

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte MARIAN L. KRUZEL

Appeal 2007-2713
Application 10/023,096
Technology Center 1600

Decided: November 21, 2007

Before ERIC GRIMES, NANCY J. LINCK, and JEFFREY N. FREDMAN,
Administrative Patent Judges.

FREDMAN, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of reducing microbial contamination of meat by treating the meat with lactoferrin, which the Examiner has rejected on grounds of obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

BACKGROUND

“Lactoferrin plays an important role in iron transport and utilization in humans” (Specification 1). The Specification discloses that “human lactoferrin is capable of binding two ferric ions with high affinity” (Specification 1). “Because it sequesters iron, lactoferrin can neutralize pathogenic microorganisms by preventing them from obtaining necessary iron at the site of entry, thereby preventing the spread of infection” (Specification 2). The Specification also teaches “[l]actoferrin can be applied to food (either solid or liquid) to retard spoilage in accordance with the present invention either alone or compounded with any of the aforesaid nutritionally acceptable carriers or diluents” (Specification 14).

Appellant teaches a “method for inhibiting food spoilage comprising adding to the food an effective amount of lactoferrin having less than about 25% metal loading” (Specification 3).

STATEMENT OF THE CASE

The Claims

Claims 1-7 are on appeal. The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). We will focus on claim 1, which is representative and reads as follows:

1. A method for reducing the microbial contamination of a meat product, comprising treating the meat product with a sufficient amount of lactoferrin selected from the group consisting of bovine, human, and recombinant human lactoferrin to reduce microbial contamination.

The Examiner has rejected claims 1-7 under 35 U.S.C. § 103(a) based on:
Chander et al., “*Lactoferrin – Antibacterial Protein of Milk,*” 32 India
Dairyman 417-18 (1980) (hereafter “Chander”).

Ryser et al., “*'New' Food Borne Pathogens of Public Health
Significance,*” 89 J. Am. Dietetic Ass’n 948-54 (July 1989) (hereafter
“Ryser”).

Stiles et al., “*Enterobacteriaceae associated with Meats and Meat
Handling,*” 41 Applied and Envtl. Microbiology 867-72 (April 1981)
(hereafter “Stiles”).

Dickson et al., “*Cell Surface Charge Characteristics and Their
Relationship to Bacterial Attachment to Meat Surfaces,*” 55 Applied and
Envtl. Microbiology 832-36 (April 1989) (hereafter “Dickson”).

The Issue

The Examiner’s position is that Chander teaches “that lactoferrin, including bovine, inhibits the growth of a variety of pathogenic and nonpathogenic micro-organisms such as *E. coli*, *Bacillus subtilis*, *Salmonella typhi*, *Vibrio cholerae*, *Shigella dysentriiae*, *Klebsiella pneumoniae*, and *Staphylococcus aureus* both *in vitro* and *in vivo*” (Answer 3). The Examiner states that the three secondary references, Ryser, Stiles and Dickson, each teach contamination of meat with microorganisms including those listed by Chander (*see* Answer 4-7).

The Appellant argues that the Chander reference does not teach treating any product (App. Br. 8). The Appellant further notes that milk is not treated by lactoferrin since lactoferrin is naturally present in milk (App. Br. 8).

The Examiner acknowledges that Chander does not teach treating a product, but contends that

he has set forth non-technical, "common sense" suggestions and/or motivations on how and why the references should be combined for the simple purpose of inhibiting meat spoilage and food poisoning that would render the instant claims *prima facie* obvious to those of ordinary skill in the art, such as food scientists or biochemists concerned with the problem of meat spoilage and food poisoning.

(Answer 8.)

In view of these conflicting positions, we frame the issue before us as follows:

Would there have been a reason for the ordinary artisan to use the known antibacterial properties of lactoferrin as taught by Chander to treat meat in order to reduce the bacterial contamination disclosed by Ryser, Stiles or Dickson?

FINDINGS OF FACT

1. Chander teaches that lactoferrin has inhibitory effects on a variety of pathogenic microorganisms, including *Bacillus subtilis*, *Staphylococcus aureus*, *Vibrio cholerae*, *Klebsiella pneumoniae*, *Escherichia coli*, *Salmonella typhi*, and *Shigella dysentariae* (Chander, at 418, col. 1-2).

2. Chander teaches that lactoferrin has an inhibitory effect *in vivo* and *in vitro* (Chander, at 417, col. 2).

3. Chander specifically teaches that "lactoferrin plays an important role in milk in controlling food poisoning, pathogenic and spoilage organisms of considerable importance" (Chander, at 418, col. 2, ll. 19-23).

4. Chander teaches that lactoferrin is present in natural milk and in colostrum (*see* Chander, at 417, col. 1, ll. 22-35).

5. Ryser teaches that “it is imperative that appropriate precautions be taken to control the presence of viable cells of these ‘emerging’ pathogens in our food supply” (Ryser, at 948, col. 2, ll. 5-7).

6. Ryser teaches that *Vibrio cholerae* and *Escherichia coli* are contaminants of various kinds of meat (Ryser, at 952-53).

7. Ryser teaches control measures to prevent bacterial contamination including pasteurization, cooking and prevention of cross contamination (*see* Ryser, at 949, table 1).

8. Ryser teaches that pathogenic bacteria are found in a variety of foods, including beef (*see* Ryser, at 952-53).

9. Stiles teaches that *E. coli* is a contaminant of meat (*see* Stiles, at 867, col. 1, ll. 1-9).

10. Stiles teaches control measures to prevent bacterial contamination including sanitation (Stiles, at 870, col. 2, ll. 26-34) and heat treatment (Stiles, at 871, col. 1, ll. 12-13).

11. Stiles teaches that there is a risk of disease from contamination of meat with coliform bacteria such as *E. coli* and *Klebsiella pneumoniae* (*see* Stiles, at 867, col. 1-2).

12. Dickson teaches that bacteria such as *E. coli* attach to meat surfaces (*see* Dickson, at 834, col. 1 (Table 3)).

13. Dickson teaches that some bacteria associated with meat products are pathogenic (*see* Dickson, at 832, col. 2, ll. 25-27).

DISCUSSION

The method of treating meat with lactoferrin to reduce microbial contamination would have been obvious based on the teachings of Chander and Ryser, Stiles, or Dickson. Chander teaches that lactoferrin inhibits pathogenic bacteria in vitro and in vivo (FF 1-2). Chander also teaches that lactoferrin plays a role in controlling pathogenic microorganisms (FF 3). Ryser teaches that control of pathogenic organisms on meat is a significant issue, which can be addressed by various treatments including heat and sanitation (FF 5-8). Stiles and Dickson also teach that pathogenic organisms are present on meat (FF 9-13).

In *KSR Int'l v. Teleflex*, the Supreme Court indicated that “[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability.” *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007).

In our opinion, it would have been predictable to apply an antimicrobial compound naturally present in milk, and therefore known to be completely safe for consumption, to control pathogenic organisms in other food contexts (*see* FF 1-8). Treatment of food to control microbial growth is not a new concept, for example, Ryser discloses the use of heat as in pasteurization (*see* FF 7). Since lactoferrin is known to inhibit the growth of pathogenic microorganisms (*see* FF 1-3), application of lactoferrin to meat simply represents an obvious variation of Chander’s teaching. Ryser, Stiles, and Dickson all teach that meat may be contaminated with pathogenic

microorganisms, including the same microorganisms that Chander teaches are inhibited by lactoferrin (*see FF 1-12*).

Appellant disputes that Chander combined with Ryser, Stiles or Dickson teach anything regarding the treatment of products, especially meat, to reduce microbial contamination (App. Br. 8-10). However, Ryser specifically teaches several treatments which reduce microbial contamination, including pasteurization, prevention of cross-contamination, and cooking (*see FF 7*). Stiles teaches heating and cooking to remove microbial contamination (*see FF 10*). As the Examiner noted,

[t]he economic and public health desire to reduce microbial contamination by using a compound that is already known to be effective against both microbes that are already known to be present in raw or undercooked crab, shrimp, oysters, ground beef and ground beef sandwiches (such as the germs that cause E. coli food poisoning and cholera) renders the instant claims *prima facie* obvious.

(Answer 7).

These health concerns are fully discussed in Ryser, who repeatedly emphasizes that foods, including pork and beef, which are contaminated with pathogenic microorganisms, represent a significant health hazard (*see FF 5*). Stiles and Dickson also show that the ordinary artisan would have been aware of the health impact of microbial contamination of meat (*see FF 9, 13*).

The Examiner has identified a specific reason to use lactoferrin on meat, which is to reduce microbial contamination on meat that is known to have contamination risks thereby reducing the risk of human disease (*see FF 4-8*). *See KSR Int'l v. Teleflex Inc.*, 127 S. Ct. at 1741 (“it can be important to identify a reason that would have prompted a person of ordinary skill in

the relevant field to combine the elements in the way the claimed new invention does”). We agree with the Examiner that those of ordinary skill in the art would have considered obvious the predictable use of lactoferrin to reduce microbial contamination in meat in view of Chander combined with Ryser, Stiles, or Dickson.

We reject Appellant’s argument that there is no reasonable expectation of success in the prior art. Appellant argues that the Examiner makes an unwarranted and unfounded conclusion regarding obviousness based upon public health concerns (App. Br. 11). As we discussed above, Ryser provides specific statements that microbial contamination of meat is a public health risk (*see* FF 5-8). Also, Chander provides a specific teaching that lactoferrin inhibits microbial growth on substrates *in vitro* (see FF 1-4). These teachings would have provided a foundation for a reasonable expectation of success since it would be expected that if lactoferrin can inhibit bacteria *in vitro*, it would inhibit bacteria on meat. *See In re O’Farrell*, 853 F.2d 894, 903-04 (Fed. Cir. 1988) (“Obviousness does not require absolute predictability of success For obviousness under § 103, all that is required is a reasonable expectation of success.”).

We also reject several of Appellant’s arguments that are specific to the Dickson or Stiles references. Appellant argues that Dickson does not teach bacteria which are normal contaminants of meat (App. Br. 9). Dickson states: “The bacteria selected represent both pathogenic and nonpathogenic strains which are associated with meat products” (Dickson, at 832, col. 2, ll. 25-27). Dickson clearly comments that some of the selected bacteria are pathogenic strains associated with meat products.

Appellant also argues that treatment of meat would destroy the purpose of Stiles, which Appellant identifies as identifying contamination of meat during the meat processing chain (App. Br. 10). There is no language in Stiles which indicates that treatment of meat to remove bacteria is undesirable. In fact, since Stiles specifically refers to both sanitation and cooking in order to remove bacteria, Stiles teaches to remove contaminants (*see* FF 10). Like our appellate reviewing court, we “will not read into a reference a teaching away from a process where no such language exists.” *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1364 (Fed. Cir. 2006).

Based on our findings and those of the Examiner, Chander combined with Ryser, Stiles, or Dickson would have suggested the invention of claim 1 to the skilled artisan. Thus, we conclude that the invention of claim 1 would have been obvious under § 103(a) based on the cited prior art.

Other issues

If Appellant resumes examination before the Examiner, the Examiner should consider The Pioneer Heritage Wild Game Cookbook (1986) (attached). We believe this reference may be anticipatory. At page 73, this cookbook teaches a recipe in which meat is soaked in milk for one hour. Bovine milk inherently comprises lactoferrin, and Chander evidences that the lactoferrin in milk may inherently result in antibacterial activity (Chander, at 418).

Appeal 2007-2713
Application 10/023,096

CONCLUSION

In summary, we affirm the rejection of claim 1 under § 103(a). Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejection of claims 2-7 under 35 U.S.C. § 103(a) as these claims were not argued separately.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

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