UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte RAPHAEL WARREN, JOHN M. BLEVINS, THOMAS J. KLOFTA, RYO MINOGUCHI, REGINA L. PENNINGTON, JAMES A. STAUDIGEL, PAUL R. TANNER, and MICHAEL L. VATTER

Appeal 2007-4515
Application 10/152,924
Technology Center 1600

Decided: April 11, 2008

Before DEMETRA J. MILLS, ERIC GRIMES, 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 an absorbent article comprising a skin care composition, which the Examiner has rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Background

"Antimicrobial agents are commonly used in the treatment of skin abnormalities or disorders that can lead to acute or chronic symptoms such as redness, acne, inflammation, rash, burning, stinging, itching, flaking/scaling skin, malodor, and the like" (Spec. 1). The Specification notes that the prior art teaches "skin care compositions comprising compounds such as hexamidine and its salts that can be included in the skin care compositions with other known skin active agents such as panthenol, and zinc oxide applied to absorbent articles" (Spec. 2).

Appellants teach "skin care compositions which comprise (a) from about 0.001% to about 0.1% by weight of hexamidine and either or both of (b) from about 0.001% to about 10% by weight of zinc oxide, and/or (c) from about 0.01% to about 10% by weight of niacinamide; and (d) a carrier" (Spec. 2).

Statement of the Case

The Claims

Claims 1-2, 4-16, and 18-20 are on appeal. We will focus on claim 1, which is representative and reads as follows:

> 1. An absorbent article comprising a skin care composition comprising:
> (a) from about 0.001% to about 0.1% by weight of hexamidine;
> (b) from about 0.001% to about 10% by weight of zinc oxide;
> (c) from about 0.01% to about 10% by weight of niacinamide; and
> (d) a carrier

The Examiner relies on the following prior art references to show unpatentability:

Yamaguchi	US 5,945,211	Aug. 31, 1999
Vega	US 6,153,209	Nov. 28, 2000
Ehrnsperger	US 6,160,200	Dec. 12, 2000
Osborne	US 6,716,441 B1	Apr. 6, 2004

The rejections as presented by the Examiner are as follows:

A. Claims 1-2, 4-8, 11, 14-16, and 18-20 stand rejected under 35 U.S.C. § 103(a) as being obvious over Ehrnsperger and Vega.

B. Claims 8, 9, 12, and 13 stand rejected under 35 U.S.C. § 103(a) as being obvious over Ehrnsperger, Vega, and Yamaguchi.

C. Claims 1-2, 4-16, and 18-20 stand rejected under 35 U.S.C. § 103(a) as being obvious over Osborne.

A. 35 U.S.C. § 103(a) rejection over Ehrnsperger and Vega

The Examiner argues that "both [Ehrnsperger] and [Vega] teach absorbent articles as in the instant claims; for absorbing bodily exudates and at the same time prevent any skin irritation caused by the exudates" (Ans. 10). The Examiner further argues that the "references teach coating at least a portion of the article with a skin protecting lotion or composition comprising several active agents as well as protective agents, including antimicrobial agents such as hexamidine" (Ans. 10). The Examiner contends that "absent any comparative data showing unexpected results, it would have been within the scope of a skilled artisan to choose the specific amounts of the antimicrobial, agent, skin barrier protectants, emollients and other skin protectants from the teachings of prior art" (Ans. 11).

Appellants argue that "the cited references provide, at best, long lists of components from which one could pick and choose certain combinations. However, the ability to pick and choose from a list is only effective when

one knows the combination sought. This, however, is impermissible hindsight analysis" (App. Br. 3-4). According to Appellants, "[o]bviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art." (App. Br. 4). Appellants contend that there "is no suggestion, teaching, or other 'indicator' for the skilled artisan to produce the specific combination claimed" (App. Br. 4).

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

Would it have been obvious to a person of ordinary skill in the art to form a skin composition comprising the specified amounts of hexamidine, zinc oxide and niacinamide based on the disclosures of Ehrnsperger and Vega?

Findings of Fact

1. Ehrnsperger teaches absorbent articles including diapers (Ehrnsperger 3:25-33).

2. Ehrnsperger teaches that the absorbent article may include "[s]uitable skin care compositions which may be used as, with, or in place of the body adhering compositions include Category I actives as defined by the U.S. Federal Food and Drug Administrations (FDA) Tentative Final Monograph on Skin Protectant Drug Products for Over-the-Counter Human Use" (Ehrnsperger 16:39-44).

3. Ehrnsperger teaches a list of Category I active compounds that includes "zinc oxide" (Ehrnsperger 16:48).

4. Ehrnsperger teaches a list of other agents in the skin care compositions that includes "protease inhibitors (e.g., hexamidine derivatives)" (Ehrnsperger 17:10).

5. Vega teaches that a "skin care composition is applied to the skin via a delivery vehicle such as an absorbent article" (Vega 13:64-65).

6. Vega teaches that the "skin care compositions useful in the present invention will generally comprise an emollient or mixture of emollients, a permeability enhancing agent and an immobilizing agent. Other optional ingredients may also be included such as skin care agents, rheological agents, antioxidants and the like" (Vega 15:20-25).

7. Vega teaches that "[r]epresentative barrier protectant type emollients useful in the present invention include, but are not limited to . . . vitamins such as B_3 (niacinamide)" (Vega 15:47-55).

8. Vega teaches that "[s]uitable vitamins include A, B_3, B_5, niacinamide" (Vega 27:51).

9. Vega teaches that the "emollients will generally comprise from about 5 to about 95 wt % of the skin care composition" (Vega 18:54-56).

10. Vega teaches that "[s]afe and effective skin care agents may be incorporated into the skin care composition for use herein. . . . These monographed materials are known to provide multiple skin benefits,such as skin protection, itch prevention, irritation prevention. . . . Category I actives presently include: . . . zinc oxide" (Vega 26:26-41).

11. Vega states that skin care agents may include protease inhibitors and antimicrobials (*see* Vega 26:50-55).

12. Vega teaches that "[p]articularly preferred skin care agents herein include: zinc oxide . . . hexamidine and its salts and derivatives" (Vega 27:4-6).

13. Vega teaches regarding optional components that "[a]ll of these materials are well known in the art as additives for such formulations and can be employed in appropriate amounts in the compositions for use herein" (Vega 25:61-64).

Discussion of 35 U.S.C. § 103(a) rejection over Ehrnsperger and Vega

"[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", *KSR* directs that "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions." *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007).

Analyzing the composition of claim 1 in the light of *KSR*, we find that the absorbent article with particular concentration ranges of hexamidine, zinc oxide, niacinamide, and a carrier is predictably disclosed by Ehrnsperger and Vega and used according to the established functions which were disclosed by Ehrnsperger and Vega (FF 1-13). Ehrnsperger teaches absorbent articles with skin care compositions (FF 1-2). Ehrnsperger identifies zinc oxide and hexamidine as useful in these compositions (FF 3-4).

Vega also teaches absorbent articles with skin care compositions (FF 5-6). Vega teaches that the skin care compositions should have emollients

(FF 6) and identifies niacinamide as a barrier type emollient that would be used in concentrations overlapping those in claim 1 (FF 7-9). Vega further identifies optional components of skin care compositions such as protease inhibitors like hexamidine and skin protectants like zinc oxide (FF 4, 10-12). Vega teaches that determining appropriate amounts in the composition is well known in the art (FF 13).

We conclude that claim 1 would have been obvious since Ehrnsperger and Vega teach all the elements of claim 1 and suggest the use of these compounds in combination for the predictable use in a skin care composition on an absorbent article (FF 1-13).

We reject Appellants' argument that there must be a specific "suggestion, teaching or other 'indicator' for the skilled artisan to produce the specific combination claimed" (App. Br. 4). "The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation." *KSR*, 127 S. Ct. at 1741. Consonant with the *KSR* decision, we think that a skin care composition composed solely of compounds taught by the prior art as being useful in skin care and without any indicia of secondary considerations presented would have been obvious.

We are also not persuaded by Appellants' argument that "impermissible hindsight was relied on, using the claimed invention as a guide to find the separate and individual pieces of disclosure in the cited references" (App. Br. 4). "In this case, the prior art does not merely disclose a genus of skin benefit ingredients without disclosing the particular claimed ingredient." *Perricone v. Medicis Pharmaceutical Corp.*, 432 F.3d 1368, 1377 (Fed. Cir. 2005). Rather Vega and Ehrnsperger specifically disclose

niacinamide, hexamidine, and zinc oxide in lists of skin care ingredients (FF 1-13). "That specific disclosure, even in a list, makes this case different from cases involving disclosure of a broad genus without reference to the potentially anticipating species." *Perricone*, 432 F.3d at 1377. While the *Perricone* analysis was in an anticipation context, the reasoning is equally apt in an obviousness analysis. If disclosure of particular skin benefit ingredients in a generic disclosure may be anticipatory as in *Perricone*, the disclosure of these ingredients may be even more supportive of an obviousness rejection, since with obviousness the "combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR*, 127 S.Ct. at 1739.

We affirm the rejection of claim 1 under 35 U.S.C. § 103(a). Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejection of claims 2, 4-8, 11, 14-16, and 18-20 under § 103(a), as these claims were not argued separately.

B. 35 U.S.C. § 103(a) rejection over Ehrnsperger, Vega, and Yamaguchi

Claims 8, 9, 12 and 13 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Ehrnsperger, Vega, and Yamaguchi.

The Examiner relies on Ehrnsperger and Vega as discussed above. The Examiner relies on Yamaguchi to reach the limitations of claims 8, 9, 12 and 13, drawn to zinc oxide fine particles on sanitary pads, which ultimately depend from claim 1. We will affirm this rejection since Appellants do not identify any defect in this rejection and rely upon overcoming the primary rejection of Ehrnsperger and Vega, which was affirmed above.

C. 35 U.S.C. § 103(a) rejection over Osborne

The Examiner argues that Osborne teaches a

> [C]omposition containing antibacterial agents such as hexamidine derivatives, release agents and skin protecting agents such as zinc oxide, zinc carbonate; and other ingredients such as vitamins. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare the claimed absorbent article with hexamidine, zinc oxide, niacinamide (vitamin B) and other carriers.

(Ans. 9).

Appellants argue that the "components identified by the Examiner are scattered about in the [Osborne] disclosure in long lists of possible components. One skilled in the art is provided no guidance as to how to combine the elements, particularly not as they are claimed in the present invention" (App. Br. 6).

Appellants also argue that "the examples provided in [Osborne] teach away from the claimed combination. In all the examples provided, in which the disclosure of [Osborne] is providing suggestion and motivation to combine, there is no hint at the claimed combination" (App. Br. 6).

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

Would it have been obvious to a person of ordinary skill in the art to form a skin composition comprising the specified amounts of hexamidine, zinc oxide and niacinamide based on the disclosure of Osborne?

Findings of Fact

14. Osborne teaches "effective delivery of a therapeutic skin care active to the skin via . . . disposable absorbent articles" (Osborne 1:9-11).

15. Osborne teaches "[s]kin care actives suitable for use herein include, but are not limited to skin conditioning agents, pH control agents, protease and/or enzyme inhibitors, anti-coenzymes, chelating agents, antibodies, antimicrobials, humectants, vitamins, skin protectants and/or skin soothing agents" (Osborne 5:27-31).

16. Osborne teaches "Examples of suitable vitamins include but are not limited to Vitamins B_3, B_5, niacinamide" (Osborne 5:37-38).

17. Osborne teaches "Anti-microbials useful in controlling or reducing microbial activities and derivatives . . . include but are not limited to hexamidine and its salts and derivatives" (Osborne 5:57-61).

18. Osborne teaches "active agents include barrier substances (such as zinc oxide)" (Osborne 2:9-10).

Discussion of 35 U.S.C. § 103(a) rejection over Osborne

Analyzing the composition of claim 1 in the light of *KSR* and Osborne, we find that an absorbent article with a skin care composition comprising hexamidine, zinc oxide, niacinamide, and a carrier is predictably disclosed by Osborne and used according to the established functions which were disclosed by Osborne (FF 14-18). Osborne teaches absorbent articles with skin care compositions (FF 14-15). Osborne identifies zinc oxide, niacinamide, and hexamidine as useful in these compositions (FF 16-18).

We conclude that claim 1 would have been obvious since Osborne teaches all the elements of claim 1 and suggest the use of these compounds in combination for the predictable use in a skin care composition on an

absorbent article (FF 14-18). Such a combination is merely a "predictable use of prior art elements according to their established functions." *KSR Int'l v. Teleflex Inc*., 127 S. Ct. 1727, 1740 (2007).

We are not persuaded by Appellants' argument that the "components identified by the Examiner are scattered about in the [Osborne] disclosure in long lists of possible components. One skilled in the art is provided no guidance as to how to combine the elements, particularly not as they are claimed in the present invention" (App. Br. 6). "In this case, the prior art does not merely disclose a genus of skin benefit ingredients without disclosing the particular claimed ingredient." *Perricone v. Medicis Pharmaceutical Corp*., 432 F.3d 1368, 1377 (Fed. Cir. 2005). Rather Osborne specifically discloses niacinamide, hexamidine, and zinc oxide in extensive lists of skin care ingredients (FF 14-18). "That specific disclosure, even in a list, makes this case different from cases involving disclosure of a broad genus without reference to the potentially anticipating species." *Perricone*, 432 F.3d at 1377. As noted above, *Perricone* analyzed in an anticipation context, but the reasoning is equally apt in an obviousness analysis. If disclosure of particular skin benefit ingredients in a generic disclosure may be anticipatory as in *Perricone*, the disclosure of these ingredients may be even more supportive of an obviousness rejection, since with obviousness the "combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR*, 127 S.Ct. at 1739.

We also reject Appellants' argument that "the examples provided in [Osborne] teach away from the claimed combination. In all the examples

provided, in which the disclosure of [Osborne] is providing suggestion and motivation to combine, there is no hint at the claimed combination" (App. Br. 6). Selection of preferred combinations for examples does not represent a teaching away. "A statement that a particular combination is not a preferred embodiment does not teach away absent clear discouragement of that combination." *Syntex v. Apotex, Inc.*, 407 F.3d 1371, 1380 (Fed. Cir. 2005). In the current case, Appellants have not provided any evidence for discouragement of any combination of compounds disclosed in Osborne (*see* App. Br. 6). Like our appellate reviewing court, "[w]e 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).

We affirm the rejection of claim 1 under 35 U.S.C. § 103(a). Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejection of claims 2, 4-16, and 18-20 under § 103(a), as these claims were not argued separately.

CONCLUSION

In summary, we affirm the rejection of claim 1 under 35 U.S.C. § 103(a) over Ehrnsperger and Vega. We also affirm the rejection of claim 1 under 35 U.S.C. § 103(a) over Osborne. We affirm the rejection of claims 8, 9, 12 and 13 over Ehrnsperger, Vega, and Yamaguchi. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejection of claims 2, 4-16, and 18-20 under § 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).

AFFIRMED

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