

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: **20480.0181-AP**

In re Application of

James S. Drouillard, et al.

Examiner: **Chhaya D. Sayala**

Serial No.: **13/685,041**

Art Unit: **1791**

Filed: **11/26/2012**

Confirmation No. **5527**

For: **METHOD AND COMPOSITION FOR INCREASING THE PROPORTION OF
DIETARY INGREDIENTS THAT ARE RESISTANT TO DEGRADATION BY
RUMINAL MICROORGANISMS**

SECOND DECLARATION OF JAMES DROUILLARD UNDER 37 C.F.R. §1.132

Mail Stop: Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

My name is James S. Drouillard. I am the first named inventor on the above captioned patent application. I have read the specification and claims, as currently amended and am familiar with the content thereof.

I am currently Professor and faculty director of the Kansas State University Beef Cattle Research Center (1995 to present), 133 Call Hall, Manhattan, Kansas 66506-1600. I have a PhD degree in Ruminant Nutrition (1989) from the University of Nebraska-Lincoln; a Masters of Science in Production Management (1986), from the University of Florida; and a Bachelor of Science in Animal Science (1985) from the University of Florida. My current areas of research emphasize:

Encapsulation strategies for ruminal protection of micronutrients;

Development of probiotic cultures for prevention of bovine and equine metabolic disorders;

Nutritional intervention strategies to reduce fecal shedding of food-borne pathogens;
Nutritional strategies to alter cattle performance and fatty composition of beef;
Utilization of biofuels co-products in growing and finishing beef cattle; and
Exogenous growth promotants.

I received the 2014 Kansas State University Professorial Performance Award; the 2013 American Feed Industry Association Award in Ruminant Nutrition Research; and the 2009 Kansas State University Professorial Performance Award.

I am an inventor on the following previously granted U.S. Patents:

Drouillard, J.S., T.J. Herald, and M.A. Greenquist. 2014. Method for encapsulation of orally ingested materials to alter site of digestion, site of action, and(or) stability. No. 8,828,421;

Drouillard, J. S. 2013. Method for altering blood lipid profiles in livestock. No. 8,377,465;

Drouillard, J.S., J. Henry, and D. Sattler. 2007. Self-cleaning animal watering device. No. 7,762,212;

Drouillard, J.S. and C. M. Coetzer. 2003. Method of manufacturing a ruminant feedstuff with reduced ruminal degradability. No. 6,506,423; and

Sun; X. S., P. Seib, G. S. Karr, and J. S. Drouillard. 2002. Biodegradable and edible feed packaging materials. U.S. Pat. No. 6,337,097.

My complete Curriculum Vitae is attached as Exhibit 1.

I am familiar with the Peterson reference (US2013/0136827) cited by the Examiner in rejecting the pending claims in the subject application. I am also familiar with the Peterson product described in the issued patent, which was marketed on a trial basis in 2008 under the trademark name "RUMAG®", see, U.S. Registration No. 3,613,473 (Exhibit 2) by the Zeotech Corporation of Fort Worth, Texas.

In a previous Declaration dated January 22, 2015, and filed in this case, I presented experimental work which was intended to provide the Examiner with some comparative data comparing the

ruminal stability of a RUMAG®/flaxseed mixture, as described in the Peterson reference, and prills made from dolomitic hydrated lime and flaxseed which were prepared according to the teachings of the present invention. The comparison which was made was between a mixture of the RUMAG® and flaxseed which was not pelletized in any way, versus a pellet or prill of the hydrated lime/flaxseed product made according to Applicant's invention. The RUMAG® product used in the comparison testing was obtained from the manufacturer.

In the latest Office Action dated April 7, 2015, the Examiner stated that Applicant's Declaration fails to overcome the claims rejection in that "it is not clear what RUMAG® is." The Examiner argues that "products can be changed in composition at the whim of the manufacturer and that the declaration fails to present any "proper comparison since declarant does not provide a detailed description of the RUMAG® composition" (Office Action of 4/07/2015, pages 16-17). The purpose of this supplemental Second Declaration is to provide experimental evidence which compares Applicant's method and product produced thereby with the exact method and product taught in the Peterson publication. Specifically, the comparison product was prepared at a Lhoist North America lab facility exactly according to the teachings of the Peterson reference in paragraphs [0030] to [0032] thereof, namely:

The Peterson comparison product was made using 60% -30 mesh Clinoptilolite Zeolite (from St. Cloud Mining - Winston, NM); 40% Type S Dolomitic Hydrate Lime (Lhoist North America - New Braunfels, TX).

Material was weighed and batch mixed in a ribbon-type mixer for 5 minutes.

Mixed batches were fed into a screw feeder that conveys into a Pin Mixer (Mars Minerals model 12D54L). The feeder was set at 27 Hz, water set and monitored between 5-10 psi (to achieve target moisture of prills - per Peterson between 15-25% moisture). Pin mixer speed was 1100 RPM.

The prills were discharged onto a conveyor belt and samples were checked for moisture. The moisture content of the prills at production was 21.3%.

Wet prills were placed in 230°F/110°C commercial lab dryer to dry the prills to <8% moisture (per the teaching of Peterson).

Dried prills (5.1% moisture) were screened; a 12X100 fraction collected, sealed, and sent to Kansas State University for in situ testing.

The prills which were compared to the Peterson product were manufactured exactly as set forth in Applicant's original Specification at page 10, line 13, to page 13, line 3.

In situ Comparison:

An in situ comparison was made under my direction at Kansas State University comparing the ruminal stability of a) a mixture consisting of equal parts of ground flaxseed and zeolite/hydrate prills manufactured in accordance with procedures described in the Peterson patent (hereafter referred to as Zeolite/Hydrate+Flaxseed), and b) Prills made from a 50:50 blend of Dolomitic Hydrate and Ground Flaxseed (hereafter referred to as Hydrate/Flaxseed Prills) made as described in Applicant's original patent Specification. Dry matter contents of flaxseed, Zeolite/Hydrate; and the Hydrate/Flaxseed Prills were determined by drying for 48 hours in a 55C forced-air oven. Aluminum pans were weighed and weights were recorded on a datasheet. Approximately 50 grams of a given product was placed into one of the aluminum pans, and total weight was recorded. Pans then were placed into a 55C oven for 48 hours, removed from the oven, placed into a dessicator, allowed to cool to room temperature, and then promptly weighed. Dry matter percent of each product was calculated as $[(\text{dry weight} - \text{pan weight}) / (\text{as-is weight} - \text{pan weight})] * 100$.

Nylon in situ bags (Ankom, Macedonia, NY) were numbered 1 through 12 using a permanent marker, and then placed into a 55C oven for 24 hours. Treatments consisted of: a) Zeolite/Hydrate+Flaxseed; b) Hydrate/Flaxseed Prills; and c) Blank (empty) bags that were used as a correction factor. Bags were then removed from the oven, placed into a dessicator, and allowed to cool to room temperature. Bags were then removed from the dessicator one at a time and quickly weighed on a laboratory balance to the nearest 0.0001 grams. Approximately 1 gram of substrate was then placed into each bag, with the exception of Blanks, which contained no substrate. For the Zeolite/Hydrate+Flaxseed treatment (bags 1-4), approximate 0.5 grams each of Zeolite/Hydrate and Ground Flaxseed (as-is weight) were placed into the nylon bags and then sealed with an impulse heat sealer. For the Hydrate/Flaxseed Prill treatment, approximately 1 gram (as-is weight) of the Hydrate-Flaxseed Prill was placed into nylon bags (bags 5-8), and bags were then sealed with an impulse heat sealer. Four additional bags with no contents (Blanks; bags 9-12) were

sealed with an impulse sealer and used as blanks to correct for dry matter and organic matter gain (via adhesion of ruminal contents and microbes to bag). All bags were then placed into a zippered nylon mesh bag (lingerie wash bag), a 250-gram weight was placed into the mesh bag, and the bag was zippered shut. The mesh bag was then suspended in the rumen of a fistulated bovine for 24 hours. Following 24 hours of incubation, the mesh bag was removed from the rumen and gently rinsed with cold water to remove particulate material adhered to the mesh bag. Individual in situ bags were then removed from the mesh bag, placed into a 4-liter plastic beaker, and gently rinsed with cold tap water to remove adhering particles from the exterior of each bag and small particles (particle size smaller than pore size of bag) from the interior of the bag. Rinse water was continuously replaced until it appeared clear and free of debris (approximately 20 minutes). Bags were then placed back into the 55C oven for 48 hours and allowed to dry thoroughly. Dried bags were removed from the oven, placed into a dessicator, and allowed to cool to room temperature. Cooled bags were then removed one at a time from the dessicator and weighed promptly. Percent disappearance of dry matter from the bags was then calculated as: $[(\text{Preincubation Sample weight} \times \% \text{dry matter}) - \text{Bag weight}] - [(\text{Postincubation sample weight} - \text{Bag weight})] \times 100$. Total organic matter of each bag was determined by placing the bags into dry, preweighed crucibles.

Crucibles were placed into a 600C muffle furnace for 24 hours. Crucibles then were removed from the furnace, placed into a dessicator, and allowed to cool to room temperature, and then weighed. The Zeolite/Hydrate prills, ground flaxseed, and the Hydrate/Flaxseed Prills were placed into the dry, preweighed crucibles and placed into the muffle furnace for 24 hours at 600C. Organic matter content was calculated as: $[(\text{weight of dry sample} - \text{weight of ash}) / \text{weight of dry sample}] \times 100$. Similarly, organic matter residue of in situ bags was measured to facilitate determination in situ organic matter disappearance. The Blank bags (incubated in rumen without substrate) again were used to correct for dry matter and organic matter accumulated during the ruminal incubation, and the average value obtained from the 4 blank bags was subtracted from each of the sample bags. Data were analyzed as a completely randomized design using the Statistical Analysis System (version 9.3; SAS Institute; Cary, NC) with 2 treatments and four replicates. Treatment was the fixed effect and replicate was the random effect. LSmeans for dry matter disappearance and organic matter disappearance were separated using the Pdiff option. Values shown in the attached graph are LSMeans with Standard Error bars.

The test results show that the prills made according to the process of the invention have substantial efficacy for protecting nutrients against microbial digestion. The percentages of both dry matter disappearance and organic matter disappearance were roughly 45 and 71%, respectively, for the test samples containing the Peterson product. These figures are to be compared with approximately 14% and 3% in the case of the product made according to the process of the present invention. The disappearance percentages for Applicant's product were a "surprising result" not initially envisioned by the present inventor. The effectiveness of the rumen by-pass protection mechanism of Applicant's inventive products were only realized as Applicant was experimenting with different sized stones, pH range titrations, etc.

Conclusion:

Applicant previously noted the Examiner's reference to a study conducted by Peterson on pages 5 and 6 of the previous Office Action. In that study, it appears that, a Total Mixed Ration (TMR) was fed to cows in the three treatment groups. In the case of the control group, no rumen buffer was fed. Buffered groups included Sodium Bicarb or RMFA (the Peterson Ruminant Mineral Feed Additive), which were added to the TMR to make up 1.4% of the total diet. In other words, the other components (mostly organic constituents) of these diets were not subjected to the agglomeration process. This being the case, it is difficult to imagine how the RFMA could impart such properties to other components of the TMR. However, there is no suggestion or teaching in Peterson that what Applicant refers to as an "animal feed ingredient" be incorporated into his prills. The Peterson prills only contain zeolite and dolomitic hydrate since the purpose of Peterson's product is not rumen by-pass, but rather to "buffer excess acid and ammonia."

Contrary to the point of the examiner, the RFMA product actually is designed to stabilize ruminal pH, thereby enhancing fermentative activity by ruminal microorganisms, which would effectively INCREASE ruminal digestion of carbohydrates, proteins, and components of lipids present in the TMR. For this reason, the Peterson reference actually "teaches away" from Applicant's presently claimed invention.

To further elaborate on the distinction between the two processes, Peterson suggests that the RFMA process renders the constituents more available within the rumen. Applicant's process is quite the opposite—essentially, a paste, which is formed from a mixture of dolomitic hydrate and water, effectively surrounds the organic components of our mixture. As the material dries, it forms

a physical barrier that is relatively impervious to ruminal microbes. The end result is that a greater proportion of the organic materials escape the rumen environment without substantial alteration. Again, the Peterson reference teaches away from Applicant's claimed method in making its constituents more available in the rumen, rather than less available.

Applicant's remaining independent claims identify and specify certain preferred "animal feed ingredients", namely an oilseed, a vitamin, an antibiotic, an enzyme, a fatty acid, an amino acid and a heavy metal. Peterson nowhere suggests such a formulation since these specified "animal feed ingredients" would not be used for the same purpose that Peterson was trying to achieve. There is no "teaching or suggestion" to me, as one skilled in the relevant arts, in reading Peterson that such "animal feed ingredients" be included in his products.

The Cecava reference is argued by the Examiner to teach that "alkaline crystalline solids" are used to increase rumen by-pass properties" (Office Action of 4/7/2015, page 6). However, even if this point is accepted, Cecava does not teach or suggest the additional "animal feed ingredients" now specified in Applicant's remaining independent claims, namely an oilseed, a vitamin, an antibiotic, an enzyme, a fatty acid, an amino acid and a heavy metal. In those cases where Applicant's formulations contain a companion mineral carbonate or mineral oxide, they also contain the additional "animal feed ingredient."

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: _____

James S. Drouillard

a physical barrier that is relatively impervious to ruminal microbes. The end result is that a greater proportion of the organic materials escape the rumen environment without substantial alteration. Again, the Peterson reference teaches away from Applicant's claimed method in making its components more available in the rumen, rather than less available.

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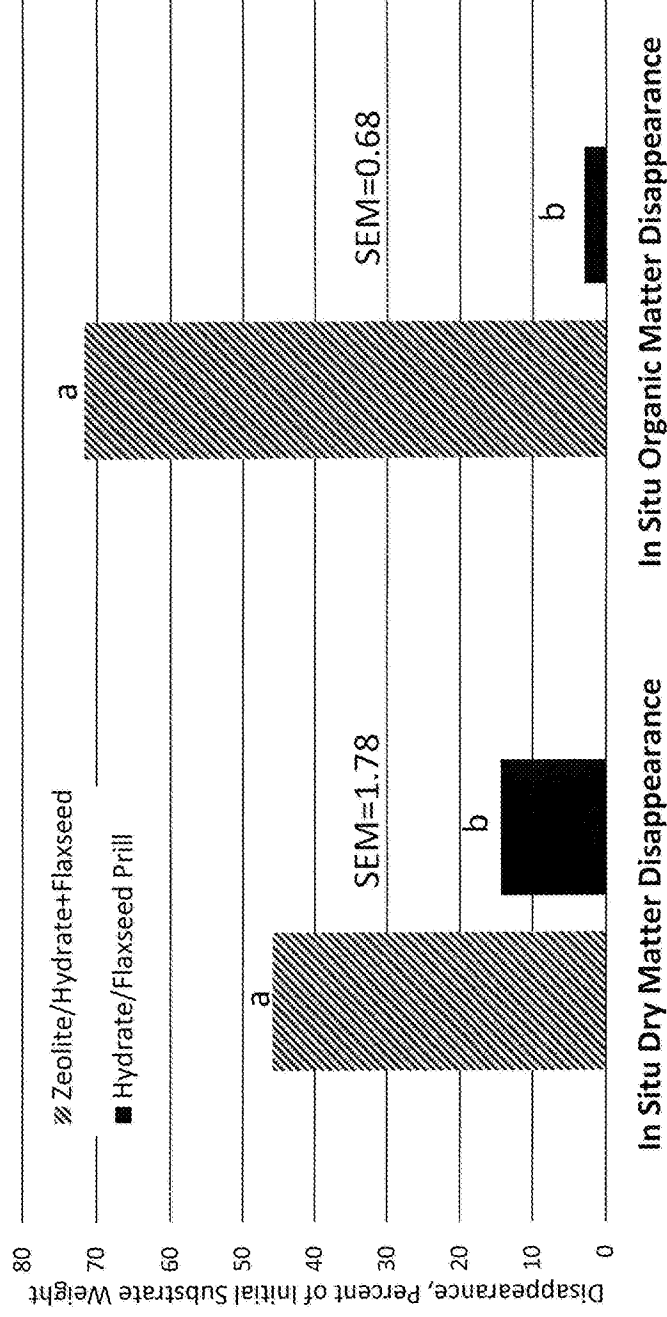
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date 10/5/15



James S. Drouillard

Disappearance of Dry Matter And Organic Matter From In Situ Bags Following a 24-hour Ruminant Incubation



SEM = Standard Error of Mean

a,b Bars within groupings are different, P < 0.01

Biographical Sketch

JAMES S. DROUILLARD

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PROFESSIONAL BACKGROUND

- Professor and faculty director of the Kansas State University Beef Cattle Research Center (1995-present). The Center has one-time capacity of 1800 research animals, allowing for the completion of 20 to 30 major research projects each year.
- Faculty director of the Preharvest Food Safety and Microbiology Laboratory since 2002, which is engaged in evaluation and manipulation of microbial fermentation, food-borne pathogens, and development of probiotics, including *Megasphaera elsdenii*.
- Assoc. Professor, Beef Cattle Nutrition/Management, Kansas State University (1995-2000)
- Director of Research & Product Development, Hubbard Milling Company (1993-1995)
- Nutritionist & Livestock Products Manager, Hubbard Milling Company (1991-1993)
- Nutrition & Product Development, Sunglo Feeds, Inc. (1989-1991)

CURRENT AREAS OF RESEARCH EMPHASIS

- Encapsulation strategies for ruminal protection of micronutrients
- Development of probiotic cultures for prevention of bovine and equine metabolic disorders
- Nutritional intervention strategies to reduce fecal shedding of food-borne pathogens
- Nutritional strategies to alter cattle performance and fatty composition of beef
- Utilization of biofuels co-products in growing and finishing beef cattle
- Exogenous growth promotants

EDUCATION

- Ph.D. in Ruminant Nutrition. 1989. University of Nebraska-Lincoln
- Master of Science in Production Management, 1986, University of Florida
- Bachelor of Science in Animal Science. 1985. University of Florida

AWARDS

- 2014 Kansas State University Professorial Performance Award
- 2013 American Feed Industry Association Award in Ruminant Nutrition Research
- 2009 Kansas State University Professorial Performance Award

PATENTS GRANTED

- Drouillard, J.S., T.J. Herald, and M.A. Greenquist. 2014. Method for encapsulation of orally ingested materials to alter site of digestion, site of action, and(or) stability. No. 8,828,421.
- Drouillard, J. S. 2013. Method for altering blood lipid profiles in livestock. No. 8,377,465.
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- Drouillard, J.S. and C. M. Coetzer. 2003. Method of manufacturing a ruminant feedstuff with reduced ruminal degradability. No. 6,506,423.
- Sun, X. S., P. Seib, G. S. Karr, and J. S. Drouillard. 2002. Biodegradable and edible feed packaging materials. U.S. Pat. No. 6,337,097.



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RUMAG

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Goods and
Services****RUMAG**

IC 005. US 006 018 044 046 051 052. G & S: Animal feed supplement for animals such as dairy and beef cattle, horses, sheep, and poultry. FIRST USE: 20080222. FIRST USE IN COMMERCE: 20080222

**Standard
Characters
Claimed****Mark Drawing
Code**

(4) STANDARD CHARACTER MARK

Serial Number

77385620

Filing Date

January 31, 2008

Current Basis

1A

**Original Filing
Basis**

1B

**Published for
Opposition**

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**Registration
Number**

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Registration Date

April 28, 2009

Owner

(REGISTRANT) Zeotech Corporation CORPORATION TEXAS P. O. Box 1718 Fort Worth TEXAS 76101

Attorney of Record

James O. Dixon

Type of Mark

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Attachment 2

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