

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMERIGEN PHARMACEUTICALS LIMITED,

Petitioner,

v.

SHIRE LLC,

Patent Owner.

Case IPR2015-02009

Patent RE 42,096

PATENT OWNER'S MOTION TO AMEND

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I. Statement of Relief Requested

Patent Owner Shire LLC moves to amend U.S. Reissued Patent RE 42,096 (Ex. 1001) under 37 C.F.R. §§ 42.121, by cancelling all of the claims that have currently been instituted for trial and proposing one substitute claim for multiple-dependent Claim 25, which removes its dependency from all instituted claims.

II. Motion to Amend

Petitioner Amerigen challenged claims 1-3, 5, 8, 9, 11, 18-21, 23, and 25 of the '096 patent. The Board instituted a trial for claims 18-21, 23, and 25. *See* Decision on Institution ("Decision," Paper 8), at 31 (claims 18-21 and 23); and at 36-38 (claims 18-21, 23 and 25). No trial was instituted for claims 1-17.

Claim 25 states:

25. The pharmaceutical composition of any one of claims 2, 13 or 18 to 20 wherein the pharmaceutically active amphetamine salt in (a) and (b) comprises mixed amphetamine salts.

Claim 25 is a multiple dependent claim, and was instituted only as it depends from claims 18-20, and not as it depends from claim 2 or claim 13. *See* Patent Owner's Request for Reconsideration, Paper 10 (pending; unopposed by Petitioner).

Patent Owner moves to amend the '096 patent by cancelling instituted claims 18-21 and 23, plus claims 22 and 24 (each of which depends from claim 18). Patent Owner also proposes new claim 26 be substituted for claim 25, and claim 25 would then be cancelled. Substitute claim 26 is identical to cancelled claim 25, with the exception that all dependencies from cancelled claims 18-20 have been removed. Thus, claim 26 is supported by the original claims and earlier disclosures. Claim 26 depends only from non-instituted claims.

Effectively, no claim is being amended, and claims are only being cancelled, because claims 18-24 are being removed, and proposed claim 26 removes three multiple dependent claims (claim 25 as it depends from claims 18-20). No other changes to the claims are being made.

Patent Owner's Motion to Amend complies with the requirements of 37 C.F.R. § 1.121. Prior to filing this motion, Patent Owner conferred with the Board by email on July 14, 2014. *See* 37 C.F.R. § 1.121(a). Patent Owner sought guidance regarding this Motion to Amend, as well as regarding its intention to request adverse judgment under 37 C.F.R. 42.73(b)(2), because the amendment cancels all instituted claims. The Board advised that the motion to amend can be submitted, while the request for adverse judgment is premature, because the Board has not yet decided the pending requests for reconsideration. Petitioner sought

reconsideration of the non-instituted claims. Patent Owner sought clarification that multiple dependent claim 25 was instituted only as it depends from instituted claims (18-20), and not from non-instituted claims (2 and 13). This Motion to Amend corresponds to Patent Owner's request for reconsideration.

This motion is timely. 37 C.F.R. § 1.121(a)(1); Paper 9, at 6. The proposed amendment cancels all instituted claims and proposes one substitute claim that cancels claim 25 as instituted, to the extent it depends from instituted claims. The amendments respond to the grounds asserted for unpatentability (37 C.F.R. § 1.121(a)(2)(i)) and they do not enlarge the scope of the claims or introduce new subject matter (37 C.F.R. § 1.121(a)(2)(i)).

The Motion to Amend also proposes a reasonable number of substitute claims, i.e., one substitute Claim 26 to replace canceled Claim 25. 37 C.F.R. § 1.121(a)(3). Appendix A provides a complete claim listing clearly showing the proposed amendments. 37 C.F.R. § 1.121(b).

Patent Owner respectfully requests that its Motion to Amend be granted.

Respectfully submitted,

Dated: July 18, 2016

/Joseph R. Robinson/
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Patent Owner's Motion to Amend has been served on attorneys for Petitioner, via electronic mail on July 18, 2016, to the following addresses provided by Petitioner:

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Respectfully submitted,

Dated: July 18, 2016

/Dustin B. Weeks/
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APPENDIX A – CLAIM LISTING**

Claim Listing Pursuant to 37 C.F.R. § 1.121(b)

1. (Not Instituted) A pharmaceutical composition for delivery of one or more pharmaceutically active amphetamine salts, comprising:

(a) one or more pharmaceutically active amphetamine salts covered with an immediate release coating; and

(b) one or more pharmaceutically active amphetamine salts that are covered with an enteric release coating that provides for delayed pulsed enteric release, wherein said enteric release coating releases essentially all of said one or more pharmaceutically active amphetamine salts coated with said enteric coating within about 60 minutes after initiation of said delayed pulsed enteric release;

wherein the pharmaceutically active amphetamine salts in (a) and (b) comprise mixed amphetamine salts.

2. (Not Instituted) A pharmaceutical composition for delivery of one or more pharmaceutically active amphetamine salts, comprising:

(a) one or more pharmaceutically active amphetamine salts covered with an immediate release coating; and

(b) one or more pharmaceutically active amphetamine salts that are covered with an enteric release coating that provides for delayed pulsed enteric release, wherein said enteric release coating releases essentially all of said one or more

pharmaceutically active amphetamine salts coated with said enteric coating within about 60 minutes after initiation of said delayed pulsed enteric release; wherein said enteric release coating has a thickness of at least 25 μ .

3. (Not Instituted) The pharmaceutical composition of claim 1 wherein the one or more pharmaceutically active amphetamine salts are coated onto a core.

4. (Not Instituted) The pharmaceutical composition of claim 1 wherein the one or more pharmaceutically active amphetamine salts are incorporated into a core.

5. (Not Instituted) A pharmaceutical composition for delivery of one or more pharmaceutically active amphetamine salts, comprising:

(a) one or more pharmaceutically active amphetamine salts covered with an immediate release coating; and

(b) one or more pharmaceutically active amphetamine salts that are covered with an enteric release coating that provides for delayed pulsed enteric release, wherein said enteric release coating releases essentially all of said one or more pharmaceutically active amphetamine salts coated with said enteric coating within about 60 minutes after initiation of said delayed pulsed enteric release; wherein the one or more pharmaceutically active amphetamine salts covered with an immediate

release coating and the one or more pharmaceutically active amphetamine salts covered with an enteric release coating are present on a single core.

6. (Not Instituted) The pharmaceutical composition of claim 1 wherein the one or more pharmaceutically active amphetamine salts covered with an immediate release coating and the one or more pharmaceutically active amphetamine salts covered with an enteric release coating are present on different cores.

7. (Not Instituted) The composition of claim 1 wherein said enteric release coating is a non-pH dependent enteric release coating.

8. (Not Instituted) A pharmaceutical composition for delivery of at least one amphetamine salt, comprising:

(a) at least one pharmaceutically active amphetamine salt covered with an immediate release coating; and

(b) at least one pharmaceutically active amphetamine salt covered with an enteric release coating, said component (a) providing for an immediate release of amphetamine salt to provide a first blood level of amphetamine salt and component (b) providing a delayed pulse enteric release of amphetamine salt that increases the blood level of amphetamine salt to a second level that is greater than the first level provided by component (a), wherein said enteric release coating releases

essentially all of said one or more pharmaceutically active amphetamine salts coated with said enteric coating within about 60 minutes after initiation of said delayed pulsed enteric release;

wherein the pharmaceutically active amphetamine salts comprise mixed amphetamine salts in (a) and (b) comprise mixed amphetamine salts.

9. (Not Instituted) The pharmaceutical composition of claim 8 wherein the one or more pharmaceutically active amphetamine salts are coated onto a core.

10. (Not Instituted) The pharmaceutical composition of claim 8 wherein the one or more pharmaceutically active amphetamine salts are incorporated into a core.

11. (Not Instituted) A pharmaceutical composition for delivery of at least one amphetamine salt, comprising:

(a) at least one pharmaceutically active amphetamine salt covered with an immediate release coating; and

(b) at least one pharmaceutically active amphetamine salt covered with an enteric release coating, said component (a) providing for an immediate release of amphetamine salt to provide a first blood level of amphetamine salt and component (b) providing a delayed pulse enteric release of amphetamine salt that increases the

blood level of amphetamine salt to a second level that is greater than the first level provided by component (a), wherein said enteric release coating releases essentially all of said one or more pharmaceutically active amphetamine salts coated with said enteric coating within about 60 minutes after initiation of said delayed pulsed enteric release; and wherein the one or more pharmaceutically active amphetamine salts covered with an immediate release coating and the one or more pharmaceutically active amphetamine salts covered with an enteric release coating are present on a single core.

12. (Not Instituted) The pharmaceutical composition of claim 8 wherein the one or more pharmaceutically active amphetamine salts covered with an immediate release coating and the one or more pharmaceutically active amphetamine salts covered with an enteric release coating are present on different cores.

13. (Not Instituted) A pharmaceutical composition for delivering one or more pharmaceutically active amphetamine salts comprising:

(a) one or more pharmaceutically active amphetamine salts covered with an immediate release coating;

(b) one or more pharmaceutically active amphetamine salts that are covered with an enteric release coating that provides for delayed pulsed enteric release, wherein said enteric release coating releases essentially all of said one or more

pharmaceutically active amphetamine salts coated with said enteric coating within about 60 minutes after initiation of said delayed pulsed enteric release; and

(c) a protective layer over the enteric release coating.

14. (Not Instituted) The pharmaceutical composition of claim 13 wherein the one or more pharmaceutically active amphetamine salts are coated onto a core.

15. (Not Instituted) The pharmaceutical composition of claim 13 wherein the one or more pharmaceutically active amphetamine salts are incorporated into a core.

16. (Not Instituted) The pharmaceutical composition of claim 13 wherein the one or more pharmaceutically active amphetamine salts covered with an immediate release coating and the one or more pharmaceutically active amphetamine salts covered with an enteric release coating are present on a single core.

17. (Not Instituted) The pharmaceutical composition of claim 13 wherein the one or more pharmaceutically active amphetamine salts covered with an immediate release coating and the one or more pharmaceutically active amphetamine salts covered with an enteric release coating are present on different cores.

18-21. (Instituted/Canceled)

22. (Not Instituted/Canceled)
23. (Instituted/Canceled)
24. (Not Instituted/Canceled)
25. (Instituted with respect to dependency from Claims 18-20/Canceled)
26. (Substitute for Claim 25) The pharmaceutical composition of any one of claims 2[[,]] or 13 ~~or 18 to 20~~ wherein the pharmaceutically active amphetamine salt in (a) and (b) comprises mixed amphetamine salts.¹

¹ Underlines (additions) and brackets or strikethrough (deletions) show the changes in Claim 26 from original Claim 25.