

**EX PARTE REEXAM**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
CENTRAL REEXAMINATION UNIT

*Ex parte* Reexamination of U.S. Patent 6,425,401 :  
: Jonnie R. Williams : Confirmation No. 6420  
: Control No.: 90/009,372 : Examiner: Brumback, Brenda  
: Filed: January 2, 2009 : Group Art Unit: 3991  
: For: METHOD FOR TREATING TOBACCO : Atty Dkt No.: 004859.00064  
: TO REDUCE NITROSAMINE :  
: CONTENT, AND PRODUCTS :  
: PRODUCED THEREBY :

**PETITION TO REOPEN REEXAMINATION PROCEEDING**

Patent Owner hereby petitions under 37 C.F.R. § 1.182 for withdrawal of the May 12, 2010 Notice of Intent to Issue *Ex Parte* Reexamination Certificate (“Notice”). The Director is authorized to charge \$ 400 for the petition fee (37 C.F.R. § 1.17(f)) to our Deposit Account 19-0733. If this amount is incorrect, the Director is authorize to debit or credit our Deposit Account 19-0733 for any deficiency or overpayment.

**Statement of Facts**

The Notice correctly states that a first Office Action was mailed on September 11, 2009 (“Office Action”); a personal interview was held on October 22, 2009 (“Interview”); and a response to the Office Action was filed November 10, 2009 (“Response”). The Notice fails to acknowledge a written Outline for Interview Summary that was filed October 21, 2009, and alleges that the Response did not include a summary of the Interview as required by 37 C.F.R. § 1.560(b). As explained below, this assertion is factually incorrect.

The Response effectively incorporated the written Outline for Interview Summary:

The courtesy extended by Examiners Brumback, Ponnaluri and Jones at the interview of October 22, 2009 is gratefully acknowledged. That interview was attended by Mr. Paul Rivard, Mr. Richard McMillan, Dr. Richard J. Lee, as well as the undersigned on behalf of the patentee. The matters discussed at the interview are reflected in the Outline for Interview Summary (previously made of record), as well as in following comments in response to the Office Action. (Response p. 2, emphasis added).

This “Outline for Interview Summary” was sent by facsimile to Examiner Brumback on October 21, 2009. Exhibit A hereto is a copy of the Outline as well as facsimile confirmation, which acknowledges receipt by the USPTO. As shown on the certificate of service, this Summary was also served on the third party requester. It was the understanding of the undersigned that this document would be officially made of record in this reexamination proceeding, an understanding which is reflected in the Response itself (“The matters discussed at the interview are reflected in the Outline for Interview Summary (previously made of record)”). (Response p. 2, emphasis added). In addition, copies of the Outline for Interview Summary were provided to Examiners Jones, Brumback, and Ponnaluri during the Interview.

The Notice alleges that the Patent Owner did not comply with § 1.560(b). This rule is reproduced below.

In every instance of an interview with an examiner in an *ex parte* reexamination proceeding, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the patent owner. An interview does not remove the necessity for response to Office actions as specified in § 1.111. Patent owner’s response to an outstanding Office action after the interview does not remove the necessity for filing the written statement. The written statement must be filed as a separate part of a response to an Office action outstanding at the time of the interview, or as a separate paper within one month from the date of the interview, whichever is later.

The Patent Owner fully complied with this requirement by filing a written summary of the Interview – both as part of the Response as well as on a separate paper filed within one month from the date of the interview. This written summary was sent by facsimile to the Examiner in advance of the Interview, and again presented to the Examiner during the Interview.<sup>1</sup> Nothing in § 1.560(b) precludes Patent Owner from relying on a written summary submitted in advance of the interview and ratified in writing subsequent to the interview. This written summary fully and accurately reflected the substance of the Interview, a fact verified in the written Response. The undersigned again reaffirms this fact. The Response filed November 10, 2009 incorporated this written summary of the Interview, thus clearly complying with § 1.560(b).

In the event that the USPTO does not reinstate the reexamination proceeding on the basis requested above, the Patent Owner, as a formality, alternatively requests reinstatement of the proceeding on the basis of unintentional delay in submitting the written interview summary pursuant to 37 C.F.R. § 1.560(b). As discussed above, the Patent Owner did submit a written summary of the interview on October 21, 2009 and adopted it in the response filed November 10, 2009. The Patent Owner received no indication of any possible deficiency in the written interview summary prior to receipt of the Notice on May 14, 2010. As noted above, Attachment A hereto is the written summary of the Interview in compliance with 37 C.F.R. § 1.560(b).

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<sup>1</sup> The cover sheet used for the facsimile transmission to Examiner Brumback on October 21, 2009 was captioned for Reexamination Control No. 90/009,375, a parallel proceeding involving the parent patent. A single interview was held on October 22, 2009 for both proceedings; and the Outline itself clearly indicates it applied to both reexamination proceedings (“OUTLINE FOR EXAMINER INTERVIEW REGARDING THE ‘649 AND ‘401 PATENTS”).

In view of the foregoing, vacatur of the Notice and reopening of the reexamination proceeding are respectfully requested.

Respectfully submitted,

Date: May 14, 2010

By: /Paul M. Rivard/  
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Registration No. 43,446  
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Attachment

Exhibit A (“OUTLINE FOR EXAMINER INTERVIEW REGARDING THE ‘649 AND ‘401 PATENTS”)

# **Exhibit A**

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 \*\*\* TX REPORT \*\*\*  
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TRANSMISSION OK

TX/RX NO 2497  
 RECIPIENT ADDRESS 0106#004859#00063#15712730961  
 DESTINATION ID  
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**FACSIMILE TRANSMITTAL SHEET**


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<b>FROM:</b>	<b>DATE:</b>	<b>TOTAL NO. OF PAGES:</b>	
Dale Hoscheit	October 21, 2009	(including cover sheet)	
<b>TO:</b>	<b>COMPANY:</b>	<b>FAX NO.:</b>	<b>PHONE NO.:</b>
Examiner Brenda Brumback	USPTO	571-273-0961	571-272-0961
<b>YOUR REFERENCE NO.:</b>	<b>OUR REFERENCE (C/M) NO.:</b>		
	004859.00063		

**RE:** Ex parte Reexamination of U.S. Patent 6,202,649

*If you do not receive all page(s) or have any problems receiving this transmission, please call:*

<b>NAME:</b>	<b>PHONE:</b>
Laura Sunderland	1-202-824-3140

**COMMENTS:**

Attached is a Brief Outline for Interview on October 22, 2009. Please confirm receipt of the Brief Outline for Interview.

Thank you



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**FACSIMILE TRANSMITTAL SHEET**

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Dale Hoscheit	October 21, 2009	12	

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<b>TO:</b>	<b>COMPANY:</b>	<b>FAX NO.:</b>	<b>PHONE NO.:</b>
Examiner Brenda Brumback	USPTO	571-273-0961	571-272-0961

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<b>YOUR REFERENCE NO.:</b>	<b>OUR REFERENCE (C/M) NO.:</b>
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**RE:** Ex parte Reexamination of U.S. Patent 6,202,649

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<b>NAME:</b>	<b>PHONE:</b>
Laura Sunderland	1-202-824-3140

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**COMMENTS:**

Attached is a Brief Outline for Interview on October 22, 2009. Please confirm receipt of the Brief Outline for Interview.

Thank you

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BOSTON

PORTLAND, OR

**EX PARTE REEXAM**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
CENTRAL REEXAMINATION UNIT

*Ex parte* Reexamination of U.S. Patent 6,202,649 :  
Jonnie R. Williams : Confirmation No. 9970  
Control No.: 90/009,375 : Examiner: Brumback, Brenda  
Filed: December 31, 2008 : Group Art Unit: 3991  
For: METHOD FOR TREATING TOBACCO : Atty Dkt No.: 004859.00063  
TO REDUCE NITROSAMINE :  
CONTENT, AND PRODUCTS :  
PRODUCED THEREBY :


**BRIEF OUTLINE FOR INTERVIEW**

Examiner Brumback,

Attached at your request, we are providing a brief outline of matters to be discussed during the interview tomorrow, October 22, 2009.

Respectfully submitted,

Date: October 21, 2009

By:   
Dale H. Hoscheit  
Registration No. 19,090  
Paul M. Rivard  
Registration No. 43,446  
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OUTLINE FOR EXAMINER INTERVIEW  
REGARDING THE '649 AND '401 PATENTS

I. BACKGROUND

- Tobacco-specific nitrosamines (TSNAs) have long been recognized as one of the most powerful and abundant carcinogens in tobacco and tobacco smoke. TSNAs were the subject of intense study for over a decade prior to the Williams' invention.
- Prior art studies hypothesized a wide variety of possible causes of TSNAs, including fertilization methods, microbial activity, tobacco type, curing method, soil conditions, and weather factors, etc.
  - The Wiernik article, which concerns air-cured tobacco and air-curing methods, states (at 74): “[A] manifold of chemical, biochemical, physiological, and microbial processes are taking place during curing, the intricate and complex mechanisms of which are not fully understood.”
  - The 1995 Peele article, which concerns flue-cured tobacco and flue-curing methods, reflects the same type of uncertainty (at 120): “Despite the large amount of scientific literature available on the chemical transformations that occur during the flue-curing of tobacco, much remains to be learned.”
- The Williams patents achieve “substantial prevention” of TSNAs by substantially preventing two causes of anaerobic conditions that lead to TSNA formation. In particular, Williams teaches not only that combustion exhaust gases must be eliminated from the curing environment, but also that airflow in the barn must be sufficient to substantially prevent anaerobic conditions.

II. PRIORITY

- Like the '649 patent, a main purpose of the provisional application is to provide tobacco in which the formation of TSNA is “substantially prevented or arrested by subjecting the harvested leaves to a sufficiently high flow of heated or unheated air...” Such technique prevents microbes from reducing nitrates to nitrites (*e.g.*, the provisional application, p. 16, lines 21-24).
- The provisional application contains essentially identical language as the Williams patents for controlled airflow, humidity, and temperature.

Claim 4, '649 Patent	'649 Patent Specification	'372 Provisional Disclosure
<p>said controlled environment comprises air free of combustion exhaust gases</p> <p>and an airflow sufficient to substantially prevent an anaerobic condition around the vicinity of said plant portion</p>	<p>“the heated air is substantially free of combustion exhaust gases including water vapor, carbon monoxide, and carbon dioxide.” (col. 11, lines 64-67).</p> <p>“the minimum flow of air is preferably about ten percent higher than the flow of flue gas commonly used in the prior art.” (col. 11, lines 43-45).</p> <p>“the air may be recirculated as long as an anaerobic condition is avoided.” (col. 12, lines 1-2).</p>	<p>“combustion exhaust gases of the heat source are not allowed to come into contact with the tobacco leaves” (p. 18, lines 19-21).</p> <p>“The minimum flow of air is approximately ten percent higher than the flow of flue gas used in the prior art.” (p. 18, lines 4-5).</p> <p>“The air may be recirculated as long as an anaerobic condition is avoided.” (p. 8, lines 16-17). “By treating the uncured tobacco leaves with a sufficiently high flow of air, the present invention avoids the establishment of an anaerobic condition.” (p. 11, lines 24-26).</p>
<p>said controlled environment is provided by controlling at least one of humidity . . .</p>	<p>“the humidity of the heated or unheated air is desirably <b>controlled</b> using a commercially-available dehumidifier or humidifier. Preferably, the heated or unheated air comprises dehumidified air with a</p>	<p>“Preferably, the humidity of the heated or unheated air is <b>controlled</b> using a commercially-available dehumidifier or humidifier.” (p. 18, lines 1-3). In contrast, prior flue curing process “maintains relative</p>

Claim 4, '649 Patent	'649 Patent Specification	'372 Provisional Disclosure
	humidity level of less than about 85% . . ." (col. 11, lines 57-63)	humidity in the barn at approximately 85%" (p. 13, lines 3-5) which is favorable to TSNA formation (p. 16, lines 10-21).
temperature,	"The temperature of the curing barn of the present invention may range from ambient (i.e., outside) temperature to as high as about 250° F or more . . . suitable temperatures may range anywhere from about 100° F to about 250° F, more preferably from about 160° F to about 170° F. (col. 12, lines 3-10)	"the flow of air may be heated . . . by providing clean heated air via a heat exchanger. . . Preferably, the convective hot air stream . . . is heated to a temperature within the range of about 100 to about 250°F, more preferably to about 160 to about 170°F. (p. 18, line 18 to p. 19, line 2)
and airflow.	<p>"the minimum flow of air is preferably about ten percent higher than the flow of flue gas commonly used in the prior art." (col. 11, lines 43-45).</p> <p>"the air may be recirculated as long as an anaerobic condition is avoided." (col. 12, lines 1-2).</p>	<p>"The minimum flow of air is approximately ten percent higher than the flow of flue gas used in the prior art." (p. 18, lines 4-5).</p> <p>"The air may be recirculated as long as an anaerobic condition is avoided." (p. 8, lines 16-17).</p>

- The claims themselves define "controlled environment" as what is disclosed in provisional application. A controlled environment "comprises" air free of combustion exhaust gases and airflow sufficient to substantially prevent anaerobic conditions, and is provided by controlling at least one of airflow, temperature or humidity. All this is taught in the provisional application.
- The claims are supported by the provisional application and are entitled to its filing date.

### III. THE PEELE PATENT

- The Peele patent is not prior art because it was not filed prior to the provisional application.
- Williams' patents describe TSNA formation resulting from anaerobic conditions. As set forth in the Williams patents, anaerobic conditions arise from: (1) combustion exhaust gases, and (2) CO<sub>2</sub> from leaf respiration.
- The Peele patent addresses, in part, only one of these aspects (*i.e.*, avoiding contact with NO<sub>x</sub> gases from combustion).
- The Peele patent does not teach "an airflow sufficient to substantially prevent an anaerobic condition."
- The Peele patent in fact teaches away from the invention, by teaching that traditional curing equipment and practices (including traditional airflows) can continue to be used, with no necessity for special processing steps to improve airflow or to control microbial conditions.
- The Peele patent also teaches different TSNA levels from Williams. Because Peele disregards one aspect of TSNA formation, Peele's method provides TSNA levels typically in the range of 1-2 ppm, as confirmed by RJR's test data and Star's own analysis. Those levels are a full order of magnitude higher than the levels obtained by the Williams' invention (*see, e.g.*, the '649 patent, col. 15, line 64 through col 16, line 3, describing levels typically less than about .05 ppm per TSNA).
- Peele's express disclaimers are the antithesis of any viable rejection under 35 U.S.C. § 102

#### IV. TOHNO

- Tohno purports to provide, in the early days of bulk-curing (1976), an improvement to a bulk flue-curing process applied to an air-cured tobacco that was native to and specific to Japan.
- While air curing this Japanese domestic tobacco provided good quality tobacco, the switch to a bulk flue-curing process for this Japanese air-cured tobacco was said to have inactivated certain plant enzymes during the browning stage, which resulted in a “nasty odor” in the tobacco when smoked.
- Tohno’s method essentially attempts to maintain plant enzymatic activity into the browning stage (a stage of curing characteristic of air-cured tobaccos but not of flue-cured tobaccos) by introducing an undefined amount of heated air coupled with a heated water spray.
- Tohno does not address either *microbial* activity or nitrate reduction that contributes to TSNA formation. Tohno does not teach or achieve “substantially prevent[ion of] ...anaerobic conditions.” Rather, it merely teaches an airflow to avoid the nasty odor resulting from applying a flue-cured process to a particular Japanese air-cured tobacco, not an airflow to prevent TSNAs, particularly as applied to U.S. processes and U.S. tobaccos.
- Instead, Tohno teaches away from the Williams’ invention, by suggesting that heat and humidity (favorable to TSNA formation) be added to the curing environment. Significantly, the introduction of heated water, such as taught by Tohno, will increase TSNAs.
- Tohno teaches no more than the prior art – *i.e.*, use of an airflow sufficient to ensure tobacco quality. But Tohno teaches an even less desirable variation – curing air accompanied by artificial introduction of high humidity (which encourages microbial activity).
- The use of conditions that encourage microbial activity is the antithesis of the claimed invention.

## V. AZUMANO

- Azumano describes an indirect-fire curing barn with controls focused on coloring and drying, and not TSNA formation.
- The wet and dry bulb temperature readings disclosed in Azumano (col. 11, lines 41 *et seq.*) indicate that, like Tohno, the tobacco is subjected to moderate temperature and high humidity conditions, which are conditions favorable for microbial growth and TSNA accumulation.
- Azumano contains no quantification of airflow or any disclosure suggesting a need for a higher than ordinary airflow. The Office Action acknowledges that Azumano does not teach substantially preventing the formation of nitrosamines by maintaining an environment free of combustion exhaust gases and by providing an airflow sufficient to substantially prevent an anaerobic condition.
- In essence, Azumano is simply an example of an indirect-fired flue-curing method which employs conditions that encourage bacterial growth. Like the Peele patent, Azumano teaches nothing about anaerobic conditions, improved airflow, or other methods for substantially preventing TSNAs.

## VI. WIERNIK

- Wiernik is an air-curing reference that reviews a variety of air-curing studies, some of which suggest that microbial activity mediates reduction of nitrate to nitrite during curing and causes TSNAs. Wiernik acknowledges that this is only one of many factors that influence TSNAs, and that “the contribution from bacteria to the formation of TSNA remains unclear.” (p. 53).
- Although the studies recited by Wiernik in some cases extended back until 1983 (or earlier), Wiernik finds no solution to the TSNA problem. Nowhere does Wiernik describe or suggest adding a fan or increasing airflow beyond that which is provided by natural convection in traditional air curing (where fans or forced air were conventionally not used).
- Wiernik ultimately concludes (at 74) that a new plant genotype may be a prerequisite to avoiding TSNA formation.
- Peele (and other RJR scientists) were aware of Wiernik but, after four years of further research, expressly disclaimed making modifications to account for microbial activity, as proposed in the Office Action.
- Wiernik only underscores how intractable the TSNA problem was to tobacco researchers. Curing was considered an “art” that ought not be tampered with. Nowhere in Wiernik does the author suggest that substantial changes to long-accepted curing practices that could threaten all important tobacco quality should be considered.
- Combining Wiernik with Azumano for an obviousness rejection would be inappropriate. Azumano teaches humidity and temperature conditions favorable to TSNA formation, and does not teach improved airflow. The only basis for interpreting Wiernik to suggest increasing airflow and other alterations in Azumano is the hindsight gleaned from reading the patentee’s own disclosure.

## VII. SCANLAN

Scanlan relates to milk, an entirely different environment from tobacco, and does not concern TSNA's. Moreover, the nitrosamines in milk were of an entirely different magnitude and complexity from TSNA's in tobacco..



## VIII. ADDITIONAL POINTS CONCERNING THE '401 PATENT

### A. TOHNO

- Tohno specifically teaches that the Japanese domestic air-cured tobacco is different from flue-cured (Virginia) tobacco “in curing process, quality and the use of raw materials”.
- The entire thrust of the Tohno disclosure is the maintenance of leaf enzyme activity into the browning stage. Such enzyme activity is undesirable in flue-curing. Proper leaf drying in a flue-curing process specifically seeks to prevent the plant enzyme activity that Tohno seeks to encourage.
- Since enzymatic activity is not desired during drying in the flue-curing process, there is simply no basis whatsoever to apply the Tohno steps to a Virginia tobacco flue-cure process.

### B. WIERNIK

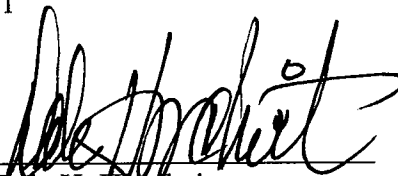
- Wiernik addresses various studies of air-cured (*e.g.*, burley) tobacco, which is different from the Virginia flue-cured tobacco addressed in the '401 patent.

Reexamination Control No. 90/009,375  
Attorney Docket No. 004859.00063

**CERTIFICATE OF SERVICE**

I hereby certify that a copy of the Brief Outline For Interview is being served on the following individuals by Federal Express on October 21, 2009:

K. Shannon Mrksich  
Robert S. Mallin  
Brinks Hofer Gilson & Lione  
455 Cityfront Plaza Drive  
Suite 3600  
Chicago, IL 60611

A handwritten signature in black ink, appearing to read "Dale H. Hoscheit", written over a horizontal line.

Dale H. Hoscheit  
Registration No. 19,090