

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEALS BOARD

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AMERIGEN PHARMACEUTICALS LIMITED,

Petitioner,

v.

SHIRE LLC,

Patent Owner

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Case No.: IPR2015-02009

Patent No.: Re 42,096

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**PETITIONER'S OPPOSITION TO MOTION TO AMEND**

The Board should deny Patent Owner's Motion to Amend to add claim 26 because Patent Owner has not demonstrated the patentability of claim 26 as required by Board precedent (as affirmed by the Federal Circuit), nor has Patent Owner met its burden of production for the same.<sup>1</sup> Further, Patent Owner did not file its Motion to Amend by the deadline required by the Scheduling Order, and should be denied for that reason as well.

Petitioner does not oppose Patent Owner's proposed cancellation of claims 18-25.

**I. The Motion To Amend Should Be Denied Because Patent Owner Has Not Made The Showings Of Patentability Required Under *Masterimage And Idle Free*.**

Patent Owner asks the Board to enter a substitute claim without Patent Owner making the required showings of patentability under *Masterimage 3D, Inc. v. RealD Inc.*, IPR2015-00040, Paper 42 (July 15, 2015). *Masterimage* makes clear

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<sup>1</sup> Patent Owner represented that Petitioner does not oppose Patent Owner's request for reconsideration. (Patent Owner's Motion to Amend, Paper 14 at 1.) Petitioner did not request an opportunity to file a response to the request, but does oppose Patent Owner's attempt to state that the multiple dependent claims are only conditionally a part of this proceeding. Petitioner will brief such opposition if the Board desires.

that the standards of *Idle Free Systems, Inc. v. Bergstrom, Inc.*, IPR2012-00027, Paper 26 (P.T.A.B. June 11, 2013) still apply. *Masterimage*, at 2. *Idle Free* requires that “in all circumstances” Patent Owner seeking an amendment will make a showing of patentable distinction over the prior art. *Idle Free*, at 6. Patent Owner did not even attempt to make the required showing of patentable distinction, and for that reason alone the Motion to Amend should be denied. Indeed, Patent Owner was required to make its argument for the validity of the substitute claim in its Motion to Amend. *Masterimage 3D*, at 4. Patent Owner did not do so.

Patent Owner has not set forth any *prima facie* case of patentability for Petitioner to rebut. Claim 25, the claim being replaced by claim 26, only adds to claims 2 and 13 the requirement that mixed amphetamine salts be present. The Board found that “mixed amphetamine salts” were disclosed by the prior art as the term was construed by the Board. (Decision to Institute, Paper 8 at 29-30.) Patent Owner argued for a different construction of “mixed amphetamine salts” which the Board found unpersuasive. (Decision to Institute, Paper 8 at 11-14.) Given, at least, the Board’s finding that it is obvious to substitute the mixed amphetamine salts of the Adderall PDR for methylphenidate, under *Idle Free* it was incumbent on Patent Owner to show patentable distinction over claims 2 and 13. *Idle Free*, at 7-8.

Under *Idle Free*, there are multiple requirements for a Patent Owner to successfully bear the burden of proving patentable distinction for a substitute

claim. First, Patent Owner could have argued the construction of the claim term of claim 25 (“mixed amphetamine salts”) that would have lent patentable distinction over claims 2 and 13 when it did not do so over claim 25. *Idle Free*, at 7. Patent Owner has not offered any claim construction in its motion nor adopted that of the Board. Patent Owner could have argued its favored interpretation of mixed amphetamine salts, or that the term was not an obvious extension of claims 2 and 13. Instead, Patent Owner has not cited any support in the specification for the claim term. (Patent Owner’s Motion to Amend, Paper 14.) Patent Owner has not made even a conclusory statement by counsel (which itself would be facially inadequate had it been made). *See Idle Free*, at 7-8.

The Patent Owner also bears the burden of showing the substitute claim’s patentable distinction over the prior art. *Idle Free*, at 7. For those purposes, the prior art includes 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.* This patent has been the subject of numerous litigations with invalidity arguments, including currently-pending litigation against Petitioner. Said invalidity arguments undoubtedly have set forth numerous items of prior art that bear on the validity claim 26. Patent Owner did not present any of this evidence in its Motion to Amend. Indeed, the prior art

known to the Patent Owner is that prior art that falls under the duty of good faith and candor of Rule 42.11. *Masterimage*, at 3.

Regarding prior art subject to the duty of candor, Patent Owner has not even apprised the Board of the parallel proceeding before the Board containing such prior art: *Mylan Pharmaceuticals Inc. v. Shire Laboratories, Inc.*, IPR2016-01033, Paper 2 (P.T.A.B. filed May 12, 2016)(challenging the same U.S. Reissue Patent Re 42,096 as this proceeding). Claim 25 is challenged in that proceeding. (*Mylan*, Paper 2 at 56-57.) Claims 2 and 13 are also challenged in that proceeding. (*Mylan*, Paper 2 at 28-31, 44-47.) Indeed, the *Mylan* proceeding will receive an institution decision no later than one month from now—November 18, 2016—and the Board’s decision there will impact the issues being decided here. Again, Patent Owner has not apprised the Board of any of this information in its Motion to Amend. Given that the *Mylan* institution decision will significantly impact the Board’s decision here, and Petitioner’s and Patent Owner’s Motions for Reconsideration are still pending, it is Petitioner’s position that the Board’s decisions on these Motions should be stayed until the *Mylan* institution decision is rendered. Notably, Patent Owner’s argument for the propriety of its amendment to add claim 26 also depends on a favorable finding of its Motion for Reconsideration asking for “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).” (Patent Owner’s Motion to Amend, Paper 14 at 2-3.)

By filing its corrected Motion to Amend on July 28, 2016, Patent Owner seeks to sidestep the requirements of *Idle Free*, as clarified in *Masterimage*, that Patent Owner show patentability of the claim over the prior art known to it. In presenting its Motion to Amend, Patent Owner also has failed to meet its discovery obligations under 37 C.F.R. § 42.51(b)(1)(iii) (“a party must serve relevant information that is inconsistent with a position advanced by the party during the proceeding concurrent with the filing of the documents or things that contains the inconsistency”) to apprise Petitioner of material information inconsistent with its position. Indeed, Patent Owner has not met, nor even attempted to meet, its burden of production.

Patent Owner also attempts to sidestep its duty of candor and good faith specific to motions to amend. Patent Owner appears to reason that if it is not “amending” the claim, then it need not apply the prior art in that proceeding or even report it to the other party.

Along with its failure to argue the patentability of substitute claim 26 in view of the prior art made of record in this proceeding before the Board, there is yet further prior art known to Patent Owner and not before the Board. Indeed, there is extensive prior art of record in the initial prosecution and the reissue proceeding.

Additionally, Petitioner provided Patent Owner with invalidity contentions in the parallel litigation which were not limited to the prior art of record in this *inter partes* review. Patent Owner is aware of the arguments for invalidity of the Re 42,096 claims from those contentions as well as from other proceedings where the prior art and arguments were never put into the record of the reissue patent, including, at least *Shire LLC v. Amerigen Pharms. Ltd.*, 14-cv-6095 (D.N.J. filed October 1, 2014); *Shire LLC v. Par Pharm., Inc.*, 15-cv-01454 (D.N.J. filed Feb. 26, 2015) and *Shire LLC v. Corepharma, LLC*, 14-05694 (D.N.J. filed Sept. 12, 2014). (See Paper No. 16 at 2-3.) That the other parties are pursuing invalidity in district court rather than the PTAB does not excuse Shire from its requirement to prove the validity of the substitute claim.

Further, the obligation to show patentability over the prior art encompasses all prior art known to the Patent Owner. That obligation is not limited to the patents and printed publications to which a Petitioner is limited in its Petition. *E.g.* *Luv N' Care, Ltd. v. Munchkin, Inc.*, IPR2015-00872, Paper 24 (P.T.A.B. Feb. 18, 2016) (granting motion to compel third-party subpoena about the on-sale date of a photographed product as prior art to oppose a motion to amend). Patent Owner also fails to inform the Board that there is reason to believe that Adderall® XR has essentially the same release profile as Focalin XR, the methylphenidate listed in the Orange Book as being covered by the Mehta reference. (Orange Book Entry for

Focalin XR, Exhibit 1081.) The facts about Focalin XR available to Petitioner could not be asserted as prior art in the Petition, but may be used as prior art against substitute claim 26. Again, Patent Owner has not met its burden of production in this regard.

There are also a multiplicity of issues under 35 U.S.C. § 112 that arise from the comparison of Adderall® XR to Focalin XR. First, when the release period of Adderall® XR does not match that of the patent as suggested by U.S. Patent Publication No. 2006/0204575, Exhibit 1082 (showing Adderall® XR essentially identical to a formulation having complete release on the order of 2 to 6 hours), there is a question as to whether the best mode was disclosed, an issue that is proper for new claims. 35 U.S.C. § 282(b)(3)(A). Second, it is not clear that the claims are enabled given the properties of Adderall® XR. The records for the testing that support the specification's examples should be made of record before the specification is taken as support for the claims. Also, it may be that under various testing methods not included in the specification, Adderall® XR does or does not have the claimed release period. Those variable testing results would render the claim indefinite because the testing is not specified. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341-1345 (Fed. Cir. 2015) (multiple methods of measuring average molecular weight render the term indefinite).



The Board plays an important role in adjudicating whether a new claim may be added to a patent, especially during litigation. Unjustified patent claims cause mischief and added burden for defendants and the courts. Indeed, Patent Owner is presently asserting Re 42,096 against Petitioner and others in litigation. If the Board allows the addition of claim 26 by Patent Owner, the Courts in those litigations will be required to give claim 26 deference and presume that it is independently valid over claims 2 and 13 (35 U.S.C. § 282(a) (“multiple dependent claims shall be presumed valid even though dependent upon an invalid claim”)), despite that claim never being reviewed by the Patent Office. That result will improperly burden Petitioner with then having to prove the claim invalid under the clear and convincing evidence standard. *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 95 (2011). This would be an inequitable result.

Rather, the patent system and federal courts that rely on this Board’s entry of claims should be provided with a claim that the Board finds to be separately patentable by at least a preponderance of the evidence, or in the alternative an examination by a patent examiner in a reexamination or reissue proceeding. Patent Owner has not respected the Board’s precedent that sets forth requirements recognizing the importance of the entry of amended claims by the Board. As such, Patent Owner’s attempt to add claim 26 without Patent Office examination should be denied.

**II. The Motion To Amend Should Be Denied Because Patent Owner Has No Excuse For Failing To File Its Motion To Amend By The Ordered Deadline.**

Under Rule 42.5(c), the Board may excuse a late action upon a showing of good cause or a separate showing that consideration on the merits would be in the interests of justice. Patent Owner can meet neither standard, so Patent Owner's Motion to Amend should be denied.

**A. Patent Owner lacks good cause because it was warned of an error in its filing and did not actually verify the correctness of its filing.**

On July 18, Patent Owner filed a motion to amend without uploading any documents. (Ex. 1083 (7/18/2016 Filing Courtesy Notice to Erik Flom); Ex. 1084 (7/28/2016 email from PTAB E2E Admin to Dustin Weeks).) Petitioner immediately contacted Patent Owner to report a problem:

We just received a notice showing me as the filer for Shire's (Patent Owner's) motion to amend. It may be that PTAB E2E has a problem of some kind. We would appreciate it if you could confirm that the paper was properly filed, and that it is PTAB E2E that has misnamed me as the filing attorney.

(Ex. 1085 (7/18/2016 email from Erik Flom to Dustin Weeks).)

Patent Owner confirmed that the motion had been properly filed, stating: "I confirm that the motion was properly filed (Joe Robinson was the filer) and the system has misnamed you as the filing attorney." (Ex. 1086 (7/18/2016 email from Dustin Weeks to Erik Flom).) Having received that confirmation from Patent

Owner, Petitioner objects to Patent Owner’s Motion to Amend as filed on July 28, 2016, ten days after DUE DATE 1 (July 18, 2016).

On July 28, 2016, Patent Owner contacted the Board stating: “but it has recently come to Patent Owner’s attention that the PTAB E2E system does not currently show that the motion was filed.” (Ex. 1087 (7/28/2016 email from Dustin Weeks to PTAB).) The PTAB E2E Admin informed Patent Owner that “[it] appears that you filed a motion, but did not upload any documents with it.” (Ex. 1084 (7/28/2016 email from PTAB E2E Admin to Dustin Weeks); *see also* below excerpt from Ex. 1084 (arrows in original from PTAB E2E Admin).)

**From:** PTAB E2E Admin <PTABE2EAdmin@USPTO.GOV>  
**Sent:** Thursday, July 28, 2016 3:00 PM  
**To:** Weeks, Dustin B; Trials  
**Cc:** PTAB E2E Admin; Flom, Erik; Wezowski, Marc; Robinson, Joseph R.; Schaffer, Robert  
**Subject:** RE: IPR2015-02009 - Status of Motion to Amend

Hello Dustin B. Weeks,

It appears that you filed a motion, but did not upload any documents with it. When uploading documents with a motion, please click “Add” and your document will appear in the grid below, then you may click submit to submit your motion and document (see below).

Do this first

Then click Submit

Name	Type	Attachment	Number	Paper Type
my motion to amend document	PAPER	Inhibit 2004 Collins Contraception 1399 Amr Definition.pdf	1	Motion

Regards,

**Derek Taylor**  
**Management Information Specialist**  
**571 272-7822**

Patent Owner then uploaded the document ten days late and separately requested that the filing date be reset in an email to the PTAB E2E Administrator, copied to the Board. (Ex. 1088 (7/29/2016 email from Dustin Weeks to PTAB E2E Admin).) Petitioner objected to any entry of a correction, especially one made by the PTAB E2E Admin, and not the Board. (Ex. 1089 (7/29/2016 email from Erik Flom to Board).)

When Patent Owner filed its motion to amend on July 28, 2016, it stated, “[t]his motion is timely” and it backdated the filing to July 18, 2016 as if a motion to reset the date had been granted. (Patent Owner’s Motion to Amend, Paper 15, at 3.) It did not cite the emails with the PTAB E2E Administrator as the reason for calling the motion “timely” but entirely omitted the circumstances of the late filing from the record. (Patent Owner’s Motion to Amend, Paper 15, at 3.)

The Motion should thus be denied for the inexcusable late filing. If there had been a misunderstanding by Patent Owner of how PTAB E2E worked on July 18, 2016, Petitioner’s email to Patent Owner should have resulted in a summary correction immediately, not a correction ten days after the event. Rather, Patent Owner assured Petitioner that the filing had been performed correctly. However, it appears that Patent Owner did not verify that the paper had actually been filed when they represented to Petitioner that they had filed their papers correctly. The excuse offered by Patent Owner for its failure to timely file is insufficient because

Patent Owner was informed, and acknowledged, that the Board's email about the filing was incorrect. Again, when Patent Owner filed the paper late, it improperly back-dated the paper to the date in the scheduling order. (Patent Owner's Motion to Amend, Paper 15, at 3.)

The Board regularly denies motions for failure to meet the dates of the rules or the scheduling order as set or as stipulated by the parties. *Olympus America Inc. v. Perfect Surgical Techniques, Inc.*, 2015 WL 3622887, IPR2014-00241, Final Written Decision, Paper 51, at 24-27 (P.T.A.B. June 8, 2015) (motion to exclude filed after stipulated date denied for lateness); *Google, Inc. v. PersonalWeb Technologies, LLC*, 2014 WL 5585272, IPR2014-00980, Decision, Paper 10, at 4-5 (P.T.A.B. Oct. 30, 2014) (motion for joinder denied as untimely); *The Scotts Company LLC v. Encap LLC*, 2014 WL 2886290, IPR2013-00110, Final Written Decision, Paper 79, at 5 (P.T.A.B. June 24, 2014) (untimely declarations not considered); *Apple Inc. v. Rensselaer Polytechnic Institute*, 2014 WL 10920508, IPR2014-00319, Decision, Paper 20, at 4 (P.T.A.B. Dec. 12, 2014) (denying argument as untimely). The Board should deny this motion for the same reason.

In another case, *Dealersocket, Inc. v. Autoalert LLC*, 2014 WL 4468531, CBM2014-00147, Order, Paper 8, at 6-7 (P.T.A.B. Sept. 8, 2014), a panel of the Board stated that prompt remedial action, explaining the inadvertent circumstance,

requesting leave for the late filing, and working with opposing counsel are the ordinary steps for correcting a late filing.

Even if Patent Owner's initial failure may have been inadvertent, the actions taken by Patent Owner when asked to investigate the filing are insufficient to meet the good cause standard. Indeed, Patent Owner, in a tardy acknowledgement of the problem, sought correction through emails rather than a motion. Still, three months after the initial due date, Patent Owner has not requested leave to file a motion to excuse the late filing. Additionally, prior to contacting the Board, Patent Owner did not confer with Petitioner, requiring Petitioner to respond to the email to the Board to protect its rights.

The fact is that Patent Owner made no use of the same-day warning by Petitioner to correct its filing and has not asked the Board to excuse the late filing. The paper Patent Owner filed does not reflect the late filing, nor does it ask to excuse its tardiness. Patent Owner's actions since the filing date do not constitute good cause to be excused. Instead, its lack of action constitutes waiver of any argument to be excused under 37 C.F.R. § 42.5(c)(3).

**B. Excusing the late filing is not in the interests of justice because Patent Owner may yet amend the claims in a reexamination or reissue proceeding.**

Patent Owner may still pursue claim amendments of any scope by reexamination or reissue after this proceeding concludes. *Idle Free Systems, Inc. v.*

*Bergstrom, Inc.*, IPR2012-00027, Paper 26, at 6 (P.T.A.B. June 11, 2016). As was shown in Part I of this Opposition, Patent Owner has made only a perfunctory effort to support its claim substitution in this proceeding. If Patent Owner's motion is denied, Patent Owner will not be deprived of any substantive right that it cannot pursue through ordinary examination channels. Also, Patent Owner's inaction after the discovery of the problem with its filing constitutes waiver of arguments that it meets the interests of justice standard just as much as it does for the good cause standard.

Dated: October 18, 2016

/Erik B. Flom/

## CERTIFICATE OF SERVICE

I certify that under 37 C.F.R. §42.6 a copy of the foregoing  
**PETITIONER'S OPPOSITION TO PATENT OWNER'S MOTION TO  
AMEND** and any exhibits identified were served upon the named individuals  
below on October 18, 2016 by email as provided by 37 C.F.R. § 42.6(e)(1) and the  
agreement of the parties:

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joseph.robinson@troutmansanders.com

Robert Schaffer  
robert.schaffer@troutmansanders.com

Dustin B. Weeks, Reg. No. 67,466  
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Dated: October 18, 2016

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