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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ANTHONY YUN and
PATRICK YUARN-BOR LEE

Appeal 2017-005980
Application 13/169,897
Technology Center 1600

Before ULRIKE W. JENKS, RYAN H. FLAX, and
TIMOTHY G. MAJORS, *Administrative Patent Judges*.

MAJORS, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellants[1] submit this appeal under 35 U.S.C. § 134 involving claims to a multi-dose active agent package. The Examiner rejected the claims for lack of patent-eligible subject matter and for obviousness. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] Appellants identify the Real Party in Interest as Palo Alto Investors. App. Br. 3.

STATEMENT OF THE CASE

According to the Specification, "[t]here are a variety of conditions that can affect a female's health" and "[c]ertain conditions increase in severity and/or occurrence during one or more phases of a female's menstrual cycle." Spec. ¶ 2. The Specification explains that "[m]ethods are provided for treating a subject for a condition," and more specifically that the "methods find use in the treatment of a variety of different conditions, including various disease conditions, that increase in severity and/or occurrence during one or more phases of the menstrual cycle." *Id.* ¶ 204.

"Also provided [in the Specification] are systems and kits for use in practicing the subject methods." *Id.*[2]; *see also id.* ¶¶ 192–200. According to the Specification, "multiple dosage units of one or more pharmacological agents may be present in a kit for multiple applications," which may be individually packaged in single or multiple containers. *Id.* ¶ 193. The Specification describes such kits as including, for example, a "monthly pack that includes daily discrete or continuous . . . doses wherein the total number of daily units present in . . . [a] monthly pack . . . may be equal to the total number of days of a month or the days of the menstrual cycle." *Id.* ¶ 194. More specifically, the Specification discloses:

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[2] The Specification lists numerous "[r]epresentative pharmacological agents . . . that may be used" in the methods and kits/packages including, *inter alia*, beta-blockers, angiotensin converting enzyme (ACE) inhibitors, statins, antihistamines, calcium channel blockers, and anti-coagulants. Spec. ¶ 67. The Specification discloses that "[d]osages for a given pharmacological agent are readily determinable by those of skill in the art by a variety of means." *Id.* ¶ 65.

> [T]he monthly pack may include a number of pills to be administered by a subject each day of the month or of the menstrual cycle wherein the pack is configured to include certain pills to be administered to a subject on certain days or during certain menstrual cycle phases, where the type, dosage, etc. of the pills of the pack may vary.

Id.

Claims 69–79, 91–94, 100, and 101 are on appeal. Claim 69, the only independent appeal, is illustrative and is reproduced below:

> 69. A multi-dose active agent package comprising:
>
> a first unit dosage of an active agent that is formulated into a pharmaceutical composition that comprises a pharmaceutically acceptable carrier, and a second unit dosage of an active agent that is formulated into a pharmaceutical composition that comprises a pharmaceutically acceptable carrier;
>
> wherein the active agent comprises a calcium channel blocker,
>
> wherein the amount of the active agent in the first unit dosage differs from the amount of the active agent in the second unit dosage; and
>
> a package, wherein the package holds each of the first unit dosage and the second unit dosage in a separate section, and
>
> wherein the first and second unit dosages of the active agent are selected to treat a subject for a condition that is increased in severity or occurrence during the luteal phase of the menstrual cycle and the pharmaceutically acceptable carrier of the first unit dosage is the same as the pharmaceutically acceptable carrier of the second unit dosage.

App. Br. 23 (Claims App.).

The claims stand rejected as follows:

I. Claims 69–79, 91–94, 100, and 101 under 35 U.S.C. § 101 for claiming patent ineligible subject matter ("Rejection I").

II. Claims 69–71, 74–79, 93, 94, 100, and 101 under 35 U.S.C. § 103(a) as obvious over Chen,[3] Price,[4] and DePadova[5] ("Rejection II").

III. Claim 72 under 35 U.S.C. § 103(a) as obvious over Chen, Price, DePadova, and Hermelin[6] ("Rejection III").

IV. Claim 73 under U.S.C. § 103(a) as obvious over Chen, Price, DePadova, and Wikander[7] ("Rejection IV").

V. Claims 69, 91, and 92 under 35 U.S.C. § 103(a) as obvious over Chen, Price, and D'Angelo[8] ("Rejection V").

VI. Claims 69–79, 91–94, 100, and 101 under U.S.C. § 103(a) as obvious over Hermelin ("Rejection VI").

Appellants identify the following related and co-pending appeals: Appeal No. 2017-005964 (US Appl. No. 12/888,172); and Appeal No. 2017-006039 (US Appl. No. 12/761,297). App. Br. 3. Like the claims in the

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[3] Chen, US 2002/0045184 A1, published Apr. 18, 2002.
[4] William A. Price et al., *Verapamil in the Treatment of Premenstrual Syndrome: Case Report*, 47 J. CLIN. PSYCHIATRY 213–14 (1986).
[5] DePadova, WO 93/02679 A1, published Feb. 18, 1993.
[6] Hermelin et al., US 6,375,956 B1, issued Apr. 23, 2002.
[7] Ida Wikander et al., *Citalopram in Premenstrual Dysphoria: Is Intermittent Treatment During Luteal Phases More Effective Than Continuous Medication Throughout the Menstrual Cycle*, 18 J. CLIN. PSYCHOPHARMACOL. 390–98 (1998).
[8] D'Angelo et al., US 5,756,117, issued May 26, 1998.

present appeal, the Examiner entered rejections for lack of patent-eligible subject matter and obviousness in these related appeals. Decisions in these related appeals are being mailed concurrently with this Decision.

I. SUBJECT MATTER ELIGIBILITY

In analyzing patent eligibility under 35 U.S.C. § 101, the Supreme Court has set forth a "framework for distinguishing patents that claim [patent-ineligible] laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014) (internal citation omitted). According to that framework, first "we determine whether the claims at issue are directed to one of those patent-ineligible concepts." *Id.* "If so, we then ask, '[w]hat else is there in the claims before us?'" *Id.* (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 78 (2012)). To answer this second question,

> we consider the elements of each claim both individually and as an ordered combination to determine whether the additional elements transform the nature of the claim into a patent-eligible application. . . . [The Supreme Court has] described step two of this analysis as a search for an inventive concept — *i.e.*, an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.

Id. (internal citations and quotation marks omitted).

The Examiner rejected all the pending claims under § 101 as being directed to a product of nature. Ans. 3–6, 19–28; *see also* Final Act. (dated Feb. 26, 2016) 3–5; *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130–31 (1948) (holding claims to a composition of different bacterial

strains was directed to "the work of nature" and, thus, patent ineligible). More specifically, according to the Examiner, claim 69 is "directed to active agents that encompasses natural products" such as divalent cations like Ni^{2+} and Cd^{2+}, or the element magnesium, which the Examiner finds are all naturally-occurring calcium channel blockers. Ans. 4 (citing Lacinová[9] and Moron[10]). As for the required pharmaceutically acceptable carrier, the Examiner finds the carrier may simply be water; so, even with the calcium channel blocker, the Examiner finds the claims "encompass a mixture of naturally occurring products" with no change in the agent's structure or properties. *Id.* at 5. Although the Examiner acknowledges that claim 69 requires a "package," the Examiner states that the package "does not change the structure or function of the recited active agents." *Id.* at 5.

Appellants argue "the claims are not directed to a product of nature." Reply Br. 2. To the contrary, Appellants contend, claim 69 is "directed to a package with two different dosages of a calcium channel blocker in different locations of the package," which "package does not occur in nature, but is instead man-made." *Id.*; App. Br. 6. Moreover, Appellants argue, "the multi-dose package system of the claimed invention is not a generic container" and instead requires "separate sections for separating two, different dosage units of a same active agent." App. Br. 7.

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[9] L. Lacinová et al., *Regulation of the calcium α_{1G} subunit by divalent cations and organic blockers*, 39 NEUROPHARMACOLOGY 1254–66 (2000).
[10] Antonio Fernandes Moron et al., *Procedures for fetal neuroprotection: use of magnesium sulfate*, 35 REV. BRAS. GINECOL. OBSTET. 339–41 (2013).

At step one of the *Alice/Mayo* analysis, we ask whether claim 69 is directed to patent-ineligible subject matter. Because all inventions, at some level, embody or apply laws of nature, abstract ideas, etc., "we tread carefully in construing this exclusionary principle lest it swallow all of patent law." *Alice*, 134 S. Ct. at 2354. Hence, we must "ensure at step one that we articulate what the claims are directed to with enough specificity to ensure the step one inquiry is meaningful." *Thales Visionix Inc. v. U.S.*, 850 F.3d 1343, 1347 (Fed. Cir. 2017).

We are unpersuaded that claim 69 is directed to a patent-ineligible product of nature. The dispute between the Examiner and Appellants is largely one of emphasis. The Examiner emphasizes the active agent in claim 69. Ans. 3–6. Appellants emphasize the claimed package with separate sections for holding different doses of the active agent. App. Br. 6–9. On this record, Appellants have the better position. True, claim 69 requires an active agent that comprises a calcium channel blocker. And, as the Examiner has shown, some naturally occurring substances are calcium channel blockers. Ans. 4. But, as the Federal Circuit has confirmed, "[a]t step one, . . . it is not enough to merely identify a patent-ineligible concept underlying the claim; [the Board] must determine whether . . . [the] patent-ineligible concept is what the claim is 'directed to.'" *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1050 (Fed. Cir. 2016).

Reading the claims in light of the Specification, we find that the claimed invention is, on balance, directed to the multi-dose *package*. Spec. ¶¶ 192–200. The package is described as providing an alleged improvement in dosing of the active agent to account for conditions that increase in

severity or occurrence during portions of the menstrual cycle, to aid with administering certain dosages to the subject on certain days, weeks, etc. *See, e.g., id.* ¶ 194. The active agent itself is, in material respects, secondary to the multi-dose package as evidenced by the fact that the Specification provides a roughly six-page laundry list of pharmacological agents (numerous well-known agents that are generically and specifically described) that can be used in combination with the package for treating a likewise generic list of conditions (e.g., cardiovascular conditions, inflammatory conditions, gastrointestinal conditions, neurologic conditions, pain, bacterial infections, and so on). Spec. ¶ 67. We are not persuaded on this record that the invention, and specifically claim 69, is directed to such pharmacological agents, which the Examiner finds encompass naturally occurring substances.

We thus conclude that claim 69 is directed to a multi-dose package having separate sections that respectively hold a plurality of unit dosage forms with different dosages of an active agent, which agent here happens to comprise a calcium channel blocker. To be sure, the features of the package are broadly recited. Whether the package and its features are new or nonobvious is not the issue. The issue, for purposes of this rejection, is whether a package with the structural features recited in claim 69 is merely directed to nature's handiwork. It is not.

The answer to the first question of the *Alice/Mayo* analysis is "no"

— we are unpersuaded claim 69 is directed to a product of nature.[11] Because the answer at step one is "no," the inquiry is over and moving to step two is unnecessary. *Thales*, 850 F.3d at 1349 ("Because we find the claims are not directed to an abstract idea, we need not proceed to step two"). Accordingly, for the reasons above, the rejection of claim 69 (and its dependent claims) under § 101 is reversed.

II. OBVIOUSNESS

a. Chen, Price, and DePadova (Rejection II)

The Examiner rejected claims 69–71, 74–79, 93, 94, 100, and 101 as obvious over Chen, Price, and DePadova. Final Act. 7–13; Ans. 7–11, 28–61. The bases of the rejection are described further below.

Appellants do not argue the rejected claims separately. We, thus, choose claim 69 as representative. 37 C.F.R. § 41.37(c)(1)(iv).

The Examiner finds that "[t]he claims in Chen (as well as paragraph [0010]) disclose that the drug packaging system contain[s] one **or more** unit dosage forms of a first drug and one **or more** unit dosage forms of a second drug." Final Act. 11; *see also* Ans. 8 (citing, e.g., claim 1 of Chen). Also, the Examiner finds, "[t]he language of the claims and specification of Chen make clear that one or more than one discrete measurable amounts of the same active agent is contemplated," and further that "paragraph [0010] states that the two drugs can be the same drug in either the same or different strengths." Final Act. 11. Chen's paragraph 10 is reproduced below:

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[11] Whether claim 69 is patent ineligible under § 101 for other potential reasons (e.g., abstract idea) is not an issue before us in this appeal.

> In other embodiments, the invention is directed to *a drug packaging system* as disclosed herein comprising packaging material comprising therein combined prescription drug therapy *comprising one or more unit dosage forms of a first drug and one or more unit dosage forms of a second drug*. Preferably, the first and second drug are independently selected from the group consisting of non-steroidal anti-inflammatory drugs, proton pump inhibitors, calcium channel blockers, *angiotensin converting enzyme (ACE) inhibitors*, anti-depressants, selective serotonin reuptake inhibitors, antihistamines, decongestants, biguanides, sulfonylureas, 3-hydroxy-3-methylglutaryl coenzyme A (HMG CoA) reductase inhibitors, anti-epileptic, and anti diabetics. *It is meant that the two drugs can be the same drug, e.g., the same strength or different strengths*.

Chen ¶ 10 (emphases added); *see also* Ans. 28–32. According to the Examiner, "Chen states in plain English that the two drugs may be the same drug, for example in the same strength or different strengths." Ans. 29; *see also* Ans. 33–34 ("It is the Examiner's reasoned belief that 'the same strength or different strengths' refers to dosage, since 'strength' typically refers to dosage in the pharmaceutical arts"); Final Act. 11 ("the phrase 'different strengths' teaches and suggests two different dosages, not two separate drugs"); *see also* Ans. 31 (explaining that Chen also teaches providing starting (i.e., loading) and maintenance doses of a drug, which is exemplified with NSAIDs); Chen ¶¶ 92, 94, 105, 106.

The Examiner finds that Chen does not expressly "teach that the first and second unit dosages of the active agent are selected to treat a subject for a condition that is increased in severity or occurrence during the luteal phase of the menstrual cycle," the Examiner contends the claimed subject matter is, nevertheless, obvious. Ans. 9–10. First, the Examiner finds this

language is functional and does not structurally limit the claims, which are "drawn to a product and not a method of treatment." *Id.* at 10. Second, the Examiner finds that Price and DePadova teach treatment of premenstrual syndrome (PMS) with, respectively, a calcium channel blocker (verapamil) and an ACE inhibitor. *Id.* Thus, the Examiner finds, the secondary references evidence that such agents are known to treat "a condition that increases in severity during the luteal phase of the menstrual cycle" and further provide a reason for selecting those agents from Chen's list of drugs for inclusion in Chen's multi-dose packages. *Id.* at 10–11 (citing *Kerkhoven*[12] for the proposition that it is prima facie obvious to combine two compositions known to be useful for the same purpose to create a third composition used for the same purpose).

We agree with and adopt the Examiner's findings concerning the scope and content of Chen, Price, and DePadova, the Examiner's reasoning on the motivation to combine the prior art, and the Examiner's conclusion of obviousness as to claim 69. Final Act. 7–13; Ans. 7–11, 28–47. In short, Chen teaches or suggests multi-dose drug packages, including one or more dosage units/forms of the drugs. *See, e.g.*, Chen ¶ 10, claims 1–2; *see also id.* at claim 19. Chen expressly identifies calcium channel blockers among a short list of suitable drugs for selection for the first and/or second drugs in the package. Chen ¶ 10, claims 1–2. And Chen explicitly discloses that the multiple "drugs [in the packaging system] can be *the same drug*, e.g., the same strength *or different strengths*." *Id.* ¶ 10 (emphases added). The

[12] *In re Kerkhoven*, 626 F.2d 846, 850 (CCPA 1980).

Examiner's interpretations of these teachings of Chen as teaching or suggesting a package including multiple dosage units of *different dosages of the same active agent*, comprising a calcium channel blocker, are reasonable on this record. *See, e.g.*, Ans. 31 ("The last sentence of paragraph [0010] of Chen is consistent with the interpretation that the two drugs can be the same drug in different strengths (dosages)."); *see also* Final Act. 11. Moreover, as the Examiner determined, Price provides further motivation to have chosen a calcium channel blocker (verapamil) from Chen's list and used to treat a condition (PMS) that increases in severity during the luteal phase of the menstrual cycle. Ans. 10–11; Price 214 ("results suggest that verapamil may be useful in treating premenstrual tension syndrome").

Appellants argue "Chen is directed to drug packaging systems for use in *combination therapy* wherein two ***different*** drugs are placed in the same package for ease of administration to a subject." App. Br. 9. According to Appellants, "each of the first and second different drugs [of Chen] may be the same *type* of drug, [but] there is no teaching or suggestion in Chen that the first and second drugs in the package can or would contain *different* amounts of the *same* active agent." *Id.*; *see also* Reply Br. 3–4.

Appellants' argument is unpersuasive. As explained above, Chen teaches that one or more dosage units of the multiple drugs may be included in a package. Chen ¶ 10, claims 1–2. And Chen further expressly teaches that the drugs may be the same drug in *different* strengths. *Id.* Insofar as Chen relates to "combination therapy," Chen suggests numerous combinations that would satisfy that objective without demonstrating error in the Examiner's interpretation of the reference, such as multiple dosage

forms of a calcium channel blocker combined with multiple dosage forms of an ACE inhibitor, NSAID, or other drugs. Chen ¶ 10; *see also* Chen claim 18 (depending from claim 1 and reciting that one or more dosage forms of a third drug).

Nor are we persuaded that the cited language in Chen's paragraph 10 is limited to "the same ***type*** of drug," as argued by Appellants. App. Br. 10. That is not what the paragraph and relevant sentence says — indeed the word "type" is never used in that paragraph or elsewhere in Chen. Chen ¶ 10. Moreover, the Examiner persuasively rebuts Appellants on this point by explaining that reference to "different strengths" in the relevant sentence of Chen is more reasonably interpreted as referring to the dosage of a drug's active agent, not a general drug type or category. *See*, *e.g.*, Ans. 30 ("The strength of a given drug typically refers to the amount of [the] drug in the dosage form or a unit of the dosage form."). Appellants provide insufficient persuasive evidence otherwise.

Appellants argue the Examiner's interpretation of the last sentence of Chen's paragraph 10 is not consistent with Chen's teachings. App. Br. 10. Appellants contend "none of Chen's examples describe a package with first and second unit dosages that contain *different* amounts of the *same* active agent" and, under the Examiner's interpretation, "a package could contain two drugs that contain the same active agent (are the 'same drug') and have the 'same strength,'" contradicting Chen's teachings related to combination therapy. App. Br. 10–11.

We remain unpersuaded. The prior art is not limited to its working examples when the rejection is based on obviousness. *Merck & Co. v.*

Biocraft Labs., Inc., 874 F.2d 804, 807 (Fed. Cir. 1989). Further, Appellants' attorney argument cannot change what Chen expressly discloses — that the multi-drug package can include one or more unit dosage forms of the *same drug* in *different strengths*. Chen ¶ 10. As explained above, the Examiner has provided a reasoned explanation of how the skilled person would interpret what is taught and suggested in Chen. *See, e.g.*, Ans. 28–32. And further, as explained above, Chen suggests that multiple drugs in multiple dosage forms (in different or the same strengths) may be included in Chen's multi-dose packages — it is not limited to only one or even two drugs, thus, providing for various means of drug-combination therapy. Moreover, as the Examiner points out, "[a]lthough Chen exemplifies NSAIDs, . . . it is clear that Chen teaches and suggests more than one unit dosage of the same active agent." Ans. 30; *see also id.* at 29 (Appellants cited paragraphs "represent[] a particular embodiment of Chen, but . . . [are] not the only embodiment[s] disclosed in Chen"). Indeed, Chen also suggests different "starting and maintenance doses of the same drug."[13] *Id.* at 31. Even if exemplified with drugs other than calcium channel blockers in Chen, a package with such starting and maintenance doses would otherwise be encompassed by the breadth of claim 69. Ans. 30–31, 46–47.

Appellants argue Price and DePadova fail to make up for Chen's deficiencies. App. Br. 11. Appellants contend the Examiner "failed to provide any evidence or otherwise provide any motivation as to why one of ordinary skill in the art would have had a reason to provide the ACE

[13] *See, e.g.*, Chen ¶¶ 92, 94, 105, 106.

inhibitor and a calcium channel blocker . . . in different dosage amounts." *Id.* Appellants further contend that "merely because Chen **allegedly** teaches a multi-dose package including two different strengths of a protein pump inhibitor and nonsteroidal anti-inflammatory drug [(NSAID)] does not provide any motivation to provide an ACE inhibitor and a calcium channel blocker in different dosages." *Id.* at 12. According to Appellants, "Chen and the secondary references cited by the Examiner are *both* directed towards completely different types of drugs." *Id.* ("Chen is directed towards administering ***proton pump inhibitors*** *and* ***nonsteroidal anti-inflammatory drugs*** to treat patients for ulcers."). And, Appellants contend, Price and DePadova teach administering a standard dose of the active agent, not different dosage units as claimed. *Id.* at 12–13.

Appellants' arguments are unpersuasive. For reasons discussed above, we disagree that Chen is deficient in the manner suggested by Appellants. The Examiner also explained that the claim language regarding treating a condition that is increased in severity during the luteal phase of the menstrual cycle was functional, and not a structural requirement of claim 69. Ans. 10. And, even to the extent required, at least Price provided a reason for treating such a condition with a calcium channel blocker — one of the drugs listed in Chen. *Id.* at 10–11, 41–45. Claim 69 does not require both an ACE inhibitor and a calcium channel blocker, and Appellants did not argue the claims separately. *Id.* at 35.

Also, contrary to Appellants' assertions, Chen's teachings are not limited to combined administration of proton pump inhibitors and NSAIDs. Quite the opposite, Chen expressly identifies suitable drugs as including

calcium channel blockers and ACE inhibitors, among others, further suggesting various drugs may be included in its multi-dose packages in the same or different strengths. Ans. 36–37; *see*, *e.g.*, Chen claims 1–2, 19, ¶ 10; *compare* Chen claim 1 (listing NSAIDs, ACE inhibitors, calcium channel blockers, and proton pump inhibitors as among the suitable drugs), *with* dependent claim 4 (reciting that the first drug is an NSAID and the second drug is a proton pump inhibitor). Chen is not directed to "completely different" drugs than Price and DePadova as Appellants argue. App. Br. 12. Again, Chen expressly identifies calcium channel blockers and ACE inhibitors as suitable agents to include in its packages. Chen ¶ 10.

Appellants assert that Price administered the same, not different, dosages of a calcium channel blocker. App. Br. 12–13. But the Examiner did not rely on Price for teaching or suggesting the inclusion of different dosages of a calcium channel blocker in a multi-dose package. Ans. 40–43. That comes from Chen. *See*, *e.g.*, Chen ¶ 10. Appellants' argument does not deal persuasively with the *combined* teachings in the art.

Finally, Appellants refer to an interview with the Examiner during which the Examiner purportedly indicated that claim 69 is broad enough to "read on situations where an initial loading dose is present with multiple maintenance doses." App. Br. 13. Appellants do not assert, much less explain, why this claim interpretation by the Examiner is incorrect. Instead, according to Appellants, "no art has been cited by the Examiner showing such a configuration." *Id.*

Appellants' contentions demonstrate no reversible error in the Examiner's rejection. It is well known in the pharmaceutical arts to

prescribe starting/loading doses followed by different maintenance doses as evidenced by at least Chen. *See*, *e.g.*, Ans. 30–31 (citing Chen ¶¶ 92, 94, 105, 106). Appellants provide no persuasive evidence to the contrary.

For the reasons above, the preponderance of the evidence on this record supports the Examiner's conclusion that claim 69 would have been obvious over Chen, Price, and DePadova. Claims 70, 71, 74–79, 93, 94, 100, and 101 have not been argued separately and thus fall with claim 69.

b. Chen, Price, DePadova, and Hermelin (Rejection III)

The Examiner rejected claim 72 as obvious over Chen, Price, DePadova, and Hermelin. Ans. 12–13, 28–61. We agree with and adopt the Examiner's findings concerning the scope and content of Chen, Price, DePadova, and Hermelin, the Examiner's reasoning on the motivation to combine the prior art, and the Examiner's conclusion of obviousness.

Appellants provide no separate argument for Rejection III, arguing only that Hermelin "fails to make up for the deficiency in Chen in view of Price in view of DePadova." App. Br. 14. We are unpersuaded of a deficiency as explained above regarding Rejection II. Accordingly, the rejection over Chen, Price, DePadova, and Hermelin is affirmed.

c. Chen, Price, DePadova, and Wikander (Rejection IV)

The Examiner rejected claim 73 as obvious over Chen, Price, DePadova, and Wikander. Ans. 13–14, 28–61. We agree with and adopt the Examiner's findings concerning the scope and content of Chen, Price, DePadova, and Wikander, the Examiner's reasoning on the motivation to combine the prior art, and the Examiner's conclusion of obviousness.

Appellants provide no separate argument for Rejection IV, arguing only that Wikander "fails to make up for the deficiency in Chen in view of Price in view of DePadova." App. Br. 14. We are unpersuaded of a deficiency as explained above regarding Rejection II. Accordingly, the rejection over Chen, Price, DePadova, and Wikander is affirmed.

d. Chen, Price, and D'Angelo (Rejection V)

The Examiner rejected claims 69, 91, and 92 as obvious over Chen, Price, and D'Angelo. Ans. 14–16, 28–61. We agree with and adopt the Examiner's findings concerning the scope and content of Chen, Price, and D'Angelo, the Examiner's reasoning on the motivation to combine the prior art, and the Examiner's conclusion of obviousness.

Appellants provide no separate argument for Rejection V, arguing only that D'Angelo "fails to make up for the deficiency in Chen and Price." App. Br. 15. We are unpersuaded of a deficiency as explained above regarding Rejection II. Accordingly, the rejection over Chen, Price, and D'Angelo is affirmed.

e. Hermelin (Rejection VI)

The Examiner rejected claims 69–79, 91–94, 100, and 101 as obvious over Hermelin. Ans. 17–19, 61–79. The bases of the rejection are described further below.

Except as provided below, Appellants do not argue the rejected claims separately. Claim 69 is representative. 37 C.F.R. § 41.37(c)(1)(iv).

The Examiner finds, *inter alia*, that Hermelin teaches "a drug dispensing apparatus that is configured to dispense tablets . . . for an

extended period of time." Ans. 17 (citing Hermelin Fig. 3 (depicting a container for long-term storage of multiple blister packs (like depicted in Fig. 2))). The Examiner finds that Hermelin teaches that "the drug packages may contain calcium channel blockers and ACE inhibitors (see column 17, lines 29-51; particularly nifedepine at line 31 and quinapril at line 50)." Ans. 17. Further, the Examiner finds, Hermelin "contemplate[s] that the package may contain two dosage units of the same agent (see, for example, claim 43)." *Id.* Claim 43 of Hermelin is reproduced below.

> **43.** A method for providing optimal therapeutic support to an animal by increasing compliance with a complex dosing regimen and facilitating administration of ***uneven doses of at least one biologically-active substance***, which comprises:
>
> providing the biologically-active substance in ***a blister pack having a first row of a plurality of predetermined areas and a second row of a plurality of predetermined areas; each predetermined area of the first row defining a recess for receiving a first dosage unit and each predetermined area of the second row receiving a second dosage unit***;
>
> wherein the first row of predetermined areas corresponds to a first time indicia and the second row of predetermined areas corresponds to a second time indicia;
>
> a second row of predetermined areas, each of the predetermined areas defining a first recess adapted to receive a second dosage unit, said second row of predetermined areas having a second time indicia; and
>
> wherein ***the first dosage unit and the second dosage unit contain uneven amounts of the biologically-active substance***.

Hermelin claim 43 (emphases added); *see also id.* 8:29–44 ("wherein the first dosage unit has a greater or lesser amount by weight of the biologically active than the second dosage unit") and claim 35 (same). The Examiner also finds that the claim language regarding selecting the agent to treat a

subject for a condition does not provide a structural limitation that distinguishes over the multi-dose package suggested in Hermelin. Ans. 18.

We agree with and adopt the Examiner's findings concerning the scope and content of Hermelin, and the Examiner's reasoning and conclusion of obviousness as to claim 69. Final Act. 13–15; Ans. 17–19, 61–79. Hermelin clearly discloses multi-dose packages with different amounts ("uneven dosing") of the same biologically-active substance. *See, e.g.*, Hermelin claims 35 and 43; *id.* at 8:29–44, 10:56–65; *see also id.* at Figs. 2–3 (showing multi-drug blister pack and extended care package including such blister packs). Hermelin teaches that biologically-active substances broadly include drugs, medicines, and the like. *Id.* at 10:38–50. Hermelin further teaches that "dosage units may be prescription or non-prescription substances, without limitation." *Id.* at 17:21–23. Hermelin, thus, suggests that the "biologically-active substances" and "dosage units" as disclosed include prescription substances — an "exemplary prescription substance[]" in Hermelin is the calcium channel blocker "nifedepine." *Id.* at 17:29–51 (disclosing, *inter alia*, nifedepine (a calcium channel blocker), quinapril (an ACE inhibitor), and "combinations thereof"). The reason for providing nifedepine (with or without other drugs) in different therapeutically effective dosage amounts ("uneven dosing") on a multi-dose package (e.g., blister pack) is reasonably suggested by Hermelin.

Appellants argue that "*in the specific embodiment* in which Hermelin allegedly discloses a multi-dose package including uneven dosage units of a biologically active substance that the biologically active substance *does not comprise a calcium channel blocker.*" App. Br. 15. Further, according to

Appellants, nifedepine is described as a "prescription substance" and "is not disclosed in Hermelin as an example of a biologically-active substance." *Id.* at 16–17 ("Hermelin fails to disclose *a single embodiment of the packaging system* providing ***different dosage units*** *of the same prescription substance (i.e., nifedepine).*"); Reply Br. 5–6.

Appellants' arguments are unpersuasive. This is a rejection for obviousness, not anticipation. Hermelin need not describe a single or particular embodiment of a multi-dose package with different/uneven dosage units of the calcium channel blocker (nifedepine), as would be necessary if anticipation was the issue. *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972) ("[P]icking and choosing may be entirely proper in the making of a 103, obviousness rejection . . . but it has no place in the making of a 102, anticipation rejection"). Moreover, as the Examiner correctly notes, when obviousness is the issue, the teachings of the prior art are not limited to the art's working examples or preferred embodiments. Ans. 66; *Merck*, 874 F.2d at 807.

More fundamentally, however, we disagree with Appellants' contention that Hermelin's biologically-active substances do not include prescription substances and, in particular, nifedepine. Appellants argue that "prescription substances" and "biologically-active substances" cannot be used interchangeably. App. Br. 17–18. According to Appellants, "Hermelin discloses that *biologically-active substances* refer to a 'hormone, steroid, vitamin, fatty acid, amino acid, sugar, carbohydrate, or mineral.'" *Id.* at 17 (citing Hermelin 10:37–38). This argument is not persuasive for at least two

reasons. First, Hermelin's *full* definition of biologically-active substances is reproduced below:

> "Biologically-active substance[s]" *refers to any substance or substances comprising a drug, active therapeutic substance*, metabolite, *medicament*, hormone, steroid, vitamin, fatty acid, amino acid, sugar, carbohydrate, polypeptide or mineral, *any substance used for treatment, prevention, diagnosis, cure or mitigation of disease or illness*, any substance which affects anatomical structure or physiological function, or any substance which alters the impact of external influences on an animal, or metabolite thereof, and *as used herein, encompasses the terms "active substance", "therapeutic substance", "agent", "active agent", "active therapeutic agent", "drug", "medication", "medicine"*[]"medicant" and the like, *without limitation*.

Hermelin 10:37–50 (emphases added). So, contrary to Appellants' suggestion, biologically-active substances are not limited to vitamins, minerals, etc. The definition expressly includes, without limitation, drugs, medicine, medications, therapeutic substances, and (like Appellants' claim 69) active agents. *Id.* This definition broadly encompasses both non-prescription and prescription substances, including the calcium channel blocker nifedepine identified in Hermelin. *Id.* at 17:29–51.

Second, additional disclosures in Hermelin show why Appellants' reading of the art is too narrow. Hermelin teaches that "[t]he dosage units of the present inventive subject matter may comprise any biologically-active substance, without limitation." *Id.* at 16:59–61. The very next paragraph of Hermelin states that "[t]he dosage units may be prescription or non-prescription substances, without limitation." *Id.* at 17:22–23. And, in the paragraph following that, Hermelin identifies "[n]on-limiting exemplary prescription substances," one of which is the calcium channel blocker

nifedepine. *Id.* at 17:29–51. Read in context, we are persuaded that the Examiner's interpretation of the art is correct, and that Hermelin teaches or suggests that the dosage units and biologically-active substances, which Hermelin discloses may be provided in uneven doses on a package, include the prescription substance nifedepine. *See*, *e.g.*, Ans. 62–63.

Appellants further contend that "it is common knowledge that even prescribing a *different unit dosage* of the same type of prescribed substance requires a *separate doctor's prescription*." App. Br. 18. Appellants contend this "lends further support" to Appellants' interpretation and that "Hermelin did not intend to interchangeably group a prescription substance as a biologically-active substance." *Id.* at 18.

We reject Appellants' interpretation of Hermelin for reasons already explained. Even assuming Appellants' attorney argument about the need for separate prescriptions is accurate, this does not persuasively demonstrate non-obviousness. *See* Ans. 71 ("there is no evidence of record suggesting any 'procedural difficulty' with regard to obtaining different prescriptions for different dosages . . ."). Doctors can write multiple prescriptions (e.g., different dosages, different frequencies of administration, etc.) if that is what a patient requires. *Id.* ("if a physician can write one prescription . . . he or she could write two"). In any event, on the record before us, Hermelin teaches or suggests the multi-dose package recited in claim 69.

Appellants argue Hermelin describes a multi-dose package that includes a single dosage unit of a prescription substance and a single dosage unit of a non-prescription substance. App. Br. 19. Appellants contend Hermelin "strongly suggests" encouraging patient compliance with more

effective combination therapy with "no indication" that "prescription substances should be administered in a varied dosage amount." *Id.*[14] And, Appellants contend, there is "no motivation to modify Hermelin to remove the single dosage unit of the non-prescription substance in favor of incorporating multiple, different dosage units of a single prescription substance." *Id.* at 20.

Appellants' arguments remain unpersuasive. As explained above, Hermelin teaches that biologically active substances may be separately included in a package in varied dosage amounts and, like the Examiner, we find that biologically active substances are reasonably interpreted as including prescription substances like the disclosed nifedepine. Hermelin claims 35 and 43; *id.* at 8:29–44, 10:37–50, 10:56–65, 16:59–17:51; *see, e.g.*, Ans. 50. As pointed out by the Examiner, Appellants cite a single embodiment (including a combination of prescription and non-prescription substances) of Hermelin and take issue with an alleged lack of motivation to alter this embodiment. Ans. 74–75. But the Examiner is not proposing

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[14] Appellants also assert that "there is strong support in the medical field to not deviate from Hermelin's method of administering combination therapy" because treating Alzheimer's patients with NSAIDs and vitamins provided greater cognitive performance as allegedly evidenced by Fotuhi. App. Br. 19–21. We are not persuaded by Appellants' contentions because Hermelin teaches that biologically active substances, which we find includes calcium channel blockers as discussed, may be provided in a package in different dosages. Hermelin claims 35 and 43; *id.* at 8:29–44, 10:37–50, 10:56–65, 16:59–17:51. Moreover, as the Examiner noted, Fotuhi is not of record. Ans. 79 ("Fotuhi et al. is not of record and cannot be evaluated"). *See* 37 C.F.R. § 41.33(d)(2) (evidence filed after the filing of the appeal will not be admitted except under limited circumstances, which are not present here).

modification of that embodiment and, instead, is relying on the broader disclosure of Hermelin related to providing uneven dosing of a biologically active substance, which includes prescription substances. *Id.* We reject Appellants' contrary interpretation of the art as already explained. As for Appellants' contentions related to combination therapy and patient compliance, those relate to a description of the background prior art in Hermelin (Hermelin 1:41–55) and demonstrate no error in the Examiner's rejection based on Hermelin's broader teachings. Ans. 76–77.

For the reasons above, the preponderance of the evidence on this record supports the Examiner's conclusion that claim 69 would have been obvious over Hermelin. Claims 70–79, 91–94, 100, and 101 have not been argued separately and therefore fall with claim 69.

In Appellants' Reply Brief, Appellants contend the Examiner erred by including claims 91 and 92 in the rejection based on Hermelin for the first time in the Examiner's Answer. Reply Br. 6. Claims 91 and 92 depend from claim 69, and require the agent be in transdermal or parenteral form. App. Br. 24–25. Appellants contend "[i]t is not seen where these dosage forms are taught or suggested in Hermelin." Reply Br. 6.

The Examiner indicated that, although claims 91 and 92 were rejected elsewhere in the record based on § 103(a), as an oversight, the Examiner neglected to list those claims in the final rejection over Hermelin. Ans. 2–3. The Examiner, nevertheless, explains that inclusion of these dependent claims does not constitute a new ground of rejection. *Id.*

If Appellants believed the Examiner's inclusion of claims 91 and 92 in the Answer improperly raised new grounds of rejection, the Appellants

could have requested that prosecution be reopened as provided by rule. 37 C.F.R. § 41.39(b)(1). Appellants did not do so, but instead maintained the appeal by filing their reply. 37 C.F.R. § 41.39(b)(2). In any event, Appellants' contentions are unpersuasive as Hermelin clearly discloses that the dosage units may be provided in a variety of forms, including oral, parenteral, and transdermal. *See*, *e.g.*, Hermelin claim 23.[15] We, thus, also affirm the rejection of claims 91 and 92 for the reasons provided above.

SUMMARY

We reverse the rejection for patent-ineligible subject matter, but affirm the rejections for obviousness on appeal.

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[15] Although the Examiner could have provided more explicit findings as to claims 91 and 92 in the Answer, we observe that in the related and co-pending appeal (2017-005964) involving similar claims to those at issue here, the Examiner indicated in an answer filed concurrent with the Answer in the present case that "Hermelin contemplate many modes of administration including transdermal and parenteral (see claim 23 of Hermelin), thus meeting limitations set forth in [the] instant claims." *See* Examiner's Answer (filed Dec. 27, 2016) in Appeal No. 2017-005964, at 15. Appellants (represented by the same counsel as in the present appeal) did not challenge the Examiner's findings related to Hermelin's teaching of transdermal or parenteral dosages in either the appeal brief or reply brief in this related appeal, which briefing was filed on the same respective days as the Appeal Brief and Reply Brief in this case.

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