

# United States Court of Appeals for the Federal Circuit

98-1258

(Serial No. 07/849,191)

IN RE JOYCE A. CORTRIGHT,

Joseph B. Taphorn, of Poughkeepsie, New York, argued for appellant.

Scott A. Chambers, Associate Solicitor, U.S. Patent and Trademark Office, of Arlington, Virginia, argued for the appellee. With him on the brief were Nancy J. Linck, Solicitor, Albin F. Drost, Deputy Solicitor, and Linda Moncys Isacson, Associate Solicitor.

Appealed from: U.S. Patent and Trademark Office  
Board of Patent Appeals and Interferences

# United States Court of Appeals for the Federal Circuit

98-1258

(Serial No. 07/849,191)

IN RE JOYCE A. CORTRIGHT

---

DECIDED: January 19, 1999

---

Before MAYER, Chief Judge, NEWMAN, and RADER, Circuit Judges.

MAYER, Chief Judge.

Joyce A. Cortright appeals the September 23 and November 28, 1997, decisions of the United States Board of Patent Appeals and Interferences sustaining the rejection of claims 1 and 15 of patent application Serial No. 07/849,191 under 35 U.S.C. § 112, ¶ 1 (1994). Because the board erred with respect to claim 1 but not claim 15, we affirm-in-part, reverse-in-part, and remand.

## Background

Cortright's patent application, filed in 1992, concerns a method of treating baldness by applying Bag Balm,<sup>®</sup> a commercially available product used to soften cow udders, to human scalp. Claims 1 and 15 are the only claims on appeal. Claim 1 recites a method of "treating scalp baldness with an antimicrobial to restore hair growth,

which comprises rubbing into the scalp the ointment wherein the active ingredient 8-hydroxy-quinoline sulfate 0.3% is carried in a petrolatum and lanolin base.” Claim 15 recites a method of “offsetting the effects of lower levels of a male hormone being supplied by arteries to the papilla of scalp hair follicles with the active agent 8-hydroxy-quinoline sulfate to cause hair to grow again on the scalp, comprising rubbing into the scalp the ointment having the active agent 8-hydroxy-quinoline sulfate 0.3% carried in a petrolatum and lanolin base so that the active agent reaches the papilla.”

The examiner rejected the claims under 35 U.S.C. § 101 (1994) as lacking utility. According to the examiner, Cortright’s statements of utility, namely, her claims of treating baldness, are suspect because “baldness is generally accepted in the art as being incurable . . . .” The examiner, therefore, required clinical evidence to establish the claimed utility, which Cortright did not supply. Furthermore, with respect to claim 15’s recitation of offsetting the effects of lower levels of a male hormone, Cortright “offered no proof that such an off-set occurs and has disclosed that this is only speculation.” The examiner also rejected the claims under 35 U.S.C. § 102(a) (1994), arguing that the admitted prior art anticipates the claims because the written description discloses that Bag Balm<sup>®</sup> has been applied to human skin and the “scalp is the skin of the head.” Cortright appealed these rejections to the Board of Patent Appeals and Interferences.

In its September 23, 1997, decision, the board reversed the section 101 rejection because the examiner did not set out sufficient reasons for finding Cortright’s statements of utility incredible. It noted that “there is no per se requirement for clinical

evidence to establish the utility of any invention” and the examples in Cortright’s application are objective evidence. The board also reversed the section 102(a) rejection because although the prior art discloses the application of Bag Balm<sup>®</sup> to human skin, it does not disclose applying it to bald, human scalp.

Despite these reversals, Cortright did not prevail because the board found a new ground for rejecting the claims: that they are based on a non-enabling disclosure in violation of 35 U.S.C. § 112, ¶ 1. The board found that Cortright’s written description does not teach those of ordinary skill in the art how to make and use the claimed invention without undue experimentation because it “fails to provide any teachings as to the administration of Bag Balm<sup>®</sup> in a manner which (i) restore[s] hair growth (claim 1), or (ii) ‘offset[s] the effects of lower levels of male hormone being supplied by arteries to the papilla of scalp hair follicles’ (claim 15).” The board explained that Example 1 does not show that applying a teaspoon of Bag Balm<sup>®</sup> to the scalp daily for about one month “restored hair growth” and that Examples 2 and 3 do not disclose the amount of Bag Balm<sup>®</sup> to apply or how to restore hair growth. With respect to claim 15, the board found that the written description “merely surmis[es] that the active ingredient, 8-hydroxy-quinoline sulfate, even reaches the papilla,” which would not enable one of ordinary skill to use the claimed method. Finally, the board observed that the breadth of the claims and the unpredictable nature of the art of hair growth aggravated its finding that those of ordinary skill in the art would not be able to practice the invention without undue experimentation.

Cortright requested reconsideration, which the board denied in a November 28, 1997, opinion. The board explained that claim 1 is not enabled because it claims “restor[ing] hair growth,” which the board interpreted as requiring the user’s hair “to return to its original state,” that is, a full head of hair. Thus, the board’s rejection was not based on complete non-enablement, as the original decision had implied, but on the claim not being commensurate with the scope of the disclosure. With respect to claim 15, the board maintained its general non-enablement rejection, adding that “there is no evidence of record that the resultant hair growth is due to (i) the stimulation of the papilla, and (ii) the offsetting [of] the effects of lower male hormone which is supplied by arteries to the papilla, and not due to some other mechanism(s).” Cortright appeals.

#### Discussion

“Whether making and using an invention would have required undue experimentation, and thus whether a disclosure is enabling under 35 U.S.C. § 112, ¶ 1 (1994), is a legal conclusion based upon underlying factual inquiries.” Johns Hopkins Univ. v. Cellpro, Inc., 152 F.3d 1342, 1354, 47 USPQ2d 1705, 1713 (Fed. Cir. 1998). Utility is a factual issue, which we review for clear error. See Cross v. Iizuka, 753 F.2d 1040, 1044 n.7, 224 USPQ 739, 742 n.7 (Fed. Cir. 1985); see also In re Zurko, 142 F.3d 1447, 1449, 46 USPQ2d 1691, 1693 (Fed. Cir.), cert. granted, 119 S. Ct. 401 (1998).

Section 112, ¶ 1 provides:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the

same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, ¶ 1. A lack of enablement rejection under section 112, ¶ 1 is appropriate where the written description fails to teach those in the art to make and use the invention as broadly as it is claimed without undue experimentation. See In re Vaeck, 947 F.2d 488, 495-96, 10 USPQ2d 1438, 1444 (Fed. Cir. 1991).

This rejection takes several forms. The PTO will make a scope of enablement rejection where the written description enables something within the scope of the claims, but the claims are not limited to that scope. See Manual of Patent Examining Procedures (“M.P.E.P.”) § 706.03(c), form ¶ 7.31.03 (Rev. 3, July 1997). This type of rejection is marked by language stating that the specification does not enable one of ordinary skill to use the invention commensurate with the scope of the claims. On the other hand, if the written description does not enable any subject matter within the scope of the claims, the PTO will make a general enablement rejection, stating that the specification does not teach how to make or use the invention. See M.P.E.P. § 706.03(c), form ¶ 7.31.02.

If the written description fails to illuminate a credible utility, the PTO will make both a section 112, ¶ 1 rejection for failure to teach how to use the invention and a section 101 rejection for lack of utility. See M.P.E.P. § 706.03(a), form ¶ 7.05.04. This dual rejection occurs because “[t]he how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical utility for the invention.” In re Ziegler, 992 F.2d 1197, 1200, 26 USPQ2d 1600, 1603 (Fed. Cir. 1993). Thus, an applicant’s failure to disclose how to

use an invention may support a rejection under either section 112, ¶ 1 for lack of enablement as a result of “the specification’s . . . failure to disclose adequately to one ordinarily skilled in the art ‘how to use’ the invention without undue experimentation,” or section 101 for lack of utility “when there is a complete absence of data supporting the statements which set forth the desired results of the claimed invention.” Environtech Corp. v. Al George, Inc., 730 F.2d 753, 762, 221 USPQ 473, 480 (Fed. Cir. 1984); see also In re Brana, 51 F.3d 1560, 1564 n.12, 34 USPQ2d 1436, 1439 n.12 (Fed. Cir. 1995) (The “absence of utility can be the basis of a rejection under both 35 U.S.C. § 101 and § 112 ¶ 1.”); In re Fouche, 439 F.2d 1237, 1243, 169 USPQ 429, 434 (CCPA 1971) (“[I]f [certain] compositions are in fact useless, appellant’s specification cannot have taught how to use them.”).

The PTO cannot make this type of rejection, however, unless it has reason to doubt the objective truth of the statements contained in the written description. See Brana, 51 F.3d at 1566, 34 USPQ2d at 1441 (“[T]he PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure. Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention’s asserted utility.”) (citations omitted); In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971) (“[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken

as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.”). The PTO may establish a reason to doubt an invention’s asserted utility when the written description “suggest[s] an inherently unbelievable undertaking or involve[s] implausible scientific principles.” Brana, 51 F.3d at 1566, 34 USPQ2d at 1441; see also In re Eltgroth, 419 F.2d 918, 164 USPQ 221 (CCPA 1970) (control of aging process). Treating baldness was once considered an inherently unbelievable undertaking. See In re Ferens, 417 F.2d 1072, 1074, 163 USPQ 609, 611 (CCPA 1969); In re Oberwener, 115 F.2d 826, 829, 47 USPQ 455, 458 (CCPA 1940).

Since then, however, treatments for baldness have gained acceptance. Rogaine® (minoxidil) and Propecia® are recognized as effective in treating baldness. See Doug Levy, FDA Approves New Treatment for Males Fighting Baldness, USA Today, Dec. 23, 1997, at A1; Pharmaceutical Companies Are Brushing up on Hair-Restorers Medicine, Los Angeles Times, Jun. 6, 1996, at D12. In addition, the PTO has granted approximately one hundred patents on methods of treating baldness. Some of these patents disclose applying an electric current to the scalp, see, e.g., U.S. Pat. No. 5,800,477, whereas others teach ingesting substances orally or applying a salve of some kind to the scalp, see, e.g., U.S. Pat. No. 5,777,134. Some patents disclose the active ingredient in chemical terms. See, e.g., U.S. Pat. No. 5,777,134 (5 alpha-reductase inhibitor); U.S. Pat. No. 5,767,152 (cyanocarboxylic acid derivatives); U.S. Pat. No. 4,139,619 (formula for minoxidil). Other patents, however,

disclose baldness remedies made from more mundane materials, such as Dead Sea mud (U.S. Pat. No. 5,679,378); emu oil (U.S. Pat. No. 5,744,128); potato peelings and lantana leaves (U.S. Pat. No. 5,665,342); and vitamin D3 and aloe (U.S. Pat. No. 5,597,575).\*

### **Claim 1**

With respect to claim 1, the examiner made a lack of utility rejection under section 101 arguing that the asserted statements of utility were incredible in light of Cortright's failure to prove utility with clinical evidence. The board first appeared to make a generic enablement rejection under section 112, ¶ 1, focusing on "the lack of any teachings or guidance as to how to perform the claimed methods and the unpredictable nature of the art of restoring hair growth." Upon reconsideration, however, the board clarified that its rejection pertained to scope. It took the position that the broadest interpretation of "restore hair growth" requires the application of Bag Balm<sup>®</sup> to "return" the user's hair "to its original state," that is, a full head of hair. Because Cortright's written description discloses results of only "three times as much hair growth as two months earlier," "filling-in some," and "fuzz," the board reasoned, it does not support the breadth of the claims.

Although the PTO must give claims their broadest reasonable interpretation, this interpretation must be consistent with the one that those skilled in the art would reach.

---

\* See also U.S. Pat. No. 5,674,510 (salve of garlic powder, brewer's yeast, grapefruit juice, acetic acid, and kelp), U.S. Pat. No. 5,750,108 (salves of tea tree oil; chlorine dioxide and acidic solution; saw palmetto berry extract), U.S. Pat. No. 5,695,748 (salves of sage, aloe, and nettles; castor oil, shea butter, wheat germ oil, and white iodine); U.S. Pat. No. 5,494,667 (salve of pine extract and bamboo extract or Japanese apricot).

See In re Morris, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997) (“[T]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art . . . .”); In re Bond, 910 F.2d 831, 833, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990) (“It is axiomatic that, in proceedings before the PTO, claims in an application are to be given their broadest reasonable interpretation consistent with the specification, . . . and that claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art.”) (emphasis added); see also M.P.E.P. § 2111.01 (“[T]he words of a claim . . . must be read as they would be interpreted by those of ordinary skill in the art.”). Prior art references may be “indicative of what all those skilled in the art generally believe a certain term means . . . [and] can often help to demonstrate how a disputed term is used by those skilled in the art.” Vitronics Corp. v. Conceptor, Inc., 90 F.3d 1576, 1584, 39 USPQ2d 1573, 1578-79 (Fed. Cir. 1996). Accordingly, the PTO’s interpretation of claim terms should not be so broad that it conflicts with the meaning given to identical terms in other patents from analogous art. Cf. Morris, 127 F.3d at 1056, 44 USPQ2d at 1029 (approving the board’s definition of claim terms consistent with their definitions in CCPA cases).

The PTO’s construction of “restore hair growth” in the present case is inconsistent with its previous definitions. U.S. Pat. Nos. 5,695,748 (“the ‘748 patent”), 5,679,378 (“the ‘378 patent”), and 5,578,599 (“the ‘599 patent”), for example, each recite a method of restoring hair growth. The ‘748 patent recites:

A process . . . for restoring hair growth which comprises the steps of:

- (a) applying a cleansing mixture of sage, aloe and nettles to the hair and scalp in an amount and for a period of time sufficient to effect cleansing and then removing same;
- (b) applying a treatment mixture of castor oil, shea butter, wheat germ oil and white iodine to the hair and scalp in an amount and for a period of time effective to treat the hair and scalp; and
- (c) heating the treatment mixture on the hair and scalp for a period of time sufficient to promote penetration of the treatment mixture into the hair and scalp and then removing the treatment mixture.

'748 patent (Claim 1) (emphasis added). The accompanying disclosure reveals five-examples in which women and men practiced the claimed method. One "subject's hair began to fill-in in the previously balding and thinning areas and the subject . . . achieved a significant degree of improvement . . . ." Id. (Example 3). For another subject, "there [was] a partial filling-in and restoration of the bald spot on the top of the subject's head." Id. (Example 4). A third subject noticed that he had "fifty percent more hair in both the frontal and middle sections of his scalp." Id. (Example 6).

The '378 patent recites:

The method for the restoration of hair growth . . . which comprises the steps of:  
 applying a finite layer of Dead Sea mud to the body surface area to be treated for the restoration of hair growth . . . ;  
 allowing said layer to be undisturbed for a finite time;  
 and  
 rinsing said layer from said surface area.

'378 patent (Claim 1) (emphasis added). The accompanying disclosure reveals an example in which a man noticed "[m]any sprouts of . . . new hair" after practicing the method for six weeks and ultimately "approximately 25% regrowth over the entire previously bald scalp." Id. (Example 1). Another example discloses the results of a

five-month study of men who practiced the invention. In this study, the participants noticed an increase in the number of new hairs on their scalp per month, which varied from 0 to 22. Although some participants reported significant growth of hair, there was no evidence that the claimed method resulted in full heads of hair. See id. (Example 3).

The '599 patent recites:

A method for increasing or restoring hair growth over the sole administration of a topical minoxidil treatment comprising the concomitant administration of:

a topical preparation of minoxidil in an amount sufficient to promote hair growth, applied to an area of skin where hair growth is to be increased or restored; and

an oral administration of  
17 beta-(N-tert-butylcarbamoyl)-4-aza-5-alpha-androst-1-en-3-one in an amount from about 0.05 to about 0.03 mg/Kg to promote hair growth such that hair growth is increased over the administration of minoxidil alone.

'599 patent (Claim 1) (emphasis added). The examples disclosed by the patent show that subjects practicing this method experienced increased growth of hair compared to those using minoxidil alone. Nevertheless, the patent does not show that this method completely cured baldness by producing a full head of hair.

In light of these disclosures, one of ordinary skill would not construe “restoring hair growth” to mean “returning the user’s hair to its original state,” as the board required. To the contrary, consistent with Cortright’s disclosure and that of other references, one of ordinary skill would construe this phrase as meaning that the claimed method increases the amount of hair grown on the scalp but does not necessarily produce a full head of hair. Properly construed, claim 1 is amply supported by the written description because Example 1 discloses the amount of Bag Balm<sup>®</sup> to

apply (about one teaspoon daily) and the amount of time (about one month) in which to expect results. These dosing instructions enable one of ordinary skill to practice the claimed invention without the need for any experimentation. Therefore, we reverse the board's rejection of claim 1.

### **Claim 15**

With respect to claim 15, the examiner made a lack of utility rejection under section 101 because Cortright "offered no proof that such an off-set occurs and has disclosed that this is only speculation." Although the board purported to reject the examiner's section 101 rejection of claim 15, its new rejection under section 112, ¶ 1 suggests that it did not disagree with the examiner entirely. The board stated that because the written description "merely 'surmises'" that the active ingredient, 8-hydroxy-quinoline sulfate reaches the papilla and offsets the lower levels of male hormone, it did not teach how to use the method of claim 15. It observed further that the written description fails to provide a working example of the subject matter of claim 15 or any evidence that "the effects of lower male hormone levels have been offset [by the claimed method], or even if Bag Balm<sup>®</sup> has reached the papilla." The board also faulted Cortright for not producing evidence that "the resultant hair growth is due to (i) the stimulation of the papilla, and (ii) the offsetting [of] the effects of lower male hormone which is supplied by arteries to the papilla, and not due to some other mechanism(s)." Moreover, it found that the written description indicates that "the underlying basis for the observed physiological phenomenon can not [sic] be predicted from the results obtained," and that this type of unpredictability alone may "provide a

reasonable doubt as to the accuracy of broad statements made in support of the enablement of a claim.”

“[I]t is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works.” Newman v. Quigg, 877 F.2d 1575, 1581, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989); see also Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565, 1570, 219 USPQ 1137, 1140 (Fed. Cir. 1983) (“[I]t is axiomatic that an inventor need not comprehend the scientific principles on which the practical effectiveness of his invention rests.”). Furthermore, statements that a physiological phenomenon was observed are not inherently suspect simply because the underlying basis for the observation cannot be predicted or explained. Therefore, the board erred in suggesting that Cortright was required to prove the cause of the resultant hair growth.

Statements relating to observations that salves applied to the scalp penetrate the skin and reach the papilla or that chemicals affect hormones do not run counter to generally accepted scientific norms. Therefore, a disclosure that the active agent, 8-hydroxy-quinoline sulfate, reached the papilla and offset lower levels of male hormones is not inherently suspect. Nevertheless, we must affirm the rejection of claim 15 because the written description fails to disclose that the active ingredient reaches the papilla or that offsetting occurs. See In re Bundy, 642 F.2d 430, 434, 209 USPQ 48, 51 (CCPA 1981) (“What is necessary to satisfy the how-to-use requirement of § 112 is the disclosure of some activity coupled with knowledge as to the use of this activity.”). Here, although the written description states that people observed hair growth after applying Bag Balm<sup>®</sup> to the scalp, it does not disclose that anyone observed the active

ingredient reach the papilla and offset the effects of lower levels of male hormones. It states, rather, that “[i]t is believed that the rubbed-in ointment offsets the effects of lower levels of male hormones in the papilla and/or provides an antimicrobial effect on infection,” and that “Applicant surmises that the active antimicrobial agent, 8-hydro[x]y-quinoline sulfate, reaches the papilla, and is effective to off-set the male hormones such as testosterone and/or androsterone, and/or kill or seriously weaken any bacteria about or in the papilla . . . .” (emphasis added). These statements reflect no actual observations. Moreover, we have not been shown that one of ordinary skill would necessarily conclude from the information expressly disclosed by the written description that the active ingredient reaches the papilla or that off-setting occurs. See Tronzo v. Biomet, Inc., 156 F.3d 1154, 1159, 47 USPQ2d 1829, 1834 (Fed. Cir. 1998) (“In order for a disclosure to be inherent . . . the missing descriptive matter must necessarily be present in the . . . application’s specification such that one skilled in the art would recognize such a disclosure.”); see also In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981) (“Inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” (quoting Hansgirk v. Kemmer, 102 F.2d 212, 214, 40 USPQ 665, 667 (CCPA 1939))). Therefore, claim 15 does not satisfy the how to use requirement of section 112, ¶ 1.

#### Conclusion

Accordingly, the decision of the United States Board of Patent Appeals and Interferences is affirmed in part and reversed in part, and the case is remanded for further proceedings in accordance with this opinion.

COSTS

Each party shall bear its own costs.

AFFIRMED-IN-PART, REVERSED-IN-PART, AND REMANDED