

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* PETER STYCZYNSKI,  
GURPREET S. AHLUWALIA, and DOUGLAS SHANDER

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Appeal 2008-1912  
Application 10/198,536  
Technology Center 1600

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Decided: March 20, 2008

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Before LORA M. GREEN, RICHARD M. LEBOVITZ, and  
JEFFREY N. FREDMAN, *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 1-8, 15-21 and 36-42.<sup>1</sup> We have

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<sup>1</sup> Claims 9-14 were cancelled in the Reply Brief (Reply Br. 1), and claims  
22-35 stand withdrawn from consideration (App. Br. 2).

jurisdiction under 35 U.S.C. § 6(b). Claim 1 is representative of the claims on appeal, and reads as follows:

1. A method of reducing human hair growth, comprising selecting an area of skin from which reduced hair growth is desired, and applying to the area of the skin, in an amount effective to reduce hair growth, a composition including  $\alpha$ -difluoromethylornithine and a dermatologically acceptable vehicle comprising urea.

The Examiner relies on the following references:

Heverhagen	US 5,271,942	Dec. 21, 1993
Boxall	WO 94/21216	Sep. 29, 1994

We affirm.

#### DISCUSSION

Claims 1-8, 15-21 and 36-42 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Boxall and Heverhagen. As Appellants do not present separate arguments as to claims 1-8, 15-21, 37, and 39-42, they stand or fall with claim 1. 37 C.F.R. § 41.37(c)(1)(vii).

Boxall is cited for teaching a composition for inhibiting hair growth, and in particular, human hair growth, comprising  $\alpha$ -difluoromethylornithine (DFMO) as the hair growth inhibiting agent (Ans. 3). The Examiner notes that Boxall “does not teach a composition for inhibiting hair growth in which the vehicle comprises urea” (*Id.*).

Heverhagen is cited for teaching a composition for removing hair from the skin comprising demineralized and sterilized water containing urea (*id.* at 4).

According to the Examiner:

It would have been obvious to combine DFMO and urea in a composition because the prior art teaches that both compounds inhibit hair growth individually. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, 1072 (CCPA 1980).

(*Id.* at 4.)

The burden is on the examiner to set forth a prima facie case of obviousness. *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The Supreme Court has recently emphasized that “the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR Int’l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). Moreover, an “[e]xpress suggestion to substitute one equivalent for another need not be present to render such substitution obvious.” *In re Fout*, 675 F.2d 297, 301 (CCPA 1982). We conclude that the Examiner has set forth a prima facie case of obvious, so we thus turn to Appellants’ arguments and evidence presented in rebuttal.

As to Boxall, Appellants argue that Boxall developed a specific vehicle that forms a stable emulsion with the “highly ionic DFMO,” which vehicle does not contain urea or a compound similar to urea (App. Br. 6-7). Heverhagen states that urea denatures proteins, and is thus chemically active, and thus, according to Appellants, a “person of ordinary skill in the art would not be motivated to add a chemically active ingredient like urea to the carefully crafted DMFO emulsion vehicle described by Boxall. That person would be concerned that adding urea to the vehicle would destabilize the emulsion.” (*Id.* at 8.)

Appellants’ arguments are not convincing. While Boxall does teach a specific vehicle, Appellants’ claim 1 recites applying a composition “including  $\alpha$ -difluoromethylornithine and a dermatologically acceptable vehicle comprising urea.” We interpret the transitional phrase “including” as synonymous with “comprising,” and thus the composition applied in the method of claim 1 does not exclude the vehicle taught by Boxall. In addition, Boxall teaches that “other water-soluble, pharmacological agents may be delivered to the skin by incorporating from about 1 to 20% of such an agent in the previously described vehicle.” (Boxall p. 7, ll. 21-29.) The urea as taught by Heverhagen would be such a water-soluble, pharmacological agent. All that is required is a reasonable expectation of success, not absolute predictability of success. *In re O’Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988).

Moreover, while Appellants argue that the ordinary artisan would not be motivated to add a chemically active agent to the vehicle of Boxall, they present no evidence that the ordinary artisan would expect urea to negatively interact with the DFMO and the vehicle taught by Boxall. Note that

arguments of counsel cannot take the place of evidence in the record. *In re Scarbrough*, 500 F.2d 560, 566 (CCPA 1974).

As to Heverhagen, Appellants argue that Heverhagen “states that urea can denature hair root proteins and that this diminishes hair growth,” but included no data to support those statements (App. Br. 6-7). Appellants assert further that Heverhagen discloses only small quantities (0.3% to 1.2%) of urea (*id.* at 7). Appellants assert that they, however “have provided *in vivo* test results . . . demonstrating conclusively that urea does not measurably reduce hair growth.” (*Id.* at 8.) Specifically, Appellants rely on paragraphs 3 and 4 of the Declaration of Gurpreet S. Ahluwalia (Exhibit 1 to the Appeal Brief), which demonstrates that a composition comprising 2% urea did not have a measurable effect on hair growth (Ahluwalia Declaration,<sup>2</sup> ¶ 4). According to Appellants:

A person of ordinary skill in the art would recognize that Heverhagen provides no data demonstrating that urea actually works to reduce hair growth. That person, to the extent interested in urea, would initially test urea to see if it, in fact, has a measurable effect on hair growth and would conclude (like applicants) that urea does not measurably reduce hair growth. In that context, there is absolutely no motivation to combine Heverhagen's urea with Boxall's DFMO-containing composition.

(App. Br. 8-9)

Heverhagen teaches the use of an agent, comprising demineralized water and sterilized water, containing a urea, for reducing human hair growth (Heverhagen col. 1, ll. 5-6, 43-45). Heverhagen also teaches that the

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<sup>2</sup> All references to the Ahluwalia Declaration are to the Second Supplemental Declaration of Gurpreet S. Ahluwalia Under 37 C.F.R. § 1.132, attached as Exhibit 1 to the Appeal Brief.

agent can contain other ingredients (Heverhagen, col. 1, 1, 58-col. 2, 1. 52).

Heverhagen specifically teaches that:

It was found, on comparison of hair growth on treated and untreated areas of the body, that the lengths of the hairs which subsequently grew on the treated areas were distinctly smaller than those on the untreated areas of the body.

(Heverhagen, col. 2, ll. 58-62.)

Thus, the ordinary artisan, reading Heverhagen, would expect that applying aqueous compositions of urea to areas of the human body would reduce hair growth.

Moreover, we find that the Ahluwalia Declaration does not teach to the contrary. In the Declaration, the compositions were tested in the Golden Syrian Hamster assay, which the Declarant states “has been used by Gillette for many years to evaluate whether compounds inhibit hair growth.”

(Ahluwalia Declaration, ¶ 3.) Heverhagen, however, reports that hair growth was reduced on areas of the human body. The ordinary artisan would understand that results obtained using animal models may not provide the same results as when used on humans. Therefore, the ordinary artisan would not read the results provided by the Ahluwalia Declaration stating that 2% urea plus a vehicle did not have a measurable effect of hair growth (Ahluwalia Declaration, ¶ 4), as necessarily being the same results that would be obtained when applied to humans. Thus, again, we do not find Appellants arguments convincing.

Appellants assert further that the “*in vivo* data submitted by [Appellants] demonstrates the unexpectedly superior hair growth-reducing properties of a composition containing DFMO and urea as compared with

compositions including either agent alone.” (App. Br. 10, relying on Ahluwalia Declaration, ¶¶ 3 and 4).

We also do not find the Ahluwalia Declaration demonstrates unexpected results sufficient to rebut the Examiner’s prima facie case of obviousness. Claim 1 encompasses a composition containing any amount of DFMO and any amount of urea, in any proportion of DFMO to urea. As noted by the Examiner, (Ans. 6), the Declaration provides results for only one test composition including both DMFO and urea. Specifically, the Declaration states that in the Golden Syrian Hamster assay, the data “clearly demonstrates that administration of 2% urea in combination with 1% DFMO provided approximately 64% inhibition of hair mass compared to either 2% urea alone, which did not have a measurable effect on hair growth (about 1% inhibition), or 1% DFMO alone which showed only about 30% inhibition of hair growth.” (Ahluwalia Declaration, ¶ 4.) Thus, Appellants showing of unexpected results are not commensurate in scope with the subject matter of claim 1.

Appellants assert that their one dose is “more than ample to demonstrate the unexpected results achieved,” as it is higher than the dose used by Heverhagen (Reply Br. 3). Appellants did, however, use a higher does, and it is unclear if the same results would be obtained if smaller amounts, such as the 0.3% to 1.2% taught by Heverhagen, were used, or if different proportions of urea to DFMO were used.

Thus, we conclude that the Examiner has set forth a prima facie case of obviousness as to claim 1 that has not been adequately rebutted by Appellants, and the rejection is affirmed as to that claims. As claims 1-8,

15-21, 37, and 39-42, stand or fall with claim 1, the rejection is affirmed as to those claims as well.

As to claim 36, Appellants argue that it includes their theory of why urea enhances penetration of DFMO through the skin, that is, it enhances the water holding capacity of the skin, which mechanism is not disclosed by either Boxall or Heverhagen (App. Br. 12).

Appellants' argument is not convincing. As set forth above, we conclude that the ordinary artisan would have been motivated to combine urea with DFMO to reduce hair growth. The ability of the urea used in the method of claim 1 to enhance the water holding capacity of the skin is an inherent property of the urea, and “[n]ewly discovered results of known processes directed to the same purpose are not patentable because such results are inherent.” *Bristol Myers Squibb v. Ben-Venue Laboratories*, 246 F.3d 1368 (Fed. Cir. 2001). Thus, we also affirm the rejection as to claim 36.

As to claims 38, Appellants argue that the claim requires at least 2% urea, whereas Heverhagen teaches “far lower quantities of urea—0.3% to 1.2% by weight.” (App. Br. 12.)

Appellants' argument is again not convincing. The concentration of urea is a result effective variable, and determining the optimum value of a result effective variables is ordinarily within the skill of the art. *In re Boesch*, 617 F.2d 272, 276 (CCPA 1980). Moreover, the Awluwalia Declaration does not convince us otherwise as claim 38 does not limit the amount of DFMO in the composition used to inhibit hair growth. Thus, the rejection is also affirmed as to claim 38.

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### CONCLUSION

In summary, we affirm the rejection of claims 1-8, 15-21 and 36-42 under 35 U.S.C. § 103(a) as being obvious over the combination of Boxall and Heverhagen.

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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