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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte KARIM AMIGHI and
ANTONIO SERENO GUERRA[1]

Appeal 2019-000134
Application 13/122,134
Technology Center 1600

Before JOHN G. NEW, RYAN H. FLAX, and JAMIE T. WISZ, *Administrative Patent Judges.*

NEW, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1] We use the word "Appellant" to refer to the "applicant" as defined in 37 C.F.R. § 1.142. Appellant identifies Laboratorios Linconsa, S.A. as the real party-in-interest. App. Br. 3.

SUMMARY

Appellant files this appeal under 35 U.S.C. § 134(a) from the Examiner's Final Rejection of claims 1, 34–41, 45, and 46 as unpatentable under 35 USC § 103(a) as being obvious over the combination of Woolfe et al. (US 2002/0081266 A1, June 27, 2002) ("Woolfe") and Zeng (US 2010/0326437 A1, December 30, 2010) ("Zeng").

We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

NATURE OF THE CLAIMED INVENTION

Appellant's invention is directed to inhalable particles comprising a stabilized amorphous form of tiotropium with a stabilizing agent. Abstr.

REPRESENTATIVE CLAIM

Claim 1 is representative of the claims on appeal and recites:

> 1. Inhalable particles consisting of a stabilized anhydrous amorphous form of tiotropium bromide and a stabilizing agent, the stabilizing agent being lactose, wherein the percentage (%) of tiotropium bromide in weight relative to the weight of tiotropium bromide and stabilizing agent is comprised between 4-8%, wherein the tiotropium bromide present in the inhalable particles contains less than 10% crystalline fractions, the inhalable particles being spray dried, and the stabilized anhydrous amorphous form of tiotropium bromide with the stabilizing agent comprises a matrix in which the tiotropium bromide is dispersed in a molecular state.

App. Br. 18.

ISSUES AND ANALYSES

We adopt the Examiner's findings, reasoning, and conclusion that the claims on appeal are *prima facie* obvious over the cited prior art. Arguments made by Appellant in the Appeal Brief and properly presented in the Reply Brief have been considered; arguments not so-presented are waived. *See* 37 C.F.R. § 41.37(c)(1)(iv) (2017); *see also Ex parte Borden*, 93 USPQ2d 1473, 1474 (BPAI 2010) (informative) ("Any bases for asserting error, whether factual or legal, that are not raised in the principal brief are waived."). We address the arguments raised by Appellant below.

Issue 1:

Appellant argues the Examiner erred in finding that Woolfe teaches or suggests the combination of a sugar derivative as a stabilizer with tiotropium. App. Br. 10–11.

Analysis

The Examiner finds that Woolfe teaches a formulation comprising a mixture of particle of drugs and excipients spray dried for administration, in which the drugs include amorphous tiotropium and the excipient is lactose. Final Act. 4 (citing Woolfe Abstr., ¶¶ 41, 94, claim 12). The Examiner finds that Woolfe teaches that the particles are spray dried. *Id.* (citing Woolfe Abstr.). The Examiner finds that Woolfe further teaches the optional use of additional excipients in preferred formulations. *Id.* (citing Woolfe ¶ 50).

The Examiner further finds that Woolfe teaches that the stabilized anhydrous amorphous form of tiotropium with the stabilizing agent comprises a matrix in which tiotropium is dispersed in a molecular state in

which the particles are a pharmaceutical composition. Final Act. 4 (citing Woolfe Abstr., ¶¶ 40–41). The Examiner finds that Woolfe teaches that its compositions may be synthesized by spray drying, and that combining the two constituents in solution before spray drying would result in a dispersion of the two ingredients. *Id.* (citing Woolfe ¶¶ 16, 72).

However, the Examiner finds that Woolfe does not expressly teach: (1) that the inhalable medicament is tiotropium bromide; or (2) that the percentage (%) of tiotropium bromide in weight relative to the weight of tiotropium bromide and stabilizing agent is comprised between 4–8%. Final Act. 6.

The Examiner finds that Zeng teaches an inhalable medicament of tiotropium bromide in the form of solid amorphous particles in combination with a sugar, the sugar being lactose. Final Act. 6 (citing Zeng Abstr. ¶ 14). The Examiner finds that Zeng teaches that the percentage of tiotropium bromide in weight relative to the weight of tiotropium bromide and stabilizing agent is between 1:10 to 1:500 (which equates to about 0.1 to 50 wt%), which encompasses the claimed range of 4–8 wt%. *Id.* (citing Zeng ¶ 23).

The Examiner concludes that it would have been *prima facie* obvious to a person of ordinary skill in the art to use tiotropium bromide, as taught by Zeng, in the pharmaceutical preparation taught by Woolfe, because Woolfe teaches the use of tiotropium and salts thereof and Zeng teaches tiotropium bromide, a tiotropium salt, which is known to be used in inhalation pharmaceutical formulations. Final Act. 7 (citing Zeng Abstr.). The Examiner concludes that a skilled artisan would have a reasonable expectation of success in combining the references, because Woolfe teaches

amorphous tiotropium salt-lactose compositions, and Zeng teaches amorphous tiotropium bromide-lactose particles in the claimed concentrations. *Id.* (citing Woolfe ¶ 94; Zeng Abstr.).

Appellant argues that Woolfe neither teaches nor suggests that the sugar derivatives can have the function of stabilizing agents. App. Br. 10. Rather, Appellant argues, a careful reading of Woolfe reveals that the sugar is not used as a stabilizer. *Id.* According to Appellant, Woolfe specifically discloses that, in addition to sugars, the formulations described may also include further excipients selected from pH stabilizers (paragraph [0044]) and that preferred formulations may also include a stabilizer an as excipient, including antioxidants, pH modifiers, or buffers. *Id.* (citing Woolfe ¶¶ 44, 50). Appellant asserts that the reference is not directed to the combination of tiotropium with a sugar, much less lactose as a stabilizing agent. *Id.*

Appellant contends that the Examiner is confusing the teachings of Woolfe with the discovery of the present invention, in which the lactose functions as both a stabilizing agent for the tiotropium bromide, and also in which the lactose can be further and separately formulated as an excipient for the stabilized amorphous tiotropium bromide/lactose particles. App. Br. 10–11. Appellant argues that the claimed invention describes at length the necessity of a stabilizing agent for preventing the desirable amorphous form of the tiotropium bromide drug active from transforming into the undesirable crystalline form. *Id.* at 11 (citing Spec. ¶¶ 29, 31, 32, 43).[2]

Appellant contends that the claimed invention also discloses the desirability, in some embodiments, of further incorporating an excipient,

[2] We note that the Specification as filed lacks numbered paragraphs.

such as lactose, for flow and delivery properties for inhalation therapy of the drug active. *Id.* (citing Spec. ¶ 39, claim 35). Appellant cites paragraph [0043] of the Specification, which, Appellant argues, explains that the stabilizing agent can be selected from chemically identical or chemically different substances. *Id.* Therefore, Appellant contends, when lactose is selected as both the stabilizing agent and the excipient, the lactose then exists in two separate components of the formulation: (1) as a stabilizing agent in intimate contact with the tiotropium bromide as part of the inhalable amorphous drug active particles; and (2) externally and separately from those drug active particles as a delivery medium excipient. *Id.* (citing Spec. ¶¶ 38, 39).

Appellant argues that, because of this alleged distinction between the dual and separate formulation and functional aspects of the lactose constituent, Woolfe is no longer relevant. App. Br. 11. According to Appellant, Woolfe does not teach lactose *as a stabilizer* for intimate admixture with the drug active component, but rather as an excipient external to the drug active component. *Id.* (citing Woolfe ¶ 56). Appellant contends that Woolfe nowhere teaches or suggests a formulation or process in which the active ingredient is intimately admixed with either a solution or suspension of a stabilizing agent prior to spray drying. *Id.* Rather, Appellant asserts, Woolfe teaches that the active ingredient is directly spray dried without such a stabilizer. *Id.* Appellant contends that, because Woolfe is allegedly inapposite and irrelevant, the Examiner is allegedly "cherry picking" unrelated passages from throughout the reference in an attempt to make a case of obviousness. *Id.*

Appellant argues further that all of the examples of Woolfe are directed to spray-dried particles made of drugs other than tiotropium and without any excipients. App. Br. 11. Appellant contends that none of the specific particles disclosed in the reference contain sugar derivatives. App. Br. 11. Appellant notes that the X-ray powder diffraction analysis on some of the examples in Woolfe strongly suggests that the spray-dried products are at least partly crystalline. *Id.* (citing Woolfe ¶¶ 91, 92, 146). Appellant further observes that, although tiotropium is listed as a possible drug, and sugar derivatives are mentioned as possible excipients, Woolfe teaches that the disclosed particles do not need to contain any excipients and that they are not necessarily amorphous. *Id.* at 11–12. To summarize, Appellant argues, Woolfe does not teach or suggest an anhydrous amorphous stable form of tiotropium bromide or how to prepare such a form. *Id.* at 12.

Appellant next points to paragraph [0094] of Woolfe, which teaches production of amorphous ipratropium (an anti-cholinergic drug having a different chemical structure from tiotropium), but only in the presence of an additional drug active, salbutamol, and using water as a solvent. App. Br. 12. In contrast, Appellant asserts, when using ipratropium alone (without the salbutamol) in water or ethanol, crystalline material was obtained. *Id.* (citing Woolfe ¶¶ 92, 93). Appellant therefore contends that the very specific components, additional drug actives, and excipients play a key role in determining the final nature of the product obtained. *Id.* Appellant asserts that one cannot merely pick and choose ingredient teachings from the cited art references in an attempt to achieve the present invention, when seemingly slight modifications can shift the final product from the amorphous to the crystalline form. *Id.*

We are not persuaded by Appellant's arguments. Woolfe teaches spray-dried powders for pulmonary or nasal administration. Woolfe Title. Woolfe teaches that: "The component or components may be an excipient designed to stabilise the drug or give better content uniformity of the drug or product." Woolfe ¶ 3.

Specifically, Woolfe teaches that:

> Any combination of drugs and excipients including mixtures of drugs and excipients, for example as referred to above may be used.… Preferred muscarine bronchial dilating agents include ipatropium, oxitropium, *tiotropium, and salts thereof.*
> …
> The particles may comprise a single drug or a combination of two or more drugs together with one or more excipients suitable for nasal of pulmonary delivery. *Excipients may be sugars, for example selected from; lactose*, mannitol, xylitol, trehalose, dextrose and other pharmaceutically acceptable sugars.

Woolfe ¶¶ 40–41 (emphases added). Woolfe thus teaches a combination of a tiotropium salt (e.g., tiotropium bromide) and lactose as an excipient. Woolfe further teaches that excipients can act as either stabilizing agents or to give better content uniformity. *Id.* at ¶ 3.

We agree with Appellant that Woolfe also teaches other optional excipients that can act as pH stabilizers, pH modifiers, and antioxidants. Woolfe ¶¶ 44, 50. However, the addition of such optional excipients does not change the fact that lactose functions as a stabilizer when used as an excipient, whether this property was recognized in the prior art or not.

More importantly, Woolfe expressly teaches the inclusion of lactose as an excipient and tiotropium as an active compound. It is Appellant's burden, therefore, to demonstrate that the inclusion of lactose as an excipient

in the compositions of Woolfe did not act as a stabilizer in those compositions.

> Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on "inherency" under 35 U.S.C. § 102, or "prima facie obviousness" under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products.

In re Best, 562 F.2d 1252, 1255 (CCPA 1977). Appellant adduces no evidence to show that the lactose added as an excipient in the compositions of Woolfe acts as a stabilizing excipient.

Appellant argues that Woolfe nowhere teaches or suggests a formulation or process in which the active ingredient is intimately admixed with either a solution or suspension of a stabilizing agent prior to spray drying. *See* App. Br. 11. However, Appellant's claims do not require that the active agent and the excipient be "intimately admixed," but rather require that the "stabilizing agent comprises a matrix in which the tiotropium bromide is dispersed in a molecular state." *See* claim 1. Appellant's Specification defines the claim term "dispersed in a molecular state," as meaning: "inhalable particles obtained by drying a solution containing both the stabilizing agent and tiotropium." Spec. 9.

Woolfe teaches producing particles by spray drying mixtures of drugs or excipients. Specifically, Woolfe teaches that "[a]ccording to a first aspect to a present invention there is provided a formulation for pulmonary or nasal administration comprising a mixture of particles of two or more drugs or

excipients produced by spray drying and suitable for administration without further processing of the particles." Woolfe ¶ 36. Woolfe thus teaches that this produces "inhalable particles obtained by drying a solution containing both the stabilizing agent and tiotropium," corresponding to the Specification's definition of "dispersed in a molecular state." *See* Spec. 9. Woolfe ¶ 38). Further, Woolfe teaches that the two or more drugs, including, preferably, tiotropium, or excipients, including lactose, are used to form particles by spray drying. *Id.* (citing Woolfe Abstr., ¶¶ 40–41). Woolfe therefore teaches that the drug and lactose are taught to be in admixture when spray dried together to form the particles, with the drug dispersed in a molecular state with the lactose. *Id.*

Woolfe further teaches lactose can be a excipient provided to improve flow characteristics of the drug containing particles. Specifically, Woolfe teaches that "[a] dosage form in accordance with the fourth to sixth aspects of this invention may incorporate an external excipient to improve flow characteristics. Examples of suitable external excipients include *lactose*, mannitol, trehalose or other sugars or mixtures thereof." Woolfe ¶ 56 (emphasis added). Woolfe thus teaches that lactose can be used *both* as an excipient in admixture with the drug when spray dried to form the particles, and additionally as an external excipient in the form of lactose particles for administration of the drug particles. *Id.*

With respect to Appellant's argument that Woolfe does not teach specific examples of a tiotropium-lactose combination, the examples of Woolfe do not provide the sole teachings of the reference upon which a person of ordinary skill may rely. Rather, in an obviousness analysis, "the proper test is whether the references, *taken as a whole*, would suggest the

invention to one of ordinary skill in the art." *In re McLaughlin*, 443 F.2d 1392, 1395, (C.C.P.A. 1971) (emphasis added); *see also Merck & Co., Inc. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989) (holding that "*all* disclosures of the prior art, including unpreferred embodiments, must be considered") (emphasis added). As we have explained *supra*, Wolfe expressly teaches the use of tiotropium salts as the active agent and the use of lactose as an excipient, the latter being both used in a spray-dried admixture with the active agent and as an external excipient.

With respect to Appellant's argument that the X-ray powder diffraction analysis on some of the examples in Woolfe strongly suggests that the spray-dried products are at least partly crystalline (*see* App. Br. 11), we note that the examples of Woolfe cited by the Examiner are directed to a mixture of salbutamol sulfate or salbutamol BP and ipratropium bromide (which Appellant acknowledges has different chemical properties than tiotropium). *See* Woolfe ¶ 78. Woolfe teaches that: "Salbutamol sul[f]ate as supplied was a crystalline material by XRD. When spray dried from aqueous solution it was amorphous[,] as evidenced by XRD[.] The amorphous material was relatively stable on heating. There was no obvious exotherm in the DSC thermogram, reflective of recrystallisation from the glass." *Id.* at ¶ 89. Woolfe further teaches that: "Spray drying from ethanolic solution also resulted in an amorphous material by XRD. Again the DSC showed no obvious exotherm indicative of recrystalli[z]ation." *Id.* at ¶ 90. Although some active agents did show evidence of some crystallization (*see id.* at ¶¶ 91–93), others expressly did not (*see id.* at ¶ 94), and none of the examples of Woolfe is directed to a tiotropium-lactose mixture.

In sum, we are not persuaded by Appellant's argument that the techniques of Woolfe necessarily teach that a tiotropium lactose necessarily crystallizes more than 10% upon spray drying. Indeed, Appellant discloses in their Specification that: "the presence of lactose in the spray-dried powders permitted to stabilize tiotropium as a tiotropium-lactose amorphous form even after storage." Spec. 20. Appellant adduces no evidence to show that this stability was not inherently a property of the spray-dried tiotropium-lactose compositions taught by Woolfe. *See in re Best*, 562 F.2d at 1255. As such, we do not find Appellant's argument in this respect persuasive.

Issue 2

Appellant argues that Zeng does not cure the alleged deficiencies of Woolfe. App. Br. 12.

Analysis

Appellant argues that Zeng discloses a medicament in the form of solid amorphous particles containing an intimate admixture of tiotropium bromide together with a pharmaceutically acceptable co-solid having a glass transition temperature of at least -50°C, such as a sugar and/or a sugar alcohol. App. Br. 12 (citing Zeng Abstr.). Appellant points out that these medicaments are in the form of freeze-dried (i.e., lyophilized) compositions, in contrast to the compositions of the present invention, which are in the form of spray-dried compositions. *Id.* at 12–13 (citing Zeng, e.g., ¶¶ 16, 18, Exs. 1, 2). According to Appellant, a person of ordinary skill in the art would have recognized the difference between compositions prepared via freeze-drying versus spray drying. *Id.* at 13. Appellant asserts that Zeng

teaches the particles as containing an intimate "admixture" of the tiotropium bromide and a co-solid, but that there is no teaching of the dispersion of the tiotropium bromide in a molecular state, as required by Claim 1. *Id.*

Appellant next points to the Declaration of Antonio Sereno Guerra, filed March 31, 2015 (the "Guerra Declaration") which, argues Appellant, demonstrates the undesired crystalline nature of the compositions taught by Zeng. App. Br. 13. Appellant states that the Guerra Declaration describes a direct comparison of tiotropium bromide/lactose compositions made according to the present patent application with those made according to Examples 1 and 2 of Zeng. *Id.* Appellant states that the Guerra Declaration states that Example 1 of Zeng describes a vacuum drying procedure at -20°C and Example 2 of Zeng describes a freeze-drying technique whereby a solution is sprayed into liquid nitrogen. *Id.* Appellant contends that the experiments described in the Guerra Declaration were conducted at the request of and under the responsibility of Mr. Guerra in the Laboratory of Pharmaceutics and Biopharmaceutics of the Université Libre de Bruxelles (ULB). *Id.* Based on the experimental results, argues Appellant, the tiotropium bromide/lactose particle samples in a 100:1 (w/w lactose-tiotropium bromide) ratio were 100% amorphous when prepared according to the present invention, however, the same ratio, when prepared according to either Example 1 or 2 of Zeng, demonstrated at most between 10.5% to 54% amorphous characteristics. *Id.* (citing Guerra Decl. Table 1).

Appellant argues that, as stated in the Guerra Declaration, because the sample produced according to Example 1 of Zeng produces particles that are not of a suitable size for use in an inhalable product, the resultant product was further micronized. App. Br. 14. Appellants assert that the Guerra

Declaration discloses, however, that micronization provided only a modest improvement in the amorphous character of the resultant product, increasing it from 10.5% to only 38%. *Id.* Therefore, Appellant contends, a micronized product based on Zeng still does not demonstrate the amorphous character of the product of the present invention. *Id.*

Appellant next points to the Guerra Declaration's disclosure that an additional formulation was prepared and tested having a lactose to tiotropium bromide ratio of 12.4:1 (weight/weight), which correspond to approximately 7.5% of the tiotropium bromide by weight. App. Br. 14. Appellant states that such a formulation is a typical formulation within the weight range of compositions of the present invention. *Id.* (citing Spec. ¶ 35). Appellant asserts that, even at this relatively low ratio of lactose to tiotropium bromide, the resultant product prepared according to the present invention resulted in particles of 100% amorphous character. *Id.*

Furthermore, argues Appellant, the tiotropium bromide/lactose particle samples of the present invention retained all their amorphous characteristics upon storage at 25°C, 40°C, 50°C, and 75°C for two and four weeks, except for a sample stored under the most extreme of the storage conditions, namely 75°C and ambient relative humidity for four weeks. App. Br. 14. In contrast, Appellant contends, the Guerra Declaration shows that samples prepared according to either Example 1 or 2 of Zeng, demonstrated highly variable and undesirable amorphous content. *Id.* at 14–15 (citing Guerra Decl. Table 2).

We are not persuaded by Appellant's arguments. Furthermore, conclude the Guerra Declaration does not persuasivley address the determinations of the Examiner's rejection. Zeng teaches methods of

preparing a tiotropium bromide-lactose composition via lyophilizing the preparation. However, the Examiner relies upon Woolfe as teaching that the composition is spray-dried, as in Appellant's claimed invention. *See* Final Act. 4; Woolfe ¶ 15. Similarly, the Guerra Declaration compares the freeze-drying preparation taught by Zeng with Appellant's composition formed by spray drying, and claims that the methods taught by Zeng do not reliably form the claimed percentage of amorphous tiotropium-lactose particles. Guerra Decl. ¶¶ 5–21.

However, if Appellant is asserting that their claimed composition possesses properties that are substantially different than those of the prior art, then Appellant must compare their results with those of the closest prior art. *See In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991). In this case, the closest prior art is Woolfe, which also teaches tiotropium salt-lactose compositions formed by spray drying. Notably, Appellant produces no evidence, either in the Guerra Declaration or elsewhere, that the methods taught by Woolfe do not produce the claimed stable greater than 90% amorphous formulation.

The Examiner relies upon Woolfe as teaching spray-dried tiotropium salt-lactose compositions. *See* Final Act. 4. Zeng is relied upon by the Examiner as teaching, *inter alia*, the claimed concentrations of tiotropium bromide and lactose. *Id.* at 6. Because Appellant does not demonstrate that the claimed composition is substantially different from the compositions of the combined cited prior art, we are not persuaded by Appellant's arguments in this respect.

Issue 3

Appellant argues that a person of ordinary skill would not have been motivated to combine Woolfe with Zeng to arrive at the present invention. App. Br. 15.

Analysis

Appellant argues that there is no teaching or suggestion in Woolfe to combine its teachings and suggestions with Zeng. App. Br. 15–16. Appellant repeats the argument *supra* that Woolfe neither teaches nor suggests a combination of tiotropium bromide and lactose, much less a stabilized amorphous form, and that Zeng is directed to compositions that are generally crystalline or that are not sufficiently stabilized, and thus that revert to a crystalline form. *Id.* at 16. Therefore, Appellant contends, a skilled artisan not have been motivated to select Zeng to remedy the deficiencies of Woolfe. *Id.*

We are not persuaded by Appellant's argument. As we have explained, both Woolfe and Zeng are directed to compounds containing a tiotropium salt (specifically tiotropium bromide, in the teachings of Zeng). Woolfe teaches spray dried compositions of this compound, and Zeng teaches the relative concentrations that are effective. We conclude that a person of ordinary skill in the art would have been motivated to combine the teachings of the two references because Zeng expressly teaches therapeutically effective concentrations of tiotropium bromide and lactose that could be incorporated into the spray-dried compositions of Woolfe. *See* Zeng ¶ 23.

Issue 4

Appellant argues that the claimed invention would not have been *prima facie* obvious to a person of ordinary skill in the art over the combined teachings and suggestions of Woolfe and Zeng. App. Br. 16.

Analysis

Appellant alleges that the Examiner is improperly picking and choosing, piecemeal, specific teachings from each of the cited references in an attempt to build a case of obviousness, selecting at least ten separate and unrelated paragraphs in each of Woolfe and Zeng. App. Br. 16. Appellant asserts that the Examiner's allegedly selectively picking and choosing specific teachings from each reference with no motivation, except the hindsight of the present invention, for attempting to combine them together is impermissible. *Id.*

We are not persuaded. We have explained *supra* why we agree with the Examiner that it would have been obvious for a person of ordinary skill in the art to combine the teachings of Woolfe and Zeng to arrive at Appellant's claimed invention.

Furthermore, with respect to Appellant's allegation that the Examiner impermissibly relied upon hindsight reasoning:

> Any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper.

In re McLaughlin, 443 F.2d at 1395. Appellant points to no evidence that the Examiner relied upon knowledge other than from the teachings of the cited references or knowledge which was within the level of ordinary skill at

the time the claimed invention was made. Consequently, we affirm the Examiner's rejection of the claims.

DECISION

The Examiner's rejection of claims 1, 34–41, 45, and 46 under 35 U.S.C. § 103(a) is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED

Claims Rejected	35 U.S.C. §	Basis	Affirmed	Reversed
1, 34–41, 45, 46	103(a)	Woolfe, Zeng	1, 34–41, 45, 46	
Overall Outcome			1, 34–41, 45, 46	