgment, each motion is decided separately on the summary judgment standard. Strauss v. Peninsula Reg'l Med. Ctr., 916 F. Supp. 528, 530 (D. Md.) (citations omitted), aff'd, 86 F.3d 1152 (4th Cir. 1996).

### III. DISCUSSION

Claim 4 of the '649 patent, a claim representative of the claims at issue, states that what is claimed is:

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.

Defs.' Mem. in Supp. of Mo. Summ. J., ex. 5 (the '649 Patent), col. 20, ll. 18-33 (emphases added). As discussed herein, the essential problem with the claims is that no one - certainly not one of ordinary skill in the art - reading the Patents-in-Suit would be able to carry out the invention. That is, the skilled artisan would not be able to know, in advance, whether a particular curing operation would infringe.

The Patents-in-Suit do not teach how to control the environment to prevent an anaerobic condition that will substantially prevent the formation of a nitrosamine. The only way to ascertain whether a curing operation process would infringe is to examine the result and, if successful in reducing TSNA production, then the operation would have infringed.

A. The Definiteness Requirement

The Patent statute, 35 U.S.C. § 112 (2001), provides in relevant part:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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 United States Court of Appeals for the Federal Circuit has stated that "[t]he primary purpose of the definiteness requirement is to ensure that the claims are written in such a way that they give notice to the public of the extent of the legal protection afforded by the patent, so that interested members of the public, e.g., competitors of the patent owner, can determine whether or not they infringe." All Dental Prodx LLC v. Advantage Dental Prods., 309 F.3d 774, 779-80 (Fed. Cir. 2002).

A determination that a patent claim is invalid for failure to meet the definiteness requirement of 35 U.S.C. § 112, ¶ 2 is a legal conclusion "that is drawn from the court's performance of its duty as the construer of patent claims." Personalized Media Commc'ns, L.L.C. v. ITC, 161 F.3d 696, 705 (Fed. Cir. 1998). Thus, definiteness is a question of law to be resolved by the court. See Atmel Corp. v. Info. Storage Devices, 198 F.3d 1374, 1378 (Fed. Cir. 1999); Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1376 (Fed. Cir. 2001).

B. Claim Construction

"The first step in any invalidity analysis is claim construction." SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp., 225 F.3d 1349, 1355 (Fed. Cir. 2000). "Ambiguity, undue breadth, vagueness, and triviality are matters which go to the claim validity for failure to comply with 35 U.S.C. § 112 ¶ 2, not to interpretation or construction." Intervet Am., Inc. v. Kee-Vet Labs., Inc., 887 F.2d 1050, 1053 (Fed. Cir. 1989) (emphasis added).

The Federal Circuit does not insist "that claims be plain on their face in order to avoid condemnation for indefiniteness." Personalized Media Commc'ns, 161 F.3d at 705. Claims are sufficiently definite if, when read in light of the specification, they reasonably apprise those skilled in the art of the scope of the invention. Id.

Star contends that the Federal Circuit has held that a claim that is capable of being construed is necessarily definite, relying upon Bancorp Services, L.L.C. v. Hartford Life Insurance Co., 359 F.3d 1367 (Fed. Cir. 2004). In Bancorp, the patent at issue related to a system for administering and tracking the value of life insurance policies in separate accounts. Id. at 1369. The district court held that the claim limitation term "surrender value protection" was not defined in the patent and was not synonymous with "stable value protection," a term that

was used and defined in the specification. Id. at 1370. Thus, the district court held that the claims at issue were "fatally indefinite." Id.

On appeal, the Federal Circuit reversed, holding that, in context, "the meaning of the term 'surrender value protected investment credits' is reasonably discernible and that the asserted claims of the '792 patent are therefore not invalid for indefiniteness." Id. at 1372. As pertinent to the instant discussion, the Bancorp court stated:

In ruling on a claim of patent indefiniteness, a court must determine whether those skilled in the art would understand what is claimed when the claim is read in light of the specification. . . .

We have held that a claim is not indefinite merely because it poses a difficult issue of claim construction; if the claim is subject to construction, i.e., it is not insolubly ambiguous, it is not invalid for indefiniteness. Honeywell Int'l, Inc. v. Int'l Trade Comm'n, 341 F.3d 1332, 1338-39 (Fed. Cir. 2003). That is, if the meaning of the claim is discernible, "even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds." Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001).

Id. at 1372 (emphases added).

The Court does not read this statement to constitute a holding that the mere fact that a district court issued a claim construction ruling regarding a term necessarily prevents

reaching a conclusion that the term is indefinite. Rather, the issue is whether the claim limitation can be construed so as not to be "insolubly ambiguous" to one skilled in the art.

In the context of an indefiniteness issue, the "construction" of a claim term is the first step - not the final or only step - in the process of determining whether it is sufficiently definite. Furthermore, if the Federal Circuit did have a view that any claim construction by a district court necessarily makes a claim definite, this Court would modify its claim construction decision so as to exclude any construction of the terms at issue.

Accordingly, this Court shall consider whether the claims at issue are indefinite by virtue of the inclusion therein, as limitations, the terms "controlled environment" and "anaerobic condition" as limitations.

### C. Terms at Issue

"[T]he determination whether a claim is invalid as indefinite 'depends on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the specification.'" Atmel, 198 F.3d at 1378 (quoting North Am. Vaccine, Inc. v. Am. Cyanamid Co., 7 F.3d 1571, 1579 (Fed. Cir. 1993)); accord Howmedica Osteonics Corp. v. Tranquil

Prospects, LTD., 401 F.3d 1367, 1371 (Fed. Cir. 2005) (stating that "[t]he definiteness of a patent claim depends on whether one skilled in the art would understand the bounds of the claim when read in light of the specification").

"The person of ordinary skill is a hypothetical person who is presumed to be aware of all the pertinent prior art." Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc., 807 F.2d 955, 962 (Fed. Cir. 1986) (addressing obviousness and citing Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 454 (Fed. Cir. 1985)). The "one skilled in the art" analysis for indefiniteness under 35 U.S.C. § 112, ¶ 2 is generally in accordance with similar analyses under § 112, ¶ 1. See Atmel, 198 F.3d at 1379-80.

1. "Controlled Environment"

The Court<sup>4</sup> has construed the term "controlled environment" to mean "controlling one or more of humidity, temperature, and airflow in the curing barn, in a manner different from conventional curing, in order to substantially prevent the formation of TSNAs." Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., No. MJG-01-1504, Order at 2 [Paper 458] (D. Md. Mar. 31, 2004).

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<sup>4</sup> By Judge Alexander Williams, no relation to the inventor, Jonnie Williams.

RJR presents a rather persuasive argument that the Patent does not inform those of ordinary skill in the art how to establish the claimed "controlled environment" or how to adjust the humidity, temperature, and airflow relative to each other and to other factors to affect the curing process. Indeed, Star itself seeks to present testimony from an expert witness, Mr. James Sturgill, that is highly supportive of RJR's position. Thus, the transcript of Sturgill's deposition includes:

Q: What is the amount of airflow used in conventional barns?

A: I don't know that I can give you a number for airflow used in conventional barns.

Q: Well, how the heck do you know where the accused barns have an airflow that was greater than what was conventionally used?

A. That's a good question.

Defs.' Mem. in Supp. of Mo. Summ. J. [Paper 668], ex. 1

(Deposition of James Sturgill) at 111-12.

James Sturgill is likely to be found by the jury to be representative of the hypothetical artisan of ordinary skill. Of course, Star, seeking to avoid summary judgment, takes the position that Sturgill is "an expert on nothing more than barn design, and not representative of one skilled in the art." RJR Mem. in Supp. of Mot. in Limine [Paper 562] at 6 (citing Star's Opp'n to Summ. J. No. 3 [Paper 308] at 22). In the summary

judgment context, the Court will assume that a jury would accept Star's position as to Sturgill so that his testimony - while not helpful to Star - would not itself establish indefiniteness.

Essentially, Star takes the position that the "touchstone for proper airflow therefore must be tied to preventing anaerobicity around the plants." Pl.s' Cross-Mo. for Summ. J. [Paper 682] at 9. Thus, Star argues that the definiteness of "controlled environment" can be appreciated only in the context of "anaerobic condition." Therefore, the Court will proceed on the basis that RJR would not be entitled to summary judgment as to the indefiniteness of the term "controlled environment" if the term "anaerobic condition" would pass muster as sufficiently definite.

D. "Anaerobic Condition"

The Court has construed the term "anaerobic condition" 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." Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., No. MJG-01-1504, Order at 1-2 [Paper 458] (D. Md. Mar. 31, 2004)

The essential problem is that the term, as construed, does not enable a person of ordinary skill in the art to practice the invention. Rather, the limitation merely states that there must be an oxygen deficiency sufficient under the circumstances of the particular curing operation to reduce the creation of TSNA's. In sum, one can know that he has practiced the invention only by finding, after a curing operation, that he has obtained a low TSNA reading.

The testimony of the inventor himself establishes that one skilled in the art cannot know, from the patent, how to conduct a curing operation that will achieve the intended result in light of the many variables associated with curing. For example:

Q: So how could one know if its an oxygen deficient condition?

A: If you cure the tobacco and you create an anaerobic situation you'll know it by the levels of the TSNA's that you'll measure.

Defs.' Mem. in Supp. of Mo. Summ. J. [Paper 668], ex. 11

(Deposition of Jonnie Williams) at 50; see also id. at 51, 54-57, 61-62.

The indefiniteness issue presented herein is analogous to that presented in Geneva Pharmaceuticals v. Glaxosmithkline PLC, 349 F.3d 1373 (Fed. Cir. 2003), in which the court found the term "synergistically effective amount" to be fatally indefinite. Id.

at 1383. In Geneva, as in the instant case, the limitation was defined in terms of the desired result, and there was insufficient guidance to enable the hypothetical artisan to determine the specific action to take without undue experimentation. Id. In the instant case, one skilled in the art would not know whether a particular curing operation arrangement was within the claim scope or not except after the fact. And, even when one knew that the result had been obtained so that the invention had been practiced, one could not know how to repeat the success in the next curing run. The Geneva court referred to such a claim limitation as "the epitome of indefiniteness." Id. at 1384.

In the context of the Patents-in-Suit, the claim limitation "anaerobic condition" may or may not warrant the label of an "epitome of indefiniteness." In any event, the term is fatally indefinite and renders the claims at issue invalid.

III. CONCLUSION

For the foregoing reasons:

1. Defendants' Motion for Summary Judgment of Invalidity Based on Claim Indefiniteness [Paper 668] is GRANTED.
2. Plaintiff's Cross-Motion for Summary Judgment that all the Asserted Claims of the Patents-in-Suit are Not Indefinite [Paper 682] is DENIED.
3. Judgment shall be entered after decision on the trial of RJR's Inequitable Conduct defense.

SO ORDERED, on Friday, January 19, 2007.

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Marvin J. Garbis  
United States District Judge