

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIODELIVERY SCIENCES INTERNATIONAL, INC.
Petitioner

v.

MONOSOL RX, LLC
Patent Owner

Case IPR2013-00315
Patent 7,425,292

Before JACQUELINE WRIGHT BONILLA, SCOTT E. KAMHOLZ, and
CHRISTOPHER L. CRUMBLEY, *Administrative Patent Judges*.

KAMHOLZ, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

BioDelivery Sciences International, Inc. (“BioDelivery”) filed a petition (Paper 5) on June 12, 2013, to institute an *inter partes* review of claims 1-55 of U.S. Patent 7,425,292 (“the ’292 patent”). BioDelivery later filed a corrected petition (Paper 12, “Pet.”). Patent Owner MonoSol Rx, LLC (“MonoSol”) filed mandatory notices (Paper 20) and a preliminary response (Paper 25, “Prelim. Resp.”). The Board, acting on behalf of the Director, has jurisdiction under 35 U.S.C. § 314.

MonoSol asserted the ’292 patent against BioDelivery in a civil action styled *MonoSol Rx, LLC v. BioDelivery Sci. Int’l, Inc. et al.*, 10-cv-05695 (D.N.J.) (“the ’695 action”). Pet. 1; Prelim. Resp. 4. BioDelivery was served with a “Second Amended Complaint” alleging infringement of the ’292 patent on September 27, 2011. Paper 20, 3. BioDelivery requested *ex parte* reexamination of the ’292 patent on January 20, 2012. Prelim. Resp. 5; Ex. 2006, 84. Reexamination No. 90/012,097 was ordered on February 16, 2012. Pet. 3. The reexamination proceeding terminated July 3, 2012, upon issuance of a reexamination certificate by which each of the original claims 1-22 was confirmed either as amended or as dependent on an amended claim, and new claims 23-55 were added. Ex. 1002, 1-2. The parties represent that the ’695 action was stayed pending resolution of the reexamination, and that it remains stayed. Pet. 2; Paper 20, 4.

We deny the petition because it was not filed within the one-year period set forth in 35 U.S.C. § 315(b).

II. ANALYSIS

Section 315(b) of Title 35 of the United States Code provides:

(b) PATENT OWNER'S ACTION.—An inter partes review may not be instituted if the petition requesting the proceeding is filed more than 1 year after the date on which the petitioner, real party in interest, or privy of the petitioner is served with a complaint alleging infringement of the patent. The time limitation set forth in the preceding sentence shall not apply to a request for joinder under subsection (c).

We must decide whether 35 U.S.C. § 315(b) bars a petition filed more than one year after a complaint alleging infringement was served on the petitioner, even when the petition challenges claims amended by a reexamination certificate issued after service of the complaint. We determine that it does.

BioDelivery contends that its petition is timely because it has not been served with a complaint alleging infringement of the claims amended in reexamination. Pet. 4-5. BioDelivery argues that issuance of the reexamination certificate effectively created a new patent—the “’292C1” patent—in which none of the claims is substantially identical to the claims in the original “’292B2” patent. *Id.* BioDelivery argues that the “’292C1” patent did not exist before July 3, 2012, and has no retroactive effect, due to substantial changes to all claims. *Id.* (citing 35 U.S.C. §§ 307(b) and 252 ¶ 1). BioDelivery asserts that, for these reasons, service of the complaint alleging infringement of the “’292B2” patent should not bar a petition challenging claims of the “’292C1” patent. *Id.* 5.

We reject BioDelivery’s argument that reexamination results in the issuance of a new patent. It does not. A reexamination certificate merely “incorporat[es] in *the patent* any proposed amended or new claim determined to be patentable.”

35 U.S.C. § 307(a) (emphasis added). The reexamination certificate itself states: “*The patent* is hereby amended as indicated below.” Ex. 1002, 2 (emphasis added). *Accord Aspx Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1341-42 (Fed. Cir. 2012) (“Unlike reissue, reexamination does not result in the surrender of the original patent and the issuance of a new patent.”). The identical reference in § 315(b), to the “the date on which the petitioner . . . is served with a complaint alleging infringement of *the patent*” (emphasis added), indicates that the timeliness analysis is to be made with reference to “the patent.”

BioDelivery’s arguments concerning the effects of reexamination as set forth in 35 U.S.C. §§ 307(b) and 252 are not persuasive. BioDelivery does not explain why these provisions, which specify the effect of an “amended or new *claim*” in a reexamined patent, should have any bearing on the applicability of § 315(b). In particular, BioDelivery does not explain how § 307(b) or § 252 nullifies service of MonoSol’s “Second Amended Complaint” alleging infringement of the ’292 patent. Those sections do not state or imply that an infringement complaint is to be treated as if it never had been served, when the asserted patent is afterward amended by reexamination. Whatever the effects of the amended claims of the ’292 patent, the complaint still stands and bars institution of *inter partes* review.

BioDelivery argues also that they have not had a full year to evaluate the claims as amended by the reexamination certificate, a period Congress deemed important when enacting the legislation. Pet. 5-6 (citing 157 CONG. REC. S5429 (daily ed. Sep. 8, 2011) (statement of Sen. Kyl)). This argument is not persuasive, because BioDelivery *had* its year to evaluate the claims, as discussed above. That year ended September 27, 2012. BioDelivery itself manufactured any supposed reduction in its evaluation time by requesting *ex parte* reexamination.

BioDelivery argues that *Fresenius USA, Inc. v. Baxter Intern., Inc.*, 721 F.3d 1330 (Fed. Cir. 2013), rendered after BioDelivery filed its petition, “is directly on point to the issue to the contested issue of standing.” Paper 29, 2. We disagree. *Fresenius* addressed a situation in which all claims at issue in a complaint subsequently were cancelled during reexamination. *Fresenius*, 721 F.3d at 1334-35. The Federal Circuit held that cancellation of all claims during reexamination was binding on a pending district court infringement litigation because no court had rendered a sufficiently “final” judgment. *Id.* at 1346-47. That is not the situation before us now.

BioDelivery was served with MonoSol’s complaint alleging infringement of the ’292 patent on September 27, 2011. The petition was filed more than one year after that date and is, therefore, barred.

III. CONCLUSION

The Board denies the petition because it was not filed within the time limit imposed by 35 U.S.C. § 315(b).

IV. ORDER

For the reasons given, it is

ORDERED that the petition challenging the patentability of claims 1-55 of U.S. Patent 7,425,292 is *denied*.

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Patent 7,425,292

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