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In Re: Patent Term Extension
Application for
U.S. Patent No. 6,953,787
Filed: July 26, 2012

December 21, 2023

ORDER TO SHOW CAUSE

This is an order to show cause based on the apparent ineligibility of U.S. Patent No. 6,953,787 (the '787 patent) for patent term extension ("PTE") request under 35 U.S.C. § 156.

Factual Background

1. On October 11, 2005, the United States Patent and Trademark Office ("USPTO" or "Office") issued the '787 patent to Smith *et al.* The patent is assigned to Arena Pharmaceuticals, Inc. ("Arena").[1]

2. On June 27, 2012 the Food and Drug Administration ("FDA") under § 505(b) of the Federal, Food, Drug and Cosmetic Act (21 U.S.C. § 355), approved the active ingredient BELVIQ® (lorcaserin hydrochloride) NDA-22529 to Arena the Marketing Applicant.[2]

3. The final approval of active ingredient BELVIQ® (lorcaserin hydrochloride) NDA-22529 was subject to Drug Enforcement Agency (DEA) scheduling recommendation under the Controlled Substances Act (CSA), 21 C.F.R. § 201.57(a)(2) and (c)(10)(i).[3]

4. On July 26, 2012, Arena filed PTE Application under 35 U.S.C. § 156 to extend the term of the '787 patent based on the regulatory review period under § 505(b) of the Federal, Food, Drug and Cosmetic Act for the human drug product BELVIQ® (lorcaserin hydrochloride).[4]

5. On September 28, 2012, pursuant to the Memorandum of Understanding ("MOU") between the USPTO and the FDA,[5] the USPTO requested assistance from the FDA in confirming that active ingredient BELVIQ® (lorcaserin hydrochloride) was subject to a regulatory review period before its commercial marketing or use as required under 35 U.S.C. § 156(a)(4).

[1] See the PTE applications Attachment D, and PTE application page 4.
[2] See the PTE application pages 3, and 4.
[3] See the Attachment C, PTE application pages 49-50. And letter filed April 1, 2016.
[4] See PTE application.
[5] See 52 Fed. Reg. 17830, May 12, 1987.

6. On February 13, 2013, the FDA confirmed that active ingredient BELVIQ® (lorcaserin hydrochloride) was approved on June 27, 2012.

7. On August 1, 2013, Arena filed notice of subsequent PTE Application under 35 U.S.C. § 156 to extend the term of the '787 patent based on the regulatory review period under § 505(b) of the Federal, Food, Drug and Cosmetic Act for the human drug product BELVIQ® (lorcaserin hydrochloride).[6]

8. On April 12, 2016, the Office pursuant to 35 U.S.C. § 156(d)(2(A)(ii) asked the FDA to determine the applicable regulatory review period (RRP) for BELVIQ® (lorcaserin hydrochloride) and publish the determination as a notice in the Federal Register.

9. On September 23, 2016, the FDA published the RRP for BELVIQ® (lorcaserin hydrochloride) in the Federal register Notice at Vol. 81 No. 185, page no. 65658.

10. On April 13, 2017, Arena reported that moving forward Eisai Inc. ("Eisai") is the marketing applicant for BELVIQ® (lorcaserin hydrochloride) and exclusive licensee under the '787 patent, thus, Eisai is authrorized to act on behalf of Arena for the purpose of PTE application under 35 U.S.C. § 156 for the'787 patent.[7]

11. On September 17, 2020, the FDA published the revocation of active ingredient BELVIQ® (lorcaserin hydrochloride) as requested by Eisai in the Federal Register Notice at Vol. 85 No. 181, page no. 58063.[8]

Analysis

Pursuant to 21 U.S.C. § 355, the FDA is mandated by Congress to review New Drug Application (NDA) filings. The data gathered during the clinical trials of NDA become part of the approval process. The goal of the NDA approval process, *in part*, is to provide enough information to permit the FDA reviewer to determine whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks.

According to the published Federal Register Notice of September 17, 2022, Eisai requested withdrawal "(revocation)" of the active ingredient BELVIQ® (lorcaserin hydrochloride).[9] The Notice, in part, provided that results from a clinial trial shows BELVIQ® (lorcaserin hydrochloride) increased risk of cancer and the FDA on January 14, 2019 requested Eisai to voluntarily withdrawa BELVIQ® (lorcaserin hydrochloride) from the interstate commerce.[10]

[6] See subsequent PTE application.
[7] Eisai is the marketing applicant for BELVIQ® (lorcaserin hydrochloride) and exclusive licensee authorized to act on behalf of Arnea. See Letter filed on April 13, 2017.
[8] See 85 Fed. Reg. 58063, September 17, 2020.

[9] *Id*.

[10] *Id*., and also see 2nd full paragraph under "Supplementary Information"

The Notice further provided that on February 13, 2020 Eisai requested the FDA withdrawa approval of BELVIQ® (lorcaserin hydrochloride) and waived its opurtunity for hearing.[11]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2020–N–1735]

Eisai, Inc.; Withdrawal of Approval of Two New Drug Application for BELVIQ (lorcaserin hydrochloride) and BELVIQ XR (lorcaserin hydrocholoride)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing the approval of two new drug applications for BELVIQ (lorcaserin hydrochloride (HCl)) tablets and BELVIQ XR (lorcaserin HCl) extended-release tablets held by Eisai, Inc., 155 Tice Blvd., Woodcliff Lake, NJ 07677 (Eisai). Eisai requested withdrawal of these applications and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of September 17, 2020.

. . .

On February 13, 2020, FDA announced it had asked Eisai to voluntarily withdraw BELVIQ and BELVIQ XR from the U.S. market because a safety clinical trial showed an increased occurrence of cancer

. . .

On February 13, 2020, Eisai requested that FDA withdraw approval of NDA 022529 for BELVIQ and NDA 208524 for BELVIQ XR under § 314.150(d) (21 CFR 314.150(d)), and waived its opportunity for a hearing.

For the reasons discussed above, and pursuant to the applicant's request, approval of NDA 022529 BELVIQ (lorcaserin HCl) tablets and 208524 BELVIQ XR (lorcaserin HCl) extended-release tablets, and all amendments and supplements thereto, are withdrawn under § 314.150(d). Distribution of BELVIQ into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

[11] *Id*., at 58064 1st full paragraph.

The right to extend the term of a patent is predicated on obtaining final FDA approval based upon regulatory review which is the result of the Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98-417, 98 Stat. 1585, commonly known as Hatch-Waxman Act. *See,* 21 U.S.C.§ 355(b), (j), (l); 35 U.S.C. § 156; and Manual of Patent Examination Procedure (MPEP) § 2750.

The PTE application is required to set forth an identification of the date on which the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred. *See,* 37 C.F.R. § 1.740(a).

The patent term extension determination is made based on the representations contained in the PTE application. 35 U.S.C. § 156(c) provides "[t]he 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* which period occurs after the date the patent is issued". Further information may be required or inquiry made of applicant before a final determination is made on whether a patent is eligible for extension. *See* 37 C.F.R. § 1.750.

Requirement to Show Cause

Since there is no longer an approved product, Eisai as authrorized entity acting on behalf of the PTE Applicant, Arena, is required to show cause with regard to its PTE application for BELVIQ® (lorcaserin hydrochloride) 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. In responding to the show cause request, Eisai should identify statutory language in 35 U.S.C. § 156 or case law that would support extension of the '787 patent that claims the product despite revocation of the active ingredient. Moreover, Eisai should explain how PTE application for a withdrawn "revoked" of active ingredient BELVIQ® (lorcaserin hydrochloride) is in compliance with requirements of 37 C.F.R. § 1.740.

Time Period For Response

Applicant has **TWO MONTHS** from the date of this letter to reply to this requirement. Extensions of time under 37 C.F.R. § 1.136 are available.

Any correspondence from applicant with respect to this matter should be submitted via the USPTO's Patent Center using the appropriate document description.

Telephone inquiries related to this notice should be directed to the undersigned at (571) 272-0909.

/Ali Salimi/

Ali Salimi
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner for Patents

cc: FDA, CDER, Office of Regulatory Policy
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Attention: Beverly Friedman

RE: BELVIQ® (lorcaserin hydrochloride)
Docket No.: FDA-2012-E-1232