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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte CHRISTOPHE CHASSARD, CHRISTOPHE LACROIX, and CHRISTIAN BRAEGGER

Appeal 2018-008790
Application 14/761,336
Technology Center 1600

Before JEFFREY N. FREDMAN, ULRIKE W. JENKS, and DAVID COTTA, *Administrative Patent Judges*.

JENKS, *Administrative Patent Judge.*

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellants[1] appeal from the Examiner's decision to reject claims directed to treating a digestive disease with live bacterial strains as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] Appellants identify the real party in interest as ETH Zurich and Universitat Zurich. Appeal Br. 2.

STATEMENT OF THE CASE

Claims 1, 4–9, and 11–16 are on appeal, and can be found in the Claims Appendix of the Appeal Brief. Claim 1 is representative of the claims on appeal, and reads as follows:

> 1. A method of treating digestive diseases or disorders, the method comprising administering to a patient a dry food composition comprising
>
> (a) viable lactic acid-producing bacteria from one or more live bacteria strains;
>
> (b) viable lactate utilizing, propionic acid-producing bacteria from one or more live Propionibacteria strains; and
>
> (c) optionally prebiotics;
>
> wherein the digestive diseases or disorders is infantile colic, and wherein the dry food composition is an infant nutritional product.

Appeal Br. 10 (Claims Appendix).

Appellants appeal the Examiner's decision[2] to reject claims 1, 4–9, and 11–16 under pre-AIA 35 U.S.C. 103(a) as obvious over Chow[3] in view of Parker.[4]

As Appellants do not argue the claims separately, we focus our analysis on claim 1, and claims 4–9 and 11–16 stand or fall with that claim. 37 C.F.R. § 41.37 (c)(1)(iv).

The issue is: Does the preponderance of evidence of record support Examiner's conclusion that a method of treating a digestive disease using a

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[2] Examiner withdrew all the rejections made in the Non-Final Office Action mailed June 29, 2017. *See* Ans. 7.
[3] Chow et al., US 2012/0171166 A1, published July 5, 2012 ("Chow").
[4] Jennifer A. Parker and Nancy J. Moon, *Interactions of Lactobacillus and Propionibacterium in Mixed Culture*, 45 J. Food Protection 326–30 (1982) ("Parker").

combination of viable lactic acid producing bacteria and viable lactate utilizing bacteria obvious?

Findings of Fact

FF1. Chow teaches a nutritional source that can help improve intestinal gut function such as reducing colic in infants. Chow ¶ 135; *see* Ans. 4. Chow teaches symbiotic combinations of one or more probiotics and human milk oligosaccharides (HMOs)(and, optionally, other prebiotic oligosaccharides). Chow ¶¶ 11, 86, 135. The symbiotic combination includes "one of a galactooligosaccharide [(GOS)] and a fructooligosaccharide (such as a short chain fructooligosaccharide) [(FOS)] and at least one HMO. The symbiotic composition promotes the colonization of beneficial intestinal microbiota in order to discourage the growth of harmful bacteria." Chow ¶ 11, *see id.* ¶ 86; *see* Ans. 4.

FF2. Chow teaches that "[p]robiotics are live microorganisms thought to be healthy for the host organism. Lactic acid bacteria (LAB) and bifidobacteria are the most common types of microbes used as probiotics." Chow ¶ 87. Examples of probiotic strains for use in the nutritional compositions include: *Lactobacillus acidophilus*, *L. casei* spp. *casei*, *L. casei* spp. *rhamnosus*, *L. bulgaricus*, *L. delbrueckii* ssp. *lactis*, *Propionibacterium acidipropionici*, and *P. freudenreichii*, among others. Chow ¶ 89; *see* Ans. 5.

FF3. Chow teaches that the mixtures "can be heat-treated and subsequently processed and packaged as a reconstitutable powder, e.g., spray dried, drymixed, agglomerated." Chow ¶ 128; *see* Ans. 4.

FF4. Parker teaches that "[l]actobacilli and propionibacteria are often found growing in mixed culture in food and other environments. . . . [The study investigated] growth patterns or growth dynamics of mixed culture . . . . The species were chosen to represent those occurring in foods and other natural environments." Parker 326. Parker studied mixed cultures with the following species: *L. acidophilus, L. casei, L. delbrueckii, L. bulgaricus, P. pentosaceum, P. shermanii, P. acidi-propionici, P. freudenreichii*. Parker 328 (table 2).

FF5. Parker teaches that "cell numbers in the mixed culture were higher than in controls, this suggests that an energy source other than glucose was being used particularly in the later stages of the fermentation." Parker 328; *see* Ans. 4. "It seems likely that *L. acidophilus* produced considerable lactic acid during the fermentation . . . which was rapidly used by the *P. shermanii* to produce acetic and propionic acids and carbon dioxide." Parker 328.

FF6. Parker teaches experiments in which bacteria were "grown in pure and mixed culture to assess associative interactions." Parker Abstract. "In *P. shermanii* and *L. acidophilus* mixed culture, a beneficial synergistic effect on growth, carbon dioxide, and volatile and nonvolatile acid production was observed." *Id.* "The benefit of using a commensalistic culture pair such as *L. acidophilus* and *P. shermanii* might be in the batch or continuous production of propionic acid. Use of this pair could result in increased rates of product formation." Parker 330.

Principle of Law

"If the claim extends to what is obvious, it is invalid under § 103." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007).

Analysis

Examiner finds that Chow teaches a method of treating infantile colic by administering a dry food composition containing prebiotic oligosaccharides and one or more live probiotics including probiotics selected from viable lactic acid producing bacteria and propionic acid producing bacteria. Ans. 4; FF1–FF3. Examiner acknowledges that "Chow does not explicitly disclose administering to a patient a composition specifically comprising both a viable lactic acid-producing bacteria and viable lactate utilizing, propionic acid-producing bacteria." Ans. 4. Examiner looks to Parker for providing a reason to select lactic acid producing bacteria and lactate utilizing bacteria in Chow's mixture. Specifically, Examiner finds that "Parker teaches increased cell number when culturing a lactic acid-producing bacteria and a lactate utilizing, propionic acid-producing bacteria." Ans. 4; FF4–FF5.

Examiner concludes

> it would [have been] obvious to one of ordinary skill in the art at the time of invention to modify the method of administering a composition comprising one or more of a viable lactic acid-producing bacteria and viable lactate utilizing, propionic acid-producing bacteria of Chow by specifically choosing both a viable lactic acid-producing bacteria and viable lactate utilizing, propionic acid-producing bacteria as taught by Parker.

Ans. 4. In other words, Parker provides a reason for selecting those bacteria that show increased growth when culturing the mixture of bacteria in an *in vitro* setting. FF5, FF6. Examiner finds that Parker provides the motivation

to utilize a particular bacterial culture pair, one that is shown to work well together ("a commensalistic culture pair") by observing increased cell count and increased product formation. Ans. 4; FF5, FF6.

Appellants contend that Parker is not analogous art. Reply Br. 2. "The problem addressed by Parker was optimizing the fermentation process by maximizing cell growth, increasing carbon dioxide production and increasing acid production," which is very different from the problem addressed with the instant claims which are directed at treating infantile colic. Reply Br. 3.

We are not persuaded by Appellants' contention.

> Two criteria have evolved for determining whether prior art is analogous: (1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.

In re Clay, 966 F.2d 656, 658–9 (Fed. Cir. 1992).

Here, Chow teaches synbiotic compositions containing probiotics and HMOs that are utilized for the colonization, i.e., growth, of beneficial intestinal microbes in order to discourage the growth of harmful bacteria. FF1. Chow achieves this by administering nutritional compositions containing HMOs, galactooligosaccharide (GOS), fructooligosaccharide (FOS), and probiotics. FF1. Chow also teaches a variety of probiotics that can be included in these nutritional compositions and the probiotics include bacteria such as *Lactobacillus acidophilus* and *Propionibacterium*. FF2. Chow is interested in supporting the growth of beneficial intestinal microbes. Therefore, Chow can be classified as belonging in the field of promoting microbial growth.

Parker is similarly concerned with promoting microbial growth. Parker specifically considered species that are often found together either in "foods and other natural environments." FF4. Parker observed that in mixed cultures that contain bacteria that produce lactic acid in conjunction with bacteria that utilize lactic acid as an energy source to produce acetic and propionic acids the cell numbers in the mixed culture system are increased. FF5.

Whether Chow and Parker can reasonably be considered as being directed to the same field of endeavor on a generic level may be debatable. The teachings of Parker, however, are clearly pertinent to the question of microbial growth that is a significant element in Chow. Without microbial growth, "colonization of beneficial intestinal microbiota" (FF1) as desired by Chow cannot occur. We recognize that the locations of microbial growth in Chow and Parker are different, gut versus petri dish, never the less both are directed at promoting microbial growth; and these teachings would be considered reasonably pertinent to the problem of optimizing microbial growth regardless of location. *See* FF1, FF5. Because we find that Chow and Parker are analogous art we are not persuaded by Appellants' contention that Parker cannot be considered as providing a reason to select a particular probiotic microbial combination in Chow.

Appellants contend that the combination does not provide a reasonable expectation of success. Reply Br. 4.

We are not persuaded by Appellants' contention. "Obviousness does not require absolute predictability of success. . . . For obviousness under § 103, all that is required is a reasonable expectation of success." *In re O'Farrell*, 853 F.2d 894, 903–904 (Fed. Cir. 1988).

Here, Chow teaches the production of nutritional supplements that can be used to treat colic in infants. FF1–FF3. Chow's nutritional supplement contains HMOs, GOS, FOS, as well as probiotics. FF1–FF2. Chow specifically discloses using a combination of "one or more probiotics." FF1. Chow provides a list of suitable probiotic microbes that includes lactic acid producing bacteria as well as lactic acid utilizing bacteria. FF2. Even though Chow suggests using more than one bacterial strain in the nutritional composition, Chow does not suggest selecting bacteria based on the products they make or the products they consume as an energy source. Examiner relied on Parker to provide a reason to select the two different types of probiotic bacteria. *See* Ans. 4. Parker teaches that in mixed culture system when using *lactobacilli* and *propionibacteria* together the cell numbers are higher. FF5. This suggests that the combination of bacteria has a beneficial effect on the growth. FF5. Based on this teaching, Examiner reasons that would have been obvious to include this beneficial probiotic growth mixture in the nutritional supplement of Chow in order to arrive at a nutritional supplement that contains the recited probiotic mixture in conjunction with the optional prebiotics such as HMOs, GOS, and FOS as claimed.

We know from Chow that administering the probiotics in conjunction with oligosaccharides promotes the colonization of the beneficial bacteria in the gut and helps to discourage the growth of harmful bacteria. FF1. The reason for combining the probiotic mixtures of lactic acid-producing and lactate utilizing bacteria is because Parker teaches that in culture the mixture of these two types of bacteria are beneficial. FF5; FF6. Therefore, we agree with Examiner that it would be reasonable to infer that in the same growth benefit would reasonably have been expected in the intestinal environment

as well. We find no error with Examiner's combination as presented and agree that the teachings of Parker suggests selecting two probiotics already recognized in Chow as beneficial for the purpose of supporting growth.

We conclude that the evidence cited by the Examiner supports a prima facie case of obviousness with respect to claim 1, and Appellants have not provided persuasive rebuttal evidence or evidence of secondary considerations that outweighs the evidence supporting the Examiner's conclusion of obviousness. Accordingly, we affirm the rejection of claim 1 as obvious over Chow and Parker.

SUMMARY

We affirm the rejection of claim 1 under pre-AIA 35 U.S.C. § 103(a) over Chow and Parker. Claims 4–9, and 11–16 fall with claim 1. 37 C.F.R. § 41.37 (c)(1)(iv).

TIME PERIOD FOR RESPONSE

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

AFFIRMED