Docket No: 029163.0026-US01
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Letters Patent of:
Brian Smith et al.

Patent No.: 6,953,787 Application No.: 10/410,991

Issued: October 11, 2005 Confirmation No.: 7841

For: $5HT_{2c}$ Receptor Modulators

RESPONSE TO THE DECEMBER 21, 2023 ORDER TO SHOW CAUSE ISSUED BY THE UNITED STATES PATENT AND TRADEMARK OFFICE REGARDING PATENT TERM EXTENSION APPLICATION

Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This paper responds to the December 21, 2023 Order to Show Cause ("Order") issued by the United States Patent and Trademark Office ("USPTO") regarding the patent term extension ("PTE") application under 35 U.S.C. §156 pertaining to BELVIQ® for U.S. Patent No. 6,953,787 ("the '787 patent") ("PTE Application"). Eisai Inc. ("Eisai"), Marketing Applicant for BELVIQ®, is authorized to act on behalf of the Applicant, Arena Pharmaceuticals, Inc., by virtue of the authorization letter submitted to the USPTO on April 13, 2017. This Response is being submitted by Eisai, through its duly authorized attorney, on behalf of the Applicant.

The Order requires Applicant to show cause with respect to the PTE Application and establish:

> (1) why the USPTO should not terminate the PTE application based on the plain language of 35 U.S.C. § 156(c); and

> (2) why the PTE application for the '787 patent should remain under consideration despite the express written request of withdrawal (revocation) of the active ingredient BELVIQ® (lorcaserin hydrochloride) and waiver of the opportunity for a hearing.

As discussed in greater detail below, Applicant submits that the PTE statute (35 U.S.C. § 156) does not condition the right to an extension on the continued approval of a drug product during pendency of a PTE application. Accordingly, the '787 patent should remain under consideration for PTE, and Applicant's second interim extension request should be granted, despite the fact that FDA's approval for BELVIQ has been withdrawn.

Continued Approval for Commercial Marketing or Use Is Not A Requirement For PTE

The stated impetus for USPTO's Order is the September 7, 2020 withdrawal of approval for BELVIQ (lorcaserin hydrochloride (HCl)) tablets and BELVIQ XR (lorcaserin HCl) extended release tablets, as published in the Federal Register Notice (85 Fed. Reg. 58,063). However, USPTO's focus on the withdrawn approval is misplaced for the reasons set forth below.[1]

First, neither 35 U.S.C. § 156 nor its associated regulations allow for the denial of a PTE application because approval of the drug product has been withdrawn during pendency of the PTE application. Indeed, the text of the PTE statute clearly states that the term of a patent "***shall*** be extended in accordance with this section" (emphasis added) if five particular requirements under 35 U.S.C. § 156(a) are met. All five of those requirements have been satisfied here. A plain reading of the PTE statute thus confirms that the '787 patent is eligible for PTE.

For example, 35 U.S.C. § 156(a)(4) requires that the drug product "*has been subject* to a regulatory review period before its commercial marketing or use" (emphasis added). That provision

[1] The fact that Eisai requested withdrawal of BELVIQ and waived its opportunity for a hearing is irrelevant to whether the PTE application for the '787 patent should remain under consideration.

is stated in the past tense, confirming that the requirement is satisfied as long as the product *previously* underwent a regulatory review period, as was the case here. Similarly, 35 U.S.C. § 156(a)(5) clarifies that "the permission for the commercial marketing or use of the product after such regulatory review period is the *first* permitted commercial marketing or use of a product" (emphasis added). *See also,* 37 C.F.R. § 1.740(a)(4) (requiring that a PTE application include "a statement that [each active ingredient] has not been previously approved for commercial marketing or use"). That language confirms that, while a product may undergo multiple regulatory review periods, only the first authorization is relevant for determining PTE eligibility. Indeed, the date of *first* permitted commercial marketing or use triggers the beginning of the sixty-day period to file a PTE application. *See* 35 U.S.C. § 156(d)(1). Thus, unlike the USPTO's suggestion, the *plain language* of the PTE statute demonstrates that the right to PTE is crystallized upon the *first* permitted commercial marketing or use (i.e. first approval of the drug product), and this right does not dissipate if approval of the drug product is subsequently withdrawn by FDA.

Second, the term "approved product" in the PTE statute is understood to be within the context of the *first* permitted commercial marketing or use. The statute in 35 U.S.C. §156(a) defines "approved product" as "the product referred to in paragraphs [35 U.S.C. § 156(a)](4) and [35 U.S.C. § 156(a)](5)," *i.e.*, the two requirements discussed in the previous paragraph that are plainly satisfied here. And elsewhere in the statute, the term "approved product" is tied to the "regulatory review period," which is used to calculate the PTE term available to a patent—"The term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product." 35 U.S.C. § 156(c). The "regulatory review period" is inextricably tied to the date of *first* permitted commercial marketing, as the end of this period is defined by this date. *See* 35 U.S.C. § 156(g)(1)(B)(ii); 37 C.F.R. § 1.775(c)(2). Thus, "approved

product" in 35 U.S.C. § 156(c), and elsewhere in the PTE statute, is not referring to the "approved" status of the product, currently or in perpetuity, but rather to the approved status of the product as of the *first* permitted commercial marketing or use. To impart any other meaning to the term "approved product" would improperly read in additional requirements for PTE eligibility that are not specified by the PTE statute.

Third, this interpretation of 35 U.S.C. § 156—that the *first* permitted commercial marketing or use is the basis for PTE eligibility despite a later withdrawal of approval—is supported by the fact that 35 U.S.C. § 156(b)(1) explicitly allows for the enforcement of a patent covering the drug product in the extension period for "*any use* approved for the product," which includes subsequent approvals to the first. Thus, although calculation of PTE term relies on the date of *first* permitted commercial marketing or use as the end of the regulatory review period (*see* 35 U.S.C. § 156(g)(1)(B)(ii); 37 C.F.R. § 1.775(c)(2)), the patent may be enforced during the extension period for any *later* use approved by FDA for the drug product. This right of enforcement for subsequent approvals would be rendered meaningless if the statute were interpreted to deny PTE eligibility if the drug product is withdrawn by FDA during pendency of the PTE application.

This right of enforcement for subsequent approvals is particularly significant here since Eisai is pursuing Phase 3 clinical studies for the use of lorcaserin hydrochloride in patients with Dravet syndrome, a severe type of epilepsy characterized by prolonged seizures that begin in the first year of life. *See* https://media-us.eisai.com/2020-09-30-Eisai-Initiates-Phase-3-MOMENTUM-1-Clinical-Trial-Study-304-of-Lorcaserin-in-Dravet-Syndrome. If Eisai obtains approval for the treatment of Dravet syndrome with lorcaserin hydrochloride, this approval would not trigger eligibility for the '787 patent to be extended since this would not be the *first* approval of lorcaserin. However, upon issuance of a PTE Certificate for the '787 patent based on the present PTE

Application, pursuant to 35 U.S.C. § 156(b)(1), the '787 patent, which claims lorcaserin hydrochloride, could be enforced during the extension period as to the subsequently approved use of lorcaserin hydrochloride for the treatment of Dravet syndrome. Accordingly, the plain meaning of 35 U.S.C. § 156 supporting continued eligibility of the '787 patent for extension is aligned with the text of the PTE statute which directs that an extended patent covering the approved product can be enforced not only in the context of the initially approved use but also in the context of any subsequently approved use. If USPTO determines that the '787 patent is not eligible for PTE *solely* because FDA's approval for BELVIQ has been withdrawn, USPTO will deprive Applicant of its right to enforce the '787 patent in an extension period for subsequent approvals it may obtain for lorcaserin hydrochloride.

The potential loss of Applicant's right to enforce the '787 patent in an extension period for subsequent approvals is magnified by the unusually long pendency of the PTE application for the '787 patent. Both the first PTE application (filed July 26, 2012) and the second PTE application (filed Aug. 1 2013) have been pending for over ten years and Applicant has been waiting almost eight years for FDA to respond to its Request for Redetermination that was filed in November 2016. If agency review of the PTE application had been more timely, a PTE certificate for the '787 patent likely would have issued before FDA's approval for BELVIQ was withdrawn in September 2020, over eight years after Applicant submitted its first PTE application. Based upon our review, it appears that the USPTO does not revoke PTE certificates after they have issued. As such, not granting a PTE Certificate here would mean that the excessive delay in agency review would have a highly prejudicial effect by preempting Applicant's rights to enforce the '787 patent in an extension period for subsequent regulatory approvals it may obtain for lorcaserin hydrochloride.

Fourth, the PTE statute makes clear that "[a] determination that a patent is eligible for

extension may be made by the Director *solely on the basis of the representations contained in the application for the extension*." 35 U.S.C. § 156(e)(1) (emphasis added). A necessary corollary of that requirement is that PTE eligibility should be based on an assessment of the facts as they are known at the time a PTE application is submitted. The withdrawal of an FDA approval after a PTE application is submitted would necessarily not be information that is "contained in the application for the extension." 35 U.S.C. § 156(e)(1). A withdrawal that postdates a PTE application therefore cannot be the basis for declaring a patent ineligible for PTE.

Fifth, this interpretation of 35 U.S.C. § 156—that the *first* permitted commercial marketing or use is the basis for PTE eligibility despite later withdrawal of approval—is also consistent with the PTE statute's purpose, which is "to compensate for the delay in obtaining FDA approval." *Merck & Co. v. Kessler*, 80 F.3d 1543, 1547 (Fed. Cir. 1996). In light of that objective, 35 U.S.C. § 156 should be construed liberally to facilitate the full restoration of patent terms held by drug sponsors. *See Meds. Co. v. Kappos*, 731 F. Supp. 2d 470, 471-72, 477-78 (E.D. Va. 2010) (recognizing that 35 U.S.C. § 156 is a "remedial statute" such that, consistent with USPTO's own past practice, the statute's provisions should be "construed liberally . . . in advancement of" an "extended patent term to offset the loss of effective patent life during the period of regulatory review of a new drug product"). If sponsors became ineligible for PTE due to a subsequent withdrawal of an initial approval, they would later be unable to obtain *any* PTE even in a scenario where the product was subsequently approved for a later use (since a PTE application must be filed within 60 days of the *first* commercial marketing authorization). That would directly undermine the purpose of the PTE statute, which is aimed at compensating patent owners for lost patent term due to regulatory review.

Denial of Applicant's Second Interim Extension Request Will Violate APA Principles

Under the Administrative Procedure Act (APA), it is arbitrary and capricious for an agency to (1) depart from a previous policy or practice without acknowledging the departure and explaining the reason for the departure (*see, e.g.*, *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016) ("When an agency changes its existing position, it . . . must at least 'display awareness that it is changing position' and 'show that there are good reasons for the new policy.'" (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515–16 (2009))); or (2) issue decisions that reach different conclusions based on materially similar circumstances (*see, e.g.*, *Burlington N. & Santa Fe Ry. Co. v. Surface Transp. Bd.*, 403 F.3d 771, 776 (D.C. Cir. 2005) ("Where an agency applies different standards to similarly situated entities and fails to support this disparate treatment with a reasoned explanation and substantial evidence in the record, its action is arbitrary and capricious and cannot be upheld.")).

Here, USPTO has explicitly stated numerous times during the pendency of the PTE application that the '787 patent is eligible for extension of patent term. *See* Sept. 28, 2012 Initial Letter re: PTE to FDA ("Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156."); April 12, 2016 Second Letter to FDA re: Regulatory Review Period ("Subject to final review, the subject patent is considered eligible for patent term extension."); Jan. 26, 2023 USPTO Order Granting Interim Extension ("The initial USPTO review of the application ***to date*** indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156.") (emphasis added).

Even more notably, however, USPTO granted a first interim extension request on January 26, 2023 *further to* the filing of a first interim extension request on December 21, 2022 in which Applicant notified USPTO of FDA's withdrawal of approval of BELVIQ on September 17,

2020 (*see* 85 Fed. Reg. 58063) and FDA's subsequent publication regarding that withdrawal (*see* 86 Fed. Reg. 12697 (March 4, 2021). In granting the first interim extension, USPTO explicitly notes that BELVIQ was approved by FDA for commercial marketing or use on June 27, 2012, and concludes that "initial USPTO review of the application to date indicates that the ['787 patent] is eligible for extension of the patent term under 35 U.S.C. § 156." Jan. 26, 2023 USPTO Order Granting Interim Extension. Thus, the Order granting the first interim extension request reflects the USPTO's prior assessment that FDA's withdrawn approval for BELVIQ has no impact on PTE eligibility. As discussed above, this prior USPTO determination follows directly from the *plain language* of the statute, since there is no requirement in the statute that a product continue to be approved for commercial marketing or use in order to receive an interim extension. *See* 37 C.F.R. § 1.760.

Nothing has changed as to the posture of the present PTE Application. As before, a final PTE certificate still cannot be issued because a final determination of the length of the regulatory review period has not yet been made by FDA. Thus, it would be arbitrary and capricious if USPTO were to deny Applicant's second interim extension request, although the circumstances are the same as under which it granted the first interim extension.

A determination that Applicant is not eligible for PTE here would also require the arbitrary application of "different standards to similarly situated entities." *Burlington*, 403 F.3d at 776. We are not aware of USPTO revoking an applicant's PTE certificate even when the regulatory approval that supported the PTE was later withdrawn. That approach reflects the correct understanding that PTE eligibility does not turn on whether a product's initial approval remains in effect. Here, USPTO would be applying an inconsistent standard if it denied an extension on the theory that a withdrawn approval makes an applicant ineligible for PTE.

For the reasons set forth above, Applicant respectfully maintains that the '787 patent should remain under consideration for PTE and that Applicant's second interim extension request should be granted promptly and, in any event, prior to the current expiration of the '787 patent on April 10, 2024. Any questions regarding this Response should be directed to the undersigned attorney of record.

Applicant does not believe that any fees are required to be submitted with this Second Interim Extension Request. However, if any fees are required, Applicant hereby authorizes any fees required to be charged to our Deposit Account No. 50-0740, under Docket No: 029163.0026-US01.

Dated: February 16, 2024

Respectfully submitted,

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