

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AMERIGEN PHARMACEUTICALS LIMITED,  
Petitioner,

v.

SHIRE LLC,  
Patent Owner.

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Case IPR2015-02009  
Patent RE42,096 E

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Before TONI R. SCHEINER, LORA M. GREEN, and  
SHERIDAN K. SNEDDEN, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

FINAL WRITTEN DECISION  
*35 U.S.C. § 318(a) and 37 C.F.R. § 42.73*

## I. INTRODUCTION

Amerigen Pharmaceuticals Limited (“Petitioner”) filed a Petition (Paper 1, “Pet.”) on October 1, 2015, requesting an *inter partes* review of claims 1–3, 5, 8, 9, 11, 18–21, 23, and 25 of U.S. Patent No. RE42,096 E (Ex. 1001, “the ’096 patent”). Shire LLC (“Shire” or “Patent Owner”) filed a Preliminary Response (Paper 7, “Prelim. Resp.”) on January 19, 2016. On April 18, 2016, we instituted an *inter partes* review with respect to claims 18–21, 23, and 25. Paper 8 (“Decision” or “Dec.”).

Subsequent to institution, Patent Owner filed a Motion to Amend.<sup>1</sup> Paper 14. Petitioner filed an Opposition to the Motion to Amend (Paper 17), and Patent Owner filed a Reply to the Opposition to the Motion to Amend (Paper 21).

The Board has jurisdiction under 35 U.S.C. § 6. This is a Final Written Decision under 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

Patent Owner’s Motion to Amend is *granted*.

### *A. Related Proceedings*

Petitioner informs us of the following related judicial matters: *Shire LLC v. Amerigen Pharms. Ltd.*, 14-cv-6095 (D.N.J. Oct. 1, 2014); *Shire LLC v. Corepharma LLC*, 14-05694 (D.N.J. Sept. 12, 2014); *Shire LLC v. Par Pharm. Inc.*, 15-cv-01454 (D.N.J. Feb. 26, 2015). Pet. 1. Patent Owner

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<sup>1</sup> Shire did not file a Patent Owner’s Response.

identifies the same related matters in its Mandatory Notices under 37 C.F.R. § 42.8(a)(2). Paper 6, 1.

In addition, trial has been instituted against claims 18–25 of the '096 patent in *Mylan Pharmaceuticals, Inc. v. Shire Laboratories, Inc.*, Case IPR2016-01033, slip. op. at 34 (PTAB Nov. 17, 2016) (Paper 8).

*B. The Asserted Grounds of Unpatentability*

We instituted trial on the following grounds. Dec. 38.

<b>References</b>	<b>Basis</b>	<b>Claims Challenged</b>
Mehta <sup>2</sup>	§ 102(e)	18–21 and 23
Mehta and Adderall PDR <sup>3</sup>	§ 103(a)	18–21, 23, and 25

II. ANALYSIS

*A. Patent Owner’s Motion to Amend and Proposed Substitute Claim 26*

Patent Owner “moves to amend U.S. Reissued Patent RE 42,096 . . . 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.” Paper 14, 1. Specifically, Patent Owner requests cancellation of “instituted claims 18–21

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<sup>2</sup> U.S. Patent No. 5,837,284, issued November 17, 1998, to Mehta et al. (“Mehta”) (Ex. 1003).

<sup>3</sup> PHYSICIANS’ DESK REFERENCE 331, 2209–11 (51st ed. 1997) (“Adderall PDR”) (Ex. 1004).

and 23, plus claims 22 and 24 (each of which depends from claim 18)” and proposes that “new claim 26 be substituted for claim 25.” *Id.* at 2; *see also*, Paper 21, 2. Instituted claim 25 and proposed substitute claim 26 are as follows:

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.

26. 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.<sup>4</sup>

Proposed substitute claim 26 is identical to multiple dependent claim 25, except that dependencies from instituted claims 18–20 have been deleted. *Id.*

According to 35 U.S.C. § 112(e), “[a] multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered.” In other words, “a multiple dependent claim is considered in the same manner as a plurality of single dependent claims.” MPEP 608.01(n).

In instituting an *inter partes* review of claims 18–21, 23, and 25, we differentiated between the limitations of claim 25 owing to its dependency from claim 2 (Dec. 29), and the limitations owing to its dependency from

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<sup>4</sup> Paper 14, Appendix A, 7 (underlining indicates an addition; bracketing and strikethrough indicate deletions).

claims 18–20 (*id.* at 29, 30, 31, 35). We did not institute an *inter partes* review of claim 2 on any ground (*id.* at 29–34), and we further noted that claim 13 had not been challenged by Petitioner (*id.* at 29 n.9). Thus, claim 25 is part of the trial only to the extent it depends from claims 18–20, and the practical effect of substituting proposed claim 26 (which depends from claim 2 or claim 13) for claim 25 would be to leave no instituted claim remaining in the trial.

*C. Petitioner’s Opposition to the Motion to Amend*

Petitioner argues that Patent Owner’s Motion to Amend should be denied with respect to entering substitute claim 26 “because Patent Owner has not demonstrated the patentability of claim 26 as required by Board precedent.” Paper 17, 2. Petitioner contends essentially that Patent Owner has not met its “burden of showing the substitute claim’s patentable distinction over not only the prior art asserted in the petition, but also all prior art of record in the initial patent prosecution, reissue proceeding, prior litigations and other prior art known to patent owner.” *Id.* at 4 (citing *Idle Free Sys. v. Berstrom, Inc.*, Case IPR2012-00027, slip op. at 6, 7 (PTAB June 11, 2013) (Paper 26)).

Petitioner’s argument is inapposite. *Idle Free* concerned, in relevant part, the burden on a patent owner “to show a patentable distinction over the prior art of record and also prior art known to the patent owner” in the instance where a feature is “added to each substitute claim, as compared to the challenged claim it replaces.” *Idle Free* at 7. As explained in *Nike v.*

*Adidas AG*, 812 F.3d 1326, 1334 (Fed. Cir. 2016), “the patent owner carries an affirmative duty to justify why newly drafted claims . . . should be entered into the proceeding.” In this instance, however, multiple dependent substitute claim 26 merely has the effect of eliminating three claims dependent on instituted claims 18–20, and preserving two claims dependent from non-instituted claims 2 and 13. As Patent Owner aptly explains, “[e]ffectively, 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)” and “[n]o other changes to the claims are being made.” Paper 14, 2.

With the cancellation of claims 18–25, and the entry of substitute claim 26, there would be no claim remaining subject to *inter partes* review in this proceeding. We agree with Patent Owner that “[t]here is no requirement for Shire to prove, after the Institution Decision, that original non-amended claims are patentable over all potential prior art, especially non-instituted claims.” Paper 21, 4.

### III. CONCLUSION

For the foregoing reasons, Patent Owner’s Motion to Amend is granted in all respects.

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#### IV. ORDER

For the reasons given, it is  
ORDERED that Patent Owner's Motion to Amend is *granted*; and  
FURTHER ORDERED that because this is a Final Decision, parties  
to the proceeding seeking judicial review of the Decision must comply with  
the notice and service requirements of 37 C.F.R. § 90.2.

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