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.
15/385,638	12/20/2016	Werner ZUMBRUNN	13164-702.305	2376

66854 7590 12/31/2019

SHAY GLENN LLP
2755 CAMPUS DRIVE
SUITE 210
SAN MATEO, CA 94403

EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
12/31/2019	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):

info@shayglenn.com
shayglenn_pair@firsttofile.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte WERNER ZUMBRUNN, GEORGIOS IMANIDIS, GUY DiPIERRO, and HANS WERNER VAN DE VENN[1]

Appeal 2019-004999
Application 15/385,638
Technology Center 1600

Before JEFFREY N. FREDMAN, DEBORAH KATZ, and JOHN G. NEW, *Administrative Patent Judges*.

NEW, *Administrative Patent Judge*.

DECISION ON APPEAL

---

[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies Chrono Therapeutics Inc. as the real party-in-interest. App. Br. 2.

SUMMARY

Appellant files this appeal under 35 U.S.C. § 134(a) from the Examiner's Final Rejection of claims 1–17 as unpatentable under 35 U.S.C. § 103(a)(pre-AIA) over the combination of Pickup et al. (US 2003/0065294 A1, April 3, 2003) ("Pickup") and Schumann (WO 00/74933 A1, December 14, 2000)[2] ("Schumann").[3]

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

We REVERSE.

NATURE OF THE CLAIMED INVENTION

Appellant's invention is directed to a transdermal device for dispensing an active agent in a solvent from an administration reservoir through an interface to a porous surface. Abstr.

REPRESENTATIVE CLAIM

Claim 1 is representative of the claims on appeal and is reproduced below.

> 1. A device for transdermal administration of an active substance, the device comprising:
>
> a pressurized reservoir;
>
> a solution of the active substance and a solvent disposed in the pressurized reservoir;

---

[2] An English machine translation of this reference is of record.
[3] The Examiner withdrew rejections under 35 U.S.C. § 112, first and second paragraphs. Ans. 3.

> a porous skin interface adapted to receive solution from the reservoir and to transfer active substance to skin; and
>
> a solvent recovery element communicating with the skin interface and adapted to receive evaporated solvent from the skin interface.

ISSUES AND ANALYSIS

We decline to adopt the Examiner's findings of fact, reasoning, and conclusion that the claims are obvious over the cited prior art. We address below the arguments raised by Appellant.

Issue

Appellant argues that the Examiner's analysis omits explicit reference to those claim limitations relating to "a solvent recovery element" in construing the claims and applying the prior art. App. Br. 8.

Analysis

The Examiner finds Pickup teaches a transdermal application device that includes a dispenser for dispensing liquid bioactive compounds from a reservoir to a transdermal patch. Final Act. 12–13 (citing Pickup ¶¶ 21–23). The Examiner finds the dispenser may include a "piezoelectric member to expel the bioactive material or liquid, which reads on a pressurized receiver." *Id.* at 12. The Examiner finds that Pickup's reservoir stores liquid formulations of bioactive agents, e.g., nicotine, and solvents, e.g., water and alcohol. *Id.* (citing Pickup ¶¶ 24–25). The Examiner finds

Pickup's "transdermal patch reads on [a] permeable interface for coupling to the skin." *Id.*

The Examiner finds that, although "Pickup teaches a patch to receive the active agent solution dispensed from the reservoir, and suggests nicotine, the reference however does not teach [a] solvent removal element as instantly claimed by claims 1 and 10." Final Act. 13. The Examiner finds Schumann teaches a transdermal patch including an active agent-containing layer and a moisture-absorbing layer. *Id.* at 13–14 (citing Schumann, 1–2, 4). The Examiner finds Schumann teaches "moisture may lead to [a] loss of structural integrity of the active agent, therefore moisture absorption by the moisture absorbent layer helps to maintain the active agents." *Id.* at 13.

The Examiner concludes that it would have been obvious to a person of ordinary skill in the art to combine Pickup's transdermal device that provides an active agent from a reservoir to a transdermal patch with a Schumann's moisture-absorbing layer to arrive at Appellant's claimed invention. Final Act. 14. The Examiner finds a skilled artisan would have been motivated to use Schumann's moisture-absorbing layer with Pickup's transdermal patch to help maintain the physical structural integrity of active agents that are sensitive to moisture, such as, nicotine. *Id.* The Examiner finds the resulting moisture layer would have been expected to "absorb and remove moisture that comes into contact with it, either from [the] environment or as a solvent from the drug delivery device." Ans. 10 (emphasis omitted).

Appellant contends that the Examiner ignores claim limitations defining the solvent recovery element. App. Br. 8. Appellant asserts that the Examiner did not address "a solvent recovery element communicating

with the skin interface and adapted to receive evaporated solvent from the skin interface," as recited by claim 1, and "a step of moving solvent from the porous skin interface into a solvent recovery element of the dispensing system," as recited by claim 10. *Id.* With respect to the prior art, Appellant contends Schumann addresses the problem of storing a transdermal system containing a moisture-sensitive agent with a moisture-absorbing layer that absorbs ambient moisture during storage. *Id.* Appellant contends "the sole function of the moisture absorbent layer 2 is to absorb ambient moisture during storage of the device so that ambient moisture does not adversely affect the drug to be delivery from the drug delivery layer." *Id.* Appellant therefore contends that Schumann's moisture-absorbing layer "does not absorb solvent from the drug delivery layer," and would not perform the step of moving solvent from the porous skin interface into a solvent recovery element. *Id.* at 9.

We are persuaded by Appellant's argument. Claim 1 recites "a solvent recovery element communicating with the skin interface and adapted to receive evaporated solvent from the skin surface." App. Br. 11. The phrase "adapted to" can mean "capable of" or "suitable for," or more narrowly "mean 'made to,' 'designed to,' or 'configured to.'" *In re Giannelli*, 739 F.3d 1375, 1379 (Fed. Cir. 2014). As discussed *infra*, we determine that "adapted to," as used in the application at issue, has the narrower meaning, i.e., the solvent recovery element is configured to receive evaporated solvent and not merely capable of doing so.

The Specification discloses that the "invention offers a combination of formula dispensing with an on- and off-turning delivery of the formula and a simultaneous solvent recovery for the purpose of maintaining a constant and

high drug delivery rate." Spec. ¶ 44. For example, the Specification describes that "[t]he solvent recovery element reclaims the solvent that was dispensed with the formulation onto the interface and was not absorbed otherwise. The solvent recovery element preferably is located within the device and comprises one or more desiccants and/or general adsorbents." *Id.* at ¶ 37. The Specification discloses a preferred embodiment wherein the solvent recovery element is "arranged close to but in non-contact with the interface." *Id.* ¶¶ 37, 63. In another embodiment, the Specification discloses "a selectively permeable membrane surrounds a sponge or absorbent material, and the selectively permeable membrane primarily allows the solvent to pass through it … this semi permeable membrane […] remains in constant contact with the diffusion surface." *Id.* ¶ 46.

The Specification illustrates a method of moving solvent from the porous interface into a solvent recovery element in Figure 1, reproduced below.

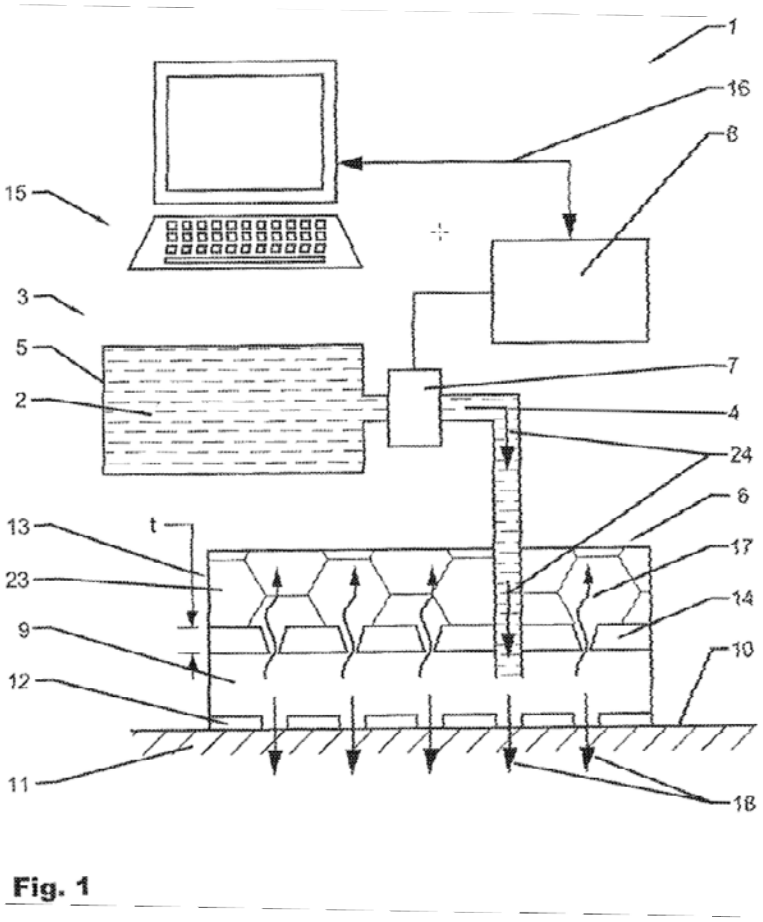

Fig. 1

Figure 1 illustrates a transdermal drug delivery system. Spec. ¶ 52

Figure 1 depicts a transdermal device with drug reservoir 5, administration reservoir 9, "interface device" 12, solvent recovery means 13, separation means 14, and absorbing material 23. Spec. ¶¶ 59–64. "The volatile solvent evaporates from the administration reservoir 9 and is guided (indicated by first arrows 17) through a separation layer 14 to the solvent recovery means 13 where it is reclaimed or discharged." *Id.* ¶ 60. "[S]olvent recovery means 13 are normally arranged at a certain distance from the interface, [and] administration reservoir 9 respectively, […] preventing uncontrolled absorption of solvent. The separation layer 14 may e.g., comprise or consist

of an inert foam or an appropriate cellular material or honeycomb." *Id.* ¶ 62. "The volatile solvent evaporates from the interface under the influence of body heat and the vapors are trapped by the solvent recovery means 13, e.g., a chamber filled with absorbing material 23." *Id.* ¶ 64. These examples, and the Specification as a whole, describe how the solvent recovery element is "adapted to" receive evaporated solvent in combination with a pressurized reservoir for dispensing an active-solvent solution and a skin interface for transferring the active substance to skin.

Consequently, the question before us is whether the combination of Pickup and Schumann teaches a moisture-absorbing layer that is "adapted to" or merely "capable of" receiving evaporated solvent. *See Giannelli*, 739 F.3d at 1380. Schumann teaches a moisture-absorbing layer for protecting the structural integrity of water sensitive drugs in storage. Schumann 2. Schumann does not address solvents, other than to teach that the moisture-sensitive layer may be prepared by forming a mixture of active ingredient and solvent, and then removing the solvent or extruding solvent-free mixtures. *Id.* at 12. More particularly, Schumann neither teaches nor suggests that the purpose of the moisture-absorbing layer is to recover solvent from the solvent-active ingredient combination. Schumann further does not teach a function of the moisture-absorbing layer after applying the transdermal patch to the skin. *See id.*, *supra.*

We agree with the Examiner that Schumann's moisture-absorbing layer might include the same absorbent materials as the claimed solvent recovery element. Ans. 5. However, even using the same absorbent materials, Schumann's moisture-absorbing layer is, arguably, merely capable of receiving evaporated solvent, but not "adapted to" do so.

"Physical capability alone does not render obvious that which is contraindicated." *Giannelli*, 739 F.3d at 1380. Schumann's moisture-absorbing layer absorbs moisture in storage and prior to use. Schumann's moisture-absorbing layer is not used for solvent recovery simultaneous with dispensing a solution. Rather, uncontrolled absorption of solvent prior to use would prevent the proper functioning of the transdermal system.

We agree with Appellant that the combination of Pickup and Schumann does not teach all of the limitations of claim 1. Likewise, the combination does not teach the method of claim 10, particularly, the step of moving solvent from the porous skin interface into a solvent recovery element of the dispensing system.

Because we find that Schumann does not disclose the claimed solvent recovery element, the prior art rejections of the remaining dependent claims on appeal that incorporate Schumann fall with the rejection of the independent claims.

CONCLUSION

The rejection of claims 1–17 as unpatentable under 35 U.S.C. § 103(a), is reversed.

REVERSED

Claims Rejected	35 U.S.C. §	References/Basis	Affirmed	Reversed
1–17	103(a)	Pickup, Schumann		1–17