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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JIANKANG LIU, YING WANG-SCHMIDT, KARIN WERTZ, and ZHIHUI FENG[1]

Appeal 2015-001172
Application 13/500,740
Technology Center 1600

Before JEFFREY N. FREDMAN, ULRIKE W. JENKS, and JOHN E. SCHNEIDER, *Administrative Patent Judges*.

JENKS, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims directed to maintaining or increasing muscle differentiation after strenuous physical exercise. The Examiner rejects the claims as anticipated. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] According to Appellants, the real party in interest is DSM IP ASSETS, B.V., Heerlen, Netherlands. (App. Br. 3.)

STATEMENT OF THE CASE

Claims 1–6 and 12 are on appeal, and can be found in the Claims Appendix of the Appeal Brief.[2] Claim 1 is representative of the claims on appeal, and reads as follows:

> 1. A method of maintaining or increasing muscle differentiation after strenuous physical exercise or under conditions where muscle is chronically inflamed, comprising administering an effective amount of hydroxytyrosol (HT) to a mammal, and observing a muscle differentiation effect.

Claim 12, the only other independent claim recites "observing a muscle differentiation effect, wherein the muscle differentiation effect is a lessening of Delayed Onset of Muscle Soreness, and wherein the muscle which is chronically inflamed is due to sarcopenia."

Appellants seek review of the following rejections:

I. claims 1–5 and 12 under 35 U.S.C. § 102(b) as being anticipated by Rietjens[3] as evidenced by Cheung[4] (App. Br. 8–12); and

II. claims 1, 6, and 12 under 35 U.S.C. § 102(b) as being anticipated by Raederstorff[5] (App. Br. 12–15).

I. Anticipation by Rietjens as evidenced by Cheung.

The Examiner finds that Rietjens discloses administering olive extracts containing hydroxytyrosol to subjects which "allows [the]

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[2] Claims 7–11 are withdrawn from consideration (*see* App. Br. 18).
[3] Rietjens et al., WO 2008/040550 A2, published April 10, 2008 ("Rietjens").
[4] Cheung et al., *Delayed Onset Muscle Soreness: Treatment Strategies and Performance Factors*, 332 Sports Med. 145–164 (2003).
[5] Raederstorff et al., WO 2007/042271 A2, published Apr. 19, 2007 ("Raederstorff").

participant to exercise or train for a longer period of tumour [sic] and to exercise more strenuously" (Final Act. 3). According to the Examiner, because the patients can exercise longer, Rietjens necessarily teaches administering hydroxytyrosolin in an effective amount (*id.* ("Hydroxytyrosol is advantageously present in the olive extract in an effective amount")).

Appellants contend that "the limitations of 'muscle differentiation' has not been considered by the Examiner in the context of the entire claim" (Reply Br. 2). "In the context of the entire claim, the manifestation of the observation is a step in the method of maintaining or increasing muscle differentiation in a person ingesting hydroxytyrosol" (*id.* at 3). Appellants' position is that the preamble should be construed as part of the claim (*id.*).

The issue is: Does the preponderance of evidence of record support the Examiner's finding that Rietjens teaches the claimed method?

Findings of Fact

FF1. Rietjens teaches that "olive extract decreases the amount of lactic acid which can accumulate in blood plasma, body and muscle cells during exercise. This allows the participant to exercise or train for a longer period of time, and to exercise more strenuously while minimizing post-exercise soreness" (Rietjens 2: 7–11; Final Act. 3).

FF2. Rietjens teaches:

> olive extracts containing hydroxytyrosol for the manufacture of a nutraceutical, preferably a medicament for the decrease of the lactate level in blood plasma, muscle or body and/or to prevent or decrease muscle fatigue, muscle pain, muscle soreness, or muscle cramps, or to recover faster from post-exercise muscle fatigue, muscle pain, muscle soreness or muscle cramps. The olive extracts of this invention are helpful in case of a

> performance of an elite athlete as well as after an exercise or performance of a less-well trained person.
>
> (Rietjens 6:1–7; Final Act. 3).

FF3. Rietjens teaches that "[h]ydroxytyrosol is advantageously present in the olive extract in an effective amount. Generally between 1 mg to about 500 mg of hydroxytyrosol" (Rietjens 9:15–16; Final Act. 3)

FF4. Rietjens teaches the administration of 200 mg hydroxytyrosol in a beverage the evening before and prior to the start of the exercise testing period (Rietjens 10–13, example 1).

FF5. Cheung teaches that Delayed Onset Muscle Soreness (DOMS) is "a type 1 strain injury and presents with tenderness or stiffness to the palpitation and/ or movement" and is "usually associated with unfamiliar high-force muscle work" (Cheung 147; Final Act. 3).

FF6. The Specification provides:

> "Observing muscle differentiation" means that the person who administered the HT or the person ingesting the HT notices a difference in muscle differentiation. This may be mainifested [sic] in the person noticing that he/she adapts to exercise better, feels better after exercise compared to exercising withour [sic] ingesting HT, and experiences less DOMS (delayed onset muscle soreness). The person or a trainer or other third party notices that the person ingesting HT responds better to training than before, or in comparison to a person of similar age, sex and fitness level who does not ingest HT.
>
> (Spec. 5).

FF7. The Specification explains "[m]uscle differentiation, i.e. the differentiation of satellite cells into new muscle fibers (myofibers, myotubes), plays a central role in mediating the growth and

regeneration of skeletal muscle both during postnatal growth and in adult life" (Spec. 1: 16–18).

Principle of Law

"A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation." *Perricone v. Medicis Pharmaceutical Corp.*, 432 F.3d 1368, 1375 (Fed. Cir. 2005). In *Cruciferous Sprout*, the court stated "[i]t is well settled that a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it." *In re Cruciferous Sprout Litigation*, 301 F.3d 1343, 1349 (Fed. Cir. 2002).

Analysis

Appellants contend that "the reference does not disclose any information regarding 'Delayed Onset' and instead only says it that the recovery is faster or the recovery time smaller" (App. Br. 9). "[S]ince the term is not stated in RIETJENS, one of ordinary skill in the art would not have any motivation to look for a definition of such a term in another reference" (*id.* at 11). Appellants contend that "[t]he differentiation of cells has not been discussed in the cited art" (Reply Br. 2). We are not persuaded.

The claimed method recites two positive methods steps, (1) the administration of hydroxytyrosol to a patient population and (2) "observing a muscle differentiation effect." Appellants urge us to interpret that the Specification requires that all three listed observations are necessarily required in order to meet the claim limitation of "observing a muscle differentiation effect" (*see* App. Br. 10). We are not persuaded by Appellants contention that the meaning of "observing a muscle differentiation effect" requires the presence of all three observed

manifestations namely: "adapts to exercise better, feels better after exercise compared to exercising without ingesting HT, **AND** experiences less DOMS" (*id.*).

> According to the Specification:
>
> "Observing muscle differentiation" means that the person who administered the HT or the person ingesting the HT notices a difference in muscle differentiation. This *may be* mainifested [sic] in the person noticing that he/she adapts to exercise better, feels better after exercise compared to exercising withour [sic] ingesting HT, and experiences less DOMS (delayed onset muscle soreness). The person or a trainer or other third party notices that the person ingesting HT responds better to training than before, or in comparison to a person of similar age, sex and fitness level who does not ingest HT.

(FF6 (emphasis added); *see* App. Br. 10). The Specification's use of the language "*may be"* when introducing the manifestations (FF6; *see* App. Br. 10), has been reasonably interpreted by the Examiner as introducing a list, and means that any one of the manifestations would reasonably meet the "observing a muscle differentiation effect" requirement of claim 1.

This interpretation is further supported by originally filed claim 2[6] that reads "[a] method according to Claim 1 wherein the muscle differentiation effect is a lessening of Delayed Onset of Muscle Soreness (DMOS)" (*see* Ans. 5 ("claim 2 recites solely the lessening of delayed onset of muscle soreness as the observing of a muscle differentiation effect and fails to recite the remaining two characteristics. It is clear that at the invention as claimed, is drawn to only one characteristic (i.e. lessening of DOMS) rather than the three characteristics of the definition. ")).

[6] Claims filed April 6, 2012.

We agree with the Examiner's interpretation that the claim limitation "observing a muscle differentiation effect" only requires one of the characteristics listed in the Specification (FF6), because any other interpretation would mean that dependent claim 2 is broader in scope than the claim form which it depends. "[T]he presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Phillips v. AWH Corp*, 415 F.3d 1303, 1315 (Fed. Cir. 2005); *see AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1242 (Fed. Cir. 2003) ("Under the doctrine of claim differentiation, dependent claims are presumed to be of narrower scope than the independent claims from which they depend"), and *Free Motion Fitness, Inc. v. Cybex Int'l, Inc.*, 423 F.3d 1343, 1351 (Fed. Cir. 2005) ("The doctrine of claim differentiation creates a presumption that each claim in a patent has a different scope).

Accordingly, the limitation of "observing muscle differentiation" as understood in light of the Specification and originally filed claims includes a selection from (1) the person noticing that he/she adapts to exercise better, (2) feels better after exercise compared to exercising without ingesting HT, and (3) experiences less DOMS (delayed onset muscle soreness). In other words, the disclosure of any one of these observations is sufficient to meet the claimed limitation of "observing muscle differentiation."

We are not persuaded by Appellants contention that "[t]he differentiation of cells has not been discussed in the cited art" (Reply Br. 2). Rietjens teaches administering hydroxytyrosol (FF1 & FF2) in an amount ranging from 1 mg to 500 mg per serving (FF3), specifically exemplifying the administration of 200 mg before commencing an exercise regime (FF4).

"Rietjens teaches the treatment of post-exercise muscle fatigue, muscle soreness, or muscle cramps with administration of an effective amount of HT. This allows for the participant to exercise or train for a longer period of tumor [sic] and to exercise more strenuously" (Ans. 6; FF1–FF4). A reference may anticipate even if the limitations are not expressly recited. *See In re Cruciferous Sprout Litigation*, 301 F.3d at 1349. The issue is whether Rietjens teaches maintaining or increasing muscle differentiation. On the molecular level, muscle differentiation is the process in which cells turn into new muscle fibers (FF7). Neither the claim nor the Specification requires that this process is observed on the molecular level, instead the Specification explains that if you find your ability to adapt to exercise is improved with the consumption of hydroxytyrosol (FF6) then this meets the claimed limitation of "observed muscle differentiation." We find no error with the Examiner's finding that Rietjens teaches administering hydroxytyrosol, in an effective amount ranging from 1–500 mg per serving to a population that is exercising (*see* FF4). The ability for this study population to "exercise or train for a longer period of time, and to exercise more strenuously while minimizing post-exercise soreness" with the consumption of hydroxytyrosol (FF1) means that muscle differentiation must necessarily have been either maintained if not improved.

We are also not persuaded by Appellants contention that "[t]he differentiation of cells has not been discussed in the cited art" (Reply Br. 2). We recognize that the Specification explains that muscle differentiation on molecular level is the ability of cells to turn into muscle fibers (FF7). However, the Specification also teaches that "observing muscle differentiation" can be through exercising better, feeling better after exercise

or by experiencing fewer sore muscles (FF6). In other words, the Specification recognizes that the underlying molecular changes in the muscle tissue, i.e. the production of more muscle fibers (FF7) can be observed by improved exercise stamina (FF6). So if you observe an improvement in your ability to exercise, this will correlated to an improvement in the muscle fiber.

Additionally, we agree with the Examiner that the preamble of the claim is not a limitation because it does not breath life and meaning into the claim. Here, the body of the claim is complete in that it requires the administration of hydroxytyrosol and an observation of an improved effect. *See Pitney Bowes Inc. v. Hewlett Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999), see e.g., Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.,* 246 F.3d 1368, 1375 (Fed. Cir. 2001) ("The steps of the . . . method are performed in the same way regardless whether or not the patient experiences a reduction in hematologic toxicity, and the language of the claim itself strongly suggests the independence of the preamble from the body of the claim.").

We are also not persuaded by Appellants contention that there is no reason to look for a definition of "delayed onset muscle soreness" (DOMS) in other references (*see* App. Br. 9 and 11). We do not agree with Appellants position that because the term DOMS is not found in Rietjens the limitation is not found in the reference (*see* App. Br. 9 and 11). We find no error with the Examiner's reliance on the definition of DOMS found in Cheung (FF5) to conclude that the improvement of "muscle fatigue and muscle soreness as is recited in Rietjens" meets the limitation of lessening DOMS (Ans. 4).

Since the Examiner has established a prima facie case of anticipation, "after the PTO establishes a prima facie case of anticipation based on inherency, the burden shifts to appellant to 'prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.'" *In re King*, 801 F.2d 1324, 1327 (Fed. Cir. 1986) quoting *In re Swinehart*, 439 F.2d 210, 212-13 (CCPA 1971). In our opinion, Appellants have not satisfied this burden because they have not provided sufficient evidence to rebut the prima facie case presented by the Examiner.

The evidence of record suggests administering a composition comprising an effective amount of hydroxytyrosol as required by claim 1. Accordingly, we affirm the anticipation rejection of claim 1. Claims 2–6 and 12 were not separately argued and fall with claim 1. 37 C.F.R. § 41.37 (c)(1)(iv).

II. Anticipation by Raederstorff

The Examiner finds that Raederstorff [] "teach[es] a method of treating diseases associated with muscle loss such as sarcopenia with administration of hydroxytyrosol" (Final Act. 3; Ans. 3).

The issue is: Does the evidence of record support the Examiner's finding that Raederstorff teaches preventing muscle wasting by administration of hydroxytyrosol?

Findings of Fact

FF8. Raederstorff teaches that "normal aging in humans is associated with progressive decrease in skeletal muscle mass and strength, a condition called sarcopenia, which contributes to frailty and falls" (Raederstorff 3:28–30; Final Act. 3). Specifically, Raederstorff explains that "[a]s

the body ages, an increasing proportion of skeletal muscle is replaced by fibrous tissue" (Raederstorff 3:27–28).

FF9. Raederstorff teaches that chronic inflammation can cause muscle wasting as well (*see* Raederstorff 4:5–8).

FF10. Raederstorff teaches that compositions containing hydroxytyrosol "may be useful for the prevention and treatment of muscle wasting leading to muscle loss and atrophy and the associated muscle disorders in animals, in particular mammals including humans" (Raederstorff 4:25–28).

FF11. Raederstorff teaches the dose of hydroxytyrosol in a food composition is between 0.3 to 1250 mg per serving. In pharmaceutical formulation the concentration can be 1-4000 mg per dose, and can include other active ingredients as well (Raederstorff 6:15-21; *see* Final Act. 3–4).

Analysis

We have reviewed Appellants' contentions that the Examiner erred in rejecting claims 1, 6, and 12 as anticipated by Raederstorff. (App. Br. 12–15.) We disagree with Appellants' contentions and adopt the findings concerning the scope and content of the prior art set forth in the Examiner's Answer and the Final Rejection (*see also* FF8–FF11).

Appellants contend that the Specification defines the meaning of "observing a muscle differentiation effect" as describing that all three listed effects must necessarily be present (App. Br. 13–14). For the same reasons discussed above (*see I.*), we are not persuaded that the Specification and originally filed claims support Appellants contention that all three listed observations must be present to meet the limitation "observing a muscle differentiation effect" in order for a reference to anticipate.

Appellants contend that muscle disease and atrophy are distinct from "from muscle soreness or sarcopenia" (App. Br. 14). We are not convinced by Appellants contention that atrophy which is the wasting or decrease in muscle differs from sarcopenia which is a decrease in skeletal muscle mass (FF8). On this record, we find that Examiner has established a prima facie case of anticipation, and Appellants have not provided sufficient evidence to rebut that prima facie case presented by the Examiner we affirm the rejections based on Raederstorff for the reasons given by the Examiner in the Final Action and Answer.

SUMMARY

We affirm the rejection of claim 1 under 35 U.S.C. § 102(b) by Rietjens evidenced by Cheung. Claims 2–6 and 12 were not separately argued and fall with claim 1. 37 C.F.R. § 41.37 (c)(1)(iv).

We affirm the rejection of claims 1, 6, and 12 under 35 U.S.C. § 102(b) by Raederstorff.

TIME PERIOD FOR RESPONSE

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