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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte EWART GRANT, BRIAN HEINRICH, SAROOP MATHARU
and NICOLAS ARCHER

Appeal 2019-000841
Application 14/810,617
Technology Center 1600

Before ULRIKE W. JENKS, TIMOTHY G. MAJORS, and

VALEK, Administrative Patent Judge.

DECISION ON APPEAL

Appellants submit this appeal\(^1\) under 35 U.S.C. § 134(a) involving
claims to a device for detecting a target molecule using a functionalized
magnetic particle that binds the target molecule and a sensor surface, which
have been rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

\(^1\) Appellants identify the real party in interest as Johnson Matthey Public
Limited Company. App. Br. 1. Herein we refer to the Office Action mailed
("Final Act."), Appeal Brief filed July 20, 2018 ("App. Br."), Examiner’s
Answer mailed Sept. 14, 2018 ("Ans.") and Reply Brief filed Nov. 14, 2018
("Reply").
STATEMENT OF THE CASE

Appellants’ Specification states that “[t]he present invention concerns an improved process for the synthesis of oxymorphone alkaloid and oxymorphone salts ... which overcomes the disadvantages associated with the prior art methods.” Spec. 1, ll. 11–17. According to the Specification, an oxymorphone acid adduct is “[c]onventionally” prepared through “hydrogenation of 14-hydroxymorphinone ... carried out at an ambient temperature, i.e. a temperature of 30°C or less. In the present process, however, the hydrogenation is carried out at one or more temperatures greater than 40°C and below the boiling point of the reaction mixture.” Id. at 2, ll. 33–35. The Specification states that “[i]n carrying out the process of the invention at a temperature greater than 40 °C, it is possible to obtain an oxymorphone acid adduct with an improved impurity profile” and “significantly reduce the levels of 6α-oxymorphol” in that product. Id. at 4, ll. 1–3.

Claims 1–4, 7, and 8 are on appeal, and can be found in the Claims Appendix of the Appeal Brief. Claims 1 and 3 are independent claims and representative of the claims on appeal. Claims 1 and 3 reads as follows:

1. An aqueous solution of oxymorphone acid adduct comprising 6α-oxymorphol in an amount ≤ about 3.00 area % as determined by HPLC, wherein the aqueous solution is a post-hydrogenation liquor.

3. Crude solid oxymorphone acid adduct comprising 6α-oxymorphol in an amount ≤ about 3.00 area % as determined by HPLC.

App. Br. 7. Dependent claims 2, 4, 7, and 8 additionally specify that the composition of claims 1 and 3 has “≤ about 50 ppm” or “≤ about 25 ppm of an α,β-unsaturated ketone.”
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Appellants seek review of Examiner’s rejection of claims 1–4, 7, and 8 under 35 U.S.C. § 103 as unpatentable over Sun. App. Br. 7–13. Appellants do not argue the dependent claims separately from claims 1 and 3. Accordingly, we focus our analysis on claims 1 and 3, and the remaining claims stand or fall with those claims. 37 C.F.R. § 41.37 (c)(1)(iv).

The issue is: Does the preponderance of evidence of record support Examiner’s conclusion that Sun renders obvious the composition of claims 1 and 3?

Findings of Fact

FF1. Sun describes “an improved method of preparing oxymorphone or a salt thereof from oripavine.” Sun 1, ll. 10–11. According to the method taught in Sun, oripavine is oxidized to obtain 14-hydroxymorphinone, which is then hydrogenated (referred to as “reducing step ii”) to obtain oxymorphone. Id. at 3, ll. 4–8, 5 (reaction scheme 1), and 7 (reaction scheme 2). Sun teaches that an oxymorphone salt may “optionally” be produced by treating the “crude oxymorphone” produced by reducing step ii) with an acid to produce an oxymorphone salt, such as oxymorphone HCl. Id. at 3, 1. 12–17. Sun explains that this method is advantageous because it produces oxymorphone or its salt “with reduced levels of alpha-beta-unsaturated ketones that do not require a tedious and complicated workup of an intermediate oxymorphone.” Id. at 2, ll. 29–31, 6, ll. 2–4 (teaching that oxymorphone produced by reducing step ii) “comprises less than 10 ppm alpha-beta unsaturated ketones”). Sun teaches that the oxymorphone HCl obtained through its method has a low amount of other impurities, including

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“less than 0.15 wt.% 6-alpha oxymorphol, more preferably less than 0.10 wt.%.” *Id.* 14, ll. 23–24; claim 48.

**FF2.** Sun teaches that “reducing step ii) is carried out at a temperature of 10 to 110°C or up to the boiling point of the solvent or solvent mixture.” *Id.* at 13, ll. 1–3. According to Sun, the reducing step preferably involves combining 14-hydroxymorphinone in “formic acid” or “acetic acid” along with an alcohol, such as “isopropanol.” *Sun* 10, ll. 13–17. Sun further describes the use of a “metal catalyst” such as “palladium chloride” to catalyze the reaction. *Id.* at 11, ll. 22–28; 19 (Ex. 1).

**FF3.** Sun teaches that “[p]referably water is present as a solvent in the present method.” *Sun* 5, l. 16. According to Sun, water can “be present as a solvent for the oxidizing agent or be a co-solvent in one or more of the steps of the method.” *Id.* at 5, ll. 17–18.

**FF4.** Sun illustrates the use of water as a co-solvent in Example 1. *Id.* at 19. There, Sun describes the oxidation of oripavine in an aqueous solution comprising water and 90% formic acid.\(^3\) *Id.* “Once the oxidation is complete, the reaction solution was transferred” to the hydrogenation vessel, a catalyst and isopropyl alcohol are added, and that “mixture was hydrogenated.” *Id.* at 19, ll. 13–16. After the hydrogenation is finished, Sun teaches that the catalyst is removed by filtration and “crude oxymorphone” may be precipitated from the “filtrate,” that is, the post-hydrogenation liquor comprising an aqueous solution of oxymorphone. *Id.* at 19, ll. 18–22.

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\(^3\) One of ordinary skill in the art would understand that 90% formic acid is itself an aqueous solution that contains 10% water.
Analysis

Examiner finds that Sun teaches an “oxymorphone product (including salt) comprising less than 0.10 w % 6-alpha oxymorphol and less than 10 ppm alpha-beta-unsaturated ketones” that meets all of Appellants’ claims, except that Sun does not explicitly “mention an aqueous solution (post hydrogenation liquor) or crude solid oxymorphone acid adduct.” Non-Final Act. 3. Examiner determines it would be obvious to prepare an aqueous solution of or crude oxymorphone acid adduct, as claimed, because “Sun teaches preparing oxymorphone by hydrogenation of 14-hydroxymorphinone . . . and furthermore, teaches that water may be present as a cosolvent in one or more of the steps.” Id.

Appellants argue claim 1 separately from claim 3. Regarding claim 1, Appellants urge that Sun teaches that the hydrogenation occurs in “an organic solvent mixture” and therefore does not teach an “aqueous solution,” as claimed. App. Br. 3–4. Regarding claim 3, Appellants contend that “Sun is directed to purified oxymorphone, not crude oxymorphone.” Id. at 5. In addition, for both claims 1 and 3, Appellants argue that Sun teaches only “conventional hydrogenation . . . at room temperature,” i.e., about 30 °C, and that “hydrogenating at 30 °C produces 6α-oxymorphol in substantially greater amounts than it is produced at the [higher] temperatures taught in Appellants’ specification.” Id. at 4–6. Thus, say Appellants, the product of the hydrogenation reaction taught in Sun would not yield a post hydrogenation liquor or crude “oxymorphone acid adduct comprising 6α-oxymorphol in an amount less than or equal to about 3.00 area %,” as claimed. Id. at 6.
We are not persuaded by Appellants’ arguments and agree with Examiner’s statement of the rejection and responses to Appellants’ arguments in the Answer, Final Action, and Non-Final Action, which we adopt and incorporate by reference. We provide the following additional comments to Appellants’ arguments.

We begin by observing that Appellants’ claims are product claims and not claims to a method for making that product. Both independent claims are directed to a composition, that is, an “aqueous solution of oxymorphone acid adduct” in claim 1 and a “crude solid oxymorphone acid adduct” in claim 3. It is undisputed that oxymorphone acid adducts, such as oxymorphone HCl, were known in the prior art. Indeed, Appellants’ Specification characterizes the invention as “an improved process which overcomes the disadvantages associated with the prior art methods” of making oxymorphone acid adducts. Spec. 1, ll. 16–17. Appellants’ claims, however, are directed only to the product of that allegedly improved process. See In re Thorpe, 777 F.2d 695, 697 (Fed. Cir. 1985) (“The patentability of a product does not depend on its method of production.”).

The compositions in claims 1 and 3 purport to be purified versions of prior art oxymorphone acid adducts comprising a lower amount of a particular impurity, 6α-oxymorphol. We agree with Examiner that such compositions are obvious over Sun. In particular, Sun teaches oxymorphone in a variety of forms, including in a post-hydrogenation solution, as a freebase, and as an oxymorphone acid adduct such as oxymorphone HCl. FF1–FF2. Sun also teaches that it is desirable to minimize impurities, such

4 The Specification identifies “oxymorphone hydrochloride” as an example of a solid oxymorphone acid adduct.” Spec. 5, ll. 23–29.
as 6-alpha oxymorphol and alpha-beta-unsaturated ketones, and teaches that its process achieves an oxymorphone HCl product with levels of 6-alpha oxymorphol and alpha-beta-unsaturated ketones that overlap with the ranges in Appellants’ claims. As such, the evidence before us is more than enough to demonstrate a prima facie showing of obviousness. See Aventis Pharma Deutschland GmbH v. Lupin, Ltd., 499 F.3d 1293, 1301–02 (Fed. Cir. 2007) (holding that claim to purified form of prior art composition was “prima facie” obvious even where there was no “explicit teaching to purify” in the prior art). Appellants have not overcome that prima facie showing.

We are not persuaded by Appellants’ argument that Sun does not teach an “aqueous solution,” as recited in claim 1. App. Br. 3–4. To the contrary, Sun teaches that that water is a preferred “co-solvent” for the hydrogenation step of its process. FF4. This is not just “[r]esidual water from wet oxymorphone,” as Appellants suggest. App. Br. 4. Rather, as shown in Sun Example 1, the post-hydrogenation reaction solution containing the oxymorphone, i.e., the “liquor” as recited in claim 1, is aqueous. See FF5.

We are likewise not persuaded by Appellants’ argument that Sun does not disclose a “crude solid oxymorphone acid adduct,” as recited in claim 3. App. Br. 5. Sun teaches that an acid, such as hydrochloric acid, can be

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5 Sun describes the amount of 6-alpha oxymorphol in its oxymorphone as preferably “less than 0.10% wt.” FF2. While expressed in different terms, this range overlaps with the “≤ about 3.00 area % as determined by HPLC” range recited in claims 1 and 3 and is sufficient to establish a prima facie case of obviousness. See In re Peterson, 315 F.3d 1325, 1329 (Fed. Cir. 2003) (“[W]e and our predecessor court have consistently held that even a slight overlap in range establishes a prima facie case of obviousness.”).
added to the post-hydrogenation reaction solution to produce oxymorphone HCl. FF2. This is the same procedure provided in the Specification for forming a “solid oxymorphone acid adduct.” Spec. 5, ll. 23–39.

Appellants’ argument that “Sun is directed to purified oxymorphone, not crude oxymorphone” is wrong for multiple reasons. First, Sun teaches both “crude oxymorphone” and “crude oxymorphone HCl” as products resulting from reducing step ii). Sun 3, l. 9–10, 19, l. 2 – 20, l. 10; FF2. Sun explains that “[t]he present method can further,” but need not, “comprise[] a step iv) of purifying the oxymorphone salt obtained from step ii). Id. at 13, ll. 27–28. Second, even if Appellants had not misinterpreted Sun, the crude product is necessarily an intermediate to the final one and therefore a skilled artisan would understand Sun to disclose both. See Appl’n of Mullin, 481 F.2d 1333, 1336 (CCPA 1973) (“It matters not one whit that [a prior art structure] was intended to be and appreciated as being an intermediate structure rather than an end use item.”).

Moreover, we are unpersuaded by Appellants’ argument that Sun is limited to “conventional hydrogenation” at 30°C. App. Br. 4. Appellants’ argument is premised on the first hydrogenation reaction described in Sun Example 1. Id. But Sun elsewhere teaches that the reducing step “is carried out at a temperature of 10 to 110°C.” FF3. Thus, Sun specifically teaches an initial hydrogenation of 14-hydroxymorphinone at temperatures exceeding 30°C and overlapping those described in Appellants’ Specification. In addition, Sun Example 1 describes a second hydrogenation reaction (step iii) in 90% formic acid and isopropyl alcohol (i.e., aqueous solution) at 70°C to form a “filtrate” (i.e., post-hydrogenation liquor) followed by the addition of hydrochloric acid to form “crude oxymorphone
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HCl.” Sun 19, 1. 29–20, 1. 10. Appellants contend that the “hydrogenation at 70°C . . . is only carried out on oxymorphine, not on 14-hydroxymorphinone as carried out by Appellants,” but that argument, even if true, pertains only to the process described in Appellants’ Specification—not the product recited in Appellants’ claims. See App. Br. 4; Reply 3. “The patentability of a product does not depend on its method of production.” In re Thorpe, 777 F.2d 695, 697 (Fed. Cir. 1985). Thus, Appellants’ arguments about Sun being limited to products produced by “conventional hydrogenation” and “successive hydrogenation reactions” do not help them to overcome Examiner’s rejection. See App. Br. 4–6; Reply 3.

Finally we are unpersuaded by the data Appellants present purporting to show the “area % of 6α-oxymorphol in post hydrogenation liquors” for Specification Example 1 (hydrogenation at 30 ±5 °C) and Examples 2–3 (hydrogenation at 60 ±5 °C). See App. Br. 4. As explained above, Sun teaches hydrogenation at the same temperatures with the same or analogous reactants to those in Examples 2 and 3 of the Specification. Compare FF3 with Spec. 14–15 (Ex. 2–3). Thus, one of ordinary skill in the art would understand and expect the product of Sun’s hydrogenation process to have similar levels of 6α-oxymorphol, even the prior art did not specifically recognize that as a benefit of Sun’s process. See King Pharmas., Inc. v. Eon Labs., Inc., 616 F.3d 1267, 1275 (Fed. Cir. 2010) (“[I]t is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable.”) (quoting In re Woodruff, 919 F.2d 1575, 1578 (Fed. Cir. 1990)).

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6 Appellants do not cite a source for this data. It is unclear if it appears in the Specification or elsewhere in the record outside of Appellants’ briefs.
For all these reasons, Appellants’ arguments fail to persuade us that Examiner erred in rejecting the claims and we therefore affirm.

SUMMARY

We affirm the rejection of claims 1–4, 7, and 8 under 35 U.S.C. § 103 as unpatentable over Sun.

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