

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**

DECLARATION

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.

The purpose of the present experimental work was 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. Applicant wishes to point out and emphasize that the comparison is being made 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.

The Peterson RUMAG® product being compared was prepared and used according to the express teaching of the Peterson reference. The Examiner refers to a study conducted by Peterson on pages 5 and 6 of the present Office Action. As I understand the study, 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. 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.

To further elaborate on the distinction between the two processes, Peterson suggests that the RFMA process renders the constituents more available within the rumen. Our 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. Furthermore, we suggest that assimilation of atmospheric CO₂ results in surface conversion of dolomitic hydrate to carbonate, which is relatively inert within the rumen. This mineral matrix, which is resistant to microbial digestion, “protects” the organic constituents embedded within. The end result is that a greater proportion of the organic materials escape the rumen environment without substantial alteration. Communion of our matrix, which can occur with physical handling or mastication, can result in exposed surfaces that are “repaired” through the recarbonation process

that occurs through exposure to relatively high concentrations of CO₂ within the ruminal environment.

We have specified in our document that the binder constitutes 10-95% by weight of the feed product. In the case of Peterson's example, the RMFA is restricted to 1.4% of the total feed mixture, and again, this is not combined with other elements of the TMR until the RMFA process is complete.

A primary aspect of the Peterson teaching deals with what he calls "hydrothermal processing."

From Peterson (2010/0310723), at Page 2, ¶0027, Line 4

"The mineral components of the subject application alone and without proper ratios of use, blending, and hydrothermal processing do not have the beneficial effects that are possible when processed and prepared as described in this application"

Page 2, ¶0031, Line 3

"The moist or wetted prill from the turbulizer 108 is then conveyed via a conveyor 118 to the heat source 110, where the wetted prill is heated from ambient temperature to at least 200 degrees F."

Claim 10 of the Peterson application:

"drying the prills at an elevated temperature for a selected duration of time to create a hydrothermal reaction."

These statements would logically differentiate Peterson's process from the presently claimed process, as our process does not necessarily employ heating, and is not dependent on hydrothermal reactions. In fact, for the agglomerates produced for our studies excess moisture was removed by exposing to moving ambient air. Furthermore, since metal oxides need not be incorporated into our mixtures, there is no resulting heat of hydration, thus the process is carried out under ambient temperatures. Dessication of the agglomerated products can be no doubt be accelerated using heated air, or potentially by subjecting products to reduced pressure, but neither is a required step in our process.

The reference to Cecava similarly is dependent on heating. In fact, Claim 1 refers to the combination of alkaline crystalline solids and water, which “reacts” to generate heat. This is the heat of hydration, which is absent in the case of hydrate/water mixtures. That said, their process is temperature dependent, while ours is not. In any case, they exploit this heating to induce a Maillard reaction. As holder of one patent that also exploits the Maillard reaction, I view myself as having considerable expertise in this area. Our current application is in no way related to this.

Experimental Protocol:

This was an in situ comparison of the ruminal stability of a) a 50:50 mixture of Rumag and Ground Flaxseed, and b) Prills made from a 50:50 blend of Dolomitic Hydrate and Ground Flaxseed. Dry matter contents of flaxseed, RuMag, and the hydrate-flaxseed prills were determined in duplicate using a 55C forced-air oven. Six aluminum pans were weighed and weights were recorded on a datasheet. Approximately 15-20 grams of product was placed into one of the aluminum pans, and total weight was recorded. Pans then were placed into a 55C oven for 96 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 overnight. 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. For the Rumag treatment (bags 1 through 4), approximate 0.5 grams each of Rumag and Ground Flaxseed (as-is weight) were placed into the nylon bags and then sealed with an impulse heat sealer. For the Prill Treatment, approximately 1 gram of the prilled Hydrate-Flaxseed blend was placed into a nylon bag (Bags 5 through 8), and bags were then sealed with an impulse heat sealer. Four additional bags with no contents (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

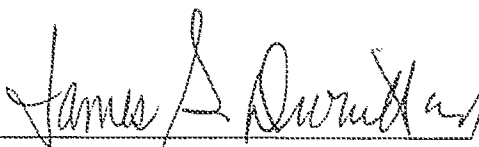
particulate material adhered to the mesh bag. Individual in situ bags were then removed from the mesh bag, placed into a 4-liter plastic beaker, and gently rinsed with cold tapwater to remove adhering particles from the exterior of each bag and small particles (particle size smaller than pore size of 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: $\frac{[(\text{Preincubation Sample weight} \times \% \text{dry matter}) - \text{Bag weight}] - [(\text{Postincubation sample weight} - \text{Bag weight})]}{[(\text{Preincubation Sample weight} \times \% \text{dry matter}) - \text{Bag weight}]} \times 100$. 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 before weighing. Similarly, Rumag, flaxseed, and the prill were placed into dry, preweighed crucibles and placed into the muffle furnace for 24 hours at 600C. Organic matter content was calculated as: $\frac{(\text{weight of dry sample} - \text{weight of ash})}{\text{weight of dry sample}} \times 100$. Blank bags 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 42 and 62%, respectively, for the test samples containing the Peterson product. These figures are to be compared with approximately 9.5% and -2% in the case of the product made according to the process of the present invention

Note that in the case of the negative result for organic matter in the attached graph that when the material is suspended in the rumen there is potential for residues of fats, proteins, or other organic constituents within the digesta to adhere to the surface of the feed particles within the bag. This also happens with the bag itself, which is why we normally include empty bags to use as a correction factor.

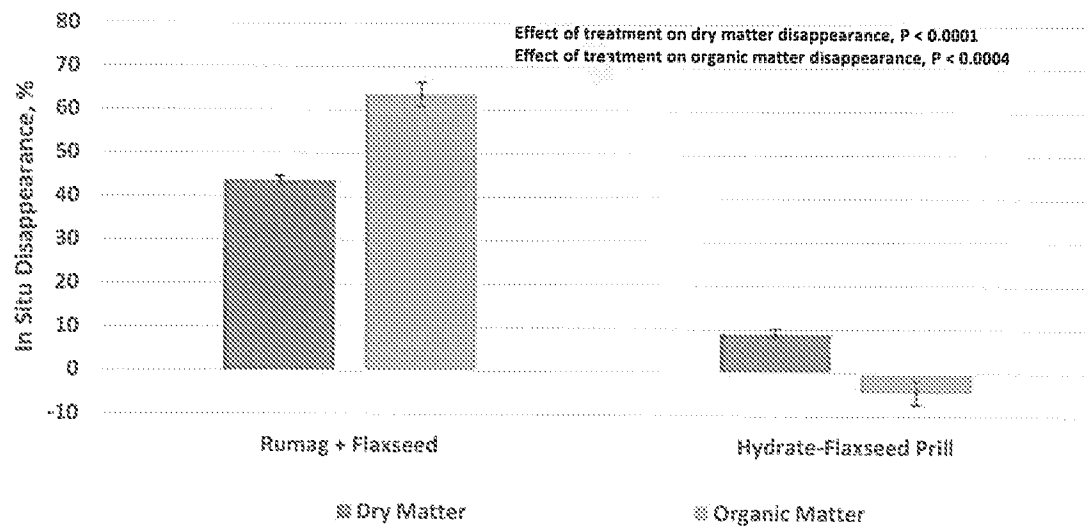
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, 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: 1/22/15



James S. Drouillard

In Situ Disappearance of Dry Matter and Organic Matter During a 24-hour Ruminal Incubation



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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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**

June 17, 2008

**Registration
Number**

3613473

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**

TRADEMARK

Register

PRINCIPAL

Live/Dead Indicator LIVE

Attachment 2

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