

-The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JAN C. SMIMON, CHRISTOPH M. SCHEMPP,
ERWIN SCHOEPPF, and BIRGIT SIMON-HAARHAUS

Appeal No. 2006-0208
Application No. 09/856,694

ON BRIEF

Before SCHEINER, ADAMS, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 36-45 and 56. Claims 36 and 37 are representative of the subject matter on appeal, and read as follows:

36. A method for treating a condition, comprising administering to a subject in need thereof an effective amount of a composition consisting of (a) pharmaceutically acceptable carrier and (b) active agent consisting of (i) hyperforin or (ii) hyperforin and hypericin, wherein said condition is selected from the group consisting of an inflammatory skin condition, a precancerous condition, a geriatric skin condition, and a microbial skin infection.
37. The method according to claim 36, wherein the condition is eczema.

Claims 36-45 and 56 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of the Hypericum Homepage,¹ Merck,² Shroot³ and Lacefield.⁴ In addition, claims 36, 38-45 and 56 stand rejected under 35 U.S.C. § 103(a) as being anticipated by the combination of Valavicius⁵ and Chavez,⁶ or the combination of Valavicius, Chavez, Hypericum Homepage and Decosterd.⁷ After careful review of the record and consideration of the issues before us, we affirm the rejection of claims 36-45 and 56 over the combination of Hypericum Homepage, Merck, Shroot and Lacefield. Because we affirm that rejection, we decline to reach the merits of the rejection of claims 36, 38-45 and 56 under 35 U.S.C. § 103(a) over the combination of Valavicius and Chavez or the combination of Valavicius, Chavez, Hypericum Homepage and Decosterd.

DISCUSSION

Claims 36-45 and 56 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Hypericum Homepage, Merck, Shroot and Lacefield.

¹ Bloomfield et al., (Hypericum Homepage), Hypericum & Depression, Ed. J. Sedillos, Prelude Press (1996), copy made available from hypericum.com; <http://hypericum.com/hyp20.htm>.

² The Merck Manual, Copyright 1995-2002, <http://www.merck.com/pubs/mmanual/section10/chapter111/111a.htm>

³ Shroot et al. (Shroot), U.S. Pat. No. 5,151,534, issued September 29, 1992.

⁴ Lacefield et al. (Lacefield), U.S. Pat. No. 4,021,553, issued May 3, 1977.

⁵ Valavicius et al. (Valavicius), "Antitumor Activity of Herbs of the Lithuanian SSR," Trudy Akademii Nauk Litovski, SSR, Series B, pp. 110-113 (a986), translation by Ralph McElroy Translation Company.

⁶ Chavez et al. (Chavez), "Saint John's Wort," Hospital Pharmacy, Vol. 32, No. 12, pp. 1621-1632 (1997).

⁷ Decosterd et al. (Decosterd), "New Hyperforin Derivatives from Hypericum revolutum VAHL with Growth-Inhibitory Activity against a Human Colon Carcinoma Cell Line," Helvetica Chimica Acta, Vol. 77, pp. 464-471 (1989).

The Hypericum Homepage reference is cited for teaching that extracts of St. John's Wort when applied topically exhibit anti-inflammatory and antibacterial effects, and that those effects are attributed to the presence of hyperforin in the extract. See Examiner's Answer, page 4. The examiner notes that the reference fails to teach the use of hyperforin in a pharmaceutical carrier. See id. at 5.

From the teachings of the Hypericum Homepage, the examiner concludes that "since hyperforin was a known and commercially available product at the time of the claimed invention (see specification, page 12), it would have been obvious to one of ordinary skill in the art to use hyperforin . . . in a method for treating inflammatory skin conditions because of its disclosed anti-inflammatory effect." Id. Moreover, according to the examiner, "it would have been . . . obvious to one of ordinary skill in the art to include a pharmaceutical carrier because it was standard practice to do so, at the time the claimed invention was made." Id.

The examiner then cites the Merck Manual for its teaching that "eczema, contact eczema, atopic eczema, hand and foot eczemas and lichen are each characterized as superficial inflammations of the skin of varying degrees." Id. at 6. Shroot and Lacefield are also cited for teaching that eczema is an inflammatory condition. The examiner concludes:

At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to topically treat any of the aforementioned eczemas with hyperforin because of the anti-inflammatory activity as disclosed by [Hypericum Homepage]. Moreover, at the time of the claimed invention, one of ordinary skill

in the art would have been motivated by [Hypericum Homepage] and Merck to topically apply hyperforin in a method for treating inflammation and eczemas with a reasonable expectation of success.

Id.

"[T]he Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art. '[The Examiner] can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.'" In re Fritch, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (citation omitted). An adequate showing of motivation to combine requires "evidence that 'a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.'" Ecolochem, Inc. v. Southern Calif. Edison Co., 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1076 (Fed. Cir. 2000). We conclude that the examiner has met the burden of establishing a prima facie case of obviousness, and the rejection is affirmed.

Appellants argue that St. John's Wort extract is not the same thing as hyperforin, as the plant extract contains at least ten different components, and is thus "a complicated combination of many different ingredients." Appeal Brief,⁸

⁸ All references to the Appeal Brief are to the "Substitute Brief on Appeal," stamped March 2, 2005.

page 7. Thus, appellants assert that although the Hypericum Homepage “mentions hyperforin as possibly being responsible for St. John’s Wort having an anti-inflammatory property when used externally, it does not teach the use of a purified, effective amount of hyperforin in a pharmaceutical composition for treating an inflammatory skin condition, a precancerous condition, a geriatric skin condition or a microbial skin infection.” Id.⁹ Moreover, according to appellants, that statement in the Hypericum Homepage cites to a reference, which maybe a better reference; but that reference was not cited and the contents are not known, and that “[I]n fact, this reference may not support the PTO’s case at all.” Reply Brief, page 2. Appellants argue further that the examiner has not provided a sufficient motivational statement to support the assertions that it would have been obvious to optimize effective volumes and concentration as a matter of routine experimentation, or that it would have been obvious to use hyperforin with a reasonable expectation of success because of its known benefit as disclosed by the Hypericum Homepage. See Appeal Brief, page 7.

Appellants also argue that Merck and the other secondary references do not cure the deficiencies of the Hypericum Homepage, as they merely disclose various types of inflammatory skin disorders, stating that the examiner’s assumption that treatment of one type of inflammation would be a treatment for

⁹ We need not address appellants’ argument that the embodiment wherein both hyperforin and hypericin are both present is not addressed by the art of record, see Appeal Brief, page 7, as the claims are not so limited.

another type “simply isn’t true.” Id. at 8. There is no scientific reason, according to appellants, to believe that such treatment would be suitable for the disorders listed in claim 36 and in the rejected dependent claims. See id. at 8. Appellants contend that the examiner “has failed to support the assumption that all substances that have anti-inflammatory properties are effective and safe for treating specific diseases that produce an anti-inflammatory response,” and thus there is no expectation of success provided by the combination. Id.

Appellants’ arguments have been considered, but are not found to be convincing. The Hypericum Homepage clearly states that “[a]nti-inflammatory and antibacterial effects of externally applied St. John’s Wort preparations have been reported and attributed the presence of hyperforin,” and thus one of ordinary skill in the art would have a reasonable expectation of success of externally applying hyperforin, the stated active ingredient, to treat inflammatory skin conditions. See In re O’Farrell, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (noting that all that is required is a reasonable expectation of success, not absolute predictability of success). Moreover, as noted by the examiner, the inclusion of a pharmaceutically acceptable carrier was a well known practice at the time of invention. As to the optimization of effective volumes and concentrations, those are result effective variables, and it would have been obvious to optimize those parameters as a matter of routine experimentation. See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 235 (CCPA 1980) (noting that the determination of the optimum values of result effective variables is ordinarily within the skill of the art); see also In re Aller, 220

F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) ("[W]here general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.").

The fact that the Hypericum Homepage cites to another reference does not take away from the teaching of the Hypericum Homepage. Although appellants argue that the "reference [relied upon by the Hypericum Homepage] may not support the PTO's case at all," appellants have not provided any evidence to that effect, and arguments of counsel cannot take the place of evidence in the record. See in re Scarbrough, 500 F.2d 560, 566, 182 USPQ 298, 302 (CCPA 1974); In re DeBlauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984).

As to the treatment of eczema as required by claim 37, and the inflammatory skin disorders recited in claim 38, the Merck Manual, as well as the Shroot and Lacefield references, establish that at the time of the invention, these were all known by the ordinary artisan to be skin inflammations. As the Hypericum Homepage states that "[a]nti-inflammatory and antibacterial effects of externally applied St. John's Wort preparations have been reported and attributed the presence of hyperforin," the ordinary artisan would reasonably expect that hyperforin could be used to treat inflammatory condition of the skin such as eczema.

With respect to claims 38, appellants assert that none of the references teach or suggest the use of hyperforin to treat lymphoma or leukemia. See Appeal Brief, page 8. Claim 38, however, is not limited to those conditions, and

thus that argument is not persuasive as to the separate patentability of that claim, and the rejection as to claim 38 is affirmed. In addition, appellants contend that they attempted to put those embodiments into an independent claim and also have separate dependent claims, but the examiner refused to enter such an amendment. See id. That is petitionable subject matter, however, and therefore the decision of the examiner not enter the amendment is not subject to review by appeal.

As to claim 56, appellants argue that “none of the art of record suggests the purity level recited in this claim.” Appeal Brief, page 4. As noted by the examiner, however, page 12 of the specification states that hyperforin is available commercially, and also states that the purity of the commercially available hyperforin is greater than 90%. Thus, the state of the art at the time of filing is that hyperforin having a purity level greater than 90% was available commercially, and the rejection as to claim 56 is also affirmed.

CONCLUSION

Because the examiner has set forth a prima facie case of obviousness over claims 36-45 and 56 over the combination of Hypericum Homepage, Merck, Shroot and Lacefield, that rejection is affirmed. As the rejection over the combination of Hypericum Homepage, Merck, Shroot and Lacefield reaches all of the claims on appeal, we decline to reach the merits of the remaining rejections of record.

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

AFFIRMED

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) BOARD OF PATENT
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Lora M. Green)
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