REMARKS

Glaxo Group Limited ("Glaxo") filed an application for patent term extension (PTE) under 35 U.S.C. §156 to extend the term of U.S. Patent No. 9,273,141 ("the '141 Patent") based on the regulatory review period for BLENREP® (belantamab mafodotin-blmf) prior to approval by the Food and Drug Administration (FDA) under §351 of the Public Health Service Act (PHSA). The USPTO acknowledges that the FDA approved the biologics license application (BLA) for BLENREP® pursuant to §351(a) of the PHSA. However, the USPTO is of the opinion that the '141 Patent is ineligible for PTE under 35 U.S.C. §156 in view of the revocation of the biologics license for BLENREP®.

Nevertheless, the USPTO issued an Order to Show Cause ("the Order") that requires Glaxo to explain (1) why the USPTO should not terminate the PTE application based on the plain language of § 156(c), and (2) why the PTE application for the '141 Patent should remain under consideration despite Glaxo's express written request of withdrawal (revocation) of BLA-761158 and waiver of the opportunity for a hearing.[1] The Order further requires Glaxo to (i) "identify statutory language in 35 U.S.C. § 156 or case law that would support extension of the '141 patent that claims the product despite revocation of the [BLA]" and (ii) "explain how a PTE application for a withdrawn 'revoked' biologics license application is in compliance with the requirements of 37 C.F.R. § 1.740."[2]

Applicant respectfully submits that the '141 Patent is eligible for PTE under 35 U.S.C. §156 for at least the following reasons.

I. The '141 Patent's term shall be extended pursuant to 35 U.S.C. §156.

Section 156 of U.S. Code Title 35 states that "[t]he term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended…from the original date of the patent" if certain criteria are met. Here, the product BLENREP® (belantamab mafodotin-blmf) satisfies all criteria:

- 35 U.S.C. §156(a)(1): The term for the '141 Patent has not expired before a PTE application was submitted.

[1] *See* Order at 4. On November 18, 2022, Glaxo requested withdrawal (revocation), in writing, of the biologics license for BLENREP and waived its opportunity for a hearing. Under 21 C.F.R. §601.5(a), the FDA revoked the biologics license for BLENREP (BLA-761158), effective as of February 6, 2023. Revocation of the biologics license for BLENREP was published by the FDA in the Federal Register on March 30, 2023 (Federal Register, Vol. 88, No. 61, page no. 19153).
[2] Order at 4.

- 35 U.S.C. §156(a)(2): The term of the patent has not been previously extended under 35 U.S.C. § 156(e)(1).
- 35 U.S.C. §156(a)(3): The PTE application was submitted by the patent's owner of record in accordance with the requirements of §156(d)(1)-(4).
- 35 U.S.C. §156(a)(4): The product BLENREP® has been subject to a regulatory review period before its commercial marketing or use. As the Order acknowledges, the FDA previously confirmed that BLENREP® was approved pursuant to BLA-761158, and the FDA published the applicable regulatory review period.[3]
- 35 U.S.C. §156(a)(5)(A): The commercial marketing or use of the product BLENREP® after the regulatory review period is the first permitted commercial marketing or use under the provisions of § 351(a) of the Public Health Service Act.

Because the statutory requirements are satisfied, the patent's term "*shall* be extended" as stated in 35 U.S.C. § 156(a). This extension is mandatory and not discretionary.[4]

II. The plain language of 35 U.S.C. §156(c) confirms BLENREP is an "approved product."

Section 156(c), which specifies the amount of time for which a patent's term shall be extended under subsection (a), does not change the '141 Patent's eligibility for PTE. Specifically, Section 156(c) states, in relevant part, that "[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." This means only that the '141 Patent's term *shall* be extended for the time equal to the regulatory review period for BLENREP®.

The Order puts literal emphasis on the phrase "*the approved product*" in 35 U.S.C. §156(c) and asks Glaxo to explain why this language does not require termination of the PTE application and why the patent term should be extended "despite revocation of the [BLA]."[5] The Order provides no further explanation for pointing to this language in §156(c). Nevertheless, Glaxo responds further as follows:

Section 156(c) refers to "the approved product" in addressing the amount of time for

[3] *See* Order at ¶¶ 6-8.
[4] *See, e.g., Norman v. United States*, 942 F.3d 1111, 1117 (Fed. Cir. 2019) ("The use of the word 'shall' means what follows is mandatory, not discretionary."); *Hyatt v. USPTO*, 797 F.3d 1374, 1380 (Fed. Cir. 2015) ("The statute begins by stating that '[a]pplications for patents shall be kept in confidence by the [PTO] and no information concerning the same given....' The 'shall' makes this language mandatory, not discretionary." (internal citation omitted)).
[5] Order at 4 (emphasis in original).

which a patent's term shall be extended. Specifically, it is "the regulatory review period for *the approved product*" that dictates the period of time for which the term shall be extended.

As explained in Section 156(a), the phrase "approved product" appearing later in the statutory section refers to the "product" addressed in subparagraphs (4) and (5) of Section 156(a).[6] Subparagraphs (4) and (5), in turn, refer to "the product" that "has been subject to a regulatory review period before its commercial marketing or use," and the requirement 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 the product under the provision of law under which such regulatory review period occurred."[7]

Here, it is undisputed that the product that was subject to a regulatory review period before its commercial marketing or use is BLENREP® for purposes of subparagraph (4). As the Order acknowledges, the FDA previously confirmed that BLENREP® (belantamab mafodotin-blmf) was approved pursuant to BLA-761158, and the FDA published the applicable regulatory review period.[8] Specifically, BLENREP® was approved by the FDA under § 351(a) of the PHSA on August 5, 2020.[9] And, for purposes of subparagraph (5), it is likewise undisputed that the commercial marketing or use of the product BLENREP® after the regulatory review period is the first permitted commercial marketing or use.[10] Thus, the phrase "the approved product" in 35 U.S.C. §156(c) refers to BLENREP®—which was subject to a regulatory review period—regardless of whether its BLA was later revoked.

The definition of "product" in Section 156(f) confirms the same. Under that Section, the term "product" is defined as "[a] drug product," and "[t]he term 'drug product' means the active ingredient of—(A) a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) ...."[11] Neither definition is tied to the BLA's status as of the date that the USPTO approves the PTE application.

As a result, the PTE application for the '141 Patent should be granted "based on the plain language of 35 U.S.C. § 156(c)" and "despite Glaxo's express written request of

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[6] *See* 35 U.S.C. §156(a) ("The product referred to in paragraphs (4) and (5) is hereinafter in this section referred to as the 'approved product'."); *see also Fisons plc v. Quigg*, 876 F.2d 99, 101 (Fed. Cir. 1989) (explaining that the last sentence in Section 156(a) is "a drafting device adopted to simplify the language of subsequent provisions in the section").
[7] *See* 35 U.S.C. §156(a)(4)-(5).
[8] *See* Order at ¶¶ 6-8. *See also* Federal Register Notice at Vol. 87, No. 133, page no. 41727 (July 13, 2022).
[9] See page 1, line 6 of the Order. See also, letter from the FDA to the USPTO dated March 1, 2021.
[10] See letter from the FDA to the USPTO, dated March 1, 2021, confirming the August 5, 2020 approval of BLENREP pursuant to BLA No. 761158 is the first permitted commercial marketing or use of BLENREP.
[11] 35 U.S.C. § 156(f); *see also* 21 U.S.C § 321(p) (FDCA definition of "new drug").

withdrawal (revocation) of BLA-761158 and waiver of opportunity for a hearing."[12] Nothing in Section 156 states that "[t]he right to extend the term of a patent is predicated on obtaining final FDA approval based upon regulatory review."[13] Instead, the statute's requirements are straightforward and predicated on the product having undergone a regulatory review period, among other requirements. Having undisputedly met that requirement and the others, as discussed above, the '141 Patent's term shall be extended.

III. The PTE application to extend the '141 Patent is compliant with the formal requirements of 37 C.F.R. §1.740.

Because the '141 Patent meets Section 156(a)'s requirements, all that remained to obtain an extension of term was submission of an application in compliance with 35 U.S.C. §156(d). Section 156(d) sets forth the formal requirements for an application for extension of patent term, including the timing of submission and the required contents of the application, which are further detailed in 37 C.F.R. §1.740.

Here, Glaxo submitted a PTE application for the '141 Patent on September 18, 2020, which was within the permitted sixty (60) day period pursuant to 35 U.S.C. §156(d)(1)[14]. The PTE application provides accurate information required to satisfy each of the formal requirements outlined in 37 C.F.R. §1.740[15]. None of that is changed by the BLA being withdrawn.[16]

Accordingly, the PTE application to extend the '141 Patent is compliant with the requisite statutory and formal requirements.

[12] Order at 4.
[13] Order at 4.
[14] See also letter from the FDA to the USPTO, dated March 1, 2021, confirming the submission of the PTE application for the '141 patent was timely within the meaning of 35 U.S.C. §156(d)(1).
[15] See pages 1-10 of of the Patent Term Extension Application Under 35 U.S.C. §156 submitted in the '141 Patent on September 18, 2020.
[16] *See* Order at 4 ("Glaxo should explain how a PTE application for a withdrawn 'revoked' biologics license application is in compliance with requirements of 37 C.F.R. § 1.740.").

Conclusion

For at least these reasons, Applicant submits that the PTE application for the '141 Patent is compliant with the requirements of 35 U.S.C. §156 and 37 C.F.R. §1.740 and should remain under consideration by the USPTO. Continued examination and issuance of a patent term extension certificate for the '141 Patent are thus respectfully requested.

Respectfully submitted,

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