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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* GUY DIPIERRO<sup>1</sup>

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Appeal 2019-005188  
Application 15/385,665  
Technology Center 1600

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

NEW, *Administrative Patent Judge*.

DECISION ON APPEAL

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<sup>1</sup> 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 1–6 and 9 as unpatentable under 35 U.S.C. § 103(a)(pre-AIA) over the combination of Strausak et al. (US 5,370,635, December 6, 1994) (“Strausak”), Pickup et al. (US 2003/0065294 A1, April 3, 2003) (“Pickup”), and M. L. Gora, *Nicotine Transdermal Systems*, 27 ANNALS OF PHARMACOTHERAPY 742–750 (1993).

The Examiner also rejected claims 2 and 3 under 35 U.S.C. § 112, second paragraph as indefinite.<sup>2</sup>

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

We AFFIRM.

## NATURE OF THE CLAIMED INVENTION

Appellant's invention is directed to a controlled drug delivery method for transdermally delivering a drug according to a programmed administration schedule that implements a desired dosage profile. Spec. ¶¶ 3, 29.

## REPRESENTATIVE CLAIM

Claim 1 is representative of claims on appeal and recited below.

1. A method of delivering nicotine to a subject, the method comprising:

wearing an automated transdermal drug delivery device during the subject's sleep such that a permeable

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<sup>2</sup> The Examiner determined that claims 8, 10–15, and 18 are allowable. Ans. 3.

membrane of the automated transdermal drug delivery device is in contact with skin of the subject; and beginning to deliver a substance comprising nicotine from a reservoir of the transdermal drug delivery device to the permeable membrane during a one hour period immediately prior to the subject's waking to transdermally administer nicotine to the subject.

App. Br. 8.

### ISSUES AND ANALYSIS

We agree with, and expressly adopt, the Examiner's findings, reasoning, and conclusion that that claims 2 and 3 are indefinite, and that the claims are obvious over the cited prior art. We address below the arguments raised by Appellant.

#### A. Rejection of claims 2 and 3 as indefinite

##### *Issue*

Appellant argues that a skilled artisan would understand the scope of the claims, in view of the Specification, with reasonable certainty. App. Br. 4.

##### *Analysis*

Claim 2 recites: "The method of claim 1 further comprising delivering the substance from the reservoir to the permeable membrane at a plurality of times corresponding to expected nicotine cravings of the subject." App. Br. 8. Claim 3 is similar, but the plurality of times correspond to the subject's meal times. *Id.* The Examiner finds claims 2 and 3 thus recite delivering nicotine *via* the claimed method to an awake subject during waking periods.

Final Act. 4. The Examiner finds claim 1, from which claims 2 and 3 directly depend, recites delivering nicotine to a subject during sleep. *Id.* The Examiner determines that delivering nicotine to a sleeping subject is incompatible with delivering nicotine to an awake subject, and therefore concludes that the contradictory claims 2 and 3 are indefinite for failing to particularly point out and distinctly claim the invention. *Id.*

Appellant argues that the indefiniteness rejection has been withdrawn because the Examiner's Answer does not mention the rejection. Reply Br. 2. Appellant further argues that: "claim 1 is not limited to wearing the device *only* while the subject is asleep." App. Br. 4. Appellant argues that claims 2 and 3 add "a step that may be performed while the subject is asleep or awake, as a skilled artisan would understand." *Id.*

First, we address the status of the rejection, followed by our substantive analysis. As acknowledged by Appellant, the Examiner did not expressly withdraw the indefiniteness rejection under 35 U.S.C. § 112, second paragraph. Reply Br. 2. However, the Examiner's Answer expressly states that: "every ground of rejection set forth in the Office action is being maintained by the Examiner" unless expressly withdrawn. The rejection therefore remains pending before us. *See* Ans. 3.

Turning to the merits, we are not persuaded by Appellant's argument. "As the statutory language of 'particularity' and 'distinctness' indicates, claims are required to be cast in clear—as opposed to ambiguous, vague, indefinite—terms." *In re Packard*, 751 F.3d 1307, 1313 (Fed. Cir. 2014). As argued by Appellant, claims 2 and 3 expand the scope of claim 1 to encompass the wearing the automated transdermal device at times, when the subject must necessarily be awake (i.e., experiencing nicotine cravings or at

mealtimes). This interpretation directly contradicts claim 1's recited limitation of "wearing an automated transdermal drug delivery device during the subject's sleep." In other words, "[a] dependent claim that contradicts, rather than narrows, the claim from which it depends is invalid." *Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1362 (Fed. Cir. 2016). Because claims 2 and 3 directly conflict with the language of claim 1, we sustain the Examiner's rejection of the claims as indefinite.

B. Rejection of claims 1–6 and 9 over Strausak, Pickup, and Gora

*Issue 1*

Appellant argues that the prior art does not teach the steps of wearing the device during the subject's sleep and beginning delivery of nicotine during a one hour period immediately prior to the subject's waking. App. Br. 5.

*Analysis*

The Examiner finds Strausak teaches a device for periodically administering nicotine from a reservoir to a subject's skin through a permeable membrane. Final Act. 6 (citing Strausak, col. 2, ll. 25–35, 51; col. 6, ll. 61–68). The Examiner finds that Strausak teaches the device may be worn for a whole day or more and may administer nicotine several times per day. Ans. 4 (citing Strausak, col. 7, ll. 7–9). The Examiner finds Pickup teaches an automated transdermal device for delivering active agents including nicotine. Final Act. 6–7 (citing Pickup ¶¶ 21–23). The Examiner finds Pickup teaches the device may be worn throughout the day or for

multiple days and may be programmed to deliver an active agent at particular times of the day. *Id.* (citing Pickup ¶ 23); Ans. 4 (citing Pickup ¶ 55).

The Examiner finds Gora teaches transdermal administration of nicotine during wakeful hours may be advantageous to closely mimic the typical pattern of smoking. Final Act. 7 (citing Gora 744). The Examiner find Gora teaches the importance of providing adequate early-morning nicotine blood concentrations as the early-morning cigarette is the most difficult to eliminate. *Id.* The Examiner finds one skilled in the art would have been motivated to use a periodic delivery device to administer nicotine just prior to the subject's waking morning time to eliminate the early morning nicotine craving taught by Gora. *Id.* Specifically, the Examiner finds one skilled in the art would have been motivated "to program the programmable transdermal device drawn from the combination of Strausak and Pickup to deliver nicotine before waking of the subject so that by the time the subject[] wakes up, a satisfying blood level of nicotine would be achieved, and craving for morning smoking would be ceased." Ans. 6. Accordingly, the Examiner concludes claim 1 would have been obvious over the prior art.

Appellant asserts that the Examiner has misconstrued the claims. App. Br. 4. Appellant contends that the Examiner omits "the limitations of wearing the device during the subject's sleep and to begin delivery of nicotine during a one hour period immediately prior to the subject's waking." *Id.* at 5. Appellant emphasizes the difference between "delivering during ... during a one hour period immediately prior to the subject's

waking” and “beginning to deliver . . . during a one hour period immediately prior to . . . waking.” Reply Br. 2–3.

We are not persuaded. The Examiner has identified methods for periodic transdermal administration of nicotine at particular times over the course of a whole day or more. Ans. 4. A whole day or more includes times during which a subject is sleeping. Gora teaches that adequate nicotine blood concentrations are especially required in the early-morning, i.e., immediately prior to a subject’s waking. Gora 744. As cited by the Examiner, Strausak teaches periodically administering nicotine, e.g., by automatically switching between a blocked state and a release state. Strausak col. 6:61–7:9. Strausak teaches that the release state may include a release time period lasting from 30 minutes to several hours. *Id.* A nicotine release interval for nicotine that begins 30 minutes before waking teaches the limitation of “beginning to deliver . . . during a one hour period immediately prior to . . . waking,” thereby addressing Gora’s need for adequate early-morning nicotine concentrations. Accordingly, we are not persuaded that the Examiner has misconstrued the claims as compared to the prior art.

## *Issue 2*

Appellant argues that the Examiner “has not provided any rationale supporting the obviousness to a skilled artisan of adding the missing subject matter to the combined disclosures of Strausak, Pickup, and Gora.” App. Br. 5.

*Analysis*

Appellant argues that “[t]he Examiner has not acknowledged the limitations of claim 1 missing from the prior art and has not provided a rationale supporting the obviousness of adding this missing subject matter to the combined disclosure of the prior art.” App. Br. 6–7. Additionally, Appellant argues that “Gora’s discussion of the use of nicotine patches teaches away from the day- and night-long administration of nicotine the Examiner purports to find in Strausak and Pickup by describing the downside of delivering nicotine while sleeping,” i.e., vivid dreams. Reply Br. 3–4 (citing Gora 744). Thus, Appellant argues that the Examiner applies impermissible hindsight by relying on Appellant’s disclosure rather than the prior art. *Id.* at 4.

We are not persuaded. Appellant misconstrues the Examiner’s rejection and the prior art. Gora teaches that continuous 24-hour transdermal dosing of nicotine provides early-morning nicotine blood concentrations, however suffers from the side effect of vivid dreams. Gora 744. Gora teaches that 16-hour dosing alleviates the side effect of vivid dreams, but does not provide adequate early-morning nicotine, and thus does not eliminate the “most difficult” cigarette. *Id.* Gora therefore teaches a need for dosing nicotine at a subject’s waking time, without continuous overnight dosing. The combination of Strausak and Pickup provides a predictable solution to Gora’s problem, i.e., periodic dosing of nicotine set to particular times during a 24-hour time period. “When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads

to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

The Examiner’s rejection “takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made and does not include knowledge gleaned only from [Appellant’s] disclosure.” *In re McLaughlin*, 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971). Therefore, we are not persuaded by Appellant’s argument that the Examiner impermissibly relied on hindsight analysis.

Accordingly, we affirm the Examiner’s rejection of claim 1. Because Appellant does not argue the dependent claims separately (*see* App. Br. 7), we affirm the Examiner’s rejection of claims 2–6 and 9.

## CONCLUSION

The rejection of claims 2 and 3 as unpatentable under 35 U.S.C. § 112, second paragraph is affirmed.

The rejection of claims 1–6 and 9 under 35 U.S.C. § 103(a) is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED

<b>Claims Rejected</b>	<b>35 U.S.C. §</b>	<b>Basis</b>	<b>Affirmed</b>	<b>Reversed</b>
2, 3	112, second paragraph	Indefiniteness	2, 3	
1-6, 9	103(a)	Strausak, Pickup, and Gora	1-6, 9	
<b>Overall Outcome</b>			1-6, 9	