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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/965,069	12/10/2015	John-Paul Mua	N64138 1090US.1 (0038.1)	4177

26158 7590 10/08/2019

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P.O. BOX 7037
ATLANTA, GA 30357-0037

EXAMINER	
NGUYEN, JOHN P	

ART UNIT	PAPER NUMBER
1619	

NOTIFICATION DATE	DELIVERY MODE
10/08/2019	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JOHN-PAUL MUA, GONG CHEN, THADDEUS JUDE JACKSON, ANTHONY RICHARD GERARDI, KYLE FORD, BARRY SMITH FAGG, and MELISSA ANN CLARK

Appeal 2018-008606
Application 14/965,069
Technology Center 1600

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and JOHN E. SCHNEIDER, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from Examiner's decision to reject claims 1–23.[2] We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as "Niconovum USA" (Appellant's March 29, 2018 Appeal Brief (Br.) 1).

[2] Pending claims 24–29 stand withdrawn from consideration (Examiner's October 27, 2017 Final Office Action (Final Act.) 2).

STATEMENT OF THE CASE

Appellant's disclosure "relates to compositions and products that contain active ingredients and, in particular, to nicotine-containing compositions and products characterized as having a pharmacological effect and that can be considered to be useful for therapeutic purposes" (Spec. 1:1–4). Claims 1, 14, and 15 are representative and reproduced below:

> 1. A protein-enriched pharmaceutical product comprising:
>
> a nicotinic compound;
>
> a protein-enriched, tobacco-derived material in an amount of about 2 percent to about 10 percent by dry weight; and
>
> one or more sugar alcohols in an amount of at least 10 percent by dry weight,
>
> wherein the protein-enriched, tobacco-derived material comprises at least 60 percent tobacco-derived protein by dry weight.

(Br. 16 (Claims App'x).)

> 14. The protein-enriched pharmaceutical product of claim 1, further comprising a binder in an amount of between 2 percent and 10 percent by dry weight.

(*Id.* at 17.)

> 15. The protein-enriched pharmaceutical product of claim 14, wherein the binder comprises pregelatinized rice starch.

(*Id.*)

Grounds of rejection before this Panel for review:

Claims 1–14 and 16–23 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Duggins,[3] Wildman,[4] and Lo.[5]

Claim 15 stands rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Duggins, Wildman, Lo, and Hsu.[6]

ISSUE

Does the preponderance of evidence relied upon by Examiner support a conclusion of obviousness?

FACTUAL FINDINGS (FF)

FF 1. Duggins "relates to compositions that contain nicotine, and in particular, to nicotine-containing pharmaceutical compositions intended to be administered to provide a pharmacological effect, or otherwise used for therapeutic purposes" (Duggins ¶ 1; *see id.* ¶ 24 ("The shape of . . . [Duggins'] composition can, in certain embodiments, resemble a wide variety of pill, tablet, lozenge, capsule, and caplet types of products"); *see generally* Final Act. 5).

FF 2. Duggins discloses:

> [A] process for preparing a multi-layered pharmaceutical composition, comprising: preparing a first formulation by combining a nicotinic compound with one or more components selected from the group consisting of[, *inter alia*,] binders, . . . sugar alcohol syrups, . . . humectants, . . . and mixtures thereof

[3] Duggins et al., US 2013/0209540 A1, published Aug. 15, 2013.
[4] Samuel Wildman, *An alternate use for tobacco agriculture: Proteins for food plus a safer smoking material*, PRINCETON UNIV. 63–77 (1996), https://www.princeton.edu/~ota/disk3/1983/8315/831507.PDF.
[5] Lo et al., US 2010/0093054 A1, published Apr. 15, 2010.
[6] Hsu et al., US 2005/0147670 A1, published July 7, 2005.

> to form a first nicotinic compound-containing mixture and forming the first nicotinic compound-containing mixture into a desired form; preparing a second formulation by combining a nicotinic compound with one or more components selected from the group consisting of[, *inter alia*,] binders, . . . sugar alcohol syrups, . . . humectants, . . . and mixtures thereof to form a second nicotinic compound-containing mixture . . . into a desired form; and applying the second formulation to the first formulation, wherein the formulations are selected from[, *inter alia*,] formulations . . . iv), as described . . . [by Duggins].

(Duggins ¶ 20; *see* Final Act. 5.)

FF 3. Duggins discloses that "[a] binder (or combination of binders) may be employed in amounts sufficient to provide the desired physical attributes and physical integrity to the pharmaceutical composition," wherein "a representative amount of binder may make up at least about 5 percent, at least about 10 percent, at least about 15 percent, at least about 20 percent, or at least about 25 percent of the total dry weight of the composition" (Duggins ¶ 58; *see id.* (Duggins discloses that "the binder material includes a natural gum," "a natural gum refers to polysaccharide materials of natural origin that are useful as thickening or gelling agents," and provides examples of natural gum binders); *see* Final Act. 5).

FF 4. Duggins discloses that formulation "iv) comprises a nicotinic compound; humectant in an amount of about 0.5% by weight or greater; sugar alcohol filler in an amount of about 20% by weight or greater; and a natural gum binder in an amount of about 10% or greater" (Duggins ¶ 15).

FF 5. Examiner finds that "Duggins does not specifically disclose [a] . . . composition comprises a protein-enriched and tobacco-derived material" (Final Act. 8).

FF 6. Wildman discloses "[a] simple method . . . for extracting the proteins from the aerial portions of fresh tobacco and other plants," wherein "[t]he water soluble proteins have unique nutritional and functional properties that could make them valuable for the package food industry and for medical use. The insoluble proteins have properties similar to soy protein" (Wildman, Abstract; *see* Final Act. 8).

FF 7. Lo discloses "methods for obtaining proteins from plant leaves for use in food and industrial products" (Lo ¶ 3; *see generally* Final Act. 8).

FF 8. Lo discloses that "[a]pproximately half of the soluble protein in plant leaves is made up of 'rubisco' (ribulose-1,5-bisphosphate (RUBP) carboxylase/oxygenase or 'RuBisCO') . . . , which is found in all known green plants, appears to be the most abundant leaf protein, and it may be the most abundant protein on earth" (*id.* ¶ 6; *see* Final Act. 8).

FF 9. Lo discloses that rubisco "has excellent binding, gelling, foaming, whipping and emulsifying characteristics . . . [and] is colorless, tasteless and odorless, which makes it attractive for incorporation into food or industrial products." (*id.* ¶ 8; *see* Final Act. 8).

FF 10. Lo "obtained crude protein yields of approximately 13% of total leaf dry weight from tobacco variety MD 609 LA, a variety of Maryland tobacco which contains low alkaloids" (*id.* ¶ 10; *see generally* Final Act. 8 (Examiner finds that "Lo discloses proteins from tobacco leaf")).

FF 11. Lo discloses a method of preparing "leaf protein powder containing 97.5% purity" and "[m]ore preferably, . . . 99% purity" (*id.* ¶ 64; *see* Final Act. 9).

FF 12. Examiner finds that although Duggins discloses "binders [that] include starched-based binders," the combination of "Duggins, Wildman and

Lo do not specifically teach that the binder comprises pregelatinized rich starch" (Final Act. 10 (citing Duggins ¶ 44)).

FF 13. Hsu discloses "pharmaceutical dosage forms having immediate release via rapid oral disintegration" (Hsu, Abstract; *see* Final Act. 10).

FF 14. Hsu discloses that "[b]inders are one or more ingredients that are added [to orally-disintegrating tablets] to form granules and/or promote cohesive compacts during compression" (Hsu ¶ 46).

FF 15. Hsu discloses that "binder will typically be present in about one percent to about 80 percent by weight of the total tablet weight," wherein "[w]hen the binder comprises starch, any pharmaceutically acceptable starch may be used in the present invention, including potato starch, rice starch, com starch and pregelatinized starch," (Hsu ¶ 47; *see* Final Act. 11).

ANALYSIS

Obviousness over the combination of Duggins, Wildman, and Lo:

"Duggins discloses a pharmaceutical composition comprising nicotinic compound and components including binders, fillers and sugar alcohol syrups" (Final Act. 9; *see* FF 2–4). According to Duggins, natural gum binders are useful as thickening or gelling agents (FF 3). Lo also discloses a binder, rubisco, a protein obtained from tobacco leave, "has excellent binding, gelling, foaming, whipping and emulsifying characteristics . . . [and] is colorless, tasteless and odorless, which makes it attractive for incorporation into food or industrial products" (FF 8–9; *see also* Final Act. 9–10 (Examiner finds that "proteins from tobacco leaf are natural, suitable for pharmaceuticals, have excellent binding characteristics, is colorless, odorless and tasteless"). Examiner further finds that "Lo

teaches a [tobacco leave] protein powder with a 99% purity (e.g. at least about 80 percent tobacco)" (Final Act. 10; *see* FF 11).

Based on the combination of Duggins, Wildman, and Lo, Examiner concludes that, at the time Appellant's invention was made, it would have been prima facie obvious

> to produce a nicotinic compound containing composition comprising one or more nicotinic compounds, a combination of binders including [protein-enriched, tobacco-derived material] . . . (e.g. RuBisCO) . . . at least one filler including a sugar alcohol and humectants; wherein the amount of . . . binder[] includes up to at least about 5 percent; wherein the amount of the at least one filler is about 20% by weight or greater; and wherein the amount of the humectants is at least about 1 percent by weight.

(Final Act. 9; *see* FF 1–11.)

Appellant contends that Duggins discloses a variety of formulations and one of ordinary skill in this art "would be led to the more focused disclosures in the Duggins reference on various formulations (*i.e.*, dissolvable, pastille, meltable, chewable, or hard coating)" (Br. 5; *see also id.* at 6 (Appellant contends that "[o]ne of skill in the art would readily appreciate that each such formulation is different, both compositionally and physically, and that certain components and amounts relevant and useful in one such formulation are not necessarily relevant and useful in another such formulation"); *id.* at 6–7). In this regard, we note that Duggins discloses that formulation "iv) comprises a nicotinic compound; humectant in an amount of about 0.5% by weight or greater; sugar alcohol filler in an amount of about 20% by weight or greater; and a natural gum binder in an amount of about 10% or greater" (FF 4). Thus, Duggins discloses a nicotinic

compound and sugar alcohol, as required by claim 1, in the same formulation.

With respect to the amount of tobacco derived material recited in claim 1, Duggins discloses that "a representative amount of binder may make up at least about 5 percent, at least about 10 percent, at least about 15 percent, at least about 20 percent, or at least about 25 percent of the total dry weight of the composition" (FF 3). Therefore, we are not persuaded by Appellant's contention that the binder concentration, of about 10% or greater, in Duggins' formulation iv) "is inconsistent with the binder content referenced in [Duggins'] paragraph [0058]" (App. Br. 7–8).

Further, on this record, Examiner finds that rubisco, a protein obtained from tobacco leaf, has excellent binding and gelling characteristics in addition to being "colorless, tasteless and odorless, which makes it attractive for incorporation into food or industrial products" (FF 9). Thus, we find no error in Examiner's conclusion that a person of ordinary skill in this art would have found it prima facie obvious to substitute rubisco for Duggins' natural gum binder because both have gelling properties (*see generally* Ans. 6 (Examiner finds that a person of ordinary skill in this art would have found it prima facie obvious to substitute rubisco for Duggins' natural gum binder); Br. 9 (Appellant appreciates Examiner's rationale that the binder "component of the Duggins reference . . . would purportedly be replaced with . . . the purported protein-enriched, tobacco-derived material of the Wildman and Lo references")). Therefore, we are not persuaded by Appellant's contention that Duggins' formulation iv), as modified by Wildman and Lo to include at least about 10% rubisco binder, is "inconsistent with the [protein] amount [of about 2 percent to about 10

percent by dry weight] recited in [Appellant's] . . . pending claim[] [1]" (App. Br. 7–8). *See In re Geisler*, 116 F.3d 1465, 1468 (Fed. Cir. 1997) (Overlapping ranges support a prima facie case of obviousness.).

In addition, a sugar alcohol concentration of at least 10 percent by dry weight, overlaps Duggins' formula iv) sugar alcohol concentration of about 20% by weight or greater of Duggins. *See id.* Therefore, we are not persuaded by Appellant's contention that Examiner

> has pointed to nothing in the cited reference[s] that would lead one specifically to a product containing both a protein-enriched, tobacco-derived material in an amount of <u>about 2 percent to about 10 percent by dry weight</u>; and one or more sugar alcohols in an amount of <u>at least 10 percent by dry weight</u>

(Br. 8).

For the foregoing reasons we are not persuaded by Appellant's contention that Examiner's conclusion of obviousness is based "on impermissible hindsight, using the present application as a guide" (*id.*).

Appellant contends that a natural gum binder has "fundamentally different properties than a protein-enriched [binder] material" (Br. 10; *see also id.* at 11 (Appellant contends that protein binders such as rubisco cannot be equated with starch-based binders as described in Duggins)). Appellant, however, fails to identify an evidentiary basis on this record to support Appellant's contention. *In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974) ("Attorney's argument in a brief cannot take the place of evidence."). In contrast, the evidence of record establishes that rubisco, a protein obtained from tobacco leaf, has excellent binding characteristics in addition to being "colorless, tasteless and odorless, which makes it attractive for incorporation into food or industrial products" (FF 9). Thus, absent evidence to the contrary, we find no error in Examiner's conclusion that a person of ordinary

skill in this art would have found it prima facie obvious to have substituted rubisco for Duggins' natural gum binder. *See In re Fout*, 675 F.2d 297, 301 (CCPA 1982) ("Express suggestion to substitute one equivalent for another need not be present to render such substitution obvious."). As mentioned above, Lo expressly discloses that rubisco has, *inter alia*, excellent gelling properties (FF9), making it an obvious alternative to a natural gum which Duggins ascribes having the same properties (FF3). Therefore, we are not persuaded by Appellant's unsupported contention that Examiner "has pointed to nothing to teach or suggest that the protein-enriched materials purportedly disclosed in the Wildman/Lo references can be reasonably equated with such gum-based [binder] materials and/or that such protein-enriched [binder] materials would be expected to serve a comparable function within the purported composition of the Duggins reference" (Br. 10; *see also id.* at 11 (Appellant contends "that one of skill in the art would have no reasonable expectation in replacing the 'starch-based binder' or the 'natural gum binder' of the Duggins reference with a protein-based material"); *id.* at 12 (Appellant contends that "the Lo reference does not quantify the 'binding' characteristics of leaf-derived proteins, much less the 'binding' characteristics purportedly exhibited by tobacco-derived proteins")).

For the foregoing reasons, we are not persuaded by Appellant's unsupported contention that "one of skill in the art would have no reasonable expectation of success in making the proposed modification to the purported composition of the Duggins reference (*i.e.*, incorporating a protein-enriched, tobacco-derived material in the recited amount therein)" (Br. 11).

To be complete, because claims 24–26 stand withdrawn from consideration, we do not address Appellant's contentions regarding these claims (*see* Final Act. 2; *cf.* Br. 12–13).

Obviousness over the combination of Duggins, Wildman, Lo, and Hsu:

As discussed above, the combination of Duggins, Wildman, and Lo suggests a composition, within the scope of Appellant's claimed invention, that is also in the form of a tablet (*see* FF 1; *see also* FF 2–11). Hsu discloses compositions in the form of tablets (FF 14). Hsu, as well as, the combination of Duggins, Wildman, and Lo also discloses compositions in the form of a tablet that comprise more than one binder (FF 3 and 14).

Based on the combination of Duggins, Wildman, Lo, and Hsu, Examiner concludes that, at the time Appellant's invention was made, it would have been prima facie obvious

> to produce a nicotinic compound containing composition comprising one or more nicotinic compounds, a combination of binders including pregelatinized rice starch, . . . [and rubisco], at least one filler including a sugar alcohol and humectants; wherein the amount of the combination of binders includes up to at least about [10] percent; wherein the amount of the at least one filler is about 20% by weight or greater.

(Final Act. 11.)

Having found no deficiency in the combination of Duggins, Wildman, and Lo, we are not persuaded by Appellant's contention that Hsu "does not remedy the deficiencies of the Duggins, Wildman, and Lo references" (App. Br. 14). Because the rejection is based on the combination of Duggins, Wildman, Lo, and Hsu, we are also not persuaded by Appellant's contention that Hsu alone "does not disclose a pharmaceutical composition with the recited components in the recited amounts" (*id.*).

CONCLUSION

The preponderance of evidence relied upon by Examiner supports a conclusion of obviousness.

The rejection of claim 1 under 35 U.S.C. § 103(a) as unpatentable over the combination of Duggins, Wildman, and Lo (Rejection I) is affirmed. Claims 2–14 and 16–23 are not separately argued and fall with claim 1.

The rejection of claim 15 under 35 U.S.C. § 103(a) as unpatentable over the combination of Duggins, Wildman, Lo, and Hsu is affirmed.

In summary:

Claims Rejected	35 U.S.C. §	Basis	Affirmed	Reversed
1–14, 16–23	103	Duggins, Wildman, Lo	1–14, 16–23	
15	103	Duggins, Wildman, Lo, Hsu	15	
Overall Outcome			1–23	

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