

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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

Appeal No. 2005-2593
Application No. 90/005,867

ON BRIEF¹

Before MARTIN, HANLON, and DELMENDO, Administrative Patent Judges.
HANLON, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on an appeal under 35 U.S.C. § 134 from the final rejection of claims 1, 2, 4-8, 10, 11, 13-17 and 25-36.² The claims on appeal are directed to a method for replenishing certain hormones as well as a hormone replenishment kit.

¹ The appellant requested an oral hearing. See Request for Oral Hearing dated January 31, 2005. The request was granted, and a hearing date was set for November 14, 2005. See Notice of Hearing mailed September 29, 2005. Counsel for the appellant did not attend the hearing. Therefore, this appeal has been decided on brief.

² Claims 3, 9, 12, 18 and 37 were also finally rejected. However, the examiner withdrew the rejection of claims 3, 9, 12, 18 and 37 in the Answer. See Examiner's Answer at 4-5, 28. Additionally, claims 19 through 24 are subject to reexamination, but the examiner previously indicated that these claims are patentable. See Final Office action (Paper No. 11).

The examiner relies on the following references:

Fahy	WO 95/32991	Dec. 7, 1995
Umbreit	DE 43 26 948	Nov. 17, 1994

Robert O. Scow & Susie N. Hagan, Effect of Testosterone Propionate and Growth Hormone on Growth and Chemical Composition of Muscle and Other Tissues in Hypophysectomized Male Rats, 77 *Endocrinology* 852-57 (1965) (hereinafter "Scow").

Walter Pierpaoli & William Regelson, The Melatonin Miracle, Nature's Age-Reversing Disease Fighting Sex-Enhancing Hormone 259-75 (Pocket Books 1995) (hereinafter "Pierpaoli").

The following rejections are at issue in this appeal:

(1) Claims 1, 2, 7, 8, 10 and 11 are rejected under 35 U.S.C. § 102(b) as being anticipated by Fahy.

(2) Claims 1, 2, 4-8, 10, 11, 13-17 and 25-36 are rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Fahy, Scow, Umbreit and Pierpaoli.

Discussion

A. Rejection of claims 1, 2, 7 and 8 under 35 U.S.C. § 102(b)

Claims 1, 2, 7 and 8 are rejected under 35 U.S.C. § 102(b) as being anticipated by Fahy. Claim 1 is directed to a hormone replenishment method and reads as follows:

1. A hormone replenishment method comprising:
measuring hormone levels in a sample of an otherwise healthy human subject's blood to determine that the level of human growth hormone and the supplemental hormones selected from the group consisting of sex hormone, melatonin hormone, adrenal hormone, thyroid hormone, and thymus hormone are below pre-determined physiological levels for an adult human; and
replenishing said level of said deficient hormones to pre-determined physiological levels.

Before we address the examiner's position and the appellant's arguments, it is necessary to interpret claim 1. The method of claim 1 requires (1) measuring hormone levels in a sample of an otherwise healthy human's blood, (2) determining that the levels of human growth hormone and certain supplemental hormones are below "pre-determined" levels for an adult human, and (3) replenishing the levels of those hormones to the "pre-determined" levels. We note that a "pre-determined" level may be a range of values. See claim 9. Also, claim 1 does not require that the "pre-determined" levels represent optimal values.

The claim includes a Markush group, i.e., "the supplemental hormones selected from the group consisting of sex hormone, melatonin hormone, adrenal hormone, thyroid hormone, and thymus hormone." The claim does not expressly indicate the number of supplemental hormones selected from the group. Nevertheless, "supplemental hormones" is plural and reasonably connotes at least two supplemental hormones. Therefore, we interpret claim 1 as requiring that the level of human growth hormone as well as the levels of at least two supplemental hormones selected from the group consisting of sex hormone, melatonin hormone, adrenal hormone, thyroid hormone, and thymus hormone be determined to be below "pre-determined" levels. This interpretation is consistent with the appellant's specification. See, e.g., specification at col. 10, lines 5-8.

Furthermore, the appellant does not expressly define the term "pre-determined"

in the specification. The American Heritage Dictionary of the English Language 1031 (William Morris ed., New College ed. 1976) (copy attached), defines the term “predetermine” as “1. To determine, decide, or establish in advance” This definition appears to be consistent with the appellant’s use of the term throughout the specification. Therefore, we further interpret claim 1 as requiring that the “pre-determined physiological levels” of the hormones be determined in advance of at least the determining step, i.e., step (2). See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584 n.6, 39 USPQ2d 1573, 1578 n.3 (Fed. Cir. 1996) (judges may rely on a dictionary definition when construing a claim term, so long as the dictionary definition does not contradict any definition found or ascertained by a reading of the patent documents, including the specification).

We now turn to the examiner’s rejection of claim 1 and the teachings of Fahy. Fahy teaches administering to a patient an amount of human growth hormone in combination with an amount of DHEA (adrenal hormone). Fahy recognizes that human growth hormone is a powerful approach to the treatment of aging. However, its widespread use is inhibited by its serious side effects, the most important of which is elevation of fasting and glucose-stimulated insulin levels. See Fahy at 1, lines 15-19. Fahy discloses that a patient’s level of human growth hormone can be increased without causing a corresponding increase in serum insulin levels by administering human growth hormone in combination with DHEA. See Fahy at 4, lines 4-10. Thus, one of ordinary skill in the art would have recognized that the invention disclosed in Fahy would be useful in the treatment of aging.

The examiner sets forth the rejection based on Fahy as follows (Answer at 5):

Fahy teaches measurement of hormones (page 8, lines 1-5), determination of normal levels, (page 5, lines 25-30); followed by concomitant administration of growth hormone (GH) and dehydroepiandrosterone (DHEA). These compounds were administered to reduce those effects associated with aging. Additionally,

these compounds were administer[ed] to provide “a radical increase in longevity” (page 1, lines 20-30).

The appellant argues that Fahy does not disclose (i) measuring human growth hormone and the supplemental hormones listed in claim 1 to determine that the hormones are below pre-determined physiological levels for an adult human or (ii) replenishing the level of the hormones to pre-determined physiological levels. Brief at 8.

Contrary to the examiner’s arguments, claim 1 does not merely require the measurement and concomitant administration of human growth hormone and a supplemental hormone such as DHEA. Rather, as explained above, the method of claim 1 requires (1) measuring hormone levels in a sample of a human’s blood, (2) determining that the levels of human growth hormone and at least two of the listed supplemental hormones are below “pre-determined” levels, and (3) replenishing the levels of those hormones to the “pre-determined” levels. Although the predetermined levels are not limited to particular amounts, the term “pre-determined” requires that the levels be decided in advance of at least the determining step, i.e., step (2).

In “Experiment 1,” Fahy establishes “basal values for glucose, insulin,

somatomedin C (a marker for growth hormone), DHEA-sulfate³], serum lipids, and testosterone” in a human patient before administration of arginine (a human growth hormone releaser) and DHEA. See Fahy at 8, lines 1-3. Thus, Fahy measures hormone levels in a human subject’s blood, including the recited “human growth hormone” (via somatomedin C), “adrenal hormone” (DHEA), and “sex hormone” (testosterone). Furthermore, Fahy compares the circulating level of somatomedin C to a predetermined level (a target range of 700-3000 units/L, particularly 1000-1600 units/L) and replenishes any measured deficiency. See Fahy at 5, lines 15-17.

As for testosterone, Fahy does not disclose that the measured level is determined to be below a predetermined level or administered to any level, including a predetermined level. As for DHEA, Fahy discloses that the amount of DHEA administered to a patient is based on two considerations, the circulating DHEA level and the circulating insulin level, neither of which satisfies claim 1. According to the first consideration, the amount of DHEA is not to exceed a predetermined level which is 100% greater than the level found in individuals 20-25 years of age. Id. at 5, lines 20-25. Significantly, this predetermined level is not a replenishment or target level. Rather, it is an upper limit on the amount of DHEA to be administered according to the second consideration, i.e., circulating insulin levels, which likewise does not require replenishment to a predetermined level. Id. at 5, lines 25-26. As explained in Fahy (p. 6, lines 17-20):

³ Fahy discloses that DHEA-sulfate is an example of a DHEA precursor. Fahy at 6, line 30.

DHEA should be given "to effect." "To effect" is defined as sufficient to lower that particular patient's insulin levels down to either basal levels or, if basal levels are elevated in comparison to an accepted standard for good health and long life, to levels deemed to maximize longevity and health.

See also claim 2 of Fahy ("said second component [DHEA] is administered at doses sufficient to maintain serum insulin levels at about the levels found in normal, healthy patients").

At most, Fahy suggests that one supplemental hormone (DHEA) is determined to be below a predetermined level. Furthermore, Fahy does not disclose that any of the supplemental hormones listed in claim 1 are replenished to predetermined levels. Therefore, the rejection of claim 1 under 35 U.S.C. § 102(b) as being anticipated by Fahy is reversed. See Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir.) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."), cert. denied, 484 U.S. 827 (1987).

Claims 2, 7 and 8 are dependent on claim 1. Therefore, the rejection of claims 2, 7 and 8 under 35 U.S.C. § 102(b) as being anticipated by Fahy is also reversed. See 37 CFR § 1.75(c) (2002) ("Claims in dependent form shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim.").

B. Rejection of claims 1, 2 and 4-8 under 35 U.S.C. § 103

Claims 1, 2 and 4-8 are rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Fahy, Scow, Umbreit and Pierpaoli.

The examiner relies on the teachings of Scow, Umbreit and Pierpaoli to

supplement the teachings of Fahy. However, the appellant argues that Scow, Umbreit and Pierpaoli fail to cure the deficiencies of Fahy. See Brief at 13.

Scow discusses the effect of testosterone and growth hormone on the growth of muscle and other tissues in rats. The examiner explains that this combination of hormones was taught as useful for ameliorating conditions associated with aging and for increasing the mass of musculature important to the sexual activity of the male.⁴ See Answer at 6. Pierpaoli relates to administering melatonin to mice to preserve aspects of their youthful state. Finally, the disclosure of Umbreit relates to measuring and administering estrogen to delay the aging process in men.

Relying on In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069 (CCPA 1980), the examiner argues that (Answer at 6-7):

It is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of two, or more conventional anti-aging agents. It would follow that the recited claims define prima facie obvious subject matter.

Assuming for the sake of argument that it would have been obvious to administer the combination of hormones disclosed in Fahy (human growth hormone and DHEA), Scow (growth hormone and testosterone), Umbreit (estrogen) and Pierpaoli (melatonin)

⁴ The appellant denies that Scow discloses administering growth hormone and testosterone to treat the effects of aging: “There is not one teaching [in Scow] of the combination as useful for ‘ameliorating conditions associated with aging.’” Reply Brief at 6. However, as explained hereinafter, the teachings of Scow, either alone or in combination with Fahy, Umbreit and Pierpaoli, fail to suggest the invention of claim 1. Therefore, it is not necessary to address this issue.

to a human patient, claim 1 requires more. As discussed above, the method of claim 1 requires (1) measuring hormone levels in a sample of a human's blood, (2) determining that the levels of human growth hormone and at least two of the listed supplemental hormones are below "pre-determined" levels, and (3) replenishing the levels of those hormones to the "pre-determined" levels.

As explained above, Fahy, at most, suggests that one supplemental hormone (DHEA) is determined to be below a predetermined level. Furthermore, Fahy does not disclose that any of the supplemental hormones listed in claim 1 are replenished to predetermined levels. Scow, Pierpaoli and Umbreit fail to cure the deficiencies of Fahy.

Specifically, neither Scow nor Pierpaoli discloses that one or more supplemental hormones listed in claim 1 are determined to be below "pre-determined" levels and are replenished to those levels. Umbreit, on the other hand, does suggest that estrogen is measured and determined to be below a particular level. See EXAMPLE in Umbreit at 6.⁵ Specifically, the trial group discussed in Umbreit's EXAMPLE consisted of thirty-eight men having an estradiol blood level of less than 25 pg/ml. While estradiol and other hormone levels were monitored throughout the trial, all of the subjects received the same dosage (1 mg) of estradiol valerate per day for one to three years. Umbreit indicates that when practicing estrogen therapy, "[t]he dose may depend on different factors such as age or individual health status, including the level of the estrogen lever

⁵ Reference herein to Umbreit is to the English translation of record in the application.

[sic] in man” and that “[t]he level of the daily estrogen dose ranges from 0.15 to 2.0 mg.” Umbreit at 5, lines 20-22. However, Umbreit does not expressly identify an estrogen replenishment level. Even assuming for the sake of argument that Umbreit does suggest that estrogen is to be replenished to a predetermined level (25 pg/ml) and that it would have been obvious to combine Umbreit’s estrogen therapy with Fahy, the result would not satisfy claim 1 because the combination of Umbreit and Fahy would only replenish one “supplemental hormone” (per the teachings of Umbreit) to a predetermined level.⁶

For the reasons set forth above, the rejection of claim 1 under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Fahy, Scow, Umbreit and Pierpaoli is reversed. Claims 2 and 4-8 are dependent on claim 1. Therefore, the rejection of claims 2 and 4-8 under

35 U.S.C. § 103 as being unpatentable over the combined teachings of Fahy, Scow, Umbreit and Pierpaoli is also reversed. See 37 CFR § 1.75(c) (2002).

C. Rejection of claims 10 and 11 under 35 U.S.C. § 102(b)

Claims 10 and 11 are rejected under 35 U.S.C. § 102(b) as being anticipated by Fahy. Claim 10 is directed to a hormone replenishment method and reads as follows:

⁶ As a result, we do not reach the appellant’s additional argument that the rejection of claim 1 fails to take into account the possibility of adverse side effects when combining different hormone therapies.

10. A hormone replenishment method comprising:
measuring hormone levels in a sample of an otherwise healthy human subject's blood to determine that the level of human growth hormone and at least two of the supplemental hormones selected from the group consisting of sex hormone, melatonin hormone, adrenal hormone, thyroid hormone, and thymus hormone are below pre-determined physiological levels for an otherwise healthy adult human; and
administering amounts of said deficient hormones to replenish said level of said deficient hormones to pre-determined physiological levels.

Similar to claim 1, we interpret claim 10 as requiring (1) measuring hormone levels in a sample of an otherwise healthy human's blood, (2) determining that the levels of human growth hormone and at least two of the listed supplemental hormones are below "pre-determined" levels, and (3) replenishing the levels of those hormones to the "pre-determined" levels.⁷

As explained above, Fahy, at most, suggests that one supplemental hormone (DHEA) is determined to be below a predetermined level. Furthermore, Fahy does not disclose that any of the supplemental hormones listed in claim 10 are replenished to predetermined levels. See section "A.," supra. Therefore, we reverse the rejection of claim 10 under 35 U.S.C. § 102(b) as being anticipated by Fahy. See Verdegaal Bros., 814 F.2d at 631, 2 USPQ2d at 1053 ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a

⁷ As in claim 1, we interpret claim 10 as requiring that the "pre-determined physiological levels" of the hormones be determined in advance of at least the determining step, i.e., step (2).

single prior art reference.”).

Claim 11 is dependent on claim 10. Therefore, the rejection of claim 11 under 35 U.S.C. § 102(b) as being anticipated by Fahy is also reversed. See 37 CFR § 1.75(c) (2002).

D. Rejection of claims 10, 11 and 13-17 under 35 U.S.C. § 103

Claims 10, 11 and 13-17 are rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Fahy, Scow, Umbreit and Pierpaoli. Again, the examiner relies on the teachings of Scow, Umbreit and Pierpaoli to supplement the teachings of Fahy. However, for the reasons discussed above, Scow, Umbreit and Pierpaoli fail to cure the deficiencies of Fahy. See section “B.,” supra.

For this reason, the rejection of claim 10 under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Fahy, Scow, Umbreit and Pierpaoli is reversed. Claims 11 and 13-17 are dependent on claim 10. Therefore, the rejection of claims 11 and 13-17 under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Fahy, Scow, Umbreit and Pierpaoli is also reversed. See 37 CFR § 1.75(c) (2002).

E. Rejection of claim 25 under 35 U.S.C. § 103

Claim 25 is rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Fahy, Scow, Umbreit and Pierpaoli. Claim 25 reads as follows:

25. A hormone replenishment kit comprising human growth hormone and at least two of the supplemental hormones selected from the group consisting of sex hormone, melatonin hormone, adrenal hormone, thyroid hormone, and thymus hormone, said human growth hormone and said at least two supplemental hormones present in an amount sufficient

in establishing a regimen for the replenishment of said human growth hormone and at least two of said supplemental hormones to predetermined physiological levels.

Claim 25 is directed to a kit comprising an amount of human growth hormone and an amount of least two supplemental hormones such as adrenal hormone and sex hormone. As explained above, Fahy suggests that human growth hormone and DHEA can be administered to a patient for the treatment of aging, and Umbreit discloses that estrogen can be administered to a patient to slow down the aging process. Umbreit also discloses that estrogen may be administered in combination with other active substances and medications such as additional hormone compositions. See Umbreit at 4, lines 19-21. The examiner explains that it is generally considered prima facie obvious to combine several compounds which are useful for the same purpose and use them for that purpose. Therefore, the examiner concludes that it would have been prima facie obvious to combine human growth hormone, DHEA and estrogen in a kit for the treatment of aging. See Answer at 28-29.

The appellant argues that there is no indication in the cited references that the supplemental hormones, e.g., adrenal hormone and sex hormone, are to be administered to establish a predetermined physiological level of each of these hormones in the blood of, for example, a human. See Brief at 22.

However, claim 25 does not impose such a requirement. Claim 25 merely recites a hormone replenishment kit wherein human growth hormone and at least two of the listed supplemental hormones are “present in an amount sufficient in establishing a regimen” to replenish those hormones to predetermined physiological levels.

Significantly, the combination of any amount of human growth hormone and at least two of the listed supplemental hormones satisfies this claim limitation, including the amount of human growth hormone and DHEA disclosed in Fahy and the amount of estrogen disclosed in Umbreit.⁸

The appellant further argues that Fahy and the Fahy Declaration note the functional relationship between hormones and the significant health risks or possible adverse side effects associated with hormone administration. Therefore, the appellant concludes that the cited references in combination do not teach or suggest that more than one supplemental hormone could be combined in a kit to be administered with human growth hormone. Brief at 22.

The appellant's argument is not persuasive. First, the appellant does not point to a specific teaching in Fahy to support its argument. Nevertheless, a review of the Fahy reference by this panel reveals that Fahy indicates that administering a male contraceptive to humans would not be desirable for a variety of reasons, including major testicular shrinkage, and administering thyroid hormone is considered hazardous. See Fahy at 3, lines 17-26. However, Fahy does not discuss significant health risks or

⁸ The amount of human growth hormone and the amount of at least two of the listed supplemental hormones "sufficient in establishing a regimen" is dependent on a number of factors including the hormone levels in the particular patient, the hormone replenishment levels, and the length of the regimen.

possible adverse side effects associated with estrogen administration.⁹

Second, in his Declaration, George M. Fahy states (Declaration of George M. Fahy dated March 19, 2002, at 3):

10. The '991 Application [Fahy] does not give any indication of the possible effect of administering HGH plus two "unrelated" hormones, though it points out, in the "Background of the Invention" section, interest in multiple hormones among proponents of anti-aging medicine.

11. To my knowledge, there can be side effects or health risks associated with hormone supplementation such as increased serum levels of insulin with HGH supplementation that increases the risk of heart disease, and possibly an increased risk of prostate cancer in men with testosterone supplementation[.]

Significantly, Dr. Fahy does not discuss any significant health risks or possible adverse side effects associated with administering estrogen in combination with human growth hormone and DHEA.

For the reasons set forth above, the rejection of claim 25 under 35 U.S.C. § 103 is affirmed.

F. Rejection of claims 26 and 27 under 35 U.S.C. § 103

Claims 26 and 27 are rejected under 35 U.S.C. § 103 as being unpatentable over

⁹ Fahy does not identify the male contraceptive referred to in the disclosure. Nevertheless, the appellant has failed to establish that estrogen is used as a male contraceptive.

the combined teachings of Fahy, Scow, Umbreit and Pierpaoli. Claim 26 reads as follows:

26. The kit of claim 25, wherein the amount of human growth hormone is provided in intravenous unit form in doses of less than 0.5 mg per day.

Fahy discloses that human growth hormone is administered by subcutaneous injection or other efficacious route every day, every other day or three times a week at an HGH equivalent dose of 0.01 to 0.05 mg/kg of body weight. See Fahy at 5, lines 6-10. According to the teachings in Fahy, a dose of less than 0.5 mg per day would be administered to a patient weighing less than 50 kg and receiving 0.01 mg/kg of human growth hormone.¹⁰ It would have been prima facie obvious to one of ordinary skill in the art to provide that dose in intravenous unit form as recited in claim 26.¹¹ See In re Kotzab, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (suggestion to modify may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art or may be implicit from the prior art as a whole). The appellant has failed to present any evidence to the contrary. Therefore, the rejection of claim 26 under 35 U.S.C. § 103 is affirmed.

The appellant argues claims 26 and 27 as a group. Brief at 6. Therefore, the rejection of claim 27 under 35 U.S.C. § 103 is also affirmed.

G. Rejection of claim 28 under 35 U.S.C. § 103

¹⁰ Claims 25 and 26 are not limited to human patients.

¹¹ The appellant does not argue that intravenous application is patentably distinct from subcutaneous injection. See Reply Brief at 24.

Claim 28 is rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Fahy, Scow, Umbreit and Pierpaoli. Claim 28 reads as follows:

28. The kit of claim 25, wherein said sex hormone comprises at least one of testosterone, progesterone, and estrogen.

As discussed above, Umbreit discloses administering estrogen to a patient. The appellant has failed to establish otherwise. Therefore, the rejection of claim 28 under 35 U.S.C. § 103 is affirmed.

H. Rejection of claim 29 under 35 U.S.C. § 103

Claim 29 is rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Fahy, Scow, Umbreit and Pierpaoli. Claim 29 reads as follows:

29. The kit of claim 25, wherein said adrenal hormone comprises dehydroepiandrosterone and pregnenolone.

The appellant argues that the references in combination fail to teach or suggest the kit of claim 25 wherein the adrenal hormone includes both DHEA and pregnenolone.

Brief at 23; Reply Brief at 25. We agree. Fahy discloses administering DHEA to a patient but does not disclose administering pregnenolone. The teachings of Scow, Umbreit and Pierpaoli fail to cure this deficiency in Fahy. Therefore, the rejection of claim 29 under 35 U.S.C. § 103 is reversed.

I. Rejection of claim 30 under 35 U.S.C. § 103

Claim 30 is rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Fahy, Scow, Umbreit and Pierpaoli. Claim 30 reads as follows:

30. A kit for increasing life expectancy and life span comprising human growth hormone and at least two of the supplemental hormones

selected from the group consisting of sex hormone, melatonin hormone, adrenal hormone, thyroid hormone, and thymus hormone, said kit for establishing a regimen for the replenishment of said human growth hormone and at least two of said supplemental hormones to predetermined physiological levels.

Claim 30 is directed to a kit comprising human growth hormone and at least two supplemental hormones such as adrenal hormone and sex hormone. As explained above, Fahy suggests that human growth hormone and DHEA can be administered to a patient for the treatment of aging, and Umbreit discloses that estrogen can be administered to a patient to slow down the aging process. Umbreit also discloses that estrogen may be administered in combination with other active substances and medications such as additional hormone compositions. See Umbreit at 4, lines 19-21. The examiner explains that it is generally considered prima facie obvious to combine several compounds which are useful for the same purpose and use them for that purpose. Therefore, the examiner concludes that it would have been prima facie obvious to combine human growth hormone, DHEA and estrogen in a kit for the treatment of aging. See Answer at 31-33.

The preamble of claim 30 also indicates that the kit is “for increasing life expectancy and life span.” However, this language is merely a statement of intended use and fails to limit the scope of the claim. See In re Paulsen, 30 F.3d 1475, 1479, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994) (the preamble of a claim does not limit the scope of the claim when it merely states a purpose or intended use of the invention). In any event, as discussed above, Fahy suggests that human growth hormone and DHEA are useful in the treatment of aging, and Umbreit discloses that estrogen can be used to

slow down the aging process. We find that one of ordinary skill in the art would have expected a patient's life expectancy and life span to be increased by treating or slowing down the aging process using a combination of human growth hormone, DHEA and estrogen.

The appellant argues that claim 30 is not prima facie obvious over the cited references because none of the references teaches administering more than two hormones. Brief at 24. It is of no moment that one reference does not teach administering human growth hormone in combination with at least two of the supplemental hormones listed in claim 30. See In re Keller, 642 F.2d 413, 426, 208 USPQ 871, 882 (CCPA 1981) (one cannot show nonobviousness by attacking references individually where, as here, the rejection is based on a combination of references). As explained above, the combined teachings of at least Fahy and Umbreit suggest

combining human growth hormone, DHEA and estrogen in a kit to treat or slow down the aging process.

The appellant further argues that there is no motivation to combine human growth hormone and at least two of the supplemental hormones listed in claim 30 because the cited references recognize that possible health risks or adverse side effects may result from combining hormones. Brief at 24. As discussed above, the appellant has failed to point to any evidence in the record which establishes that combining human growth hormone, DHEA and estrogen would have been expected to result in possible health risks or adverse side effects. See In re Schulze,

346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965) (arguments in the brief do not take the place of evidence in the record).

Finally, the appellant argues that the references do not provide any motivation for a kit comprising the recited hormones which establishes a regimen for replenishing the hormones to pre-determined physiological levels. Brief at 24. Significantly, the phrase “said kit for establishing a regimen for the replenishment” of the recited hormones to predetermined physiological levels is merely functional language and does not further limit the structure of the kit. Cf. In re Casey, 370 F.2d 576, 580, 152 USPQ 235, 238 (CCPA 1967) (the manner or method in which a machine is to be utilized is not germane to the issue of the patentability of the machine itself). In any event, the appellant has failed to establish that the amount of human growth hormone and DHEA administered in Fahy and the amount of estrogen administered in

Umbreit is not sufficient to establish a regimen for replenishing these hormones to predetermined physiological levels.¹²

For the reasons set forth above, the rejection of claim 30 under 35 U.S.C. § 103 is affirmed.

¹² Again, we note that the amount of human growth hormone and the amount of at least two of the listed supplemental hormones “for establishing a regimen” for replenishing those hormones to predetermined physiological levels is dependent on a number of factors including the hormone levels in the particular patient, the hormone replenishment levels, and the length of the regimen.

J. Rejection of claims 31 and 32 under 35 U.S.C. § 103

Claims 31 and 32 are rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Fahy, Scow, Umbreit and Pierpaoli. Claim 31 reads as follows:

31. The kit of claim 30, wherein the amount of human growth hormone is provided in intravenous unit form in doses of less than 0.5 mg per day.

Fahy discloses that human growth hormone is administered by subcutaneous injection or other efficacious route every day, every other day or three times a week at an HGH equivalent dose of 0.01 to 0.05 mg/kg of body weight. See Fahy at 5, lines 6-10. According to the teachings in Fahy, a dose of less than 0.5 mg per day would be administered to a patient weighing less than 50 kg and receiving 0.01 mg/kg of human growth hormone.¹³ It would have been prima facie obvious to one of ordinary skill in the art to provide that dose in intravenous unit form as recited in claim 31.¹⁴ See Kotzab, 217 F.3d at 1370, 55 USPQ2d at 1317 (suggestion to modify may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art or may be implicit from the prior art as a whole). The appellant has failed to present any evidence to the contrary. Therefore, the rejection of claim 31 under 35 U.S.C. § 103 is affirmed.

¹³ Claims 30 and 31 are not limited to human patients.

¹⁴ The appellant does not argue that intravenous application is patentably distinct from subcutaneous injection. See Reply Brief at 26.

The appellant argues claims 31 and 32 as a group. Brief at 6. Therefore, the rejection of claim 32 under 35 U.S.C. § 103 is also affirmed.

K. Rejection of claim 33

Claim 33 is rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Fahy, Scow, Umbreit and Pierpaoli. Claim 33 reads as follows:

33. The kit of claim 30, wherein said sex hormone comprises at least one of testosterone, progesterone, and estrogen.

As discussed above, Umbreit discloses administering estrogen to a patient. The appellant has failed to establish otherwise. Therefore, the rejection of claim 33 under 35 U.S.C. § 103 is affirmed.

L. Rejection of claim 34 under 35 U.S.C. § 103

Claim 34 is rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Fahy, Scow, Umbreit and Pierpaoli. Claim 34 reads as follows:

34. The kit of claim 30, wherein said adrenal hormone comprises dehydroepiandrosterone and pregnenolone.

The appellant argues that the references in combination fail to teach or suggest a kit containing an adrenal hormone comprising dehydroepiandrosterone and pregnenolone. Brief at 25; Reply Brief at 27. We agree. Fahy discloses administering DHEA to a patient but does not

disclose administering pregnenolone. The teachings of Scow, Umbreit and Pierpaoli fail to cure this deficiency in Fahy. Therefore, the rejection of claim 34 under 35 U.S.C. §

103 is reversed.

M. Rejection of claims 35 and 36 under 35 U.S.C. § 103

Claims 35 and 36 are rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Fahy, Scow, Umbreit and Pierpaoli. Claim 35 reads as follows:

35. A method of inhibiting physiological conditions associated with biological aging comprising:
measuring hormone levels in a sample of an otherwise healthy human subject's blood to determine that the level of human growth hormone and at least two of the supplemental hormones selected from the group consisting of sex hormone, melatonin hormone, adrenal hormone, thyroid hormone (T-3), and thymus hormone are below pre-determined physiological levels for an adult human; and
replenishing said level of human growth hormone and said at least two supplemental hormones to pre-determined physiological levels.

The examiner argues that claim 35 defines nothing more than the use of two or more conventional anti-aging agents. Answer at 35. We disagree. Similar to claims 1 and 10, the method of claim 35 requires (1) measuring hormone levels in a sample of an otherwise healthy human subject's blood, (2) determining that the levels of human growth hormone and at least two of the listed supplemental hormones are below "pre-determined" levels, and (3) replenishing the levels of those hormones to the "pre-determined" levels.¹⁵

¹⁵ As in claims 1 and 10, we interpret claim 35 as requiring that the "pre-determined physiological levels" of the hormones be determined in advance of at least the determining step, i.e., step (2).

As explained above, Fahy, at most, suggests that one supplemental hormone (DHEA) is determined to be below a predetermined level. Furthermore, Fahy does not disclose that any of the supplemental hormones listed in claim 35 are replenished to predetermined levels. The teachings of Scow, Pierpaoli and Umbreit fail to cure the deficiencies in Fahy. See section "B.," supra. Therefore, the rejection of claim 35 under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Fahy, Scow, Umbreit and Pierpaoli is reversed.

Claim 36 is dependent on claim 35. Thus, the rejection of claim 35 under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Fahy, Scow, Umbreit and Pierpaoli is also reversed. See 37 CFR § 1.75(c) (2002).

Conclusion

The rejection of claims 1, 2, 7, 8, 10 and 11 under 35 U.S.C. § 102(b) as being anticipated by Fahy is reversed.

The rejection of claims 1, 2, 4-8, 10, 11, 13-17, 29 and 34-36 under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Fahy, Scow, Umbreit and Pierpaoli is reversed.

The rejection of claims 25-28 and 30-33 under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Fahy, Scow, Umbreit and Pierpaoli is affirmed.

AFFIRMED-IN-PART

JOHN C. MARTIN
Administrative Patent Judge

ADRIENE LEPIANE HANLON
Administrative Patent Judge

)
)
)
)
)
)
) BOARD OF PATENT
) APPEALS AND
) INTERFERENCES
)

Appeal No. 2005-2593
Application No. 90/005,867

26

ROMULO H. DELMENDO
Administrative Patent Judge

)
)
)
)
)
)

BLAKELY SOKOLOFF TAYLOR & ZAFMAN
12400 WILSHIRE BOULEVARD
SEVENTH FLOOR
LOS ANGELES, CA 90025-1030