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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

YEDA RESEARCH & DEVELOPMENT CO. LTD,
Patent Owner.

Case PGR2016-00010
Patent 9,155,776 B2

Before TONI R. SCHEINER, LORA M. GREEN, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION
Denying Institution of Post Grant Review
37 C.F.R. § 42.208

I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Petitioner") filed a Petition requesting post grant review of claims 1–30 of U.S. Patent No. 9,155,776 B2 (Ex. 1001, "the '776 patent"). Paper 2 ("Pet."). Yeda Research & Development Co. Ltd. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 7 ("Prelim. Resp."). For the reasons provided below, we deny the Petition.

A. Related Proceedings

Petitioner states that the '776 patent, along with three additional related patents, is involved in the following proceedings:

> *Teva Pharms. USA, Inc. v. Mylan Pharms. Inc.*, No. 14-01278 (D. Del. Oct. 6, 2014); *Teva Pharms. USA, Inc. v. Mylan Pharms. Inc.*, No. 14-00167 (N.D. W. Va. Oct. 7, 2014). Other pending litigations involving these same four patents include *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, No. 14-cv-01171 (D. Del. Sept. 10, 2014); *Teva Pharms. USA, Inc. v. Dr. Reddy's Labs.*, No. 14-cv-01172 (D. Del. Sept. 10, 2014); *Teva Pharms. USA, Inc. v. Dr. Reddy's Labs.*, No. 14-cv-05672 (D.N.J. Sept. 11, 2014); *Teva Pharms. USA, Inc. v. Synthon Pharms. Inc.*, No. 14-cv-01419 (D. Del. Nov. 18, 2014); *Teva Pharms. USA, Inc. v. Synthon Pharms. Inc.*, No. 14-cv-00975 (M.D.N.C. Nov. 19, 2014); and *Teva Pharms. USA, Inc. v. Amneal Pharms., LLC*, No. 15-cv-00124 (D. Del. Feb. 3, 2015). These litigations have been consolidated as *In re Copaxone 40 mg Consolidated Cases*, No. 14-cv-01171 (D. Del. Sept. 10, 2014).

Pet. 4; *see also* Paper 5, 1–2 (listing related proceedings that "may affect or be affected by a decision in this proceeding"). Patent Owner lists also several *inter partes* review proceedings that involve patents related to the '776 patent. Paper 5, 3.

B. The '776 Patent (Ex. 1001)

The '776 patent issued on October 13, 2015, with Ety Klinger as the listed inventor. Ex. 1001. The '776 patent claims priority as follows:

> This application is a continuation of U.S. Ser. No. 14/630,326 filed on Feb. 24, 2015, which is a continuation of *U.S. Ser. No. 13/770,677, filed on Feb. 19, 2013, now U.S. Pat. No. 8,969,302*, which is a continuation of U.S. Ser. No. 12/806,684, filed on Aug. 19, 2010, now U.S. Pat. No. 8,399,413, which claims the benefit of priority of U.S. Provisional Application[ ] Nos. 61/337,612 filed Feb. 11, 2010[,] and 61/274,687, filed Aug. 20, 2009, the contents of all of which are hereby incorporated by reference in their entirety.

Id. at 1:4–12 (emphasis added).

The '776 patent is drawn to alleviating a symptom of relapsing-remitting multiple sclerosis "comprising administering . . . three subcutaneous injections of a therapeutically effective dose of glatiramer acetate ['GA'] over a period of seven days with at least one day between every subcutaneous injection." *Id.* at 2:56–65. Moreover, the invention is drawn also to "increasing the tolerability of GA treatment . . . [by] reducing the frequency of subcutaneous injections of a pharmaceutical composition comprising a therapeutically effective dose of glatiramer acetate to three times over a period of seven days with at least one day between every injection." *Id.* at 2:66–3:8.

According to the '776 patent,

> "tolerability" relates to the level of discomfort associated with GA treatment. Tolerability is associated with the frequency and severity of post injection reactions and injection site reactions. Tolerability influences the period that a patient can follow GA treatment.

Id. at 7:38–42.

The '776 patent discloses that "injection site reaction (ISR) refers to a reaction such as erythema, hemorrhage, induration, inflammation, mass, pain, pruritus, urticaria, and welt that [o]ccurs immediately around the site of injection." *Id.* at 7:34–37.

C. Illustrative Claim

Petitioner challenges claims 1–30 of the '776 patent. Claims 1, 5, 12, and 16 are the independent claims. Claim 1 is illustrative of the challenged claims, and is reproduced below (emphasis added):

> 1. A method of treating a human patient suffering from a relapsing form of multiple sclerosis, while inducing *reduced severity of injection site reactions in the human patient relative to administration of 20 mg of glatiramer acetate s.c. daily*, the method consisting of one subcutaneous injection of 1 ml of a pharmaceutical composition comprising 40 mg of glatiramer acetate on only each of three days during each week of treatment with at least one day without a subcutaneous injection of the pharmaceutical composition between each day on which there is a subcutaneous injection, wherein the pharmaceutical composition is in a prefilled syringe, and wherein the pharmaceutical composition further comprises mannitol and has a pH in the range 5.5 to 7.0,
>
> so as to thereby treat the human patient with *reduced severity of injection site reactions relative to administration of 20 mg of glatiramer acetate s.c. daily*.

Id. at 16:35–50.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–30 of the '776 patent on the following grounds (Pet. 8):

References	Basis	Claims Challenged
n/a	§ 112, first paragraph, lack of written description	1–30

References	Basis	Claims Challenged
McKeage[1]	§ 102	1–30
McKeage and Copaxone label[2]	§ 103	1–30

Petitioner relies also on the Declaration of Ari J. Green, M.D. Ex. 1003.

II. ANALYSIS

Post-grant reviews are available only for patents "described in section 3(n)(1)" of the Leahy-Smith America Invents Act ("AIA"), Pub L. No. 112-29, 125 Stat. 284 (2011). AIA § 6(f)(2)(A). Those patents are patents that issue from applications "that contain[] or contained at any time . . . a claim to a claimed invention that has an effective filing date in section 100(i) of title 35, United States Code, that is on or after" "the expiration of the 18-month period beginning on the date of the enactment of" the AIA. *Id.* § 3(n)(1). Because the AIA was enacted on September 16, 2011, post grant reviews are available only for patents that issue from applications that, at one point, contained at least one claim with an "effective filing date," as defined by 35 U.S.C. § 100(i), on or after March 16, 2013. Our rules require that each petitioner for post grant review certify that the challenged patent has an effective filing date that renders the patent available for post-grant review. 37 C.F.R. § 42.204(a) ("The petitioner must certify that the patent for which review is sought is available for post-grant review . . . .").

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[1] Kate McKeage, *Glatiramer Acetate 40 mg/mL in Relapsing-Remitting Multiple Sclerosis: A Review*, CNS DRUGS (published online Apr. 24, 2015) ("McKeage") (Ex. 1011).

[2] Copaxone Prescribing Information (Jan. 2014) ("Copaxone label") (Ex. 1012).

Petitioner argues that the Specification of the '776 patent fails to provide written description support for the following claim limitation: "reduced severity of injection site reactions relative to administration of 20 mg glatiramer acetate s.c. daily." Pet. 1. Petitioner alleges further that "neither the alleged priority application, filed on August 20, 2009, nor any later patent applications claiming priority thereto, disclose that a regimen of 40 mg three-times-per-week reduces the severity of ISRs." *Id.* Thus, Petitioner asserts that although the '776 patent claims priority to a provisional application filed on August 20, 2009, its effective filing date is no earlier than the date of the filing of the application that matured into the '776 patent, i.e., May 22, 2015. *Id.* at 3 (citing 35 U.S.C. § 100(i)(1)). As such, Petitioner avers that the '776 patent is eligible for post grant review. *Id.* Moreover, Petitioner contends that because the '776 patent has an effective filing date of May 22, 2015, the claims are anticipated and rendered obvious by McKeage (Ex. 1011), which bears a publication date of April 24, 2015. *Id.*

Patent Owner responds that the '776 patent is not eligible for post grant review, as it is not subject to the first-inventor-to-file provisions of the AIA. Prelim. Resp. 6. Specifically, according to Patent Owner, the United States Patent and Trademark Office "already considered this question, and determined that the '776 patent is a pre-AIA patent." *Id.* That is, according to Patent Owner, "the Examiner expressly stated that the application was examined under [the first to invent] provisions." *Id.* at 20 (citing Ex. 1002, 35, 261).

Patent Owner contends further that during prosecution the Examiner determined that the subject matter of the claims of the application that

matured into the ’776 patent “was ‘fully disclosed’ in the ancestor [ ] Application, which issued as U.S. Patent No. 8,692,302 [“the ’302 patent”].” *Id*. at 20–21. In particular, Patent Owner argues that in rejecting the claims for obviousness-type double-patenting over the ’302 patent, the Examiner found:

> Although the claims at issue are not identical, they are not patentably distinct from each other because the patent claims fully encompass the subject matter of the pending claims. For example, pending claims 32 and 37 differ from patented claim 7 only in the recitation of consequences that were inherent to the process recited in patented claim 7. ***Because the subject matter claimed in the instant application is fully disclosed in the ’302 patent and is covered by the patent***, the subject matter of each of pending claim 32 and 37 could have been presented as a properly dependent claim in the application from which the ’302 patent issued.

Id. at 21 (quoting Ex. 1002, 265 ¶ 2). Thus, Patent Owner asserts, “it would be unfair and inefficient for a patent owner to be subjected to post grant review proceedings of a pre-AIA patent, that was treated as a pre-AIA patent during prosecution.” *Id.* at 21–22.

We agree with Patent Owner that the issue of whether the ’776 patent is a first-inventor-to-file patent was addressed by the Examiner during prosecution, as stated in the following notice:

Notice of Pre-AIA or AIA Status

> 2) The present application is being Examiner under the pre-AIA first to invent provisions.

Ex. 1002, 35, 261.

Furthermore, as noted by Patent Owner, the Examiner found in rejecting the claims for obviousness-type double patenting over the ’302 patent that the claims of the application that matured into the ’776 patent

were "fully disclosed in the '302 patent and is covered by that patent." *Id.*, 265 ¶ 2. As set forth in the priority statement of the '776 patent, the '302 patent issued from application number 13/770,677, which was filed on February 19, 2013. Ex. 1001, 1:4–12. That date is before the March 16, 2013, critical date for post grant review eligibility.

Moreover, Patent Owner contends that although the Petition addresses the 2009 priority application, "it is completely silent on the disclosure in the other pre-March 16, 2013 ancestor applications from which the '776 patent claims priority and which it incorporates by reference." Prelim. Resp. 7. Specifically, Patent Owner asserts that the "burden is on Petitioner to demonstrate there is a break in a patent's priority chain and the patent is not entitled to a priority date," especially in the instant case, where during prosecution the application that matured into the '776 patent was accorded priority. *Id.* at 23. According to Patent Owner:

> To make even a *prima facie* showing (which it has not) regarding the effective filing date of the '776 patent, [Petitioner] was required to address each and every challenged claim in view of the disclosures of each and every one of these ancestor applications (including claims filed in a preliminary amendment along with the application) that are incorporated by reference in the '776 patent, and address how a [person of ordinary skill in the art] would interpret these disclosures at each time point of the filing of an application prior to March 16, 2013.

Id. at 25.

Patent Owner contends, therefore, that as Petitioner did not address whether any of the applications to which the '776 patent claims priority provide support for the claims of the '776 patent, Petitioner has not met its burden of demonstrating that the '776 patent is a first inventor to file patent. *Id.*

According to Petitioner, although it has the ultimate burden of persuasion, Patent Owner "bears the initial burden to submit evidence and argument showing that the '776 patent's claims are entitled to a filing date before May 22, 2015." Pet. 23 (citing *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327, 1329 (Fed. Cir. 2008)). Petitioner asserts that if Patent Owner fails to meet that initial burden of production, "the '776 patent has a priority date of May 22, 2015 and it is available for post-grant review." *Id.*

We conclude that Patent Owner's argument supports our denial of the Petition. Petitioner focused its argument that the '776 patent has an effective filing date of the date of filing of the application that matured into the '776 patent on the 61/274,687 provisional application, which was filed on August 20, 2009. Notably, Petitioner did not address any of the original claims of the applications included in the chain of priority, which can be used to satisfy the written description requirement. *See In re Koller*, 613 F.2d 819, 823 (CCPA 1980) (noting that an original claims may constitute its own description."); *but see Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1349 (Fed. Cir. 2010) (en banc) (noting that "[a]lthough many original claims will satisfy the written description requirement, certain claims may not"). For example, Patent Owner points out that the '687 application included claim 10, which was directed to a "method of increasing the tolerability of GA treatment." Prelim. Resp. 27. Patent Owner contends that "[a] POSA would understand that claim 10 of the '687 application, read in light of the specification, is referring to a method of increasing tolerability relative to the 20 mg/day subcutaneous dose of GA," and further points out

that "[t]olerability in the patent was specifically defined to include an improvement in severity." *Id.* at 27–28.

As to Petitioner's argument regarding Patent Owner's burden of production, we find that Patent Owner met that burden by pointing to the Examiner's findings as to the effective filing date of the '776 patent during prosecution, as well as by pointing to supporting disclosures in the original priority application. Moreover, the ultimate burden of persuasion remains with Petitioner, and for the reasons discussed above, Petitioner has not demonstrated that it is more likely than not that the '776 patent has at least one claim having an effective filing date on or after March 16, 2013. *See* 35 U.S.C. § 324(a).

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has not demonstrated that the '776 patent is eligible for post-grant review.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is denied, and no trial is instituted.