EXHIBIT 7

MEMORANDUM

DATE: April 5, 2024

Janice L. Weiner -S Digitally signed by Janice L. Weiner -S Date: 2024.04.05 12:41:31 -04'00'

FROM: Janice Weiner, J.D., M.P.H., Principal Regulatory Counsel
Division of Regulatory Policy I, Office of Regulatory Policy, CDER

TO: NDA 205029/S-013: Epinephrine Injection, 30 mg/30 mL (1 mg/mL)

SUBJECT: Unavailability of a 30-month Stay for Patents Submitted After the Date of Submission of an Original 505(b)(2) Application

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This memorandum describes the Agency's determination that a 30-month stay of approval of NDA 205029/Supplement 013 ("S-013") is not available based on Endo Par Innovation Company, LLC's; Par Pharmaceutical, Inc.'s; and Par Sterile Products, LLC's (collectively "Par") patent infringement action against BPI Labs, LLC ("BPI Labs") and Belcher Pharmaceuticals, LLC ("Belcher") that was initiated within 45 days of receiving notice of the paragraph IV certifications to U.S. Patent Nos. 9,119,876 ("the '876 patent") and 9,295,657 ("the '657 patent") on August 29, 2023, because information on the '876 and '657 patents was submitted to FDA after December 4, 2012, the date of submission of the original NDA 205029 (see section 505(c)(3)(C) of the Federal Food, Drug, and Cosmetic (FD&C) Act).

Relevant Background

On December 4, 2012, Belcher's NDA 205029 for epinephrine injection, 1 mg/1 mL (1 mg/1 mL) solution in 2 mL ampules, was submitted pursuant to section 505(b)(2) of the FD&C Act. To support approval of NDA 205029, Belcher relied, in part, on FDA's finding of safety and effectiveness for Impax Laboratories' (then owned by Amedra Pharmaceuticals, LLC) Twinject Auto-Injector (epinephrine) injection (NDA 020800). FDA approved NDA 205029 on July 29, 2014, with the indication to increase mean arterial blood pressure in hypotension associated with septic shock.

On March 23, 2015, Belcher submitted an efficacy supplement (Supplement 001, "S-001") to its NDA 205029 seeking approval of a new indication (induction and maintenance of mydriasis during ocular surgery) and new route of administration (intraocular). To support approval of S-001, Belcher relied on FDA's finding of safety and effectiveness for an additional listed drug, Par Sterile Product's Adrenalin (epinephrine) injection (NDA 204200). FDA approved S-001 on October 23, 2015.

On September 1, 2015, the U.S. Patent and Trademark Office (PTO) issued the '876 patent to Par Pharmaceutical, Inc., and on January 14, 2016, Par Sterile Products, LLC submitted Form FDA 3542 to FDA declaring that the '876 patent claims the drug product that is the subject of NDA 204200.

On March 29, 2016, the U.S. PTO issued the '657 patent to Par Pharmaceutical Inc., and on April 12, 2016, Par Sterile Products, LLC timely submitted Form FDA 3542 to FDA declaring that the '657 patent claims an approved method of using Adrenalin.

On July 27, 2022, Belcher notified FDA of the change in ownership of NDA 205029 from Belcher to BPI Labs in accordance with 21 CFR 314.72.

On April 21, 2023, BPI Labs submitted a CMC supplement S-013 to its NDA 205029 seeking approval of a new 30 mg/30 mL (1 mg/mL) multi-dose vial presentation of epinephrine injection. To support approval of S-013, BPI Labs continued to rely on FDA's findings of safety and effectiveness for Twinject Auto-Injector (NDA 020800) and Adrenalin (NDA 204200).

On June 20, 2023, FDA sent correspondence to BPI Labs requesting that BPI Labs "submit as part of your supplement a patent certification or statement under 21 CFR 314.50(i)(1)." BPI Labs amended S-013 on July 20, 2023, with paragraph IV certifications with respect to U.S. Patent Nos. 7,297,136; 7,621,891; 7,905,352; and 10,166,334 listed in the Orange Book under NDA 020800 for Twinject Auto-Injector, and paragraph IV certifications with respect to the '876 and '657 patents listed in the Orange Book under NDA 204200 for Adrenalin. Notification of the paragraph IV certifications to the NDA holder of NDA 204200 for Adrenalin occurred on July 20, 2023, and July 21, 2023. BPI Labs submitted documentation of receipt of notice of the paragraph IV certifications to the NDA holder of NDA 204200 on July 21, 2023. BPI Labs did not provide adequate documentation of receipt of notice of paragraph IV certification with respect to the patents listed under Twinject Auto-Injector NDA 020800.

On August 21, 2023, FDA issued a complete response letter for S-013 to BPI Labs citing inadequate documentation of receipt of notice of paragraph IV certification with respect to notification to the patent owner(s) for the four patents listed under Twinject Auto-Injector NDA 020800.[1] BPI Labs amended S-013 on August 28, 2023, in response to the Agency's complete response letter and provided additional documentation of receipt of notice of paragraph IV certification that was determined to be adequate with respect to the patents listed under Twinject Auto-Injector NDA 020800. BPI Labs was not sued for patent infringement with respect to the patents listed under Twinject Auto-Injector NDA 020800.

On October 13, 2023, BPI Labs confirmed for FDA that on August 29, 2023, Par filed a complaint against BPI Labs and Belcher for patent infringement with respect to the '876 and

[1] We note that on January 2, 2024, FDA issued a corrected complete response letter notifying BPI Labs that the following major deficiency had been omitted from the August 21, 2023, complete response letter: "Manufacturing: Following surveillance inspection of the (b) (4) testing facility listed in this application, FDA conveyed deficiencies to the representative of the facility. Satisfactory resolution of the observations is required before this sNDA may be approved." The corrected letter stated "This replacement complete response letter incorporates the correction of the error. The effective complete response date will remain August 21, 2023, the date of the previous complete response letter." (b) (4) testing facility (b) (4), prior to the tentative approval action on S-013 on December 28, 2023.

‘657 patents listed under Adrenalin NDA 204200 in the United States District Court for the Middle District of Florida, Tampa Division.[2]

On December 28, 2023, FDA issued a tentative approval letter for S-013, stating “[f]inal approval of your application is subject to expiration of the 30-month period provided for in section 505(c)(3)(C) of the FD&C Act, and/or exclusivity.”

In January 2024, CDER determined that the tentative approval action taken on S-013 on December 28, 2023 had been issued in error. CDER concluded that there was no possibility of a 30-month stay with respect to an action for infringement of the patents listed under Adrenalin NDA 204200 because information regarding the ‘876 and ‘657 patents was submitted to NDA 204200 after the date on which Belcher’s original application (excluding an amendment or supplement to the application) had been submitted. As noted above, Belcher’s NDA 205029 was originally submitted on December 4, 2012, and patent information for the ‘876 and ‘657 patents was submitted to NDA 204200 on January 14, 2016, and April 12, 2016, respectively.

On February 14, 2024, BPI Labs was notified of the approval action for S-013. A subsequent corrected approval letter was issued on February 16, 2024, correcting the receipt date for S-013 that had been included in the February 14, 2024, letter.

Analysis

Section 505(c)(3)(C) of the FD&C Act provides, in relevant part, that a 30-month stay of approval of a 505(b)(2) application is available only if patent infringement litigation was initiated within the 45-day period after receipt of notice of a paragraph IV certification for a patent for which information was submitted to the Secretary “***before the date on which the application (excluding an amendment or supplement to the application) was submitted***” (emphasis added). This limitation on the availability of a 30-month stay was added by section 1101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173) (MMA).

In the preamble to the proposed rule to implement portions of the MMA, FDA explained:

> We are proposing to revise § 314.107(b)(3)(i)(A) [21 CFR 314.107(b)(3)(i)(A)] to reflect one of the central elements of the MMA’s amendments to the FD&C Act: The limitation on multiple 30-month stays of approval of a 505(b)(2) application or an ANDA containing a paragraph IV certification to certain patents submitted to FDA on or after August 18, 2003. Proposed § 314.107(b)(3)(i)(A) states that a 30-month stay of approval is available only when the patent owner or exclusive patent licensee initiates a patent infringement action within the statutory timeframe in response to a paragraph IV certification to a patent submitted to FDA before the date on which the original 505(b)(2) application or [abbreviated new drug application] ANDA[3] was submitted... [T]he MMA expressly provides that, for purposes of determining the availability of a 30-month stay,

[2] See Civil Action No. 8:23-01953.

[3] See also 505(j)(5)(B)(iii) of the FD&C Act.

> the date of submission of a 505(b)(2) application or ANDA does not include the date of submission of an amendment or supplement to the 505(b)(2) application or ANDA (see section 505(c)(3)(C) and (j)(5)(B)(iii) of the FD&C Act). ***In other words, there will be no possibility of a 30-month stay with respect to an action for infringement of a patent listed after the reference product is approved if the patent was submitted to FDA on or after the date the 505(b)(2) application or ANDA was first submitted.*** Due to this limitation, most 505(b)(2) applications and ANDAs will be subject to no more than one 30-month stay of approval.[4]

Accordingly, a 30-month stay of approval of NDA 205029/S-013 is not available based on Par's patent infringement action against BPI Labs and Belcher that was initiated within 45 days of receiving notice of the paragraph IV certifications to the '876 patent and the '657 patent on August 29, 2023, because information on the '876 and '657 patents was submitted to FDA after December 4, 2012, the date of submission of the original NDA 205029 for epinephrine injection (see section 505(c)(3)(C) of the FD&C Act).

The prior tentative approval letter, issued on December 28, 2023, was issued in error, without consideration of the fact that the statute explicitly excludes the date of submission of an amendment or supplement to a 505(b)(2) application from the "date on which the application … was submitted" for the purposes of determining the availability of a 30-month stay.[5] The letters issued on February 14, 2024, and February 16, 2024, accurately reflect the status of S-013 as approved, and the Agency intends to issue an additional letter to clarify that S-013 is approved as of December 28, 2023.

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[4] "Abbreviated New Drug Applications and 505(b)(2) Applications; Proposed Rule," 80 FR 6802, 6862 (Feb. 6, 2015) (emphasis added). FDA finalized 21 CFR 314.107(b)(3)(i)(A) in 2016. See "Abbreviated New Drug Applications and 505(b)(2) Applications; Final Rule," 81 FR 69580, 69655 (Oct. 6, 2016).

[5] The Agency has identified examples in which FDA has recognized a 30-month stay for new strength supplements for abbreviated new drug applications (ANDAs) based on an infringement action brought for patents listed after the date the original ANDA was submitted. To the Agency's knowledge, the 30-month stays for these new strength supplements for ANDAs have either expired or have otherwise been terminated by a court and thus are moot. In these examples, the Agency appears to have recognized a 30-month stay because a new strength supplement is referencing a new listed drug with separately listed patent(s) in the Orange Book. However, the Agency looked more closely at these issues in the context of NDA 205029/S-013 and reevaluated the statutory language at section 505(j)(5)(B)(iii) of the FD&C Act. Section 505(j)(5)(B)(iii) of the FD&C Act does not exclude new strength supplements from the provision that limits the availability of a 30-month stay to patents for which the NDA holder submitted information to FDA "before the date on which the application (excluding an amendment or supplement to the application) . . . was submitted" and largely mirrors the language at section 505(c)(3)(C) of the FD&C Act. As a result of this reevaluation, FDA intends to change its practice with respect to new strength supplements for ANDAs and bring it into conformity with the statutory text. Going forward, the result will be that a 30-month stay will not be available for new strength supplements for ANDAs for patents submitted after the original ANDA was submitted (even where those patents were submitted before the submission of the new strength supplement). Because it is not directly implicated by this decision, FDA has not yet completed its assessment of new strength amendments that may be implicated by this issue. If FDA identifies any example in which FDA erroneously determined that there is an active 30-month stay either in the context of a new strength supplement or new strength amendment, it will review its decision to ensure that it conforms with the statutory text.