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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte PETER HOLM TYGESEN, KARSTEN LINDHARDT, MARTIN REX OLSEN, GINA ENGSLEV FISCHER, JAN MARTIN OVERGARD, GEORG BOYE, NIKOLAJ SKAK, and TORBEN ELHAUGE

Appeal 2018-007370
Application 15/373,022
Technology Center 1600

Before RAE LYNN P. GUEST, DEBORAH KATZ, and JOHN E. SCHNEIDER, *Administrative Patent Judges*.

KATZ, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellant[1] seeks our review[2] under 35 U.S.C. § 134(a), of the Examiner's decision to reject claims 22–40. We have jurisdiction under 35 U.S.C. § 6(b). We AFFIRM.

Appellant's Specification is directed to strategies for making pharmaceuticals resistant to abuse. (Spec. ¶¶ 30–34.)

Appellant's only independent claim, claim 22, recites:

> An abuse-deterrent tablet formulated for oral administration of an opioid, the tablet consisting of a tablet composition and, optionally, a cosmetic coat, wherein:
>
> the tablet composition comprises:
>
> (a) about 1-60 % w/w of the opioid; and
>
> (b) about 40-98 % w/w of a polyethylene oxide (PEO) selected from the group consisting of (i) a single PEO having an average molecular weight of from about 400,000 daltons to about 900,000 daltons and (ii) two or more PEOs having a combined average molecular weight of from about 400,000 daltons to about 900,000 daltons,
>
> wherein the cosmetic coat, when present, covers at least a portion of the tablet composition, and dissolves within 30 minutes after contact with aqueous media,
>
> wherein the tablet composition exhibits a viscosity of at least 170 mPas when measured by Viscosity Test #2, or a viscosity of at least 46 Pas when measured by Viscosity Test #1, such that the tablet composition, when subjected to a liquid environment, forms a viscous hydrogel that resists passage through a hypodermic needle.

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[1] We use the word "Appellant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party-in-interest as Egalet Ltd. (Appeal Br. 3.)

[2] We consider the Final Office Action issued September 27, 2017 ("Final Act."), the Appeal Brief filed February 20, 2018 ("Appeal Br."), the Examiner's Answer issued on May 18, 2018 ("Ans."), the Reply Brief filed July 9, 2018 ("Reply Br.").

(Appeal Br. 21, Claims App.) The structural limitations of claim 22 encompass a tablet that comprises (a) about 1–60 % w/w of the opioid; and (b) about 40–98 % w/w of a single PEO having an average molecular weight of from about 400,000 daltons to about 900,000 daltons.

The Examiner rejected claims 22–40 as being obvious under 35 U.S.C. § 103(a) as being unpatentable over Downie (International Application Publication WO 2008/086804 A2, published July 24, 2008). (Final Act. 3–7.)

Findings of Fact

1. Downie is directed to abuse resistant pharmaceutical compositions that include one or more polyglycols and one or more active substances and is resistant to crushing. (*See* Downie abstract; Final Act. 4.)

2. Downie teaches that polyethylene glycols or polyethylene oxides with molecular weights in a wide range of molecular weights, including from about 100,000 to about 900,000 daltons, are suitable as polymers in the compositions provided. (*See* Downie 12:22; Final Act. 4.)

3. Downie specifically teaches that polyethylene oxides with molecular weight of about 400,000 daltons are suitable as a polymer in the compositions provided. (Downie 12:4–16.)

4. Downie also teaches that a mixture of polyethylene oxides with different average molecular weights can be used to obtain a polyethylene oxide with the desired average molecular weight. (*See* Downie 13:12–13; Final Act. 4.)

5. Downie teaches that the drug may be present in a concentration from about 0.01% to about 40% in the compositions provided. (*See* Downie 19:1–5; Final Act. 4.)

6. Downie teaches that the polymers can be in the compositions provided at concentrations of from about 10 to 90% in the compositions provided. (Downie 14:8; Final Act. 4.)

7. Downie teaches that the drug substance can be opioids, such as hydrocodone, morphine, or oxycodone. (Downie 15–17; Final Act. 4.)

8. Downie teaches that the pharmaceutical compositions provided by be used in the preparation of tablets. (*See* Downie 10:30–32.)

Analysis

The Examiner finds that Downie teaches a pharmaceutical composition having 10 to 90% polymer and 0.01% to about 40% drug, wherein the polymer can be PEO with a molecular weight of about 400,000 daltons and the drug can be an opioid. (*See* Ans. 4.) The Examiner finds further that the limitations in claim 22 to a range of viscosity as measured by certain tests ("a viscosity of at least 170 mPas when measured by Viscosity Test #2, or a viscosity of at least 46 Pas when measured by Viscosity Test #1") and the limitation to the forming "a viscous hydrogel that resists passage through a hypodermic needle" are inherent properties of the tablets taught in the prior art because those tablets are the same or substantially the same as the claimed tablets. (*See* Ans. 5–6.) The Examiner cites *Atlas Powder Co. v. lreco, Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999), to determine that Appellant is merely claiming an unappreciated property of a prior art composition. (*See* Ans. 6.) We agree with the Examiner.

Appellant argues that the Examiner fails to identify any reason that would have led one of ordinary skill in the art to make the selections of the claimed PEO molecular weights and percentages of opioid from the broad genus taught in Downie to obtain an abuse-deterrent tablet as claimed. (*See*

Appeal Br. 11.) Specifically, Appellant argues that Downie does not discuss the viscosity of its compositions, does not discuss any hydrogel-forming properties of its compositions, and does not discuss the preparation of tablets that deter abuse by injection. (*See* Appeal Br. 13.) We are not persuaded by these arguments.

A tablet as recited in claim 22 encompasses a tablet comprising (a) about 1–60 % opioid and (b) about 40–98 % w/w of a PEO having an average molecular weight of about 400,000 daltons. Downie teaches compositions that can be in tablet form can comprise PEO having an average molecular weight of about 400,000. (*See* Downie 12:4–11; *see* FFs 3 and 8.) Downie also teaches that such tablets can comprise 0.01– 40% drug, including several opioids, and about 10–90% polymer. (Downie 14:8 and 18:1–5; *see* FFs 5 and 6.) Thus, although Downie does not present a single embodiment that encompasses all of the limitations of claim 22, if one of ordinary skill in the art had followed the express guidance in Downie to use a PEO of average molecular weight of about 400,000 in a tablet, he or she would also know that opioids could be included at a concentration up to 40% and that the PEO polymer could be included at concentrations up to 95%.

"The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims. . . . These cases have consistently held that in such a situation, the applicant must show that the particular range is *critical*." *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990). Accordingly, in the absence of evidence that the concentration of opioid or PEO recited in claim 22 is critical, we are persuaded that a tablet with PEO of average molecular

weight 400,000, as expressly taught in Downie, with the recited concentrations of opioid and PEO would have been obvious.

Appellant argues that "[t]he rejection on appeal is based on unguided selections and combinations of individual disclosures in Downie that are pieced together in hindsight in an attempt to arrive at a tablet as claimed." (Appeal Br. 10.) This argument is unpersuasive because Downie expressly teaches PEO of average molecular weight 400,000 daltons as a polymer for use in tablets. Although the teachings of PEO size, polymer concentration, drug concentration, and tablet form are found in different places within the text of Downie, they express alternate embodiments of the subject matter taught. Given that PEO having an average molecular weight of 400,000 is expressly taught, one need only select a concentration of polymer and opioid that falls within a very large portion of the ranges taught in Downie to arrive at the claimed tablet. Downie teaches that each of these limitations can be selected for a drug formulation, providing a reason for their selection, contrary to Appellant's argument. (*See* Appeal Br. 11.)

Appellant argues further that the closest prior art to the tablets recited in claim 22 would have to be selected from Downie's examples, but that each of Examples 1–7 provide compositions with PEO having a lower average molecular weight than recited in the claims (100,000, 200,000, and/or 300,000 daltons), not PEOs within the claimed range of 400,000 to 900,000 daltons. (*See* Appeal Br. 11.)

We disagree that the closest prior art to Appellant's claim 22 are the examples of Downie. "All the disclosures in a reference must be evaluated, including nonpreferred embodiments, . . . and a reference is not limited to the disclosure of specific working examples." *In re Mills*, 470 F.2d 649, 651

(CCPA 1972) (citation omitted). Downie expressly teaches using PEO of average molecular weight 400,000 daltons. Thus, we disagree that the closest prior art is found only in the examples of Downie. Appellant's argument that the only comparison that the Examiner should have made is between the examples of Downie and the claimed composition is based on a misapprehension of the law. (*See* Appeal Br. 11–13.)

Appellant argues further that Downie does not provide a reasonable expectation of success in obtaining a tablet that exhibits the recited viscosity limitations as abuse-deterrent properties. (*See* Appeal Br. 13–14.) Appellant argues that Downie does not discuss viscosity, hydrogel-forming properties, or deterrence of abuse through injection for the compositions it teaches. Appellant notes that Downie is directed to a different mode of abuse-deterrence, which is addressed by adjusting the relative solubilities of a composition in water and alcohol. (*See id.*)

We are not persuaded by this argument because one of ordinary skill in the art would have had a reasonable expectation of success in formulating a tablet with (a) about 1–60 % w/w of the opioid; and (b) about 40–98 % w/w of PEO having an average molecular weight of about 400,000 daltons from the teachings of Downie. Appellant has not directed us to persuasive evidence that such a tablet would not inherently possess the other properties, such as viscosity, recited in claim 22.

Appellant cites *In re Stephan Co.*, 868 F.3d 1342 (Fed. Cir. 2017), but we do not find that case to be informative of the facts before us now. (*See* Appeal Br. 13–14.) In *Stephan*, the claims at issue recited a surfactant with a cloud point above at least 70°C, whereas the prior art taught a surfactant component with an ideal cloud point above only 60°C. *See Stephan*, 868

F.3d at 1346. In contrast, the facts of the current case are that Downie expressly teaches embodiments within the scope of limitations of claim 22. Thus, unlike the facts of *Stephan*, the actual teachings of Downie would have provided a reasonable expectation that a tablet as claimed could be formulated successfully.

Appellant presents a declaration under 37 C.F.R. § 1.132 by inventor Nikolaj Skak, which reportedly presents experimental data from the compositions of the examples in Downie. (*See* Appeal Br. 14–17; *see* Declaration under 37 C.F.R. § 1.132, executed June 28, 2017 by Nikolaj Skak ("Skak Decl.").) Appellant argues that Mr. Skak's declaration shows that the compositions of Downie's examples do not exhibit the viscosity properties recited in claim 22. (*See* Appeal Br. 14–17.)

We agree with the Examiner that the data presented by Mr. Skak does not address the compositions for which Downie was cited. (*See* Ans. 7 and 19.) Contrary to Appellant's arguments, compositions with PEO having an average molecular weight of 400,000 daltons as taught in Downie are the closest prior art, not the examples, which include polymers of different average molecular weight. Appellant's argument that "the Skak Declaration presents experimental data on the closest examples of Downie, which use PEO with an average molecular weight outside of the claimed range" (*see* Appeal Br. 16), is unpersuasive because Downie actually teaches PEO within the claimed range. Downie does not merely provide a suggestion about compositions with PEO of average molecular weight about 400,000 daltons – it expressly teaches it.

Appellant argues further that the Examiner improperly relied on inherency to meet the viscosity properties recited in claim 22. (*See* Appeal

Br. 17–19.) Although the use of inherency in the obviousness context is limited, if a claim limitation is necessarily present, or the natural result of a combination of elements explicitly disclosed by the prior art, inherency may be properly implemented. *See PAR Pharm., Inc. v. TWI Pharm., Inc.*, 773 F.3d 1186, 1195–96 (Fed. Cir. 2014). Under the facts of this case, the Examiner properly relied on inherency because Downie expressly teaches PEO having an average molecular weight of about 400,000 daltons in drug compositions. Appellant does not argue or direct us to persuasive evidence that any feature other than the average molecular weight of the PEO, such as the concentration of opioid or PEO, is responsible for the viscosity and other abuse-deterrent characteristics recited in claim 22. To the contrary, Appellant argues that the compositions recited in the examples in Downie do not exhibit viscosities as recited in claim 22 because

> PEO having an average molecular weight of 100,000, 200,000 and/or 300,000 daltons (as used in the Examples of Downie) and PEO (or two or more PEOs) having an average molecular weight of from about 400,000 daltons to about 900,000 daltons (as recited in the claims) have structural and functional differences that impact their viscosity and hydrogel-forming properties.

(Appeal Br. 12.) Thus, the teaching in Downie of a drug composition including PEO having an average molecular weight of about 400,000 daltons inherently teaches a drug composition with the viscosity and other abuse-deterrent features recited in claim 22.

Appellant has not persuaded us that the Examiner erred in rejecting claim 22 as being obvious over Downie. Accordingly, we affirm the rejection of claim 22 and the claims that depend on it.

Appellant argues separately for the patentability of claims 33 and 34. (*See* Appeal Br. 19–20.) We are not persuaded by these arguments. Claim 33 depends from claim 22 and recites an abuse-deterrent tablet "wherein the tablet composition comprises a single PEO having an average molecular weight of about 400,000 daltons." (*See* Appeal Br. 22.) Because, as explained above, Downie expressly teaches using PEO of average molecular weight about 400,000 daltons, the Examiner did not err in determining that claim 33 would have been obvious over Downie. Appellant's arguments, which are similar to those discussed above, are not persuasive.

Appellant also provides similar arguments against the rejection of claim 34. (*See* Appeal Br. 20.) Claim 34 depends on claim 22 and recites an abuse-deterrent tablet "wherein the tablet composition comprises a single PEO having an average molecular weight of about 600,000 daltons." (*See* Appeal Br. 22.) Downie expressly teaches that PEO having a molecular weight of about 600,000 daltons is suitable for the drug formulations it provides. (*See* Downie 12:4–7.) Therefore, for the reasons discussed above, the Examiner did not err in determining that claim 34 would have been obvious over Downie.

Conclusion

Upon consideration of the record and for the reasons given, we affirm the Examiner's rejection.

In summary:

Claims Rejected	**35 U.S.C. §**	**Reference(s)/Basis**	**Affirmed**	**Reversed**
22–40	103(a)	Downie	22–40	
Overall Outcome			22–40	

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

AFFIRMED