UNITED STATES PATENT AND TRADEMARK OFFICE

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In Re: Patent Term Extension
Application for
U.S. Patent No. 8,492,416
Filed: April 12, 2016

August 3, 2020

REQUIREMENT FOR INFORMATION PURSUANT TO 37 C.F.R. 1.750

This is in response to an application for patent term extension (PTE) of U.S. Patent No. 8,492,416 ("the '416 patent"), filed April 12, 2016, by UCB Biopharma SPRL, the patent owner of record. The product identified in the application is BRIVIACT® (brivaracetam), as oral solution (NDA-205838). The NDA-205838 was approved for commercial use and sale by the Food and Drug Administration (FDA) on February 28, 2016. An extension of 698 days is requested.

Applicant has concurrently filed PTE applications seeking patent term extensions for the U.S. Patent Nos. 6,784,197 and 6,911,461 based on the same approved product, BRIVIACT® (brivaracetam), injection (NDA-205837) and as tablet (NDA-205836). Both NDA-205837 and NDA-205836 were approved by the FDA on February 28, 2016.

A. **Pursuant to 37 C.F.R. § 1.750, applicant is required to submit information to assist the USPTO in determining whether their multiple PTE requests comply with the requirement of 35 U.S.C. § 156(a)(5)(A) which states:**

> **(a)**The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b), if—
> **(5)(A)** except as provided in subparagraph (B) or (C), 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 the product under the provision of law under which such regulatory review period occurred
>
> **and 35 U.S.C. § 156(c)(4), which provides:**
>
> in no event shall more than one patent be extended under subsection (e)(1) for the same regulatory review period for any product.

The issue is whether 35 U.S.C. § 156 permits a patent owner who owns more than one patent to obtain more than one patent term extension for the same FDA approved product. Applicant has filed multiple PTE applications directed to the same product (brivaracetam). If applicant contends that more than one patent may be extended based on the approval of brivaracetam, then applicant is required to provide legal support pursuant to the 35 U.S.C. § 156, expressly demonstrating that the statute permits multiple term extensions based on the same product.

Absent a convincing showing, the Office plans to issue only one PTE directed to BRIVIACT® (brivaracetam).

B. Statement of Facts:

Applicant has obtained FDA approval for the product brivaracetam, as evidenced by the FDA letter attached as Appendix C to each of the PTE applications. Applicant has filed a total of three applications for PTE based on the FDA's approval of brivaracetam:

- one application for extension filed in the '416 patent;
- one applications for extension filed in U.S. Patent No. 6,784,197
- one applications for extension filed in U.S. Patent No. 6,911,461

Applicant is seeking patent term extensions for multiple patents based on the same approved product.

C. Analysis:

Applicant is seeking to obtain multiple patent term extensions for the same product. Doing so would violate 35 U.S.C. §§ 156(a)(5)(A) and (c)(4) and 37 C.F.R. § 1.785(b), and is not supported by recent case law.

Pursuant to 21 U.S.C. § 301, the Food and Drug Administration (FDA) is mandated by Congress to review Investigational New Product (IND) filings. The data gathered during the clinical trials of an IND become part of the New Drug Application (NDA) process. The goal of the NDA, *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.

The FDA practice entails review of those NDA applications that are filed concurrently directed to the same active ingredient(s) and share the same data (e.g. clinical efficacy and safety). *See*, FDA Guidance for Industry – Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees, www.fda.gov/media/72397/download. Consequently, barring any issues during the review process, *i.e.*, dosage forms or methods of administration, all of the NDA applications having the same ingredient(s) are reviewed at the same time and approved on the same date. The FDA does not consider the patent term extension program when reviewing NDA applications. Thus, the FDA as part of its mandate provides concurrent approvals for the same product on the same date with no consideration to possible future patent term extension requests.

The right to a PTE based upon regulatory review is the result of the Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98-417, 98 Stat. 1585 (codified at 21 U.S.C.§ 355(b), (j), (l); 35 U.S.C. § 156) commonly known as Hatch-Waxman Act. The act codified as 35 U.S.C. § 156 is designed to restore time lost from the patent term for those patents awaiting premarket government approval from a regulatory agency. *See* Manual of Patent Examination Procedure (MPEP) § 2750.

Although both FDA approvals received the same date, they cannot both be considered as "first" approved under § 156(a)(5)(A) and they cannot both constitute distinct regulatory review periods

under § 156(a)(4). These interpretations go against the plain statutory language, which states: "the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred." There cannot be more than one "first permitted commercial marketing or use" of the product or more than "a" (single) regulatory review period of the product, subject to patent term extension. *Id.* Additionally, § 156(c)(4) states that "in no event shall more than one patent be extended under subsection (e)(1) for the same regulatory review period for any product." Hence, subsection (c)(4) limits the right of a patent owner to obtain more than one extension based on time lost for the "same" regulatory review period for "any product." *See,* 35 U.S.C. § 156(c)(4) and 37 C.F.R. § 1.785(b).

The Federal Circuit has explained that by passing § 156 "Congress did not [intend to] compensate a loss of term for all patents affected by regulatory review period." *See Novartis AG v. Ezra Ventures LLC,* 909 F.3d 1367, 1372 (Fed. Cir. 2018). The court further stated that §156 only permits the extension of one patent based on the approval of one product and allows the patent holder to choose which patent to extend. *See id.* at 1369. The *Ezra* court stated that §156(c)(4) provides for a patent owner having multiple patents that cover the same product to make "a choice among its qualifying patents." *See id.* Therefore, under the holding of *Ezra* it cannot reasonably be asserted that each regulatory period is distinct and more than one patent should be extended.

Still further, there has been no recognition either by Congress or the courts that the plain meaning of §156 contemplates providing multiple patent extensions for different means of administering the same approved product. *See Arnold Partnership v. Rogan,* 246 F. Supp.2d 460 (E.D. Va. 2003). In *Arnold Partnership* the district court distinguished the focus of the FDA approval process, which is the claimed drug as a whole, from the focus of § 156, which is the active ingredient of the drug. *Id.* at 465. In endorsing the USPTO's policy of extending the patent term for combination drug patents only if one of the active ingredients had not been previously approved by the FDA, the court described the rationale underlying Congress's enactment of §156. In particular, the court noted that Congress declined to include in the Act provisions to allow extensions for new dosage forms and delivery systems, "demonstrat[ing] its intent that only 'new, pioneer chemical entities were to have their effective lives legislatively renewed.'" *Id* at 465-6 (quoting *Fisons plc v. Quigg,* No. 86-1804, 1988 WL 150851 (D.D.C. 1988), *aff'd* 876 F.2d 99 (Fed. Cir. 1989)). Applicant has obtained FDA approval for one product (brivaracetam), albeit which has different modes of administration; consequently applicant is entitled to extend the term of only one patent.

Recently, the Federal Circuit explained that the plain statutory language of §156 limits "a patent term extension under 35 U.S.C. § 156 [to] only . . . the active ingredient of an approved product, or an ester or salt of that active ingredient." *Biogen Int'l v. Banner Life Sciences LLC, 956 F.3d 1351, 1353* (Fed. Cir. 2020). The court explained that the active ingredient under § 156(f) "is defined by what is approved [by the FDA] and is specified on the drug's label." *Id* at 1357. Here, the product (active ingredient) approved by the FDA and specified on the label is brivaracetam.

Section 156 does not allow for multiple extension of patents beyond the one patent per one approved product. The regulatory review period of BRIVIACT® (brivaracetam) can be used as a basis for extension of only one patent. *See* 35 U.S.C. § 156(c)(4) and 37 C.F.R. § 1.785(b).

Therefore, the Office plans to limit applicant to extending only one patent for the approved product (brivaracetam).[1]

Once the Notice of Final Determination is made available to the Applicant, Applicant can then make a selection for one patent to be extended from among their multiple PTE filings based on the approval of BRIVIACT® (brivaracetam).

In conclusion, the Office plans to issue one PTE under 35 U.S.C. § 156 for BRIVIACT® (brivaracetam)

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 electronic filing systems (EFS-Web or Patent Center) and should be addressed as follows:

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

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 Patent Examination Policy

[1] The Office acknowledges that in the past it has permitted more than one extension when multiple forms of administration of the same drug product were applied for and approved by the FDA on the same day. However, the Office believes that the proper interpretation of the statute, especially in light of recent court decisions discussed in this requirement for information, mandates that only a single patent be extended for any given drug product, regardless of the number of forms of administration approved by the FDA.

cc: FDA, CDER, Office of Regulatory Policy
10903 New Hampshire Avenue,
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Attention: Beverly Friedman

RE: BRIVIACT® (brivaracetam)
(NDA 205838)
Docket No.: FDA-2016-E-2529