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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SHIGETO UCHIYAMA, TOMOMI UENO,
and TOSHIMI SUZUKI[1]

Appeal 2017-005387
Application 14/034,824
Technology Center 1600

Before ERIC B. GRIMES, JOHN G. NEW, and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a composition comprising a specific strain of bacteria, which have been rejected for lack of adequate description in the Specification and for being directed to a product of nature. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part.

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[1] Appellants identify the Real Party in Interest as Otsuka Pharmaceutical Co., Ltd. (Br. 2.)

STATEMENT OF THE CASE

The Specification states that "it is reported that equol as the active metabolite of soy isoflavone is a key factor in the expected efficacies in clinical application." (Spec. 1.) "The present invention relates to equol-producing lactic acid bacterial strain [and] a composition comprising said lactic acid bacterial strain." (*Id.*) "A specific example of said lactic acid bacterial strain is *Lactococcus* 20-92 (FERM BP-10036)." (*Id.* at 4.)

Claims 1 and 7–9 are on appeal.[2] Claims 1 and 9 are illustrative and reads as follows:

> 1. A composition comprising *Lactococcus garvieae* 20-92 deposited under accession number FERM BP-10036, and an effective amount of an added preservative.
>
> 9. A composition comprising *Lactococcus garvieae* 20-92 deposited under accession number FERM BP-10036, wherein said composition is in the form of fermented milk or fermented soy milk, said fermented milk or fermented soy milk having been fermented by said *Lactococcus garvieae* 20-92.

The claims stand rejected as follows:

Claims 1, 7, and 8 under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement (Final Action[3] 3), and

Claims 1 and 7–9 under 35 U.S.C. § 101 as being directed to a natural product (Final Action 4–5).

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[2] Claims 2 and 4 are also pending; the Examiner has indicated that these claims are allowable. (Ans. 2.)
[3] Office Action mailed March 3, 2016.

I

The Examiner has rejected claims 1, 7, and 8 under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. The Examiner finds that the insertion of "'an effective amount of an added preservative' is considered to be the insertion of new matter" because

> [i]t neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of the use of "an effective amount of an added preservative". There is no indication as to the intended effectiveness, for example.

(Final Action 4.)

Appellants argue that "persons of skill in the art would understand, from the *explicit disclosure* in the specification that a 'preservative' may be added . . . that the inventors were in possession of the concept of using an 'effective amount' of the preservative." (Br. 7.)

We agree with Appellants that the Specification adequately describes a composition comprising *Lactococcus garvieae* 20-92 and an effective amount of a preservative. The Specification states that "[t]he equol-producing lactic acid bacteria-containing composition of the invention can be processed into pharmaceutical preparations." (Spec. 23:20–22.) The Specification also states that "where necessary, colorant, preservative, flavoring, corrigent, sweetener, and other drugs can be incorporated into the pharmaceutical product of the invention." (*Id.* at 25:4–6.) The Specification states that "[o]n ingestion (administration) of the composition of the invention, the microorganism in the composition finds its way alive into the

lower digestive tract or settles there as part of the intestinal flora, whereby the expected efficacy is expressed." (*Id.* at 25:26–29.)

"In the prosecution of a patent, the initial burden falls on the PTO to set forth the basis for any rejection, *i.e.*, a prima facie case." *Hyatt v. Dudas*, 492 F.3d 1365, 1369 (Fed. Cir. 2007). "In the context of the written description requirement, an adequate prima facie case must . . . sufficiently explain to the applicant what, in the examiner's view, is missing from the written description." *Id.* at 1370. "[T]he test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010).

In this case, we conclude that the Specification's disclosure of pharmaceutical preparations comprising the lactic acid bacterium *Lactococcus garvieae* 20-92 and a preservative would have been recognized by those skilled in the art as showing possession of the claimed composition. We agree with Appellants (Br. 7–8) that the Specification's description of including a preservative in the disclosed composition would have been recognized as describing a composition comprising an effective amount of a preservative, because an effective amount would be required to achieve the function of preserving the viability of the bacteria in the composition, as intended.

The Examiner reasons that "[t]here is no evidence of record to show that a composition comprising *L. garvieae* 20-92 is preserved by any preservative whatsoever, what amount would be 'effective' for this purpose, or for how long the composition is preserved without loss of viability and

under which conditions." (Ans. 3.) As discussed above, however, the test for adequate written description is whether the Specification shows that the inventors were in possession of what is later claimed, and in this case the Specification shows constructive possession of a composition comprising *Lactococcus garvieae* 20-92 and an effective amount of a preservative.

II

The Examiner has rejected claims 1 and 7–9 under 35 U.S.C. § 101 as being directed to a natural product. The Examiner finds that "the *Lactococcus garviae* [sic] strain isolated from nature is not markedly different from the *Lactococcus garviae* [sic] as it is found in nature and it is naturally found in milk." (Final Action 4.) The Examiner also finds that "there is no evidence of record that addition of any preservative in 'an effective amount' results in a markedly different property for the material. . . . Therefore, the claims as a whole do not recite something markedly different than the judicial subject-matter eligibility exception of natural products." (*Id.* at 5.)

We agree with the Examiner that claim 1 encompasses a product that is not markedly different from naturally occurring bacteria, and therefore is directed to patent-ineligible subject matter.

> Even before the Supreme Court's recent decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, [569] U.S. [576], 133 S.Ct. 2107, 186 L.Ed.2d 124 (2013), the Court's opinions in *Chakrabarty* and *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 68 S.Ct. 440, 92 L.Ed. 588 (1948), made clear that naturally occurring organisms are not patentable.

In re Roslin Institute (Edinburgh), 750 F.3d 1333, 1336 (Fed. Cir. 2014). The *Roslin Institute* court explained that the mixture of naturally occurring

bacteria claimed in *Funk Bros.* was held to be "not patent eligible because the patentee did not alter the bacteria in any way." *Id.* "Thus, while the method of selecting the strains of bacteria might have been patent eligible, the natural organism itself—the mixture of bacteria—was unpatentable because its 'qualities are the work of nature' unaltered by the hand of man." *Id.*

By contrast, "[t]he patent at issue in *Chakrabarty* claimed a genetically engineered bacterium that was capable of breaking down various components of crude oil." *Id.* "[T]he Court held that the modified bacterium was patentable because it was 'new' with '*markedly different characteristics from any found in nature* and one having the potential for significant utility.'" *Id.* (emphasis added by the *Roslin Institute* court). "Accordingly, discoveries that possess 'markedly different characteristics from any found in nature,' are eligible for patent protection. In contrast, any existing organism or newly discovered plant found in the wild is not patentable." *Id.* (citation omitted).

Here, the Specification states that *Lactococcus garvieae* 20-92 is a naturally occurring strain of bacteria. (Spec. 4:31–33.) The composition of claim 1 combines the naturally occurring bacteria with "an effective amount of an added preservative." (Claim 1.) In the context of the claimed composition, we interpret "an effective amount" to be one that preserves the viability of the bacteria, because the Specification states that, on ingestion, "the microorganism in the composition finds its way alive into the lower digestive tract or settles there as part of the intestinal flora." (Spec. 25:26–29.)

However, the Specification provides no guidance, by way of definition or otherwise, regarding how much viability is required for a given amount of a given preservative to be considered "effective," or how long viability must be maintained in order for a given amount of a preservative to be considered an "effective amount," or under what circumstances the viability must be maintained. The claimed bacterial strain was "isolated from human stools," and grown *in vitro*, demonstrating that the isolated, but naturally occurring, bacteria were viable. (Spec. 4:29 to 5:10.)

Appellants have not pointed to evidence showing that the viable bacteria in the claimed composition are "markedly different," *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980), from the viable bacteria naturally found in human stools. We therefore conclude that the evidence of record supports the Examiner's position that the composition of claim 1 encompasses patent-ineligible subject matter and is unpatentable under 35 U.S.C. § 101.

Appellants argue that the patentability of the claimed composition is supported by "the revised § 101 Guidance issued December 16, 2014" and "[s]pecifically, Example 2 of the 'Nature-Based Products Examples' sheet (which accompanied the December 16, 2014, Guidance)." (Br. 8.) Appellants argue that this example included a hypothetical claim to pomelo juice and an effective amount of an added preservative, which was found to confer a property that was markedly different from the juice itself, because adding the preservative resulted in the juice spoiling "in a few weeks" rather than "in a few days." (*Id.* at 9.) Appellants argue that "the preserving effects of a preservative constitute a markedly different property – in much

the same way as a preservative that prevents spoiling of a fruit juice does." (*Id.*)

This argument is not persuasive, because it is not supported by evidence showing that an "effective amount" of a preservative, in the context of claim 1, would result in the bacteria of the claimed composition having a markedly different rate of losing viability than the bacteria in their natural state. The facts of the hypothetical example cited by Appellants state that the pomelo juice mixed with an effective amount of a preservative spoils in a few weeks rather than a few days. Here, by contrast, and as pointed out by the Examiner (Final Action 5), the evidence of record does not show that an effective amount of a preservative changes the properties of the claimed bacteria in a manner comparable to the weeks-versus-days change posited by the cited hypothetical example.

We therefore affirm the rejection of claim 1 under 35 U.S.C. § 101. Claims 7 and 8 have not been argued separately and therefore fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

With regard to claim 9, Appellants argue that

> this *fermented* diary product, *which has been fermented by the specific bacteria recited in the claim*, does not occur in nature, and is not merely a *mixture* of otherwise naturally-occurring products (since the microorganism acts, e.g., enzymatically, to change the structure and properties of the dairy product (pre- and post-fermentation). Additionally, the Examples in the present specification convey that storing this bacteria in soymilk fermented with the bacteria results in an extended shelf life, with retention of equol-producing activity, which is a "markedly different" functional property.

(Br. 10.)

We will reverse the rejection of claim 9. As Appellants point out, the Specification's examples show that fermenting milk or soy milk with *Lactococcus garvieae* 20-92 results in properties in the resulting product that are different from those of the natural products themselves. For example, the Specification states that in both daidzein-supplemented basal medium and in soy milk, "the production of equol began to be noticed at hour-48 following the start of incubation" and that, with soy milk, "at the inoculation level of 4.00%, the production of equol was as large as 57.0 μg/mL at hour-96 of incubation." (Spec. 32:22 to 33:2.) In the daidzein-supplemented basal medium, by contrast, production of equol did not exceed about 10 μg/mL during the course of the experiment. (*See* Fig. 3.)

The Specification also states that,

> as far as cow'[s] milk is concerned, the equol-producing ability (activity) is sustained to week-4 of low-temperature storage at 4°C after completion of culture in both cases of 1L and 2L. Moreover, in the case of 2L of cow's milk, the activity was found to be sustained to day-51, that was the last day of monitoring of the storage stability at 4°C. In the case of 1L of commercial skim milk, too, the equol-producing ability (activity) was apparently sustained to day-34, the last day of monitoring of the low-temperature storage stability at 4°C after completion of culture.

(*Id.* at 35:5–15.) The Specification states that "equol as the active metabolite of soy isoflavone is a key factor in the expected efficacies in clinical application," including "in breast cancer, carcinoma of the prostate, and climacteric and postmenopausal osteoporosis." (*Id.* at 1.)

Thus, the evidence supports Appellants' position that fermenting either milk or soy milk with *Lactococcus garvieae* 20-92 results in a product that has properties that are markedly different from any of the naturally occurring products by themselves; specifically, an enhanced amount of

equol, which is disclosed to have clinical application in disorders such as breast cancer, prostate cancer, and postmenopausal osteoporosis. The resulting product therefore would be expected to have applications that are not shared by milk, soy milk, or *Lactococcus garvieae* 20-92 by themselves.

In response to Appellants' argument, the Examiner cited evidence to show that *L. garvieae* "naturally occurs in fermented milk." (Ans. 4.) The Examiner concludes that the cited evidence "clearly demonstrate[s] that at least cow's milk naturally contains *L. garvieae*, which milk would be naturally fermented at room temperature and comprise the strain." (*Id.* at 5.)

Claim 9, however, is not directed to a product comprising *L. garvieae*, generally, but to the specific strain of *L. garvieae* that Appellants refer to as *Lactococcus garvieae* 20-92. The Specification makes clear that "[f]rom [its] cultural and biochemical characteristics, the strain of the invention is classified into *Lactococcus garvieae* which is a gram-positive coccus but differs from its type strain . . . in the utilization of starch." (Spec. 6:14 to 7:2.) Thus, the fact that some strain(s) of *L. garvieae* are naturally found in cow's milk is not adequate to establish that the fermented product of claim 9 is naturally occurring.

SUMMARY

We reverse the rejection of claims 1, 7, and 8 under 35 U.S.C. § 112, first paragraph.

We affirm the rejection of claims 1, 7, and 8 under 35 U.S.C. § 101.

We reverse the rejection of claim 9 under 35 U.S.C. § 101.

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-IN-PART