

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEALS BOARD

AMERIGEN PHARMACEUTICALS LIMITED,

Petitioner,

v.

SHIRE LLC,

Patent Owner

Case No.: IPR2015-02009

Patent No.: Re 42,096

PETITIONER'S OPPOSITION TO MOTION TO AMEND

Polaris Innovations LTD Exhibit 2008

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.¹ 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

¹ 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

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