M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: October 3, 2023

FROM: Mustafa Ünlü, PhD, JD
Director, Office of Therapeutic Biologics and Biosimilars, Policy Staff

TO: BLAs 761058 and 761118

TO: Nikolay P. Nikolov, MD
Office Director (Acting)
Office of Immunology and Inflammation

SUBJECT: Expiration of first interchangeable exclusivity ("FIE") when section 351(l)(6) litigation ends prior to the submission of an application for interchangeability.

This memorandum makes typographical corrections to the memorandum of the same title dated September 29, 2023.

This memorandum discusses the application of sections 351(k)(6)(A)-(C) of the Public Health Service Act ("PHS Act")[1] in determining the expiration of first interchangeable exclusivity ("FIE") when patent litigation is initiated under section 351(l)(6) in connection with an application for a proposed biosimilar biological product ("biosimilar product") and ends prior to the submission of a supplement for interchangeability for the first interchangeable biosimilar biological product ("interchangeable product").[2]

This issue arises in the context of three Biologics License Applications ("BLA"s). As detailed in section II, AbbVie Inc.'s Humira is the reference product, Boehringer Ingelheim Pharmaceuticals Inc.'s Cyltezo 40 mg/0.8 mL, 20 mg/0.4 mL, and 10 mg/0.2 mL are the first interchangeable products to Humira 40 mg/0.8 mL, 20 mg/0.4 mL, and 10 mg/0.2 mL, and Pfizer, Inc.'s Abrilada 40 mg/0.8 mL, 20 mg/0.4 mL, and 10 mg/0.2 mL, respectively, are licensed biosimilar products to Humira. Pfizer submitted a supplement to its BLA seeking to license Abrilada 40 mg/0.8 mL, 20 mg/0.4 mL, and 10 mg/0.2 mL as interchangeable with Humira 40 mg/0.8 mL, 20 mg/0.4 mL, and 10 mg/0.2 mL, respectively. The Purple Book[3] currently indicates unexpired periods of FIE for Cyltezo 40 mg/0.8 mL, 20 mg/0.4 mL, and 10 mg/0.2 mL, which block approval of the products in the supplement for Abrilada.

[1] All statutory references in this document are to the PHS Act unless otherwise noted, or needed for clarity.
[2] In this memorandum, "biosimilar product" refers to a biological product that has been licensed as a biosimilar biological product but has not been licensed as an interchangeable biosimilar biological product, and "interchangeable product" refers to a biological product that has been licensed as an interchangeable biosimilar biological product.
[3] https://purplebooksearch fda.gov/

Upon review of the factual record (described generally in Section II), and in consultation with the Division of Rheumatology and Transplant Medicine (DRTM), the Office of Therapeutic Biologics and Biosimilars within the Center for Drug Evaluation and Research (CDER) recommends a determination FIE expired on April 15, 2023 for Cyltezo injection 40 mg/0.8 mL and 20 mg/0.4 mL for subcutaneous use, and on September 18, 2023 for Cyltezo injection 10 mg/0.2 mL for subcutaneous use.

A discussion of OTBB's reasoning follows.

I. LEGAL BACKGROUND

Section 351(k) of the PHS Act (42 U.S.C. § 262(k)) provides an abbreviated licensure pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference product and sets forth the requirements for applications for a proposed biosimilar product and for a proposed interchangeable product.

The term *biosimilar* or *biosimilarity* is defined in the PHS Act "in reference to a biological product that is the subject of an application under [section 351(k)]" to mean "that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components" and that "there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product."[4] The term reference product is defined as the single biological product licensed under section 351(a) against which a biological product is evaluated in a 351(k) application.[5]

To meet the standard for interchangeability, an applicant must provide sufficient information to demonstrate biosimilarity. The information in an application for interchangeability must also demonstrate that the biological product can be expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.[6]

For the first interchangeable biosimilar biological product to be approved as interchangeable with a reference product approved by FDA, section 351(k)(6)[7] provides for a period of exclusivity during which FDA is prohibited from approving a second or subsequent biological product as interchangeable as follows:

> **6) Exclusivity for first interchangeable biological product**

[4] Section 351(i)(2) of the PHS Act.
[5] Section 351(i)(4).
[6] *See* section 351(k)(4).
[7] On December 29, 2022, the President signed the Consolidated Appropriations Act, 2023 into law, which among other things, contains the Food and Drug Omnibus Reform Act of 2022 (FDORA). FDORA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the PHS Act. Section 3206 of the Consolidated Appropriations Act amends section 351(k)(6) of the PHS Act to provide for clarifications to exclusivity provisions for first interchangeable biosimilar biological products. Pub. L. No. 117-328. The amendments did not change the text of the applicable statutory text, i.e., subsections of 351(k)(6)(A)-(C) of the PHS Act. In any event, we reach the same result under both versions of the statute.

> Upon review of an application submitted under this subsection relying on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use until the earlier of-
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> (A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;
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> (B) 18 months after-
>
> (i) a final court decision on all patents in suit in an action instituted under subsection (*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or
>
> (ii) the dismissal with or without prejudice of an action instituted under subsection (*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or
>
> (C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (*l*)(6) and such litigation is still ongoing within such 42-month period; or
>
> (ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (*l)*(6).

For the purposes of this memorandum, we refer to a patent infringement action instituted under section 351(l)(6) as "351(l)(6) litigation" or "section (l)(6) litigation."

II. FACTUAL BACKGROUND

This issue arises in the context of three BLAs:

- BLA 125057, Humira (adalimumab), applicant: AbbVie Inc. (AbbVie), which contains the reference products[8] at issue
- BLA 761058, Cyltezo (adalimumab-adbm), applicant: Boehringer Ingelheim Pharmaceuticals, Inc. (BI)
- BLA 761118, Abrilada (adalimumab-afzb), applicant: Pfizer, Inc. (Pfizer)

In this case, the first interchangeable products were originally licensed as biosimilar products. The biosimilar product applicant was sued under 351(l)(6), and that litigation began and ended

[8] FDA interprets a "reference product" within the meaning of section 351(i)(4) to refer to a particular combination of strength, dosage form, and route of administration for a particular biological product. BLA 125057 contains several reference products under that interpretation. The 40 mg/0.8 mL, 20 mg/0.4 mL, and 10 mg/0.2 mL Humira products each have a different strength, and each therefore constitutes a different reference product.

before the applicant sought licensure of its biosimilar products as interchangeable products. To assess the eligibility of the Abrilada products for approval as interchangeable, this memo analyzes the statutory language to determine which, if any, of the dates described in sections 351(k)(6)(B) and 351(k)(6)(C) are potential expiration dates of FIE for the Cyltezo products.[9] This memo describes FDA's application of the statutory provisions with respect to this scenario.[10]

A summary of relevant dates is as follows:

- 10/27/2016 – BI submitted an original BLA seeking licensure of BI 695501 injection 40 mg/0.8 mL for subcutaneous use as a proposed biosimilar product to Humira.

- 08/02/2017 – AbbVie Inc. and AbbVie Biotechnology Ltd initiated a patent infringement action against BI, Boehringer Ingelheim International Gmbh, and Boehringer Ingelheim Fremont, Inc.[11]

- 08/25/2017 – FDA licensed BI Cyltezo injection 40 mg/0.8 mL for subcutaneous use as a biosimilar product to Humira injection 40 mg/0.8 mL for subcutaneous use.[12]

- 05/14/2019 – AbbVie Inc. and AbbVie Biotechnology Ltd, and BI, Boehringer Ingelheim International Gmbh, and Boehringer Ingelheim Fremont, Inc. entered into a joint stipulation of dismissal wherein all claims, affirmative defenses, and counterclaims were dismissed without prejudice.

- 11/15/2019 – FDA licensed Pfizer's Abrilada injection 40 mg/0.8 mL, 20 mg/0.4 mL, and 10 mg/0.2 mL for subcutaneous use as a biosimilar product to Humira injection 40 mg/0.8 mL, 20 mg/0.4 mL, and 10 mg/0.2 mL for subcutaneous use.[13]

- 12/16/2020 – BI submitted a supplement to its BLA seeking licensure of Cyltezo injection 40 mg/0.8 mL and 20 mg/0.4 mL for subcutaneous use as interchangeable with Humira injection 40 mg/0.8 mL and 20 mg/0.4 mL for subcutaneous use.

- 10/15/2021 – FDA approved BI's Cyltezo injection 40 mg/0.8 mL and 20 mg/0.4 mL for subcutaneous use as the first interchangeable product to Humira injection 40 mg/0.8 mL and

[9] FIE expires upon the earliest of the dates defined in sections 351(k)(6)(A)-(C).
[10] For clarity, the scope of this memo is limited to the situation described herein. The relative timing of 351(l)(6) litigation and the submission of an application for the first interchangeable product may differ for different biological products, and present factual scenarios that have not been fully considered in this memo.
[11] *AbbVie Inc. et al v. Boehringer Ingelheim International GmbH et al, 17-cv-1065-MSG-RL* (D. Del.) (filed 2 August 2017), https://images.law.com/contrib/content/uploads/documents/394/2433/AbbVie-Boehringer-complaint.pdf.
[12] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/761058Orig1s000ltr.pdf
[13] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/761118Orig1s000ltr.pdf

20 mg/0.4 mL for subcutaneous use, respectively.[14,15] The approval letter included the following request: "Additionally, if applicable, please submit a general correspondence to this 351(k) BLA informing the Agency of the date of any final court decision (as defined in section 351(k)(6)) on all patents in suit in an action instituted under subsection (l)(6) or the date of dismissal with or without prejudice of any action instituted under subsection (l)(6) within 30 days of such date or within 30 days of this approval if such date occurred prior to approval."

- 11/12/2021 – In response to the request in the approval letter dated October 15, 2021, BI sent a general correspondence letter to FDA stating, "Section 351(k)(6)(B) of the PHSA refers specifically to 'suit in an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product,' which we interpret to mean 351(l)(6) litigation arising as a result of submission of a BLA or sBLA seeking licensure as interchangeable. As such, we consider prior 351(l)(6) litigation, such as that with respect to the initial BLA submission for Cyltezo, to be outside the scope of your request. Boehringer Ingelheim has not been sued for patent infringement under section 351(l)(6) with respect to the sBLA seeking licensure as interchangeable. We do not, therefore, believe that we have an applicable court decision or dismissal to report."

- 11/19/2021 – BI submitted a supplement to its BLA seeking licensure of Cyltezo injection 10 mg/0.2 mL for subcutaneous use as interchangeable with Humira injection 10 mg/0.2 mL for subcutaneous use.

- 12/14/2021 – Pfizer submitted a supplement to its BLA seeking licensure of Abrilada 40 mg/0.8 mL, 20 mg/0.4 mL, and 10 mg/0.2 mL as interchangeable with Humira 40 mg/0.8 mL, 20 mg/0.4 mL, and 10 mg/0.2 mL, respectively.

- 03/18/2022 – FDA approved BI's supplement for interchangeability for Cyltezo injection 10 mg/0.2 mL for subcutaneous use.[16]

- 10/14/2022 – FDA took a Provisional Determination action on Pfizer's supplement for Abrilada injection 40 mg/0.8 mL, 20 mg/0.4 mL, and 10 mg/0.2 mL for subcutaneous use, because the unexpired periods of first interchangeable exclusivity for Cyltezo injection 40 mg/0.8 mL, 20 mg/0.4 mL, and 10 mg/0.2 mL for subcutaneous use prevented FDA from approving any of the products in the supplement.

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[14] Due to a settlement agreement with AbbVie, BI planned to market Cyltezo on or after July 1, 2023. See https://www.boehringer-ingelheim.com/us/press-release/boehringer-ingelheim-announces-resolution-cyltezo-patent-litigation.

[15] Because this was the first time this combination of strength, dosage form, and route of administration were approved for 40 mg/0.8 mL and 20 mg/0.4 mL injection for subcutaneous use as interchangeable with their respective reference products in Humira, each interchangeable product became eligible for first interchangeable exclusivity on this date.

[16] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/761058Orig1s011ltr.pdf. As this was the first time this combination of strength, dosage form, and route of administration was approved as interchangeable with its corresponding reference product in Humira, this interchangeable biosimilar product (10 mg/0.2 mL injection for subcutaneous use) became eligible for a separate period of first interchangeable exclusivity on this date.

On November 16, 2022, Pfizer requested a meeting with FDA to discuss the expiration of Cyltezo's first interchangeable exclusivity. FDA denied the meeting request and invited Pfizer to submit a memorandum to FDA summarizing its views on this issue. FDA requested that Pfizer grant permission for FDA to share Pfizer's memorandum with BI and give BI an opportunity to comment on the expiration of FIE for its products. On December 22, 2022, Pfizer submitted a memorandum to FDA asserting that the first interchangeable exclusivity for Cyltezo had already expired or would expire on April 15, 2023. On January 5, 2023, FDA held a teleconference with representatives from BI, shared that a third party was challenging the expiration of FIE for Cyltezo, and asked BI if they would be interested in participating in a memorandum exchange with the third party so that FDA could also consider BI's views on this subject. On January 7, 2023, BI emailed FDA and shared that BI was interested in an exchange of memoranda.

On January 24, 2023, FDA emailed Pfizer and BI to outline the process of an exchange of memoranda between the parties: Pfizer would share its memorandum by email with FDA and BI, BI would have 30 business days to respond by email to both BI and FDA, and Pfizer would have 15 business days to provide a reply. Accordingly, on January 25, 2023, Pfizer emailed its memorandum, dated December 22, 2022, to BI and FDA ("Pfizer memo"). There were no substantive differences between the memorandum that was submitted to FDA on December 22, 2022, and the memorandum that was sent to BI and FDA on January 25, 2023. On March 8, 2023, BI emailed its response memorandum to Pfizer and FDA ("BI response") and on March 27, 2023, Pfizer emailed its reply memorandum to BI and FDA ("Pfizer reply").

On July 1, 2023, BI announced that the Cyltezo products were now commercially available in the United States.[17]

III. PFIZER'S ARGUMENTS

Pfizer submitted a memorandum to FDA on December 22, 2022, and sent that memorandum, dated December 22, 2022, with minor edits but no substantive changes, to BI and FDA on January 25, 2023. Pfizer's position is that Cyltezo's first interchangeable exclusivity had already expired as of the date of Pfizer's memorandum or expired on April 15, 2023.

Specifically, Pfizer asserts that section 351(k)(6)(C)(ii) applies (i.e., provides a potential expiration date) because there has been no 351(l)(6) litigation over BI's supplement seeking interchangeability. Therefore, Pfizer concludes that the first interchangeable exclusivity for Cyltezo should expire 18 months after licensure as an interchangeable product on April 15, 2023.[18]

In the alternative, Pfizer asserts that under a plain reading of the statute, BI is "the applicant that submitted the application for the first approved interchangeable biosimilar biological product"

[17] https://www.boehringer-ingelheim.com/us/press-releases/interchangeable-biosimilar-now-available-us

[18] Pfizer does not separately address Cyltezo 40 mg/0.8 mL, 20 mg/0.4 mL, and 10 mg/0.2 mL and appears to assert that a single expiration date applies to all interchangeable products in Cyltezo. As discussed in this memorandum, we disagree.

within the meaning of section 351(k)(6)(B)(ii).[19] Thus, the joint stipulation of dismissal entered on May 14, 2019, in AbbVie's suit against BI was "the dismissal … of an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product" as described in section 351(k)(6)(B)(ii), and accordingly any FIE expired 18 months later, on November 20, 2020.[20]

In any case, Pfizer emphasizes that "under no interpretation of the statute, however, would § 351(k)(6)(A) be applicable" because one of the triggers in section 351(k)(6)(B)(ii) or (C)(ii) should apply.[21]

IV. BI'S ARGUMENTS

On March 8, 2023, BI submitted a response to Pfizer's memorandum. BI takes the position that Cyltezo's FIE will not expire until one year after its first commercial marketing under section 351(k)(6)(A) because, BI argues, none of the section 351(k)(6)(B) or (C) provisions apply and thus there can be no earlier expiration date than that defined by section 351(k)(6)(A). Further, BI argues that because the original and high concentrations of Humira should be considered to have the same strength under BI's interpretation,[22] Cyltezo's exclusivity "covers all 10 mg, 20 mg and 40 mg adalimumab products, regardless of presentation or concentration."[23]

According to BI, the only date that could be applied to determining the expiration of Cyltezo's FIE is one year after first commercial marketing under section 351(k)(6)(A). Accordingly, BI rules out any possible expiration dates under sections 351(k)(6)(B) and 351(k)(6)(C) for Cyltezo. BI argued that under section 351(k)(6)(B), dismissal of a patent infringement action is only relevant if it pertains to "'an action instituted under subsection (l)(6) against the applicant *that submitted the application for the first approved interchangeable biosimilar biological product.*' *Id.* § 262(k)(6)(B) (emphasis added)."[24] BI asserts that the dismissal of the patent infringement litigation on May 14, 2019 related to BI's application that sought licensure of Cyltezo as a biosimilar product, and not as an interchangeable product, and therefore that dismissal cannot be the basis for calculating a potential expiration date under section 351(k)(6)(B)(ii).

Additionally, BI concludes that the potential expiration date under section 351(k)(6)(C)(ii) also does not apply to Cyltezo because BI and AbbVie did not engage in the so-called "patent dance"

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[19] Pfizer Memo at 4.
[20] *Id.* Pfizer's memo identifies this date as November 20, 2020, although OTBB has calculated the date to be November 14, 2020.
[21] *Id.*
[22] BI's assertion is not consistent with the agency's interpretation of "strength" for biosimilar and interchangeable products as articulated in the draft guidance for industry, *New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 3)* (September 2021). On December 2, 2020, BI submitted a citizen petition to FDA requesting, among other things, that FDA, "interpret the term 'strength' in section 351(k) of the PHS Act for parenteral solutions to mean 'total drug content,' without regard to concentration…." *See* www.regulations.gov, docket number FDA-2020-P-2247. We do not need to address that pending citizen petition for the purposes of determining the expiration dates for Cyltezo 40 mg/0.8 mL, 20 mg/0.4 mL, and 10 mg/0.2 mL, in part because Pfizer is seeking licensure of Abrilada as interchangeable in those same concentrations.
[23] BI response at 2.
[24] *Id.* at 3.

under section 351(l)(6) with respect to the interchangeable application for Cyltezo. BI claims that section 351(k)(6)(C)(ii) only applies if "there is a decision not to bring a patent infringement lawsuit 'under subsection (l)(6).'"[25] BI asserts that "subsection (l)(6)" as used in 351(k)(6)(C)(ii) "describes a specific step in a complex, multi-step process" under which "patent litigation for biological products is designed to take place in successive waves."[26] BI focuses its argument on the premise that litigation in the "first wave" is commenced "under subsection (l)(6)" pursuant to a statutory process, which involves, in part, agreement on the patents that will be litigated in the first wave or if the parties cannot agree, then they must engage in a defined process to identify the patents.[27] Once the patents are identified, patent litigation must be initiated under subsection (l)(6) within 30 days.

BI identifies "two circumstances in which first wave litigation under subsection (l)(6) can be avoided."[28] One is that the reference product applicant is not required to sue under subsection (l)(6) if the parties explicitly agree not to initiate litigation in the first wave. Two, the reference product applicant is not required to sue under subsection (l)(6) if, absent an agreement, neither party identifies a patent for litigation.

BI interprets the reference in 351(k)(6)(C) to a lawsuit "under subsection (l)(6)" to refer to the process for triggering first wave patent litigation under subsection (l)(6) – including the process requirements for determining that a lawsuit will not be brought under subsection (l)(6). Under this interpretation, section 351(k)(6)(C)(ii) only applies "if the patent dance has been initiated and only if, pursuant to that process, the parties either (a) explicitly agreed not to initiate first wave litigation, or (b) failed to identify any patents for first wave litigation during the "exchange" process. . . ."[29] Accordingly, BI concludes that because BI and AbbVie did not engage in the patent dance with respect to the interchangeable application for Cyltezo, and therefore did not engage "in the necessary procedural steps" for determining whether or not to initiate first wave litigation "under subsection (l)(6)", there is no potential expiration date under section 351(k)(6)(C)(ii).[30] That is, according to BI, the only potential expiration date that exists under these factual circumstances is the date described in section 351(k)(6)(A).

BI also states that policy reasons favor its interpretation because it maintains incentives for companies to develop interchangeable products. BI explains that the first interchangeable exclusivity provision in section 351(k)(6) was Congress's way of incentivizing the development of interchangeable products that may be substituted for the reference product, similar to generic products. BI points out that many products are licensed as biosimilar products first, and then licensed as interchangeable products later. BI suggests that by applying the statutory provisions in sections 351(k)(6)(B) or 351(k)(6)(C) in these situations, potential periods of first interchangeable exclusivity could expire while the products are still licensed only as biosimilar products and before the products are licensed as interchangeable. BI speculates that without the

[25] *Id.*
[26] *Id.*
[27] *Id.*
[28] *Id.*
[29] *Id.* at 4.
[30] *Id.*

incentive of first interchangeable exclusivity, fewer interchangeable products would be developed and available to engage in price competition.[31]

V. FDA'S APPLICATION OF THE STATUTE, CONSISTENT WITH ITS LANGUAGE AND PURPOSE

Having considered the arguments set forth by Pfizer and BI regarding the applicability of sections 351(k)(6)(A), 351(k)(6)(B)(ii), and 351(k)(6)(C)(ii) to determine the expiration of the FIE for Cyltezo injection 40 mg/0.8 mL, 20 mg/0.4 mL, and 10 mg/0.2 mL for subcutaneous use, we decline to adopt either Pfizer's or BI's proposed interpretation.[32]

As an initial matter, Congress in drafting the statutory language in section 351(k)(6) does not seem to have explicitly accounted for the fact that some interchangeable products would first be licensed as biosimilar and later licensed as interchangeable products, with 351(l)(6) litigation occurring in the interim. Nevertheless, this is the case for Cyltezo. Accordingly, the statutory text is ambiguous, as the different interpretations put forth by Pfizer and BI also strongly suggest. In applying section 351(k)(6) to the present facts, we considered the language of the statute in context and the arguments of the parties, as well as the structure and purpose of the statute, which is to provide appropriate incentives for both innovation and competition.[33] We were thus mindful of Congress's desire to both provide a meaningful opportunity for a period of exclusivity for the first interchangeable product, without allowing the applicant of such product to have unilateral control of the start and end date for that period of exclusivity, as reflected in the statutory framework that calculates the expiration of FIE based on the earlier of specified events. Adopting an interpretation that would allow a first interchangeable product's applicant plenary control over the entry of competing interchangeable products could enable manipulation and distortion of the market, which would undo the incentives for competition that Congress sought to put in place.

Accordingly, we read the statutory language referring to 351(l)(6) litigation such that section 351(k)(6)(B) and 351(k)(6)(C)(i) will only apply (i.e., define potential expiration dates) if the application that resulted in the 351(l)(6) litigation was an application[34] for the first

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[31] *Id.*

[32] For brevity, this document will refer to Cyltezo injection 40 mg/0.8 mL, 20 mg/0.4 mL, and 10 mg/0.2 mL for subcutaneous use as "Cyltezo". This does not mean that we agree with BI on the scope of FIE for these products. *Contra* BI Response at 2, 5.

[33] *See* section 7001(b) of the Affordable Care Act (describing the sense of the Senate that the biosimilar pathway should "balanc[e] innovation and consumer interests.").

[34] We interpret the term "application" in its broadest sense, to include supplements. This is consistent with the Agency's longstanding interpretation of the same term in the context of other exclusivity provisions, such as orphan-drug exclusivity. *See* section 527 of the FD&C Act. There is an alternative interpretation that the reference to "application" in section 351(k)(6)(B) and (k)(6)(C) means an original application, and does not include a supplement. Section 351(k)(4) refers to applications and supplements separately, which would bolster that interpretation. Moreover, a supplement would not trigger 351(l)(6) litigation, making 351(k)(6)(B) inapplicable to supplements, but applicable to original applications – a strange and likely unintended result. However, in this case, we do not have to reach that question because we decide it on a different theory. The 351(l)(6) litigation at issue began and ended before the supplement for interchangeability was submitted for Cyltezo, and this means the patent

interchangeable product, and not any prior application for any other product, including an application seeking only biosimilarity for the product later determined to be the first interchangeable product. In other words, for sections 351(k)(6)(B) and 351(k)(6)(C)(i) to apply, the section 351(l)(6) litigation has to be over the application (including any supplement) seeking interchangeability for the first interchangeable product, not any other previous application or supplement submitted by the applicant. Under this reading, because the 351(l)(6) litigation at issue in this case commenced and concluded[35] before BI submitted its supplement for interchangeability, it is not the type of litigation that can be a basis for a potential expiration date under section 351(k)(6)(B), and thus that provision cannot determine Cyltezo's FIE. For the same reasons, as discussed in more detail below, section 351(k)(6)(C)(ii) would apply, because it considers the exclusivity expiration date in the absence of such litigation, and there was no such litigation here.

In summary, we disagree with Pfizer's contention that Cyltezo's FIE expired under section 351(k)(6)(B)(ii), though we agree, as set forth below, that it expired on April 15, 2023 for the 40 mg/0.8 mL and 20 mg/0.4 mL strengths[36] under section 351(k)(6)(C)(ii).

We read section 351(k)(6) such that at least one of the triggers to end FIE in section 351(k)(6)(B) and section 351(k)(6)(C) will apply. Because 351(l)(6) litigation will always either be concluded, be ongoing, or not have been initiated, section 351(k)(6)(B) and 351(k)(6)(C) will always provide a calculable potential expiration date for a period of FIE to compare against the potential expiration date provided by section 351(k)(6)(A). Adopting a different interpretation would be inconsistent with the statute's text and structure and would undermine its purposes to promote competition in the biological product marketplace by leaving only the expiration trigger in section 351(k)(6)(A). That outcome would leave FIE expiry entirely within the control of the applicant and could lead to anti-competitive outcomes, should the applicant elect to refrain from marketing its product.

A. Applicability of Section 351(k)(6)(B)

Under section 351(k)(6)(B), FIE expires 18 months after either a final court decision (section 351(k)(6)(B)(i)), or dismissal (section 351(k)(6)(B)(ii)), of a section 351(l)(6) litigation. Because the section 351(l)(6) litigation for Cyltezo was dismissed, only section 351(k)(6)(B)(ii) is potentially applicable here, and section 351(k)(6)(B)(i) will not be discussed (though the same considerations would be relevant).

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infringement litigation was over an application for biosimilarity, not over an application for interchangeability. Thus, we do not interpret the statute such that 351(l)(6) litigation occurs when there is a patent infringement action initiated over an application for a proposed biosimilar product.

[35] The facts in this matter do not require us to reach the question of whether section 351(k)(6)(B) would apply if the 351(l)(6) litigation had commenced but not concluded before an application for interchangeability was submitted, and we need not answer that question in this matter. At no time during the litigation under consideration here was an application for an interchangeable product at issue in that litigation.

[36] Pfizer did not address the expiration of the FIE for Cyltezo injection 10 mg/0.2 mL for subcutaneous use, which was approved on March 18, 2022. For the same reasons laid out in this memo for the 40 mg/0.8 and 20 mg/0.4 mL strengths, that product's FIE expired 18 months after approval (i.e., September 18, 2023) under section 351(k)(6)(C)(ii).

Here, BI submitted an original biologics license application for a proposed biosimilar to Humira on October 27, 2016. Subsequently, AbbVie initiated a patent infringement action against BI on August 2, 2017. FDA licensed BI's Cyltezo as a biosimilar product to Humira injection 40 mg/0.8 mL on August 25, 2017. The patent infringement action was later dismissed on May 14, 2019. Throughout this time period, Cyltezo was not licensed or seeking licensure as an interchangeable product. In fact, the supplement seeking interchangeability of Cyltezo with Humira was not submitted until December 16, 2020. If section 351(k)(6)(B)(ii) were to apply, any period of FIE for Cyltezo would have expired 18 months from the date of the dismissal—November 14, 2020.

Pfizer asserts that this is the case – because, in Pfizer's view, the phrase "the applicant that submitted the application for the first approved interchangeable biosimilar biological product" (hereafter "first applicant"), must mean BI. Pfizer then concludes that the dismissal of the 351(l)(6) litigation between AbbVie and BI "fulfills the statutory criteria in [section] 351(k)(6)(B)(ii)."[37] Determining whether BI is or is not the first applicant for purposes of section 351(k)(6)(B) would seem to turn on the answer to the following question: What is the relevant timepoint at which to evaluate the applicability of section 351(k)(6)(B) —when the 351(l)(6) litigation concluded (in which case BI is not the first applicant, because there was then no first approved interchangeable product), or upon approval of an application for the first interchangeable biosimilar product, which is when it becomes eligible for FIE (in which case BI is the first applicant)? While the statute could potentially be read to support either view, we need not answer this question at this time. This is because determining whether BI is the first applicant does not necessarily end the inquiry. To determine whether the FIE expiry triggers in section 351(k)(6)(B) apply, we must also apply the phrase "an action instituted under [section 351(l)(6)]" to the facts presented here.

Even if we assume, for the sake of argument, that BI *is* the first applicant, we must still determine whether the 351(l)(6) litigation against BI would trigger FIE expiry under section 351(k)(6)(B). Contrary to Pfizer's assertion, we do not think that the litigation between AbbVie and BI qualifies. First, though the statute simply refers to "an action instituted under subsection (l)(6)," this phrase cannot be read to mean *any* previous 351(l)(6) litigation instituted against a first applicant regardless of the product at issue in the litigation. Otherwise, 18 months after the conclusion of its first section 351(l)(6) litigation, an interchangeable product applicant would forever lose the ability to qualify for FIE for *any other* future interchangeable product.

For that reason, though there is no explicit limitation in section 351(k)(6)(B) for "an action instituted under subsection (l)(6)," any interpretation of the phrase must incorporate at least some limitation as to the relationship between the litigation and the first interchangeable product. Without such limitation, the term would apply to the first 351(l)(6) challenge against an applicant over any application for any biological product (whether for biosimilarity or interchangeability, and regardless of reference product), and thus that litigation would trigger FIE expiry under section 351(k)(6)(B) for any subsequent first interchangeable product submitted by that applicant. Affected applications would necessarily include, for example, those not referencing the same reference product as that in the application which triggered that 351(l)(6) litigation. We do not understand Congress's intent was to erase all future FIE for an

[37] Pfizer memo at 4.

applicant after the conclusion of the first "action instituted [against it] under section [351(l)(6)]."[38] While interpreting the phrase "an action instituted under subsection (l)(6)" in section 351(k)(6)(B) without any implicit limitation is "possible linguistically," doing so "fails to serve any conceivable statutory purpose."[39] Thus, the phrase must at the very least be limited to 351(l)(6) litigation involving the same reference product as in the interchangeability application.

Once we acknowledge that the phrase "an action instituted under subsection (l)(6)" must carry some implicit limitation, we look to the rest of the provision to supply a reasonable basis for such limitation. We find the best source for a limitation in the phrase that follows in the same sentence —"application for the first approved interchangeable biosimilar biological product." We agree with BI that the term "'action instituted under section (l)(6)' must be linked to 'the application for the first approved interchangeable biosimilar biological product.'"[40] Specifically, we conclude that the phrase "application for the first approved interchangeable biosimilar product" means an application seeking a determination of interchangeability for the first approved interchangeable product. This takes into account the entirety of section 351(k)(6)(B)(ii), and does not divorce the reference to 351(l)(6) litigation earlier in the sentence from the phrase "application for the first approved interchangeable biosimilar product." We thus further conclude that the phrase "an action instituted under subsection (l)(6)" in section 351(k)(6)(B) excludes 351(l)(6) litigation that was conducted before an "application for the first approved interchangeable biosimilar product" existed, even where there was 351(l)(6) litigation over an application for biosimilarity relying on the same reference product.

This interpretation is also reasonable as a practical matter. It benefits public health to encourage applicants to submit their BLAs seeking biosimilarity or interchangeability as soon as practical to increase competition and access. If we interpret the statute in such a way that 351(l)(6) litigation which commenced and concluded before the application for the first interchangeable product had been submitted triggers the FIE expiry clock under section 351(k)(6)(B), applicants may choose to either delay submitting their BLA until they have a data package that can support licensure of their proposed product as an interchangeable, or they may submit an application for biosimilarity only, and may not seek licensure as interchangeable at all because their biological product will likely not have a chance to benefit from FIE. Applicants should have a reasonable incentive to seek interchangeability even after obtaining licensure as a biosimilar product.

Accordingly, we conclude that, to be consistent with the text, structure, and intent of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), the 351(l)(6) litigation referenced in section 351(k)(6)(B) has to be one over an application seeking licensure as an interchangeable product."[41] Because the 351(l)(6) litigation between AbbVie and BI commenced and concluded before the application for the first interchangeable product had been submitted, section 351(k)(6)(B) does not apply in this case. We therefore reject Pfizer's assertion that Cyltezo's FIE expired under section 351(k)(6)(B)(ii).

[38] Section 351(k)(6)(B)(i)-(ii).
[39] *Abbott Labs v. Young*, 920 F.2d 984, 989 (1990), *cert. denied*, 502 U.S. 819 (1991).
[40] BI response at 3.
[41] *See* section 351(k)(6)(B)(i)-(ii).

B. Applicability of Section 351(k)(6)(C)(ii)[42]

At the same time, we agree with Pfizer's alternative position that Cyltezo's first interchangeable exclusivity expired 18 months after approval as an interchangeable product by application of section 351(k)(6)(C)(ii). Section 351(k)(6)(C)(ii) provides for FIE expiry "18 months after approval" of the first interchangeable product where "the applicant that submitted the [first interchangeable] application has not been sued under section 351(l)(6)."[43] We agree with Pfizer that the phrase plainly refers to the absence of litigation over the interchangeability application because the phrase "'submitted such application' is tied to, and relates back to, the term 'interchangeable' in the same clause."[44,45] Moreover, this provision uses almost identical language to section 351(k)(6)(B) to describe the type of patent action ("under subsection (l)(6)") and the application at issue ("[application for] the first [approved] interchangeable biosimilar biological product").[46] For the same reasons as above, the reference to a suit under section 351(l)(6) in section 351(k)(6)(C)(ii) is best read to refer to an action over the "interchangeable biosimilar biological product . . . application."[47] Like section 351(k)(6)(B), therefore, the triggers for FIE expiry in section 351(k)(6)(C) also turn on whether the applicant that submitted the first interchangeable product application was sued over *that* application, and not any other application. Not only does this provide a consistent interpretation between the two sections, but it addresses (and provides potential triggers based on) all possible outcomes of 351(l)(6) litigation (including the lack thereof), and properly implements the statute's purpose. Because 351(l)(6) litigation will always either be concluded, be ongoing, or not have been initiated, under this interpretation sections 351(k)(6)(B) and (C) will, in combination, always provide a calculable potential expiration date for a period of FIE to compare against the potential expiration date provided by section 351(k)(6)(A), with section 351(k)(6)(C)(ii) acting as a catch-all to prevent an applicant from having total control over when FDA can approve competing interchangeable products in the absence of 351(l)(6) litigation. If it were possible for neither the triggers based on 351(l)(6) litigation nor the trigger based on the absence of 351(l)(6) litigation to apply, the only possible trigger would be under section 351(k)(6)(A), which provides for FIE expiry one year after first commercial marketing. This could lead to anti-competitive behavior, for example, where the applicant enters into an agreement with the reference product applicant not to start marketing its interchangeable product as part of settling the patent infringement action,[48] which would result blocking all other interchangeable products indefinitely.

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[42] Section 351(k)(6)(C)(i), which describes a date "42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (l)(6) and such litigation is still ongoing within such 42-month period" is not applicable here for at least the reason that the litigation between AbbVie and BI was commenced over BI's biosimilar biological product application, and not its interchangeable biosimilar biological product application, as set out regarding section 351(k)(6)(B)(ii).

[43] Section 351(k)(6)(C)(ii).

[44] Pfizer memo at 4.

[45] We agree with Pfizer that "the phrase 'submitted such application' is intrinsically tied to, and relates back to, the term 'interchangeable' in the same clause." That is, we agree that "submitted such application" refers to the "interchangeable biosimilar application in the same sentence. *See* Pfizer reply at 3.

[46] *See* section 351(k)(6)(C)(ii).

[47] *See id.*

[48] *See, e.g.*, FTC, *Pay-for-Delay: When Drug Companies Agree Not to Compete*, https://www.ftc.gov/news-events/topics/competition-enforcement/pay-delay.

Under section 351(k)(6)(C)(ii), FIE potentially expires 18 months after approval of the first interchangeable biosimilar biological product. FDA approved Cyltezo 40 mg/0.8 mL and 20 mg/0.4 mL on October 15, 2021 as the first interchangeable products to Humira 40 mg/0.8 mL and 20 mg/0.4 mL, respectively, and approved Cyltezo 10 mg/0.2 mL on March 18, 2022 as the first interchangeable product to Humira 10 mg/0.2 mL. As explained above, the FIE expiration date provided for under section 351(k)(6)(C)(ii) is applicable to Cyltezo because "the applicant that submitted [the first interchangeable biosimilar biological product] application has not been sued under section(l)(6)."[49] No patent infringement action was initiated against BI in connection with its submission of a supplement seeking interchangeability for any of its 40 mg/0.8 mL, 20 mg/0.4 mL, or 10 mg/0.2 mL injection for subcutaneous use biosimilar products. Thus, under section 351(k)(6)(C)(ii), FIE for Cyltezo 40 mg/0.8 mL and 20 mg/0.4 mL potentially expired on April 15, 2023 (i.e., 18 months after the date of approval) and FIE for Cyltezo 10 mg/0.2 mL potentially expired on September 18, 2023. Based on BI's July 1, 2023 statement that the Cyltezo interchangeable products were commercially available in the United States at that date,[50] the potential expiration date provided under section 351(k)(6)(A) (i.e., 1 year after first commercial marketing) will, for all three products, necessarily be later than the potential expiration date provided under section 351(k)(6)(C)(ii). Accordingly, Cyltezo's first interchangeable exclusivity expired on April 15, 2023 (i.e., 18 months after the date of approval) for the 40 mg/0.8 mL and 20 mg/0.4 mL injection for subcutaneous use, and on September 18, 2023, for the 10 mg/0.2 mL injection for subcutaneous use.[51]

BI, on the other hand, argues that section 351(k)(6)(C)(ii) does not apply to Cyltezo because BI and AbbVie never engaged in the patent information exchange process outlined in section 351(l) over BI's interchangeability applications.[52] In BI's view, FIE expiry under section 351(k)(6)(C)(ii) only occurs under a very limited set of circumstances. BI relies on the fact that section 351(l) describes several steps before an infringement action can commence under section 351(l)(6).[53] BI claims that the phrase "applicant that submitted such application has not been sued under subsection (l)(6)"[54] can only be interpreted to mean that those prior steps *must* have been taken without resulting in an action under section (l)(6). In other words, under BI's interpretation, section 351(k)(6)(C)(ii) only applies when, after engaging in the "patent dance" of section 351(l), the reference product applicant decides not to (or is unable to) initiate an action

[49] *Id.*
[50] https://www.boehringer-ingelheim.com/us/press-releases/interchangeable-biosimilar-now-available-us
[51] As described above, BI submitted another supplement to its BLA seeking licensure of Cyltezo 10 mg/0.2 mL for subcutaneous use, which was approved on March 18, 2022, and was eligible for first interchangeable exclusivity, which expired on September 18, 2023, also under section 351(k)(6)(C)(ii).
[52] We note that BI's initial position appeared to be closer to our interpretation. As described above, *see supra*, at 4, on November 12, 2021, BI told FDA that "Boehringer Ingelheim has not been sued for patent infringement under section 351(l)(6) with respect to the sBLA seeking licensure as interchangeable." We agree with BI's earlier position.
[53] *See* BI response at 3 (the reference to section 351(l)(6) "describes a specific step in a complex, multi-step process created by Congress for identifying which patents will be subject to patent infringement litigation and when such litigation can or must commence.").
[54] Section 351(k)(6)(C)(ii).

under section 351(l)(6).[55] BI asserts that because this process never occurred for its interchangeable application,[56] we cannot interpret section 351(k)(6)(C)(ii) to apply to Cyltezo.[57]

BI's interpretation is not consistent with the plain language of section 351(k)(6)(C)(ii), nor does it fit well (or at all) within the structure of the entire FIE provision. The phrase "has not been sued under subsection (l)(6)", on its face, means that no patent infringement lawsuit was filed against the first applicant under section 351(l)(6). We agree with BI to a limited extent: giving this phrase its broadest possible meaning makes little sense. Under that interpretation, once a first applicant is not sued over an application for a first interchangeable product, it would face FIE expiry under section 351(k)(6)(C)(ii) over any subsequent application for all of its first interchangeable products. For the reasons explained above, the phrase should be interpreted to refer to a patent infringement action initiated under section 351(l)(6) over an application for the first interchangeable product.[58]

But that does not mean that we agree with BI's reading of the statute. First, if the phrase "has not been sued under subsection (l)(6)" meant that the section 351(l) process was initiated but did not result in a patent infringement action, there would be no way for FDA to know that's what happened. There is currently no mechanism provided in the statute that notifies FDA when the section 351(l) process is initiated; rather, the only statutory requirement to make FDA aware of 351(l)(6) litigation applies *after* 351(l)(6) litigation commences.[59] Thus, FDA cannot differentiate cases where an applicant was not "sued under [section 351(l)(6)]" after the 351(l) process was initiated from those where the 351(l) process of patent information exchange was not initiated at all. Second, if Congress intended the phrase "not . . . sued under subsection (l)(6)" to mean that the parties must first engage in exchanging patent information and make an affirmative decision not to engage in patent infringement litigation, then it would likely have written the statute so as to include those limitations. The distinction asserted by BI is not supported by the FIE provision's bare reference to paragraph 6 of section 351(l).[60] The phrase "not been sued under subsection (l)(6)" more reasonably and simply means that no action instituted under section 351(l)(6) has been filed by the reference product applicant against the applicant for the first interchangeable biological product.

Significantly, "under subsection (l)(6)" also appears in section 351(k)(6)(B). To give the FIE provision its full effect, we must construe it as a whole. As previously explained, we read section 351(k)(6) such that subsections (B) and (C), taken together, always provide a calculable potential expiration date as a part of a complete statutory structure that provides a meaningful opportunity for a period of exclusivity to the first interchangeable product after approval while preventing applicants from gaming the benefits of exclusivity to indefinitely delay

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[55] *See* BI response at 3-4.
[56] BI submitted supplements to its BLA seeking licensure of Cyltezo as an interchangeable product. (*See supra* at 4.)
[57] *See id.* at 3.
[58] We note that we similarly rejected Pfizer's analogously over-broad reading of 351(k)(6)(B)(ii)'s reference to "the applicant that submitted the first approved interchangeable biosimilar biological product" in section V.A.1. above.
[59] *See* section 351(l)(6)(C)(i) (requiring a biosimilar applicant to submit to FDA a copy of the complaint of a patent litigation initiated under section 351(l)(6)).
[60] *See* Pfizer reply at 4 ("What BI wants is to shield interchangeable biosimilar applications filed via a supplement, which could result in parking of interchangeable exclusivity or gamesmanship in structuring applications vis-à-vis patent litigation.").

interchangeable competition, as would be possible if the FIE provision were read such that subsection 351(k)(6)(A) would provide the only applicable expiration date under facts such as these. The FIE expiry triggers in section 351(k)(6)(B) and (C) thus work together to provide a definite potential end date for exclusivity (depending on whether patent litigation between the reference product applicant and the applicant for the first interchangeable product has concluded,[61] is ongoing,[62] or did not occur[63]), as an alternative, if earlier, to the expiry trigger of section 351(k)(6)(A). Thus, our conclusion that BI was not sued under section 351(l)(6) for purposes of section 351(k)(6)(C)(ii) is consistent with its text as well as the overall structure of the FIE provision.

BI claims that the FIE provision was created to spur the development of interchangeable products. That incentive structure would be undermined, BI says, if FIE could be "triggered so easily that it routinely would expire before it could be utilized."[64] But any incentives under the Act must be calibrated so as not to unreasonably delay competition. Here, BI's first interchangeable product was approved over 18 months ago, in October 2021, and its FIE started running at that time. Contrary to BI's claim, the reason it could not "utilize" (as it conceives that term) the FIE which accrued to its products has little to do with how easily section 315(k)(6)(C)(ii) is triggered (or not). The reason BI was not able to capitalize to its liking on its interchangeable products' FIE is because it voluntarily entered into a settlement agreement with AbbVie that prevented BI from marketing Cyltezo products until July 1, 2023.[65] However, regardless of BI's business decisions regarding the marketing of its own products, FDA was prohibited from approving other products as interchangeable with Humira from the time the Cyltezo products were approved until their FIE had expired—under these facts, an eighteen-month period during which no competing interchangeable products could be approved.[66] How BI chose to "utilize" Cyltezo's exclusivity does not negate the fact that Cyltezo received the first interchangeable exclusivity defined in section 351(k)(6). Under the facts present here, and our interpretation of the FIE provision in its entirety, where there has been no 351(l)(6) litigation over the application for the first interchangeable products, that exclusivity expires no later than eighteen months after approval.[67]

On the other hand, BI's interpretation would undermine the balance Congress struck in the BPCI Act because it would allow the applicant for the first interchangeable product to delay competition for any other interchangeable product, potentially indefinitely, by refusing to engage in the "patent dance." That would not be consistent with the purpose of the statute and the intent

[61] Section 351(k)(6)(B).
[62] Section 351(k)(6)(C)(i).
[63] Section 351(k)(6)(C)(ii).
[64] BI response at 4.
[65] See https://www.boehringer-ingelheim.com/us/press-release/boehringer-ingelheim-announces-resolution-cyltezo-patent-litigation.
[66] As BI knows, this prohibition was not merely theoretical: but for Cyltezo's FIE, the Abrilada products could have been approved as interchangeable on October 14, 2022.
[67] It seems reasonable to assume that Congress intentionally defined different FIE expiration dates under section 351(k)(6)(A), (B), and (C) in order to balance the incentives provided to applicants to pursue FIE for their interchangeable products, and the interest in getting such products on the market as soon as possible. One explanation for why the expiration date provided for in section 351(k)(6)(C)(ii) is potentially 6 months later than the expiration date provided for in section 351(k)(6)(A) could be that this gives the applicant for the first interchangeable product up to 6 months after approval to begin marketing their interchangeable product.

of Congress, which, as BI also agrees, is to encourage "true price competition among biological products," and would also undermine the potential to resolve patent disputes early, as contemplated by section 351(l).[68] If BI were to decide not to market its product, "the incentive structure created by Congress to encourage the development of IC biological products would be eviscerated."[69] Under such an interpretation, reference product applicants would be able to delay all interchangeable competition on the basis of settlement agreements reached with the applicant for the first interchangeable product before the application for interchangeability has been submitted.

VI. CONCLUSION

For the reasons set forth above, OTBB recommends a determination that first interchangeable exclusivity expired on April 15, 2023 for Cyltezo injection 40 mg/0.8 mL and 20 mg/0.4 mL for subcutaneous use, and on September 18, 2023 for Cyltezo injection 10 mg/0.2 mL for subcutaneous use.

Sincerely,

{See appended electronic signature page}

Mustafa Ünlü, PhD, JD
Director, Policy Staff
Office of Therapeutic Biologics and Biosimilars
Office of New Drugs
Center for Drug Evaluation and Research

[68] BI response at 4.
[69] *Id.*

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