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Liuchun Yang
Gilead Sciences, Inc.
333 Lakeside Dr
Foster City, CA 94404

In Re: Patent Term Extension
Application for
U.S. Patent No. RE44,599
Filed: September 17, 2014

February 8, 2024

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

This is in response to the two applications for patent term extension (PTE) under 35 U.S.C. § 156 for U.S. Patent No. RE44,599 ("the '599 patent") filed on September 17, 2014 in the United States Patent and Trademark Office ("USPTO" or "Office"). The current patent owner of record is Gilead Sciences, Inc. ("Gilead" or "Applicant"). The product identified in the two PTE applications is ZYDELIG® (idelalisib) for NDA-205858 and NDA-206545. Both NDA-205858 and NDA-206545 were approved by the Food and Drug Administration (FDA) on July 23, 2014. Applicant's response of November 21, 2023 to previously mailed Order to Show-Cause is acknowledged. Applicant's timely response of November 21, 2023 is under consideration, once the response to this request is received the Office will collectively respond to the Applicant.

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 (idelalisib). If applicant contends that more than one patent may be extended based on the approval of idelalisib, then applicant is required to provide legal support pursuant to 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 after considering all of Applicant's argument plans to issue only one PTE directed to ZYDELIG® (idelalisib).

B. Statement of Facts:

Applicant has obtained FDA approval for the product idelalisib, as evidenced by the FDA letter attached as Attachment E1 for (NDA-205858) and Attachment E2 for (NDA-206545) of the PTE applications. Applicant has filed a total of four applications for PTE based on the FDA's approval of delafloxacin:

- two applications for extension filed in the '599 patent;
- two applications for extension filed in U.S. Patent No. RE44,638

Of the two applications for extension filed in the '599, one is based on NDA-205858 and the other is based on NDA-206545.

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 no 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 treatment plans of 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 (idelalisib), even if the product is used to treat different cancer types; 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 idelalisib.

Section 156 does not allow for multiple extension of patents beyond the one patent per one approved product. The regulatory review period of ZYDELIG® (idelalisib) 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 (idelalisib).[1]

After reviewing all of Applicant's submissions and once it is determined that the issuance of the Notice of Final Determination is warranted, then Applicant can make a selection for one patent to be extended from among their multiple PTE filings based on the approval of ZYDELIG® (idelalisib).

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

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 (e.g., TERM.INF.RES—Response to Requirement for Information sent under 37 CFR 1.750).

Telephone inquiries related to this determination 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 Associate Commissioner for Patents

cc: FDA, CDER, Office of Regulatory Policy
10903 New Hampshire Avenue,
Bldg. 51 Room 6250
Silver Spring MD 20993-0002

Attention: Beverly Friedman

RE: ZYDELIG® (idelalisib)
Docket Nos.: FDA-2015-E-2604
and FDA-2015-E-2619

[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.