UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/002,199	06/07/2018	Alex Micka	H-MP-00251USCON.1(596260)	2651

24289 7590 05/20/2022

Mallinckrodt LLC
675 McDonnell Boulevard
Hazelwood, MO 63042

EXAMINER	
PIPIC, ALMA	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
05/20/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

MallinckrodtPatent@Polsinelli.com
patents@mnk.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ALEX MICKA, KAI FENG,
TSZ CHUNG LAI, and JONATHAN GAIK

Appeal 2021-003755
Application 16/002,199
Technology Center 1600

Before JASON V. MORGAN, JOHN E. SCHNEIDER, and MICHAEL A. VALEK, *Administrative Patent Judges*.

VALEK, *Administrative Patent Judge.*

DECISION ON APPEAL

Appellant[1] submits this appeal under 35 U.S.C. § 134(a) involving claims to a process for preparing an immediate release, abuse deterrent solid dosage form. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

---

[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies SpecGX, LLC as the real party in interest. Appeal Br. 1. Herein, we refer to the Final Action mailed July 2, 2020 ("Final Act."); Appellant's Appeal Brief filed December 30, 2020 ("Appeal Br."); Examiner's Answer mailed March 31, 2021 ("Ans.").

STATEMENT OF THE CASE

"The present disclosure generally relates to pharmaceutical compositions that provide immediate release of active ingredients and have abuse deterrent properties." Spec. ¶ 2. The Specification explains that attempts "to diminish the abuse of opioid solid dosage forms" such as "includ[ing] gel-forming high molecular weight polymers" that make them "difficult to crush and pulverize into a powder" have been made, but these polymers "retard the release of the active ingredient from the dosage forms, making them unsuitable for immediate release formulations." *Id.* at ¶ 4. According to the Specification, "there is a need for oral solid dosage forms that provide immediate release of the active ingredient yet are resistant to abuse." *Id.* at ¶ 5.

Claims 1–3, 5–7, 9, and 10 are on appeal and can be found in the Claims Appendix of the Appeal Brief. Claim 1 is the only independent claim and representative of the claims on appeal. It reads as follows:

> 1. A process for preparing a solid dosage form, the process comprising:
>
> (a) blending at least one active pharmaceutical ingredient (API) or pharmaceutically acceptable salt thereof, about 10% w/w to about 25% w/w of at least one natural gum comprising glucomannan, about 25% w/w to about 35% w/w of a combination of a hydrophilic gelling polymers comprising (i) at least one cellulose ether, (ii) polyethylene oxide having an average molecular weight of about 100,000, and (iii) a polyethylene oxide having an average molecular weight of about 4,000,000, and about 40% w/w/ to about 50% w/w of an effervescent system to form a mixture;
>
> (b) compressing the mixture into a solid dosage unit; and
>
> (c) heating the solid dosage unit at a temperature from about 50°C to less than about 90°C for 1 to 3 hours to form the solid dosage form;

wherein the solid dosage form deters abuse and provides immediate release of the at least one API.

Appeal Br., Claims App. i.

Appellant seeks review of Examiner's rejection of claims 1–3, 5–7, 9, and 10 as obvious over Tygesen '130,[2] Tygesen '259,[3] and Mohammad.[4] Appeal Br. 5. The issue for this rejection is whether the preponderance of the evidence supports Examiner's conclusion that claim 1, including the step of blending the ingredients recited in step (a), would have been obvious over the articulated combination of Tygesen '130, Tygesen '259, and Mohammad.

Analysis

Examiner relies on Tygesen '130 as teaching the combination of ingredients recited in step (a) to prepare a solid dosage form that deters abuse and provides immediate release. Final Act. 4–5. Examiner's rejection cites the other references only for their teachings relating to the "concentration of the effervescent system" and the heating step (c). *See id.* at 5–7. According to Examiner, "it would have been *prima facie* obvious to a person of ordinary skill in the art" to have combined the ingredients recited in step (a) because Tygesen '130 teaches blending these ingredients and "describes the dosage form as providing immediate release and being abuse resistant." *Id.* at 8, 10.

Among other things, Appellant contends that a skilled artisan would not have had a reasonable expectation of successfully arriving at the process

[2] US 2010/0203130 A1, published Aug. 12, 2010 ("Tygesen '130").
[3] US 2010/0204259 A1, published Aug. 12, 2010 ("Tygesen '259").
[4] US 2012/0135075 A1, published May 31, 2012 ("Mohammad").

recited in claim 1 from the teachings in Tygesen '130. *See* Appeal Br. 7–8. According to Appellant,

> Tygesen '130 lists hundreds of polymers, diluents, binders, lubricants, disintegrants, gelling agents, plasticizers, and release modifiers that can be included at any concentration from 0-95% w/w in the abuse deterrent compositions disclosed therein. The Applicant has estimated that Tygesen '130 discloses at least about 17 trillion possible combinations of polymers, diluents, binders, lubricants, disintegrants, gelling agents, plasticizers, and/or release modifiers (not considering possible concentrations). Although 17 trillion is a finite number, a person of ordinary skill in the art could not easily traverse even a fraction of the possible combinations mentioned in Tygesen '130, especially considering that this reference provides no hint or suggestion about which ingredients to combine to arrive at an immediate release, abuse resistant solid dosage form. Rather, the person of ordinary skill in the art would have to undertake considerable, trial and error experimentation with no reasonable expectation of successfully arriving at the solid dosage f[or]m as specified in claim 1.

Id. Appellant further contends that Examiner has not provided a sufficient rationale for why the combination articulated in the rejection would have been obvious from the teachings in Tygesen '130 and the other cited references. *See id.* at 8–11.

On this record, we are persuaded by Appellant's arguments. As Appellant points out, "the overall teaching of Tygesen '130 is related to **controlled release compositions** that are resistant to abuse." Appeal Br. 3. Examiner's finding that Tygesen '130 also teaches immediate release formulations is premised on a single statement appearing in the abstract that provides "[t]he present invention provides immediate release pharmaceutical compositions . . . that are resistant to abuse." *See* Ans. 8 ("[T]he one sentence in the Abstract is sufficient to provide motivation to the skilled

artisan to make an immediate release, abuse resistant dosage form."). However, Examiner has not shown that Tygesen '130 teaches one of skill in the art *what ingredients to combine* to achieve an immediate release as opposed to a controlled release composition. Instead, Tygesen '130 provides a list of possible categories of excipients (*see* Tygesen '130 ¶ 203) and numerous other lists with examples of excipients within each of those categories (*id.* at ¶¶ 204–20).[5] Appellant asserts, and Examiner does not dispute, that there are many trillions of possible combinations that can be made from these lists. Yet, Examiner does not identify any teaching in Tygesen '130, nor in the other cited references, suggesting which excipients and polymers should be used to achieve an immediate release formulation.

Instead, Examiner acknowledges that "Tygesen '130 does not distinguish excipients for controlled release from excipients for immediate release" and reasons "[t]hus, it would have been reasonable to interpret the teachings of Tygesen '130 to mean that all of the recited excipients are suitable" for making both "immediate release" and "controlled release" forms. Ans. 6. We do not agree that this is a reasonable interpretation of the reference. First, Examiner has not pointed to evidence that one of skill in the art would understand that the same ingredients can produce both immediate release and controlled release forms. Second, Tygesen '130 teaches that release of the API from its dosage forms, which comprise an inner matrix surrounded by a shell, can be affected by a variety of factors

[5] To the extent the rejection relies on ingredients in Tygesen '130's drug "matrix composition" in addition to its excipient lists, we note that Tygesen '130 provides similarly long lists of the polymers that might be used to form to form that matrix. *See* Tygesen '130 ¶¶ 137–51.

such as the content and configuration of the shell and inner matrix, modifications to the API, as well as the presence of other excipients. *See, e.g.,* Tygesen '130 ¶¶ 61, 94, 192, 202, 209, 210. Such teachings evidence that, among other things, the choice of ingredients used to prepare the dosage form will affect the release and thus contradict Examiner's interpretation of the reference.

Nor is this a case where the prior art reference can be interpreted as teaching a "multitude of effective combinations" all of which are suitable for producing the desired property or effect. *See Merck & Co., Inc. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989). As Appellant points out, Tygesen '130 lists hundreds of possible excipients, resulting in many "trillions" of possible combinations at least some of which are said to result in controlled release—not immediate release—compositions. *See* Appeal Br. 7. Thus, contrary to Examiner's interpretation, it cannot be the case that any and all of these possible combinations will provide immediate release dosage forms.

In sum, Examiner has not articulated a sufficient rationale for selecting the particular combination of ingredients recited in step (a) of claim 1 from the excipient lists in Tygesen '130, nor sufficiently shown that a skilled artisan would reasonably expect the claimed combination to provide an immediate release, as opposed to controlled release, dosage form. For these reasons, Examiner has not met the burden to establish a prima facie showing of obviousness for claim 1.[6] Accordingly, we reverse the rejection.

[6] Because there is no prima facie showing, we do not reach Appellant's argument that its evidence of unexpected results is sufficient to overcome

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–3, 5–7, 9, 10	103	Tygesen '130, Tygesen '259, Mohammad		1–3, 5–7, 9, 10

REVERSED

Examiner's prima facie case. *See* Appeal Br. 11–12.