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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BARBARA HAEBERLIN, FRANK STOWASSER, WOLFGANG WIRTH, ANTON BAUMBERGER, STEPHEN ABEL, SEBASTIAN KAERGER, and THOMAS KIECKBUSCH

Appeal 2017-010593
Application 14/960,472[1]
Technology Center 1600

Before DONALD E. ADAMS, MICHAEL J. FITZPATRICK, and ELIZABETH A. LAVIER, *Administrative Patent Judges*.

Opinion for the Board filed by *Administrative Patent Judge* ADAMS

Opinion Dissenting filed by *Administrative Patent Judge* FITZPATRICK

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This Appeal under 35 U.S.C. § 134(a) involves claims 1–6 (Final Act.[2] 2). Examiner entered a rejection under 35 U.S.C. § 103(a). We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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[1] Appellants identify "Novartis AG" as the real party in interest (App. Br. 2).
[2] Examiner's April 21, 2016 Final Office Action.

STATEMENT OF THE CASE

Appellants' disclosure "relates to organic compounds and their use as pharmaceuticals, or more specifically a process for preparing dry powders of glycopyrronium salts" (Spec. 1). Claim 1 is representative and reproduced below:

> 1. A process for preparing a dry powder formulation of a glycopyrronium salt for inhalation that comprises the steps of (a) *mixing a glycopyrronium salt and* 3 to 5% by mass of *magnesium stearate*, based on the total amount of glycopyrronium salt and magnesium stearate, *to give a homogeneous blend*; (b) *micronising the blend*; and (c) admixing carrier particles to the micronized blend to form a dry powder formulation, wherein the carrier particles are mixed with the blend of micronized glycopyrronium salt and magnesium stearate in a ratio of 200:1 to 20:1 by mass.

(App. Br.[3] 8 (emphases added).)

Claims 1–6 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Morton[4] and Bannister.[5]

ISSUE

Has Examiner established that the combination of Morton and Bannister makes obvious a method of preparing a dry powder formulation of glycopyrronium salt that comprises, *inter alia*, the steps of *mixing glycopyrronium salt and magnesium stearate (MgSt) to form a homogenous blend* and *micronizing this blend*?

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[3] Appellants' April 6, 2017 Appeal Brief.
[4] Morton et al., WO 2005/025536 A2, published Mar. 24, 2015.
[5] Bannister et al., WO 01/76575 A2, published Oct. 18, 2001.

ANALYSIS

As Appellants explain, "[a]t the heart of this [A]ppeal is the disagreement between Appellant[s] and the Examiner with respect to the interpretation of the language of claim 1 and the teachings of the Morton reference" (Reply Br.[6] 2). Therefore, we begin our obviousness analysis with an interpretation of Appellants' claim 1.[7]

Initially, we recognize Examiner's finding that "the term 'homogenous blend' is understood in the context of the present invention to be a thorough mixture of the two components (the active drug – glycopyrrolate, and the additive material – MgSt), to produce a cohesive mixture" (Ans. 9).

We further recognize that "[u]nless the steps of a method actually recite an order, the steps are not ordinarily construed to require one." *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1342 (Fed. Cir. 2001); *see Loral Fairchild Corp. v. Sony Corp.*, 181 F.3d 1313, 1322 (Fed. Cir. 1999) (stating that "not every process claim is limited to the performance of its steps in the order written"). Nevertheless, an order "can ensue when the method steps implicitly require that they be performed in the order written." *Interactive Gift*, 256 F.3d at 1342. Such an implicit order of claimed method steps was found in *Mantech*, wherein our reviewing court held "that the sequential nature of the claim steps is apparent from the plain meaning of the claim language." *Mantech Envtl. Corp. v. Hudson Envtl.*

[6] Appellants' August 4, 2017 Reply Brief.
[7] Appellants' claims 2–6 depend directly or indirectly from Appellants' claim 1 (*see* App. Br. 8).

Servs., Inc., 152 F.3d 1368, 1376 (Fed. Cir. 1998). In this regard, the *Mantech* court explained:

> Step (a) provides the wells. No monitoring or injecting of the groundwater can occur until wells are provided; hence, step (a) must be performed first. Step (b) introduces acetic acid, via the wells provided in step (a), into the groundwater of the contaminated region. Hence, in order to accomplish step (b), the wells of step (a) must already have been provided. Step (c) introduces an aqueous solution of ferrous ion into said groundwater region for mixing with "said acidified groundwater". . . . In order for the aqueous solution to mix with the acidified groundwater, the acid must have already mixed with the groundwater to form acidified groundwater. Hence step (b) necessarily comes before step (c). Step (d) introduces a treating flow of hydrogen peroxide solution into the groundwater. The hydrogen peroxide solution undergoes a Fenton-like reaction "in the presence of said acidic conditions and said ferrous ion." Because the acidic conditions and the ferrous ion must be present before the hydrogen peroxide can undergo the Fenton-like reaction, step (d) must come after both steps (b) and (c).

Id. at 1375–76 (emphasis omitted) (footnote omitted).

On this record, Appellants' claim 1 requires, *inter alia*, the steps of (a) preparing a *homogenous blend* by mixing glycopyrronium salt and magnesium stearate and (b) micronizing the *homogenous blend*. By analogy to *Mantech*, Appellants' homogenous blend cannot be micronized before it is prepared. Thus, Appellants' claimed method step (a) must come before Appellants' method step (b) (*see* App. Br. 8). Therefore, we are not persuaded by Examiner's assertion that Appellants' "claims do not explicitly require that the mixing step to form a homogenous blend occurs 'prior to'" the step of micronizing the homogenous blend (Ans. 8), because the order is

implied. As Appellants make clear "[t]he plain reading of the claims necessitates sequential performance of the steps" (Reply Br. 2).

Morton, as relied upon by Examiner, discloses a two-step process, wherein a drug is jet-milled "on its own" and then this jet-milled drug is co-jet milled with an additive material, e.g., magnesium sterate, to coat "the small active particles with . . . additive material" (Morton 27:4–9; *id.* at 19:15–16 ("[a]dvantageously, the additive material comprises a metal stearate"); *see* Final Act. 3–4). Although Morton discloses that the product produced by co-jet milling a jet-milled drug with an additive material may be further *mixed* with a carrier,[8] Examiner failed to identify, and we do not find, a disclosure in Morton of mixing a drug with an additive material, such as magnesium sterate, to form a *homogenous blend* prior to milling such a homogenous blend, as required by Appellants' claimed invention. To be sure, Examiner fails to identify any portion of Morton that discloses mixing two reagents to form a *homogenous blend*. Examiner further failed to identify a disclosure in Bannister that makes up for this deficiency in Morton (*see* Ans. 4; *cf.* Reply Br. 3 ("Morton . . . fails to disclose the first step of the claimed process which requires the mixing of the glycopyrronium salt and magnesium stearate to form a homogenous blend prior to micronizing the mixture"); App. Br. 6 (Bannister fails to make up for the deficiencies in Morton).

Although Examiner asserts that Morton "explicitly teaches a step of blending the previously jet-milled active drug (in this case, glycopyrrolate)

[8] *See* Morton 20:17–19 ("composite active particles produced by co-jet milling . . . are mixed with carrier particles made of an inert excipient material"); *see also* Final Act. 4.

with the additive material . . . [, e.g., magnesium sterate,] and then jet milling the blend to coat the drug particles with the additive material," Examiner fails to identify, and we do not find, such a mixing or blending step in Morton (Final Act. 4; *see also id.* at 3–5; Ans. 3 (citing Morton 27:4–9 and 18–22); *cf.* Reply Br. 3 (although the comprising language of Appellants' claims "allows for the possibility of prior steps such as pre[-] milling the active particle, . . . Morton . . . fails to disclose the first step of the claimed process which requires the [preparation of] . . . a homogenous blend prior to micronizing the mixture")). *See In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."). Thus, we agree with Appellants' contention that the combination of Morton and Bannister "fail[s] to teach or suggest mixing glycopyrronium salt and magnesium stearate to give a homogenous blend prior to micronization" (Reply Br. 2).

Examiner also appears to assert that co-jet milling glycopyrrolate with magnesium sterate will, at some point in the milling process, inherently result in the creation of a homogenous blend of the two reagents, thereby meeting the first step of Appellants' claimed method and any subsequent milling of the combined reagents will satisfy the second step of Appellants' claimed method (*see* Ans. 8 (Morton "expressly teaches that the process of jet milling achieves 'blending of the active and additive particles' so as to

generate the coated particles (see, e.g., [Morton,] p.25, l.25-26)");[9] *see also id.* at 8–9 ("[t]he fact that the homogenous blending occurs subsequent to the mixing step but during the jet-milling process is immaterial because the instant claims do not expressly require that the active drug and additive material are 'pre-mixed' to form a homogenous blend *prior to* initiating the micronization process")). Examiner, however, failed to establish an evidentiary basis on this record to support a conclusion that any blending of reagents during a milling process inherently produces a *homogenous blend* or, assuming that a homogenously blended product is formed during the milling process, the milling process will inherently be continued beyond the formation of a homogenously blended product. In this regard, we note that Morton discloses only that co-jet milling a drug, e.g., glycopyrrolate, with an additive material, e.g., magnesium sterate results in coating "the small active [drug] particles with . . . additive material" (Morton 27:4–9). Examiner thus failed to establish an evidentiary basis on this record to support a conclusion that a person of ordinary skill in this art would have considered the coating of one reagent with another represents a homogenous blend, even if Examiner's definition of homogenous is adopted (*see* Ans. 9) or that, if such a coated product represents a homogenously blended product, that this coated product is further milled which, for the reasons discussed above, would be required by Appellants' claimed method. Inherency "may not be established by probabilities or possibilities. The mere fact that a certain

[9] Morton discloses "[i]n one embodiment, the jet milling is carried out at a grinding pressure of between 0.1 and 3 bar, to achieve blending of the active and additive particles" (Morton 25:25–26).

thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citation omitted).

For the reasons set forth above, we find that Appellants' claimed method requires the preparation of a homogenous blend of reagents prior to the claimed micronization step, not the speculative creation of a homogenous blend at some point during a micronization step. Therefore, we once again find ourselves in agreement with Appellants' contention that the combination of Morton and Bannister "fail[s] to teach or suggest mixing glycopyrronium salt and magnesium stearate to give a homogenous blend prior to micronization" as is required by Appellants' claimed method (*see* Reply Br. 2).

CONCLUSION

Examiner failed to establish that the combination of Morton and Bannister makes obvious a method of preparing a dry powder formulation of glycopyrronium salt that comprises, *inter alia*, the steps of *mixing glycopyrronium salt and magnesium stearate (MgSt) to form a homogenous blend* and *micronizing this blend*. Therefore, the rejection of record is reversed.

REVERSED

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BARBARA HAEBERLIN, FRANK STOWASSER, WOLFGANG WIRTH, ANTON BAUMBERGER, STEPHEN ABEL, SEBASTIAN KAERGER, and THOMAS KIECKBUSCH

Appeal 2017-010593
Application 14/960,472
Technology Center 1600

Before DONALD E. ADAMS, MICHAEL J. FITZPATRICK, and ELIZABETH A. LAVIER, *Administrative Patent Judges*.

FITZPATRICK, *Administrative Patent Judge*, dissenting.

I dissent from the decision of the Board. I would affirm the Examiner's rejection of claims 1–6.

Claim 1 recites:

> 1. A process for preparing a dry powder formulation of a glycopyrronium salt for inhalation that comprises the steps of (a) mixing a glycopyrronium salt and 3 to 5% by mass of magnesium stearate, based on the total amount of glycopyrronium salt and magnesium stearate, to give a homogeneous blend; (b) micronising the blend; and (c) admixing carrier particles to the micronized blend to form a dry powder formulation, wherein the carrier particles are mixed with the blend of micronized glycopyrronium salt and magnesium stearate in a ratio of 200:1 to 20:1 by mass.

Appeal Br. 8. Thus, claim 1 is a process claim. It recites three steps—(a), (b), and (c)—but does not recite an order for them.

When presented with such a claim, the steps should not ordinarily be construed to require an order. *Interactive Gift Exp., Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1342–43 (Fed. Cir. 2001) ("Unless the steps of a method actually recite an order, the steps are not ordinarily construed to require one."). In *Interactive Gift*, the Federal Circuit construed such a process claim to not require its steps to be performed in a particular order because "nothing in the claim or the specification directly or implicitly require[d] such a narrow construction." *Id.*

Here, the majority state that "Appellants' homogenous blend cannot be micronized before it is prepared. Thus, Appellants' claimed method step (a) must come before step (b)." *Supra* 4. However, claim 1 should not be construed to preclude simultaneous or overlapping performance of steps (a) and (b). In other words, claim 1 does not have a negative limitation precluding micronizing of a non-homogenous blend. So long as a homogenous blend ultimately is micronized (even for a short period of time), step (b) is satisfied. Thus, I agree with the Examiner's construction that claim 1 does not "require that the active drug and additive material are 'pre-mixed' to form a homogeneous blend *prior to* initiating the micronization process." Ans. 8–9.

But ultimately, for the majority (as opposed to Appellants), the issue is not whether Morton discloses step (a) prior to step (b) but whether Morton discloses step (a) at all. *Supra* 5 ("To be sure, Examiner fails to identify any portion of Morton that discloses mixing two reagents to form a *homogenous blend*.").

With regard to step (a), the Examiner cited Morton's teaching of co-jet milling glycopyrronium bromide and MgSt. Final Act. 4. In response to pre-appeal arguments by Appellants, the Examiner explained as follows:

> Applicant is incorrect that these teachings in Morton et al. do not adequately provide for a mixing step of glycopyrronium bromide and MgSt to provide a homogenous blend. Morton et al. explicitly teaches a step of blending the previously jet-milled active drug (in this case, glycopyrrolate) with the additive material (Morton et al. explicitly discloses that MgSt is the preferable additive material to be used) and then jet milling the blend to coat the drug particles with the additive material, which clearly meets Applicant's claimed steps of mixing the glycopyrronium salt with the recited amount of MgSt to provide a homogenous blend and then micronizing the blend.

Id.; *see also In re Schaumann*, 572 F.2d 312, 317 (CCPA 1978) (anticipation does not require *ipsissimis verbis* teaching).

In their Appeal Brief, Appellants never challenge whether Morton discloses step (a). They challenge instead whether Morton discloses step (a) "prior to" micronizing. Appeal Br. 5 ("The References fail to teach or suggest mixing glycopyrronium salt and magnesium stearate to give a homogenous blend prior to micronization."), 6 ("Appellant respectfully submits that Morton still fails to disclose the first step of the claimed process which requires the mixing of the glycopyrronium salt and magnesium stearate to form a homogenous blend prior to any micronization step.").

Nonetheless, in the Answer, the Examiner sufficiently rebuts any such argument. *See* Ans. 9 ("If it is Appellant's position that Morton et al. is allegedly deficient for not explicitly teaching that the blending of the active drug glycopyrrolate) with the additive material (MgSt) is 'homogeneous' *per se*, then this argument is unavailing."). In that regard, the Examiner

expressly construes the term "homogenous" and shows that Morton discloses step (a), stating as follows:

> The term "homogeneous" as used in Appellant's claim 1 is a relative term to define the degree of uniformity of the mixture, and is not particularly defined in the accompanying specification to require a specific degree of distribution of the components within the mixture, or a specific manner of mixing that results in a particular degree of uniformity. Applying the broadest reasonable interpretation standard stipulated by MPEP § 2111, the term "homogenous blend" is understood in the context of the present invention to be a thorough mixture of the two components (the active drug - glycopyrrolate, and the additive material - MgSt), to produce a cohesive mixture, which is exactly what is produced in Morton et al. for micronization via his blending and jet-milling process. Note, further, that Morton et al. explicitly teaches the purpose of his mixing step to combine the two components (active drug and additive material) for further jet-milling, which necessarily requires a thorough blending of the two components to provide a cohesive mixture in which the active drug particles are coated with additive material and micronized (see, e.g., p.27, 1.4–9).

Id.; *see also id.* at 8 (Morton "teaches mixing the jet-milled active drug - glycopyrrolate - with the additive material - MgSt - to form a mixture that is then subjected to co-jet milling, a process that necessarily thoroughly blends and micronizes the blended mixture.").

In their Reply Brief, Appellants again do not challenge the Examiner's construction of "homogeneous" or the Examiner's finding that Morton teaches step (a). Instead, Appellants challenge whether Morton teaches step (a) "prior to" step (b). *See* Reply Br. 2 ("The References fail to teach or suggest mixing glycopyrronium salt and magnesium stearate to give a homogenous blend prior to micronization."), 3 ("Appellant respectfully submits that Morton still fails to disclose the first step of the claimed process

which requires the mixing of the glycopyrronium salt and magnesium stearate to form a homogenous blend prior to micronizing the mixture.").

The Examiner found that Morton's co-jet milling would provide a "homogenous blend" of the co-jet milled components. In my view, Appellants have not shown any error in this finding.

Thus, I would sustain the rejection.