

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SAMI CHEMICALS AND EXTRACTS, LTD,
Appellant

Appeal 2007-3482
Reexamination Control 90/007,327¹
Patent 5,804,596
Technology Center 3900

Decided: December 13, 2007

Before TEDDY S. GRON, ADRIENE LEPIANE HANLON and
CAROL A. SPIEGEL, *Administrative Patent Judges*.

SPIEGEL, *Administrative Patent Judge*.

DECISION ON APPEAL

¹ The patent under reexamination is based on Application 08/807,652, filed 27 February 1997. The real parties-in-interest are said to be Sabinsa Corporation and Sami Labs Limited (Brief on Appeal filed 27 June 2006 ("App. Br.") at 1).

INTRODUCTION

Sami Chemicals and Extracts, Ltd. ("Appellant") appeals under 35 U.S.C. §§ 134 and 306 from the final rejections of claims 1-34. We have jurisdiction under 35 U.S.C. § 6(b). We AFFIRM.

THE SUBJECT MATTER ON APPEAL

The subject matter on appeal is directed to methods of promoting lean body mass "in a human individual in need thereof" by administering "an effective amount" of forskohlin, a compound isolated from *Coleus forskohli* plants, to the individual. Claims 1, 5, and 31 are illustrative of the subject matter on appeal and read as follows:

1. A method of promoting lean body mass in a human individual in need thereof, comprising administering to the individual a lean body mass promoting effective amount of forskohlin.
5. A method of shifting the proportion between lean body mass and adipose tissue in favor of lean body mass in a human individual in need thereof, comprising administering to the individual a proportion shifting effective amount of forskohlin.
31. The method of claim 1, wherein the method promotes the synthesis and secretion of hormones which promote lean body mass.

THE REJECTIONS

The Examiner relies upon the following references of record as evidence of unpatentability:

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Kazuo²

JP-6-133731

May 17, 1994

Greenway et al. ("Greenway III"), "Regional Fat Loss from the Thigh in Obese Women after Adrenegic Modulation," *Clinical Therapeutics*, Vol. 9, No. 6, pp. 663-669 (1987).

Greenway et al. ("Greenway IV"), "Topical Fat Reduction," *Obesity Research*, Vol. 3, Suppl. 4, pp. 561S-568S (November 1995).

Appealed claims 1, 5, 9-10, and 31-34 stand rejected under 35 U.S.C. § 102(b) as anticipated by Kazuo; claims 1, 5, 11-12, and 31-34 stand rejected under 35 U.S.C. § 102(b) as anticipated by Greenway III or Greenway IV; claims 1-34 stand rejected under 35 U.S.C. § 103(a) over Kazuo; and, claims 31-32 stand rejected under 35 U.S.C. § 112, first paragraph (lack of written descriptive support) (Ans.³ at 4, 5, 7, 8 and 11).

We have also considered the certified translation of Figure 1 of Kazuo, the Badmaev Declaration,⁴ and the Godard⁵ article provided by Appellant in support of its position (App. Br. at 34). We have not considered the printout from the National Library of Medicine referenced in Appellant's Reply Brief since no printout was found attached thereto (Reply Br.⁶ at 7).

² This decision refers and cites to the USPTO translation of Kazuo, "Diet Food," by Akiko Smith dated 25 August 2005 and to the certified English translation of Kazuo Diagram 1 supplied by the Appellant.

³ Examiner's Answer mailed 7 November 2006 ("Ans.").

⁴ Declaration under 37 C.F.R. § 1.132 by Dr. Vladimir Badmaev filed 23 February 2006 ("the Badmaev Declaration"). Dr. Badmaev is a named co-inventor of the patent under reexamination.

⁵ Godard et al. ("Godard"), "Body Composition and Hormonal Adaptations Associated with Forskolin Consumption in Overweight and Obese Men," *Obesity Research*, Vol. 13, No. 8, pp. 1335-1343 (8 August 2005).

⁶ Reply Brief under 37 C.F.R. § 41.41 filed 5 January 2007 ("Reply Br.").

Appellant has grouped the claims into three groups, i.e., (i) claims 1-4, 9, 11, 13, 15-17, 19, 21, 23, 25, 27, 29, and 33; (ii) claims 5-8, 10, 12, 14, 18, 20, 22, 24, 26, 28, 30, and 34; and, (iii) claims 31 and 32 (App. Br. at 3). However, Appellant has not separately argued the patentability of claims 31 and 32 over the prior art (see e.g., App. Br. at 7 and 17). Therefore, we decided this appeal on the basis of claims 1 and 5 relative to the prior art; and, on the basis of claim 31 relative to written description. Further, arguments not raised in the principal brief are waived. 37 C.F.R. § 41.37(c)(1)(vii).

We preface our discussion of the rejection under § 112, first paragraph, by considering the disclosure of Appellant's specification; and, of the prior art rejections by construing the appealed claims.

FINDINGS OF FACT ("FF")

The following findings of fact are supported by a preponderance of the evidence of record.

A. The '596 patent specification

- [1] The '596 specification describes "a method of promoting lean body mass in an individual, comprising administering to the individual a lean body mass promoting effective amount of forskohlin" ('596 patent at 2:66 to 3:2).
- [2] Forskohlin is said to be a chemical found in the *Coleus forskohli* plant that activates the enzyme adenylate cyclase (AC) ('596 patent at 3:12-13 and 46-47).
- [3] Adenylate cyclase activation is said to initiate a cascade of processes, i.e., increased cyclic adenosine monophosphate (cAMP) levels,

- leading to activation of a hormone-sensitive lipase which releases fatty acids from body adipose depots, ultimately resulting in activation of triiodothyronine (T₃), activation of phosphorylase in skeletal muscles, insulin secretion and the synthesis and secretion of anabolic steroid hormones ('596 patent at 3:61 to 4:10).
- [4] Stimulation with forskohlin is said to be known in the literature to result in a number of effects, including lipolysis in fat cells *in vitro*, potentiation of insulin secretion, increased synthesis of body steroids, increased release of adrenocorticotropic hormone (ACTH), and decreased intraocular pressure ('596 patent at 2:19-34).
- [5] The '596 patent describes oral, topical or parenteral administration of forskohlin in an amount of from ~ 10 to ~ 60 mg/day to promote lean body mass ('596 patent at 4:23-25 and 47-48).
- Other findings of fact follow below.

WRITTEN DESCRIPTION

The test for compliance with the written description requirement is whether the disclosure of the application, as originally filed, reasonably conveys to those skilled in the art that the inventor had possession at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991).

Claims 31 and 32 stand rejected under § 112 for insufficient written description. Representative claim 31 limits the method of claim 1 to a method which "promotes the synthesis and secretion of hormones which produce lean body mass." According to the Examiner, disclosure of "the

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synthesis and secretion of *anabolic steroid* hormones' [in Appellant's specification] (column 4, lines 9-10), . . . does not provide full description of the genus, the hormones" (Ans. at 11, original emphasis, bracketed text added). The Examiner states that the term "hormones" includes both catabolic and anabolic hormones as well as steroid and non-steroid hormones (Ans. at 27). However, the Examiner has not provided any reasoned basis for her interpretation of claim 31. To the contrary, the 596 patent discloses that stimulation with forskohlin is said to be known in the literature to result in increased synthesis of body steroids and increased secretion of ACTH, a peptide hormone (FF 4). The Examiner has not explained why one skilled in the art would not have found these disclosures reasonably sufficient to provide written support for the method of claim 31. Indeed, in *In re Herschler*, 591 F.2d 693, 697 (CCPA 1979), the court found adequate written descriptive support for broad claims to processes for topically administering a physiologically active steroidal agent to a human or animal by concurrently administering the steroidal agent with dimethyl sulfoxide ("DMSO"), even though the specification only disclosed one example of a "physiologically active steroidal agent." As the court noted, "[w]ere this application drawn to novel 'steroidal agents,' a different question would be posed." *Id.* at 701.

Since the Examiner has failed to establish that the '596 specification would not have reasonably conveyed the method of claim 31 to one skilled in the art, we REVERSE the rejection of claims 31 and 32 under § 112, first paragraph.

ANTICIPATION AND OBVIOUSNESS

The scope and content of claimed subject matter must first be determined in order to explore the relationship of the invention claimed to the prior art. *In re Steele*, 305 F.2d 859, 862 (CCPA 1962). Accordingly, we first determine the scope and content of the claimed subject matter. In particular, we address the meaning of the terms "promoting," "administering," an "effective amount," and "a human individual in need thereof" as recited in the claims on appeal.

A. Claim construction

Claims in reexamination "will be given their broadest reasonable interpretation." *In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984). *See In re Zletz*, 893 F.2d 319, 322 (Fed. Cir. 1989) ("An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.").

1. "promoting"

The ordinary meaning of "promoting" is, in relevant part, to further or help bring into being (see e.g., Merriam-Webster's COLLEGIATE DICTIONARY, tenth edition (1998) at 933 (copy attached)). The language, "A method of promoting lean body mass," of claim 1 is unambiguous on its face. Moreover, construing "promoting" as furthering or helping to bring about is consistent with the '596 specification.

[6] According to Appellant's specification, forskohlin is believed to promote formation of lean body mass by improving absorption of nutrients and their preferential incorporation into lean body mass via

- activation of AC and the resulting increased levels of cAMP and its actions ('596 specification at 3:45-53).
- [7] Further according to the '596 specification, the prior art suggests that the known in vitro lipolysis (hydrolytic degradation of fat) effect of forskohlin in adipocytes (fat cells) is due to increased levels of cAMP and its actions ('596 specification at 2:19-26).
- [8] More generally, the '596 specification states that "an ideal weight management approach should be to reduce body weight to acceptable levels by restoring the optimal proportions of fat to lean body mass" ('596 specification at 1:67 through 2:3).
- [9] In other words, "the general purpose of improving the overall health" of an individual would be served "[b]y maintaining or increasing the lean body mass while simultaneously reducing body fat" ('596 specification at 2:3-6).

Therefore, we broadly interpret "promoting" lean body mass, consistent with the '596 specification, as "furthering or bringing about" lean body mass. "Promoting" lean body mass is not limited solely to "increasing" lean body mass, but also encompasses furthering lean body mass by maintaining lean body mass; reducing body fat relative to lean body mass; inducing cAMP mechanisms; and, improving absorption of nutrients and their preferential incorporation into lean body mass.

2. "administering"

There are a number of conventional, well-known ways of administering a compound or composition. Among the most common are oral ingestion; intravenous, subcutaneous or intramuscular parental

injection; and, topical administration to the skin or mucous membranes. The '596 specification describes oral, topical and parental administration of forskohlin (FF 5). Appellant individually claims oral (claims 9-10, 17-18, 21-22, 25-26, and 29-30), topical (claims 11 and 12), and parenteral (claims 12 and 14) administration of forskohlin. Therefore, we broadly construe "administering," as recited in both independent claims 1 and 5 as encompassing any conventional, well known way of administering a compound or composition.

3. "effective amount"

Claims 1 and 5 recite administering "a lean body mass promoting effective amount" and "a proportion shifting effective amount" of forskohlin, respectively. We broadly construe the "effective amount" of forskohlin recited in claim 1 as an amount which promotes lean body mass. We broadly construe the "effective amount" of forskohlin recited in claim 5 as an amount which shifts the ratio of lean body mass to fat in favor of lean body mass by either reducing the amount of fat while simultaneously maintaining or increasing lean body mass or by increasing the amount of lean body mass while simultaneously maintaining or decreasing fat.

We further construe the scope of an "effective amount" broadly to encompass both systemic and localized effectiveness. The '596 specification provides for the same amount of forskohlin, i.e., ~10 to ~60 mg/day, to be administered orally, topically or parenterally (FF 5). The '596 specification is silent as to minimum blood levels or other systemic indicators of forskohlin concentration needed for effectiveness to promote lean body mass or to shift the ratio of lean body mass to fat in favor of lean body mass.

4. "human individual in need thereof"

The claims require that the method be performed on "a human individual in need thereof" and that the method be used for "promoting lean body mass" (claim 1) or for "shifting the proportion between lean body mass and adipose tissue in favor of lean body mass" (claim 5). The claimed invention is not limited to treating obesity or weight excess and, therefore, is not limited to an obese or an overweight individual. The '596 specification does not specifically define a "human individual in need" of the claimed method. Therefore, we broadly construe a "human individual in need thereof" to be an individual wanting more lean body mass or wanting to lessen or prevent accumulation of fat (adipose tissue). In other words, a "human individual in need thereof," as recited in the appealed claims, encompasses an obese person wanting to decrease body fat, a person seeking to prevent accumulation of excess body fat, and a weightlifter wanting to increase muscle mass.⁷

B. Anticipation

Claimed subject matter is anticipated if "each and every limitation is found either expressly or inherently in a single prior art reference." *Bristol-*

⁷ See e.g., The transcript of the oral hearing at 7:22 through 8:3, i.e.,

MR. BERMAN: In other words, the weightlifter example you gave I think is a suitable example where the weightlifter may be in an ideal physical condition, but yet still may wish to promote even more lean body mass by taking this nutritional supplement.

JUDGE SPIEGEL: So given this discussion, am I to understand that a human individual in need thereof is a subjective determination?

MR. BERMAN: Yes, I believe that's the position that the federal circuit is taking as well.

Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1374 (Fed. Cir. 2001). The doctrine of inherency may not be used to establish anticipation unless a prior inherency can be established as a certainty. Probabilities or possibilities will not be sufficient to establish an inherent event. *Continental Can Co. U.S.A., Inc. v. Monsanto, Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991).

1. Anticipation based on Kazuo

Claims 1, 5, 9-10, and 31-34 stand rejected under 35 U.S.C. § 102(b) as anticipated by Kazuo (Ans. at 4-5).

[10] Kazuo discloses a diet food containing a plant extract from *Coleus forskohlii* root or powder which "selectively promotes a lipid metabolism" by activating AC, thereby increasing cAMP levels, which leads to activation of a hormone-sensitive lipase (Kazuo at 3, ¶ 5).

[11] According to Kazuo, "[t]he present invention attempts to present an effective diet food that can prevent fat from being stored in a body while eating freely to take the necessary nutrients" (Kazuo at 2, ¶ 3).

[12] In Experiment II, seven female volunteers took a forskohlin plant extract supplement three times a day before eating a normal meal for two weeks (Kazuo at 7, ¶ 10).

[13] Experiment II was said to recognize the effectiveness of forskohlin extract "for prevention of obesity" (Kazuo at 8, ¶ 11).

[14] Kazuo concluded that by taking forskohlin as a dietary supplement "one can prevent the fat accumulation in one's body while eating normally and taking necessary nutrition" (Kazuo at 8, ¶ 12).

[15] The Examiner finds that Kazuo's method inherently promotes lean body mass and a shift in the proportion of lean body mass and adipose tissue in favor of lean body mass as recited in claims 1 and 5, respectively (Ans. at 4-5).

The Examiner's findings are sufficient to establish a prima facie case of anticipation. Experiment II of Kazuo is directed to prevention of obesity (FF 13), i.e., preventing accumulation of excess body fat (see e.g., Merriam-Webster's COLLEGIATE DICTIONARY, tenth edition (1998) at 801 (copy attached)). Preventing accumulation of excess body fat shifts the proportion of lean body mass and adipose tissue in favor of lean body mass as recited in claim 5 and promotes lean body mass as recited in claim 1. Moreover, Kazuo recognizes that forskohlin stimulates AC-activation induced increases of cAMP mechanisms (FF 10), which also promotes lean body mass as recited in claim 1. The volunteers participating in Experiment II were administered an amount of forskohlin effective for the prevention of obesity and are "humans in need thereof" by virtue of wanting to prevent fat accumulation (FFs 13 and 14).

Appellant argues that Kazuo does not administer "an effective amount" of forskohlin (App. Br. at 8-12 and 17-18) to "a human in need thereof," as required by claims 1 and 5 (App. Br. at 13-18).

According to Appellant, "Kazuo et al. is intended to address fat reduction and accumulation of fat" whereas "the present invention can even be achieved without weight loss" as evidenced by the Godard paper (App. Br. at 16, original emphasis). Appellant argues that Table 1 of Godard shows that those receiving forskohlin maintained the same overall body

weight, while increasing lean body mass and decreasing fat mass (App. Br. at 16). Thus, Appellant concludes that the female volunteers in Kazuo are not "humans in need thereof" as recited in the appealed claims (App. Br. at 16).

[16] Table 1 in Godard is said to show a significant difference between changes in fat mass and bone mass in forskohlin- and placebo-treated subjects, but not in changes in body weight or lean body mass (Godard at 1337, Table 1, column titled "Change (pre - post)").

[17] Notably, a significant increase in lean body mass is said to be shown in both forskohlin- and placebo-treated subjects on an individual basis (Godard at 1337, Table 1, lines 6 and 11 (each beginning with "LBM (kg)").

A person, such as a female volunteer in Kazuo's Experiment II, who wants to prevent excess fat accumulation (having too much adipose tissue) is a "human in need" of promoting lean body mass and/or shifting the proportion of lean body mass/adipose tissue in favor of lean body mass giving the claim term its broadest reasonable interpretation consistent with Appellant's specification (see claim construction § A.4). As discussed above, the claimed invention is not limited to treating a human with obesity or pure weight excess issues. Similarly, as pointed out by the Examiner (Ans. at 20), the claimed invention does not require that lean body mass promotion and/or shifting the proportion of lean body mass and adipose tissue in favor of lean body mass be achieved without weight loss. Finally, Godard is of little, if any, probative value. Appellant has not explained the tests, data or significance of the results described in Godard in general, or

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listed in Table 1 in particular (App. Br. at 16). For example, according to Table 1 in Godard, a significant increase in lean body mass is said to have been shown in the test subjects, whether they received forskohlin or not (placebo) (FF 17). In short, Appellant has failed to show that the Examiner erred in finding that the human volunteers of Kazuo are "human[s] in need thereof" as recited in claims 1 and 5 (Ans. at 19). *See e.g., Mehl/Biophile International Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999) (finding anticipation of a method of hair depilation by an article teaching a method of skin treatment but recognizing the disruption of hair follicles, citing *In re King*, 801 F.2d 1324, 1326 (Fed. Cir. 1986)).

Appellant also argues that Kazuo does not disclose or suggest administering "an effective amount" of forskohlin as claimed, relying on the Badmaev Declaration to support its position.

[18] Vladimir Badmaev is a co-inventor of the '596 patent and Vice President of Medical and Scientific Affairs of Sabinsa Corporation, one of the assignees of the '596 patent (Badmaev Declaration at 1, ¶ 1).

[19] Dr. Badmaev testified that data from two clinical studies showed that "in subjects provided with an oral dose of 50 mg forskohlin per day, at least 3 months of treatment is needed for a significant loss in body weight, and at least 8 weeks of treatment is needed to significantly increase lean body mass" (Badmaev Declaration at 2, ¶ 3).

Appellant calculated that Kazuo administered a daily dose of about 3.186 mg forskohlin per day to each subject during the two week duration of Experiment II (App. Br. at 9). According to Appellant, this is too small a

dosage over too short a time period to change body composition in any meaningful way and, therefore, Kazuo does not disclose or suggest an "effective amount" of forskohlin as required by the claimed invention (App. Br. at 9).

Even assuming *arguendo* that each subject ingested ~3.1.86 mg forskohlin per day in Kazuo's Experiment II, this argument is not persuasive of Examiner error. None of the claims on appeal require any minimum degree or amount of lean body mass promotion or shift in the proportion of lean body mass/adipose tissue in favor of lean body mass, let alone some undefined "significant increase" in lean body mass. For example, claim 5 is directed to a method of shifting the proportion of lean body mass/adipose tissue in favor of lean body mass. Decreasing the amount of adipose tissue without affecting lean body mass (e.g., fat reduction as addressed by Kazuo) would shift their relative proportion as required by claim 5. Furthermore, lean body mass may be "promoted" by various means including reducing body fat relative to lean body mass and inducing cAMP mechanisms (which Kazuo recognizes forskohlin does). Moreover, whether the subjects in Kazuo's Experiment II experienced any "significant" loss in body weight is irrelevant to the claimed invention which is not directed to a method of "significant" weight loss. Finally, the Badmaev Declaration is of little, if any value, in rebutting the Examiner's prima facie case of anticipation because it fails to set forth a nexus between the claimed invention and the supporting evidence. The claimed invention is not limited to oral administration of 50 mg per day of forskohlin in an extract of unknown composition for at least 8 weeks to obese and/or overweight subjects. The

Badmaev Declaration is silent as to other possible contributory factors to weight loss and/or increased lean body mass, e.g., increased exercise or walking, decreased total caloric intake, increased water intake, etc. *In re Grunwell*, 609 F.2d 486 (CCPA 1979); *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991). In other words, the Badmaev Declaration failed to establish a nexus between the claimed invention and the data from the two clinical studies relied upon. Thus, Appellant has failed to show that the Examiner erred in finding that Kazuo administered "an effective amount" of forskohlin to the volunteers of Experiment II.

Based on the foregoing, we AFFIRM the rejection of claims 1, 5, 9-10, and 31-34 under § 102(b) as anticipated by Kazuo.

2. Anticipation based on Greenway III or IV

Claims 1, 5, 11-12, and 31-34 stand rejected under 35 U.S.C. § 102(b) as anticipated by Greenway III or Greenway IV⁸ (Ans. at 5-8).

[20] In the respective study 3s of Greenway III and IV, four obese women topically administered a forskohlin (colforsin) cream (25×10^{-5} mol/L) to one thigh and a placebo cream to the other for four weeks (Greenway III at 664 and 667; Greenway IV at 565S).

[21] All four women lost a mean of 1.0 ± 0.61 cm more girth from the thighs treated with forskohlin cream than from the control thighs (Greenway III at 667 and Figure 4; Greenway IV at 566S and Figure 4).

⁸ As noted by Appellant (App. Br. at 18), the disclosures of Greenway III and Greenway IV appear to be cumulative.

- [22] Greenway III and IV concluded that local fat can be reduced with topical application of forskohlin cream (Greenway III at 669; Greenway IV at 567S).
- [23] Greenway IV further concluded that thigh girth loss with topical forskohlin cream does not require weight loss; and, without weight loss, redistribution of the fat from the thighs to the intra-abdominal area seems unlikely (Greenway IV at 567S, col. 2, ¶ 3).
- [24] Greenway IV goes on to state that "[t]he amount of fat mobilized would presumably redistribute through all other fat depots" (Greenway IV at 567S, col. 2, ¶ 3).
- [25] Greenway IV still further concluded that since many women, whether or not they are obese, are concerned about the appearance of their thighs and the women receiving this cream "experienced an improved self-image which can result in tangible improvements in their perceived quality of life" (Greenway IV at 567S, col. 2, ¶ 4).
- [26] The Examiner finds that Greenway's (citing Figures 4 of Greenway III and IV) method inherently promotes lean body mass or shifts the proportion between lean body mass and adipose tissue in favor of lean body mass in an individual in need thereof by topical administration of forskohlin in a lean body mass promoting effective amount or proportion shifting amount to the thighs of obese women (Ans. at 6-8).

The Examiner's findings are sufficient to establish a prima facie case of anticipation. The respective study 3s of Greenway III and IV describe a method of localized fat (adipose tissue) reduction in a woman's thigh by

topical administration of an effective amount of forskohlin cream to the thigh of a human individual in need thereof (FFs 20-22), i.e., a method of promoting lean body mass or proportion shifting the lean body mass/adipose tissue ratio in favor of lean body mass as recited in claims 1 and 5. Further, Greenway IV teaches that such a human individual in need thereof may or may not be an obese woman (FF 23).

Appellant argues that the regional (thigh) lipolysis of Greenway III/IV leads to a systemic redistribution of body fat, without affecting total body fat or systemically shifting the proportion of lean body mass and adipose tissue in favor of lean body mass (App. Br. at 19). However, we decline to adopt Appellant's narrow interpretation limiting the claimed invention to systemic use and effectiveness (see claim construction discussion above).

Specifically, Appellant argues that Greenway III/IV fails to administer an "effective amount" of forskohlin (App. Br. at 20-22 and 24-25) to a "human individual in need thereof" (App. Br. at 23-25). Based on the Badmaev Declaration, and assuming that topical and oral dosing provide equivalent *in vivo* levels of forskohlin, Appellant calculates that "the subjects in Study 3 would have required about ½ liter of ointment per application" and such levels would not have been used in the Greenway studies (App. Br. at 21). Acknowledging that forskohlin might have produced localized fat reduction in the Greenway studies, Appellant nevertheless argues that the fat mobilized from the thighs would presumably redistribute elsewhere (App. Br. at 22). Finally, Appellant argues that dosage regime of Greenway III/IV is insufficient to provide an effective amount of forskohlin in view of the Badmaev Declaration showing that an

oral dose of 50 mg forskohlin per day significantly increased lean body mass only after eight weeks of treatment (App. Br. at 22).

As discussed above, we construe the scope of an "effective amount" broadly to encompass both systemic and localized effectiveness. Greenway III/IV disclose localized effective promotion of lean body mass and shifting of the ratio of lean body mass/adipose tissue in favor of lean body mass (FFs 20-22; see also Ans. at 22). None of the claims on appeal require any minimum degree or amount of lean body mass promotion or proportional shift in lean body mass/adipose tissue ratio, let alone an undefined "significant increase" in lean body mass. Secondly, Appellant has overstated Greenway IV's position on fat redistribution. According to Greenway IV, redistribution of fat from the thighs to the intra-abdominal area seems unlikely in the absence of weight loss; and, thigh girth reduction does not require weight loss (FF 23). Nonetheless, redistribution of fat from one depot (e.g., thigh) to another depot (e.g., intra-abdominal area) is only an issue if the claims are limited to systemic effectiveness, which they are not. Finally, the Badmaev Declaration is entitled to little, if any, weight for the reasons discussed above in regard to the Kazuo-based anticipation rejection. Thus, for the reasons given, Appellant has failed to show that the Examiner erred in finding that Greenway III and IV each administered an "effective amount" of forskohlin as required by claims 1 and 5.

Appellant also argues that neither Greenway III nor IV administer forskohlin to "a human individual in need thereof" because regional lipolysis does not necessarily lead to total body fat or weight reduction (App. Br. at 23 and 25). A woman who wants to reduce the girth of her thighs by

reducing the fat accumulated therein is a "human in need" of promoting lean body mass and/or shifting the proportion of lean body mass/adipose tissue in favor of lean body mass, albeit localized to her thighs, giving the claim term its broadest reasonable interpretation consistent with Appellant's specification. Since we decline to adopt Appellant's narrow construction of the claimed invention, we are not persuaded by this argument. Hence, Appellant has failed to show that the Examiner erred in finding that the women participating in study 3 of Greenway III and Greenway IV are "human[s] in need thereof" as recited in claims 1 and 5 (Ans. at 24).

Based on the foregoing, we AFFIRM the rejections of claims 1, 5, 11-12, and 31-34 under § 102(b) as anticipated by either Greenway III or Greenway IV.

C. Obviousness

A claimed invention is not patentable if the subject matter of the claimed invention would have been obvious to a person having ordinary skill in the art. 35 U.S.C. § 103(a); *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727 (2007); *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966). Facts relevant to a determination of obviousness include (1) the scope and content of the prior art, (2) any differences between the claimed invention and the prior art, (3) the level of ordinary skill in the art, and (4) relevant objective evidence of obviousness or non-obviousness. *KSR*, 127 S.Ct. at 1734; *Graham*, 383 U.S. at 17-18. It is well settled that "anticipation is the epitome of obviousness." *Cornell v. Sears Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983) (quoting *In re Fracalossi*, 681 F.2d 792, 794 (CCPA 1982)).

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Claims 1-34 stand rejected under 35 U.S.C. § 103(a) as obvious over Kazuo (Ans. at 8-11).

Appellant submits that claims 1-34 are unobvious over Kazuo for the same reasons claims 1, 5, 9-10, and 31-34 are not anticipated by Kazuo (App. Br. at 26-28). We find claims 1, 5, 9-10, and 31-34 to be anticipated by Kazuo under 35 U.S.C. § 102(b). Since "anticipation is the epitome of obviousness," we conclude that claims 1-34 are rendered obvious under 35 U.S.C. § 103(a) over Kazuo. *Fracalossi*, 681 F.2d at 794.

Based on the foregoing, we AFFIRM the rejection of claims 1-34 under § 103(a) as obvious over Kazuo.

CONCLUSION

Upon consideration of the record and for the reasons given, it is ORDERED that the Examiner's rejection of claims 31 and 32 as unpatentable under 35 U.S.C. § 112, first paragraph, is REVERSED;

FURTHER ORDERED that the Examiner's rejection of claims 1, 5, 9-10, and 31-34 as unpatentable under 35 U.S.C. § 102(b) as anticipated by Kazuo is AFFIRMED;

FURTHER ORDERED that the Examiner's rejection of claims 1, 5, 11-12, and 31-34 as unpatentable under 35 U.S.C. § 102(b) as anticipated by either Greenway III or Greenway IV is AFFIRMED;

FURTHER ORDERED that the Examiner's rejection of claims 1-34 as unpatentable under 35 U.S.C. § 103(a) as obvious over Kazuo is AFFIRMED; and

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FURTHER ORDERED that 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

MAT

Enc: USPTO translation of Kazuo by Akiko Smith dated 25 August 2005.

Merriam-Webster's COLLEGIATE DICTIONARY, tenth edition (1998) at 801 and 933.

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