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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/044,546	10/02/2013	Jonathan Broomhead	28958.07.0016	8678

23418 7590 09/10/2019

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ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
09/10/2019	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JONATHAN BROOMHEAD, FANG CHI, RON CRAVENS, GEORGE ROBERT GOSS, RICHARD JAFFEE, SARA LEANN JOHNSTON, MICHAEL MCPHERSON, and RONDA JEAN WILLIAMS
(APPLICANT: OIL-DRI CORPORATION OF AMERICA)

Appeal 2019–003471
Application 14/044,546[1]
Technology Center 1600

Before DONALD E. ADAMS, ULRIKE W. JENKS, and MICHAEL A. VALEK, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This Appeal under 35 U.S.C. § 134(a) involves claims 87–152 (App. Br. 5). Examiner entered a rejection under 35 U.S.C. § 103(a). We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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[1] Appellants identify "Oil-Dri Corporation of America" as the real party in interest (App. Br. 3).

STATEMENT OF THE CASE

Appellants' disclosure "relates to a mixture of clay, a yeast product and optionally, glutamate, and uses thereof, in particular for decreasing effects of an enteric disease" (Spec.[2] ¶ 3). Claims 87 and 126 are representative and reproduced below:

> 87. A method for treating an enteric disease comprising a bacterial enteric disease comprising Necrotic Enteritis (NE) or mitigating the effects of exposure to a bacterial enteric disease causing organism comprising a Clostridium in an avian or pig susceptible to the enteric disease comprising administering to the avian or pig a composition comprising a mixture of 50 to 80% (w/w) of a Clostridium-toxin adsorbing smectite clay as a first ingredient of the composition, *10% (w/w) to about 35% (w/w) of a second ingredient of the composition consisting essentially of* whole yeast, non-whole yeast yeast mannan, non-whole yeast yeast mannan oligosaccharide, non-whole yeast yeast beta glucan, non-whole yeast yeast cell component, non-whole yeast yeast cell wall or *citric acid press cake*, and about 5% (w/w) to about 10% (w/w) of a glutamate as a third ingredient of the composition, wherein the administering of the composition is from 100 to 1000 mg/kg body weight / day or the administering is through the composition being present in a feed in an amount comprising about 0.05% (w/w) to about 0.50% (w/w) of the feed, to thereby treat the bacterial enteric disease or mitigate the effects of exposure to the bacterial enteric disease causing organism comprising a Clostridium.

(App. Br. 22 (emphasis added).)

> 126. A feed comprising a composition for treating an enteric disease comprising a bacterial enteric disease comprising Necrotic Enteritis (NE) or mitigating the effects of exposure to a bacterial enteric disease causing organism comprising a Clostridium in an avian or pig susceptible to the enteric disease comprising a mixture of 50 to 80% (w/w) of a Clostridium-toxin adsorbing smectite clay as a first ingredient of the

[2] Appellants' October 2, 2013 Specification.

> composition, *10% (w/w) to about 35% (w/w) of a second ingredient of the composition consisting essentially of* whole yeast, non-whole yeast yeast mannan, non-whole yeast yeast mannan oligosaccharide, non-whole yeast yeast beta glucan, non-whole yeast yeast cell component, non-whole yeast yeast cell wall or *citric acid press cake*, and about 5% (w/w) to about 10% (w/w) of a glutamate as a third ingredient of the composition, wherein the composition is present in the feed in an amount comprising about 0.05% (w/w) to about 0.50% (w/w) of the feed.

(*Id.* at 25–26 (emphasis added).)

Claims 87–152 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Holzgraefe,[3] Darlington,[4] Amlan,[5] Hofshagen,[6] Weese,[7] Howes,[8] and Watanabe.[9]

ISSUE

Does the preponderance of evidence relied upon by Examiner support a conclusion of obviousness?

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[3] Holzgraefe et al., US 2007/0048432 A1, published Mar. 1, 2007.
[4] Darlington, Jr., et al., US 2010/0272769 A1, published Oct. 28, 2010.
[5] Amlan International, *Calibrin-Z*, available at http://web.archive.org/web/20091019094809/http://www.amlan.com/cal-z.html, last accessed June 27, 2015.
[6] Hofshagen et al., *Toxin Production by Clostridium Perfringens Isolated from Broiler Chickens and Capercaillies (Tetrao urogallus) with and without Necrotizing Enteritis*, 36 Avian Dis. 837–43 (1992).
[7] Weese et al., *Evaluation of the Ability of Di-tri-octahedral Smectite to Adhere to Clostridium difficile Toxins and Clostridium perfringens Enterotoxin In Vitro*, 48 AAEP Proceedings 127–30 (2002).
[8] Howes et al., US 6,045,834, issued Apr. 4, 2000.
[9] Watanabe et al., EP 2 314 172 A1, published Apr. 27, 2011.

FACTUAL FINDINGS (FF)

FF 1. Holzgraefe discloses

> methods and compositions for increasing production in animals by feeding the animals a composition which includes *a soluble dextrin product*. The composition may be fed to the animal in the form of a complete feed, a concentrate, a pre-mix, and a top-dress and may be in either a liquid or solid formulation.

(Holzgraefe, Abstract (emphasis added); *see* Final Act.[10] 5.)

FF 2. Holzgraefe discloses that its "*soluble dextrin product* may . . . be fed to the animal as a feed composition *in conjunction with* at least one other product, such as, for example, *a mannanoligosaccharide product*" (Holzgraefe ¶ 38 (emphasis added)).

FF 3. Holzgraefe discloses that "[m]annanoligosaccharide products . . . comprise oligosaccharides" and that "[o]ligosaccharides suitable *for use in combination with the soluble dextrin product* according to certain non-limiting embodiments of the present disclosure may include, . . . yeast cultures" (Holzgraefe ¶ 39 (emphasis added); *see id.* ¶ 40 (Holzgraefe defines "the term 'yeast culture' . . . as the product comprising mycelium of yeast fermentation and the media on which it was grown, such as, for example, a presscake"); *id.* ¶ 42 (Holzgraefe's presscake may be a "citric acid press cake"); *see* Final Act. 5.)

FF 4. Holzgraefe discloses that "where the soluble dextrin product is fed to the animal in the form of a complete feed, the soluble dextrin product may comprise from 0.1% to 2.0% by weight of the complete feed product" (Holzgraefe ¶ 34; *see id.* ¶ 35 (Holzgraefe discloses "where the soluble dextrin product is fed to the animal in the form of a concentrate, the soluble

[10] Examiner's October 4, 2017 Final Office Action.

dextrin product may comprise from 0.28% by weight to 10% by weight of the concentrate" and "[t]he concentrate may be used in the final complete feed at from 10% by weight to 35% by weight of the final complete feed composition"); *id.* ¶ 36 (Holzgraefe discloses "where the soluble dextrin product is in the form of a pre-mix, the soluble dextrin product may comprise from 2% by weight to 50% by weight of the pre-mix" and "added to the feed product in an amount comprising 2% by weight to 5% by weight of the final complete feed"); *id.* ¶ 37 (Holzgraefe discloses "where the soluble dextrin product is in the form of a top-dress . . . the soluble dextrin should be top-dressed on an animal feed composition or product in an amount that is equivalent to soluble dextrin concentrations of 0.1% to 2.0%, by weight")).

FF 5. Holzgraefe exemplifies nursery swine complete feed compositions comprising a mannanoligosaccharide product, CitriStim™, at a concentration of 0.2% by weight of the composition (Holzgraefe ¶ 96; *see generally* Final Act. 5).

FF 6. Holzgraefe discloses that

> the animal feed composition comprising the soluble dextrin is capable of decreasing the growth of *E. coli*, *Salmonella*, *Clostridium* and/or other harmful bacteria of combination of bacteria in the gastrointestinal tract, such as, for example, in the latter portions of the gastrointestinal tract (i.e., the large intestine) of an animal upon feeding the animal feed composition comprising the soluble dextrin to the animal.

(Holzgraefe ¶ 50; *see id.* at 18: claim 5; *see* Final Act. 5.)

FF 7. Examiner finds that Holzgraefe does not teach a composition comprising clay or monosodium glutamate (*see* Final Act. 5 and 6).

FF 8. Darlington discloses layered phyllocilicates, such as smectite clay, "are useful for adsorbing and/or binding to and, thereby, inactivating viruses, bacteria and fungi" and "methods of inactivating a virus, bacteria or fungus and methods of treating a viral, bacterial or fungal infection" (Darlington, Abstract; *id.* ¶ 81; *see* Final Act. 5–6).

FF 9. Darlington discloses that its layered phyllosilicates may be administered to avian and swine species (Darlington ¶ 24; *see also id.* ¶ 39 (Darlington discloses compositions comprising layered phyllosilicates and a therapeutic agent, such as, *inter alia*, an antimicrobial agent, an extracellular matrix component, a cellular component, and a biological agent); *see also* Final Act. 6).

FF 10. Darlington's

> preferred layered phyllosilicate is a smectite clay, including but not limited to a montmorillonite clay, that is predominantly (greater than about 50% by weight) sodium or calcium (sodium or calcium ions outnumber any other cation in the interlayer spaces between adjacent clay platelets) montmorillonite clay so that the concentration of clay dispersed in water can be as high as about 15% by weight.

(Darlington ¶ 81; *see* Final Act. 5–6.)

FF 11. Darlington discloses that its layered phyllosilicate material "is used to treat or prevent infections caused by Gram-positive bacilli including, . . . Clostridium sp. (e.g., Clostridium botulinum, Clostridium botulinum, Clostnidium perfringens, Clostnidium tetani)" (Darlington ¶ 112; *see* Final Act. 6).

FF 12. Examiner relies on Amlan to disclose "Calibrin-Z . . . a highly-refined montmorillonite sorbent mineral that has a high affinity and capacity

to sequester the most common mycotoxins found in feed grains and forages worldwide, particularly zearalenone" (Final Act. 6).

FF 13. Examiner relies on Hofshagen to disclose that "C. perfringens may be an important etiological factor in the development of necrotizing enteritis" (Final Act. 6).

FF 14. Weese discloses that "di-tri-octahedral smectite was effective in neutralizing *Clostridium difficile* toxins A and B as well as *Clostridium perfringens* enterotoxin in vitro" and "may be a useful option for the treatment of clostridial colitis in horses" (Weese, Abstract; *see* Final Act. 6).

FF 15. Howes discloses:

> A method of removing mycotoxins from animal feeds is described whereby a combination of a modified yeast cell wall extract and a mineral clay is fed to animals in amounts sufficient to inactivate mycotoxins present in the feeds. The yeast cell wall extract/clay mixture may be admixed with feeds, incorporated directly into pelleted feeds, or fed directly to animals.

(Howes, Abstract; *see* Final Act. 6.)

FF 16. Watanabe discloses:

> [A]n additive for livestock feed and constitutions of a feed composition for livestock to improve the feed conversion ratio and the body weight gain efficiency by increasing the feed intake of livestock. The feed intake of livestock can be increased by an additive for livestock feed, which comprises monosodium L-glutamate and L-tryptophan, wherein a mass ratio of free monosodium L-glutamate (provided that all converted into monosodium L-glutamate monohydrate) and free L-tryptophan (GLU/TRP ratio) is from 0.5 to 30.

(Watanabe, Abstract; *see* Final Act. 6–7.)

ANALYSIS

Based on the combination of Holzgraefe, Darlington, Amlan, Hofshagen, Weese, Howes, and Watanabe, Examiner concludes, *inter alia*, that, at the time Appellants' invention was made, it would have been prima facie obvious to formulate a composition, for administration to animals, comprising a citric acid presscake, as disclosed by Holzgraefe, smectite clay, as disclosed by Darlington, and monosodium L-glutamate, as taught by Watanabe (*see* Final Act. 7–8). In this regard, Examiner reasons that "[r]outine optimization of concentrations based on the suitable amounts already disclosed in the prior art references is also prima facie obvious and reasonably expected to succeed" (Final Act. 7–8). We are not persuaded.

Initially, we note that Holzgraefe discloses that a citric acid presscake is an example of a mannanoligosaccharide product, which is distinct from Holzgraefe's soluble dextrin product (*see* FF 1–3; *cf.* App. Br. 8 (Appellants contend that "the yeast relied on in . . . [Examiner's Final Office Action] is only one of a laundry list of possible dextrins of the Holzgraefe composition"); Ans. 5 (Examiner finds that "[o]ne would be motivated to optimize the amount of yeast in order to make an effective composition which has sufficient amounts of dextrin product such as critric acid presscake that may be added to animal feed at a convenient effective amount[]")).

In addition, although Holzgraefe provides an extensive disclosure of concentration ranges for its dextrin product (*see e.g.*, FF 4), Examiner does not identify a disclosure in Holzgraefe of the mannanoligosaccharide product, i.e. citric acid presscake, concentration. Nevertheless, we find that

Holzgraefe discloses a composition comprising a mannanoligosaccharide product at a concentration of 0.2% by weight of the composition (*see* FF 5).

Examiner, however, fails to identify an evidentiary basis on this record to support a conclusion that even if the citric acid press cake component of Holzgraefe's composition was optimized, such optimization would have resulted in a citric acid presscake concentration within Appellants' claimed range of 10% (w/w) to about 35% (w/w) (*cf.* Ans. 4–5 (Examiner incorrectly relies upon the concentration range provided for Holzgraefe's dextrin product to establish a concentration range for Holzgraefe's citric acid presscake). *See In re Sebek,* 465 F.2d 904, 907 (CCPA 1972) (Although "it may ordinarily be the case that the determination of optimum values for the parameters of a prior art process would be at least prima facie obvious, that conclusion depends upon what the prior art discloses with respect to those parameters."). On this record, Examiner failed to establish an evidentiary basis to support a conclusion that optimizing Holzgraefe's citric acid presscake concentration would result in the concentration recited in Appellants' claims. *See In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.").

Examiner further failed to establish an evidentiary basis to support a conclusion that any of Darlington, Amlan, Hofshagen, Weese, Howes, and Watanabe alone or in combination make up for the foregoing deficiency in Holzgraefe (*see* FF 8–16).

For the foregoing reasons, we find that Examiner failed to establish a prima facie case of obviousness on this record. Therefore, we have not considered Appellants' secondary evidence of non-obviouness (*see* Johnston Declarations[11]; *see also* App. Br. 12–19; Reply Br. 2–4).

CONCLUSION

The preponderance of evidence relied upon by Examiner fails to support a conclusion of obviousness. The rejection of claims 87–152 under 35 U.S.C. § 103(a) as unpatentable over the combination of Holzgraefe, Darlington, Amlan, Hofshagen, Weese, Howes, and Watanabe is reversed.

REVERSED

[11] First Declaration of Sara LeAnn Johnston, unsigned; Second Declaration of Sara LeAnn Johnston, signed August 4, 2016, and Third Declaration of Sara LeAnn Johnston, signed April 12, 2017.