

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SATOSHI MATSUBARA, HIROKO HAYAKAWA,
YASUHISA SHIMAKAWA, MITSUYOSHI KANO,
HARUE SONE, and FUMIYASU ISHIKAWA

Appeal 2009-006581¹
Application 10/398,507
Technology Center 1600

Decided: February 10, 2010

Before TONI R. SCHEINER, DEMETRA J. MILLS, and
FRANCISCO C. PRATS, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the rejection of claims 17-23 and 25, directed to a method for improving bone metabolism in a human or animal subject. We have jurisdiction under 35 U.S.C. § 6(b).

¹ Heard January 14, 2010.

STATEMENT OF THE CASE

Claims 17-20 and 25 are representative:

17. A therapeutic method for improving bone metabolism in a human or animal subject comprising:

selecting a human or animal having a tendency toward a decrease in bone density, and

therapeutically administering to said human or animal subject fermented soy milk which is obtained by fermenting soy milk with one or more microorganisms selected from the group consisting of *Lactobacillus casei*, *Lactobacillus mali*, and *Bifidobacterium breve*.

18. The method of Claim 17, wherein said subject is human.

19. The method of Claim 17, wherein said subject has osteoporosis.

20. The method of Claim 17, wherein said subject is a post-menopausal female.

25. The therapeutic method of Claim 17, wherein said subject is a human affected with osteoporosis and said subject is administered 100 to 1,000 g per day of a fermented soy milk having a soybean solid component content of at least 6%.

The claims stand rejected as follows:

- Claims 17 and 19-23 under 35 U.S.C. § 102(b) as anticipated by Kikuchi-Hayakawa,² as evidenced by Yamaguchi³ and Potter.⁴

² Hiroko Kikuchi-Hayakawa et al., *Effects of Soy Milk and Bifidobacterium Fermented Soy Milk on Lipid Metabolism in Aged Ovariectomized Rats*, 62 BIOSCI. BIOTECHNOL. BIOCHEM. 1688-1692 (1998).

³ Masayoshi Yamaguchi et al., *Effect of vitamin K₂ (menaquinone-7) in fermented soybean (natto) on bone loss in ovariectomized rats*, 17 J. BONE MINER. METAB. 23-29 (1999).

⁴ Susan M. Potter et al., *Soy protein and isoflavones: their effects on blood lipids and bone density in postmenopausal women*, 68(suppl) AM J. CLIN. NUTR. 1375S-1379S (1998).

- Claim 18 under 35 U.S.C. § 103 as unpatentable over Kikuchi-Hayakawa, Harrison,⁵ and Hayakawa.⁶
- Claim 25 under 35 U.S.C. § 112, first paragraph, as lacking written descriptive support (new matter).
- Claim 25 under 35 U.S.C. § 112, second paragraph, as indefinite.

We affirm the anticipation and obviousness rejections, and reverse the new matter and indefiniteness rejections.

ANTICIPATION

Issue

The Examiner rejected claims 17 and 19-23 as anticipated by Kikuchi-Hayakawa, as evidenced by Yamaguchi and Potter.

The Examiner finds that Kikuchi-Hayakawa administers fermented soy milk to ovariectomized rats, which have a tendency toward a decrease in bone density, and therefore inherently discloses a therapeutic method for improving bone metabolism (Ans. 4-5).

Appellants contend that Kikuchi-Hayakawa doesn't disclose "a therapy for treating a decrease in bone density" because the rats "were not selected for a tendency toward a decrease in bone density, but rather to determine the effects of soy milk products on lipid metabolism" (App. Br. 10).

⁵ Eric Harrison et al., *The Effect of Soybean Protein on Bone Loss in a Rat Model of Postmenopausal Osteoporosis*, 44 J. NUTR. SCI. VITAMINOL. 257-268 (1998).

⁶ JP 10-130160, Application of Hiroko Hayakawa, published May 19, 1998. All references are to the English language translation.

The issue raised by this rejection is: Have Appellants established that the Examiner erred in finding that Kikuchi-Hayakawa discloses a therapeutic method for improving bone metabolism by administering fermented soy milk to an animal having a tendency toward bone loss?

Findings of Fact

FF1 Kikuchi-Hayakawa describes administration of soy milk, and soy milk fermented by *Bifidobacterium breve*, to aged, ovariectomized, no longer menstruating, estrogen-deficient female rats to evaluate the effects of soy milk and fermented soy milk on lipid metabolism (Kikuchi-Hayakawa 1688-1689).

FF2 Kikuchi-Hayakawa teaches that fermentation of soy milk by *Bifidobacterium breve* “change[s] the physicochemical character of soy protein” and “causes the release of aglycones from isoflavone glucosides” (Kikuchi-Hayakawa 1688), which are more easily absorbed than the glycosides (*id.*, at 1691).

FF3 Yamaguchi teaches that ovariectomizing rats induces bone loss, and that administering vitamin K₂, which is “highly contained in the fermented soybean (*natto*),” prevents this bone loss (Yamaguchi 23).

FF4 Potter teaches that “postmenopausal women are at risk for health problems related to estrogen deficiency, such as cardiovascular disease and osteoporosis” (Potter 1375S), and that soy proteins and isoflavones have a beneficial effect on lipid metabolism and bone density in postmenopausal women (*id.*).

FF5 The Examiner finds that “Kikuchi-Hayakawa’s method meets the steps recited in the instantly claimed method and uses the same identical *Bifidobacterium breve* YIT4065 strain for fermenting the soy” (Ans. 5), and

therefore, “would necessarily bring about the recited effect, i.e., therapeutic improvement in bone metabolism” (*id.* at 9 (emphasis omitted)).

FF6 In addition, the Examiner finds, based on the evidence provided by Yamaguchi and Potter, that Kikuchi-Hayakawa’s aged, ovariectomized, estrogen-deficient rats “qualify as animals having osteoporosis” (Ans. 5), and as non-menstruating postmenopausal females (*id.* at 4).

Principles of Law

“To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently.” *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

“It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable.” *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990). When “a claimed new benefit or characteristic of an invention otherwise in the prior art” is an inherent property of the old invention, “the new realization alone does not render the old invention patentable.” *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1377 (Fed. Cir. 2005). “[A] limitation or the entire invention is inherent and in the public domain if it is the ‘natural result flowing from’ the explicit disclosure of the prior art.” *Id.* (citations omitted).

As summarized in *Perricone*, *id.* at 1375-76:

A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation. *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 (Fed. Cir. 1992). Thus, a prior art reference without express reference to a claim limitation may nonetheless anticipate by inherency. *See In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 (Fed. Cir. 2002). “Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claims

limitations, it anticipates.” *Id.* (quoting *MEHL/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999). Moreover, “[I]nherency is not necessarily coterminous with knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art.” *Id.*; see also *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition in the prior art) (citing *In re Cruciferous Sprout Litig.*, 301 F.3d at 1351; *MEHL/Biophile*, 192 F.3d at 1366).

“Thus, when considering a prior art method, the anticipation doctrine examines the natural and inherent results in that method without regard to the full recognition of those benefits or characteristics within the art field at the time of the prior art disclosure.” *Id.* at 1378.

Analysis

Claims 17 and 21-23

Appellants don’t provide separate arguments for claims 21-23, therefore, we select claim 17 as representative of this group of claims. 37 C.F.R. § 41.37(c)(1)(vii) (2006).

Appellants contend that Kikuchi-Hayakawa’s ovariectomized rats “were not selected for a tendency toward a decrease in bone density, but rather to determine the effects of soy milk products of lipid metabolism” (App. Br. 10), therefore, Kikuchi-Hayakawa’s method “is not a therapy for treating a decrease in bone density as required by claim 17” (*id.*).

Appellants’ argument is not persuasive. There is no dispute that Kikuchi-Hayakawa discloses administering fermented soy milk to ovariectomized rats (FF1). The Examiner has provided unrefuted evidence establishing that ovariectomized rats exhibit a decrease in bone density (FF3), i.e., that ovariectomized rats have “a tendency toward a decrease in

bone density” as required by the claims. Appellants have not identified any manipulative difference between Kikuchi-Hayakawa’s method and the claimed method. As discussed above, the claimed method “is inherent and in the public domain if it is the ‘natural result flowing from’ the explicit disclosure of the prior art” (*Perricone*, 432 F.3d at 1377), regardless of whether the inherent result is recognized.

Claims 19 and 20

Claim 19 depends from claim 17 and further requires that the subject has osteoporosis. Claim 20 depends from claim 17 and requires that the subject is a post-menopausal female.

Appellants contend that Kikuchi-Hayakawa “does not disclose that . . . [the ovariectomized rats] had osteoporosis as required by claim 19” or “treating a post-menopausal female as required by claim 20” (App. Br. 10).

This argument is not persuasive. The Examiner has provided objective evidence in support of his or her finding that Kikuchi-Hayakawa’s, aged, ovariectomized, non-menstruating, estrogen-deficient rats, are post-menopausal females with osteoporosis (FF3-FF6). Appellants have not provided any evidence to the contrary.

Conclusions of Law

Appellants have not shown that the Examiner erred in finding that Kikuchi-Hayakawa discloses a therapeutic method for improving bone metabolism by administering fermented soy milk to an animal having a tendency toward bone loss. Nor have Appellants established that the Examiner erred in finding that Kikuchi-Hayakawa’s animal subjects were not post-menopausal females with osteoporosis.

The rejection of claims 17 and 19-23 as anticipated by Kikuchi-Hayakawa is affirmed.

OBVIOUSNESS

Issue

The Examiner rejected claim 18, which depends from claim 17 and specifies that the subject is human, as unpatentable over Kikuchi-Hayakawa, Harrison, and Hayakawa.

The issue raised by this rejection is: Have Appellants established that the Examiner erred in concluding that it would have been obvious to administer fermented soy milk to a human subject with a tendency toward bone loss, given the teachings of Kikuchi-Hayakawa, Harrison, and Hayakawa?

Additional Findings of Fact

FF7 Kikuchi-Hayakawa teaches that “[p]ostmenopausal women have a high risk of coronary heart disease, which has been found to be at least partially attributable to an unfavorable lipid metabolism” (Kikuchi-Hayakawa 1688), and that “[t]he potential roles of dietary soy in prevention and treatment of chronic diseases, notably heart disease and cancer, have long been known” (*id.*).

FF8 Kikuchi-Hayakawa discloses administering fermented soy milk to ovariectomized, estrogen-deficient rats, but doesn’t disclose administering it to human subjects.

FF9 Appellants acknowledge that Kikuchi-Hayakawa teaches that soy milk fermented by *Bifidobacterium breve* “induces a greater decrease in plasma cholesterol than soy milk . . . i.e., increases the HDL cholesterol

level and decreases the VLDL+LDL cholesterol level” (App. Br. 11) in ovariectomized, estrogen-deficient rats.

FF10 Harrison teaches that the ovariectomized rat is a suitable model for postmenopausal osteoporosis in human women (Harrison 257).

FF11 Hayakawa teaches that soy milk fermented by *Bifidobacterium* lacks the “distinctive unpleasant odor and taste” of unfermented soy milk, and “has excellent lipid metabolism-improving effects” (Hayakawa 3).

Analysis

Appellants contend that “[t]here is no motivation to modify the method of Kikuchi-Hayakawa to administer *fermented* soy milk to a human having decreased bone metabolism because the prior art does not suggest that fermented soy milk also induces a greater effect (if at all) for bone metabolism improvement as it does for plasma cholesterol level compared to soy milk” (App. Br. 11).

This argument is not persuasive. The evidence of record establishes that estrogen-deficiency was known to be associated with osteoporosis and unfavorable lipid metabolism in ovariectomized rats and postmenopausal women (FF1, FF3, FF4, FF7). Yamaguchi teaches that vitamin K₂, a component of fermented soybeans, prevents bone loss in ovariectomized rats (FF3), while Harrison teaches that the ovariectomized rat is an appropriate model for post-menopausal humans with respect to bone metabolism (FF10). Moreover, Kikuchi-Hayakawa teaches that soy milk and fermented soy milk both improve lipid metabolism in ovariectomized rats (FF9), but that fermented soy milk is more effective, and contains more easily absorbable aglycones released from the soy isoflavone glucosides (FF2, FF9). Finally,

Hayakawa teaches that fermented soy milk is more palatable than unfermented soy milk (FF11).

Given the recognized health benefits of both soy milk and fermented soy milk on conditions associated with estrogen-deficiency, we agree with the Examiner that it would have been obvious to administer fermented soy milk to post menopausal women, who have a tendency toward unfavorable lipid metabolism *and* decreased bone density. Whether or not one would have expected fermented soy milk to have a *greater* effect on bone density than unfermented soy milk is irrelevant, absent evidence of unexpected results.

Conclusions of Law

Appellants have not established that the Examiner erred in concluding that it would have been obvious to administer fermented soy milk to a human subject with a tendency toward bone loss, given the teachings of Kikuchi-Hayakawa, Harrison, and Hayakawa.

WRITTEN DESCRIPTION

The Examiner rejected claim 25 as lacking written descriptive support. According to the Examiner, the limitation “fermented soy milk having a soybean solid component content of ‘at least 6%’” is new matter (Ans. 7).

Additional Findings of Fact

FF12 The Specification, as originally filed, teaches that “[t]he fermented soy milk can be used as is, [or] concentrated to a certain degree” (Spec. 7: 5-6), it can be provided in “liquid, paste, or solid” form (*id.* at 7:

4), and that “fermented soy milk having a soybean solid content of 6% is ingested in an amount of 10-1,000 g a day per person” (*id.* at 7: 9-10).

Analysis

We will reverse this rejection. We agree with Appellants that “the application conveys to a person of skill in the art that the applicants had possession of the claimed invention” (Reply Br. 2). The Specification, as originally filed, discloses administering fermented soy milk with a soybean solid content of 6% in variable amounts (10-1,000 g a day per person), and in various forms (FF12). We agree that one of skill in the art would understand from the Specification that variable percentages of solids, i.e., higher percentages of solids, were contemplated as well.

INDEFINITENESS

The Examiner rejected Claim 25 as indefinite because it “lack[s] proper antecedent basis in the limitation: ‘a fermented soy milk’” (Ans. 4).

We will reverse this rejection as well. We agree with Appellants that one of skill in the art would understand that claim 25 “is directed to administering the same fermented soy milk as that recited in claim 17” from which it depends (Reply Br. 3).

SUMMARY

- The rejection of claims 17 and 19-23 under 35 U.S.C. § 102(b) as anticipated by Kikuchi-Hayakawa is affirmed.
- The rejection of claim 18 under 35 U.S.C. § 103 as unpatentable over Kikuchi-Hayakawa, Harrison, and Hayakawa is affirmed.

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- The rejection of claim 25 under 35 U.S.C. § 112, first paragraph, as lacking written descriptive support (new matter) is reversed.
- The rejection of claim 25 under 35 U.S.C. § 112, second paragraph, as indefinite is reversed.

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)(1)(iv)(2006).

AFFIRMED-IN-PART

dm

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