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CITIZEN PETITION

Bayer HealthCare LLC (referred to herein as Bayer, individually or together with its affiliates) submits this petition under 21 C.F.R. § 10.30 and section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations to request that the Commissioner of Food and Drugs take the action set forth below in Section A with respect to abbreviated new drug application (ANDA) 216421 for azelastine hydrochloride nasal spray, 205.5 mcg/spray, OTC, which references Bayer's new drug application (NDA) 213872. Apotex Inc. or Apotex Corp. (individually or collectively, Apotex) is the applicant for ANDA 216421.

A. Action Requested

Bayer requests that the Food and Drug Administration (FDA or the Agency) confirm that FDA will stay the final approval of ANDA 216421 until the expiration of the 30-month period beginning on the date when Bayer received the notice described in FDCA § 505(j)(2)(B) (i.e., the paragraph IV notice) of the submission of ANDA 216421 with a certification described in FDCA § 505(j)(2)(A)(vii)(IV) (i.e., a paragraph IV certification), absent any event specified in FDCA § 505(j)(5)(B)(iii) that would cause the stay to be shortened, lengthened, or terminated.

B. Statement of Grounds

FDA should apply a 30-month stay of approval of ANDA 216421 because all of the statutory prerequisites for a stay have been met. *First*, Apotex made a paragraph IV certification as to each of the three patents currently listed in the Orange Book in connection with NDA 213872.[1] *Second*, Bayer and a co-plaintiff initiated litigation alleging Apotex's infringement of the three patents in connection with ANDA 216421 "before the expiration of 45 days after the date on which" Bayer received a paragraph IV notice from Apotex.[2] *Third*, Bayer submitted to

[1] *See* Complaint, *Bayer Healthcare LLC v. Apotex Inc.*, No. 21-cv-01429-WCB, ECF No. 1, ¶ 2 (D. Del. Oct. 7, 2021) (attached hereto as Exhibit 1).

[2] FDCA § 505(j)(5)(B)(iii); *see* Complaint ¶¶ 2, 26, *supra* note 1.

FDA the required information for the three patents before Apotex submitted its original ANDA 216421.[3]

This third prerequisite for a 30-month stay is satisfied because Bayer submitted information for each of the three patents on a Form 3542a with NDA 213872 on August 20, 2020, as required by FDCA § 505(b)(1) and FDA's regulations.[4] Bayer's submission of this patent information with the original NDA preceded Apotex's submission of original ANDA 216421. Within 30 days after the approval of NDA 213872, Bayer further complied with the statute and FDA's regulations by again submitting information for each of these patents on a Form 3542 on July 8, 2021.[5]

In the event that Apotex submitted ANDA 216421 before Bayer submitted the Forms 3542, Bayer still met the statutory requirement to submit patent information to FDA "under [FDCA § 505](b)(1) or (c)(2) before the date on which the [ANDA] (excluding an amendment or supplement to the [ANDA] . . . was submitted."[6] Under the plain language of the statute, this prerequisite is met if patent information is submitted under either section 505(b)(1) or (c)(2) before the original ANDA was submitted. The statute does not require that patent information be submitted under both provisions before the ANDA is submitted. Bayer satisfied this requirement by submitting patent information under section 505(b)(1)—i.e., the information on Form 3542a—before the submission of ANDA 216421.

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[3] *See* FDCA § 505(j)(5)(B)(iii) (requiring that patent information be "submitted to the Secretary under [FDCA § 505](b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application) . . . was submitted").

[4] *See* FDCA § 505(b)(1) (2018) (requiring that the "applicant . . . file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.") (emphasis added) (attached hereto as Exhibit 2); 21 C.F.R. § 314.53(c)(2)(i) (requiring the submission of specified "information" in an "[o]riginal declaration," i.e., Form 3542a); 21 C.F.R. § 314.53(d)(4)(i) (describing Form 3542a as "[p]atent information submitted with the filing of an NDA, amendment, or supplement); Forms 3542a for U.S. Patent Nos. 8,071,073, 8,518,919, and 9,919,050 (attached hereto as Exhibit 3).

[5] *See* FDCA § 505(c)(2); 21 C.F.R. § 314.53(b)(2)(ii); Forms 3542 for U.S. Patent Nos. 8,071,073, 8,518,919, and 9,919,050 (attached hereto as Exhibit 4).

[6] FDCA § 505(j)(5)(B)(iii) (emphasis added). FDA need not address this point if, instead, Apotex submitted ANDA 216421 after Bayer submitted the Forms 3542.

Because all of the statutory requirements for a 30-month stay are met, FDA should apply a stay with respect to ANDA 216421. To withhold a 30-month stay on these facts would be contrary to the plain language of the statute and the legislative purpose of both the 30-month stay and the 2003 amendments that established the relevant prerequisites for a stay, as discussed below.

I. Background

A. Patent Listing, Patent Certification, and the 30-Month Stay

Under the version of the FDCA that was in effect when Bayer submitted NDA 213872, an NDA applicant was required to "file with the application," among other things,

> the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.[7]

FDA's regulations require the NDA applicant to submit this information with the NDA on Form 3542a.[8] The statute and an FDA regulation further require that no more than 30 days after the NDA has been approved, the NDA holder again must submit information for a patent, this time on Form 3542.[9] The contents of Forms 3542 and 3542a overlap in large part (although only Form 3542 requires the submission of a "use code" for a method-of-use patent) and are outlined in FDA's regulations, the forms themselves, and the accompanying instructions.[10]

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[7] FDCA § 505(b)(1) (2018), *supra* note 4. Congress later amended this provision in the Orange Book Transparency Act of 2020, enacted on January 5, 2021, to require the submission of this patent information "as part of the application." *See* Orange Book Transparency Act, Pub. L. No. 116-290, § 2(a), 134 Stat. 4889, 4889 (2021) (attached hereto as Exhibit 5).

[8] 21 C.F.R. § 314.53(c)(2)(i), (d)(4)(i); *see also* FDA, *Instructions for Filling Out Form FDA 3542a—Patent Information Submitted with the Filing of an NDA, Amendment, or Supplement, Form FDA 3542 Supplement* (Nov. 2019) (Form 3542a Instructions) (attached hereto as Exhibit 6); *Abbreviated New Drug Applications and 505(b)(2) Applications*, 81 Fed. Reg. 69,580, 69,596 (Oct. 6, 2016) (attached hereto as Exhibit 7).

[9] FDCA § 505(c)(2); 21 C.F.R. § 314.53(c)(2)(ii).

[10] 21 C.F.R. § 314.53(c)(2)(i)-(ii); FDA, Form 3542a (Apr. 2021) (attached hereto as Exhibit 8); FDA, Form 3542 (Apr. 2021) (attached hereto as Exhibit 9); Form 3542a Instructions,

An ANDA must include an appropriate patent certification or statement "with respect to each patent which claims the [reference listed drug (RLD)] or which claims a use for such [RLD] and for which information is required to be filed under" FDCA section 505(b) or (c).[11] One type of patent certification, known as a "paragraph IV certification," reflects the ANDA applicant's assertion that a patent is "invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the ANDA is submitted."[12]

The statute and FDA's regulations require an ANDA applicant to notify the NDA holder and each patent owner of the submission of an ANDA with a paragraph IV certification.[13] The ANDA applicant must send this notice no later than 20 days after the date of the postmark on FDA's letter notifying the ANDA applicant that the ANDA has been accepted for review (i.e., has been "received.").[14] This notice must include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed."[15]

Under the patent statute as amended by the Hatch-Waxman Amendments, the submission of an ANDA with a paragraph IV certification is an act of patent infringement.[16] Accordingly, upon receipt of the paragraph IV notice, the NDA holder or patent owner may sue the ANDA applicant for patent infringement.

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supra note 8; FDA, *Instructions for Filling Out Form FDA 3542—Patent Information Submitted Upon and After Approval of an NDA or Supplement* (Form 3542 Instructions) (attached hereto as Exhibit 10).

[11] FDCA § 505(j)(2)(A)(vii), (viii); *see also* 21 C.F.R. § 314.94(a)(12). An NDA submitted under section 505(b)(2) of the FDCA is subject to a similar patent certification requirement with respect to the listed drug(s) relied upon. *See* FDCA § 505(b)(2)(A)-(B), 21 C.F.R. § 314.54(a)(1)(vi).

[12] 21 C.F.R. § 314.94(a)(12)(i)(*4*)(*i*); FDCA § 505(j)(2)(A)(vii)(IV) (omitting "unenforceable").

[13] *Id.* § 505(j)(2)(B)(ii).

[14] FDCA § 505(j)(2)(B)(ii); 21 C.F.R. § 314.95(b); *see also* 21 C.F.R. §§ 314.3(b) (defining "paragraph IV acknowledgment letter"), 314.101(b) ("Receipt of an ANDA means that FDA has made a threshold determination that the [ANDA] is substantially complete.").

[15] 21 C.F.R. § 314.95(c)(7); *see also* FDCA § 505(j)(2)(B)(iv).

[16] 35 U.S.C. § 271(e)(2)(A).

To enable patent litigation to be resolved before FDA approves an ANDA and the applicant launches the generic product,[17] the FDCA includes the following provision for a stay of ANDA approval if specified conditions are met:

> If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) . . . .[18]

This provision requires that ANDA approval be stayed if, within 45 days of receipt of the paragraph IV notice, "an action is brought for infringement of the patent that is the subject of the certification" and information for the relevant patents was submitted to FDA "under [FDCA § 505](b)(1) or (c)(2)" before the date on which the original ANDA was submitted.[19] If these requirements are met, FDA cannot grant final approval of the ANDA for a period of 30 months, subject to modification by the court "because either party to the action failed to reasonably cooperate in expediting the action," or termination of the stay depending on how the litigation is resolved.[20]

The requirement that patent information be submitted to FDA before the submission of the original ANDA, as a prerequisite for a 30-month stay, was added to the FDCA by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).[21] Due to

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[17] *See* 81 Fed. Reg. at 69,582 (describing "the statutory purpose of the stay" as "to allow time for patent infringement claims to be litigated prior to approval of the potentially infringing product"), *supra* note 8; *Abbreviated New Drug Applications and 505(b)(2) Applications*, 80 Fed. Reg. 6802, 6805 (proposed Feb. 6, 2015) (same) (attached hereto as Exhibit 11).

[18] FDCA § 505(j)(5)(B)(iii).

[19] FDCA § 505(j)(5)(B)(iii) (emphasis added).

[20] *Id.*

[21] MMA, Pub. L. No. 108-173, § 1101(a), 117 Stat 2066, 2449 (2003) (attached hereto as Exhibit 12).

this prerequisite, a paragraph IV certification to a newly issued patent for which information is submitted to FDA after an original ANDA has been submitted cannot provide the basis for a 30-month stay.

B. Key Facts

Bayer holds NDA 213872 for Astepro® Allergy (azelastine hydrochloride nasal spray, 205.5 mcg/spray, OTC) and Children's Astepro® Allergy (azelastine hydrochloride nasal spray, 205.5 mcg/spray, OTC). Bayer submitted this NDA to FDA on August 20, 2020.[22] To comply with the statute and FDA's regulations, Bayer submitted a Form 3542a with NDA 213872 on that date for each of the following three patents: U.S. Patent Nos. 8,071,073; 8,518,919; and 9,919,050 (collectively, the Patents).

FDA approved NDA 213872 on June 17, 2021.[23] As required by section 505(c)(2) of the FDCA and FDA's regulations, Bayer submitted a Form 3542 for each of the three patents on July 8, 2021, a date that was within 30 days after FDA approved the NDA.[24]

By letters dated August 25 and 26, 2021, Apotex notified Bayer that Apotex had submitted ANDA 216421 referencing NDA 213872 and had submitted a paragraph IV certification as to each of the Patents.[25] On October 7, 2021—within 45 days after receiving Apotex's paragraph IV notices—Bayer and a co-plaintiff filed a complaint against Apotex in the United States District Court for the District of Delaware alleging infringement of the Patents in connection with ANDA 216421.[26]

Bayer submits this citizen petition to obtain confirmation from FDA that final approval of ANDA 216421 will be subject to a 30-month stay because the statutory prerequisites for a stay have been satisfied.

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[22] FDA, Approval Letter, NDA 213872, at 1 (June 17, 2021) (attached hereto as Exhibit 13).

[23] *Id.*

[24] *See* Forms 3542, *supra* note 5; Letter from Cherise Adair, Bayer HealthCare LLC, to Nushin Todd, MD, PhD, FDA, re: NDA 213-872 Astepro Allergy (azelastine hydrochloride) nasal spray 205.5 mcg per spray and Children's Astepro Allergy (azelastine hydrochloride) nasal spray, 205.5 mcg per spray New Patent Information for Purpose of Orange Book Listing Sequence # 0025 (July 8, 2021) (attached hereto as Exhibit 14).

[25] *See* Complaint ¶¶ 2, 33-35, 56-58, 78-80, *supra* note 1.

[26] Complaint, *supra* note 1.

II. Discussion

A. The plain language of the statute requires that ANDA 216421 be subject to a 30-month stay.

FDA should apply a 30-month stay to ANDA 216421 because the statutory prerequisites for a stay are met regardless of whether Apotex submitted this ANDA before or after Bayer submitted the Forms 3542 for the Patents.

Section 505(j)(5)(B)(iii) of the FDCA (quoted above in section I.A.) establishes the following three prerequisites for a 30-month stay:

1. The ANDA applicant must have made a paragraph IV certification.

2. A patent infringement suit must have been filed during the 45-day period after the date on which the NDA holder or patent owner received the paragraph IV notice.

3. The required information for the patent-in-suit must have been submitted to FDA under section 505(b)(1) or section 505(c)(2) of the FDCA before the submission date of the original ANDA (i.e., not an ANDA amendment or supplement) that FDA later accepted for review (i.e., "received").

All three of these eligibility requirements have been satisfied. *First*, Apotex submitted a paragraph IV certification to each of the Patents in connection with ANDA 216421.[27] *Second*, on October 7, 2021—during the 45-day period after Bayer received Apotex's paragraph IV notices—Bayer and a co-plaintiff filed suit against Apotex alleging infringement of the Patents in connection with ANDA 216421.[28] *Third*, Bayer submitted information for the Patents to FDA on Forms 3542a, pursuant to section 505(b) of the FDCA, before Apotex submitted the original ANDA 216421.[29]

Bayer's submission of information for the Patents on Forms 3542a with the original NDA 213872 satisfies the third eligibility requirement regardless of whether Apotex submitted its original ANDA before Bayer submitted Forms 3542 following FDA's approval of NDA 213872. The patent information that must be submitted before the date of ANDA submission is that

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[27] *See* Complaint ¶¶ 34, 57, 79, *supra* note 1.

[28] Complaint, *supra* note 1.

[29] *See* Forms 3542a, *supra* note 4.

which was submitted to FDA "under [FDCA § 505](b)(1) or (c)(2)."[30] Bayer submitted the Forms 3542a to satisfy the requirement under section 505(b)(1) that an NDA applicant "file with the application" specified patent information.[31] Because Bayer submitted the Forms 3542a with the original NDA 213872, they necessarily preceded Apotex's submission of an ANDA referencing this NDA, and thus fulfilled this statutory requirement for eligibility for a 30-month stay.

This analysis would not change even if Bayer only submitted patent information a second time on Forms 3542 following approval of the NDA—as required by section 505(c)(2) of the FDCA and FDA's regulations—after Apotex submitted original ANDA 216421.[32] To satisfy the statutory prerequisite for a 30-month stay, patent information must have been submitted under either "subsection (b)(1) or (c)(2)."[33] It is axiomatic that the term "or" in a statute describes alternatives and should not be construed to require a combination of the enumerated elements.[34] Accordingly, Bayer's submission of the Forms 3542a pursuant to subsection (b)(1) before Apotex's submission of the ANDA satisfied the prerequisite relating to the relative timing of submission of the patent information and ANDA, without regard to the timing of submission of the Forms 3542 pursuant to subsection (c)(2).

FDA's regulations should be interpreted in a manner that is consistent with the plain language of the statute to apply a 30-month stay to ANDA 216421. For the reasons discussed above, all of the prerequisites for a 30-month stay described in 21 C.F.R. § 314.107(b)(3)(i)(A) (quoted below) are satisfied here:

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[30] FDCA § 505(j)(5)(B)(iii) (emphasis added).

[31] *See* FDCA § 505(b)(1) (2018), *supra* note 4. Bayer's submission of the Forms 3542a with the original NDA also would have been required under the current version of this provision, which requires the submission of this patent information "as part of the application." FDCA § 505(b)(1).

[32] *See* FDCA § 505(c)(2) (requiring that "[n]ot later than 30 days after the date of approval of an application submitted under subsection (b)," the NDA holder "shall file with the Secretary the patent number and the expiration date of any patent described in subsection (b)(1)(A)(viii) . . . .").

[33] FDCA § 505(j)(5)(B)(iii) (emphasis added).

[34] *See, e.g.*, *Chao v. Day*, 436 F.3d 236-37 (D.C. Cir. 2006) (collecting authorities and concluding that the use of "or" in the definition of "fiduciary" in the Employee Retirement Income Security Act of 1974 indicates that "Congress plainly framed [the definition] in the alternative").

> [I]f, with respect to patents for which required information was submitted under § 314.53 before the date on which the 505(b)(2) application or ANDA was submitted to FDA (excluding an amendment or supplement to the 505(b)(2) application or ANDA), the applicant certifies under § 314.50(i) or § 314.94(a)(12) that the relevant patent is invalid, unenforceable, or will not be infringed, and the patent owner or its representative or the exclusive patent licensee brings suit for patent infringement within 45 days of receipt of the notice of certification from the applicant under § 314.52 or § 314.95, the 505(b)(2) application or ANDA may be approved 30 months after the later of the date of the receipt of the notice of certification by any owner of the listed patent or by the NDA holder (or its representative(s)) . . . .[35]

Specifically, Apotex submitted a paragraph IV certification to each of the Patents in connection with ANDA 216421,[36] Bayer and a co-plaintiff filed suit against Apotex during the 45-day period after Bayer received Apotex's paragraph IV notices, and Bayer submitted patent information under 21 C.F.R. § 314.53 (specifically, on Forms 3542a that are required under 21 C.F.R. § 314.53(c)(2)(i)) before Apotex submitted the original ANDA 216421.

It would be contrary to the statute for FDA to rely upon 21 C.F.R. § 314.107(b)(2) to deny a 30-month stay as to ANDA 216421 if Apotex submitted this ANDA before Bayer submitted the Forms 3542 for the Patents. This provision reads as follows:

> If the holder of the approved NDA for the listed drug submits patent information required under § 314.53 after the date on which the 505(b)(2) application or ANDA was submitted to FDA, the 505(b)(2) applicant or ANDA applicant must comply with the requirements of § 314.50(i)(4) and (6) and § 314.94(a)(12)(vi) and (viii) regarding submission of an appropriate patent certification or statement. If the applicant submits an amendment certifying under § 314.50(i)(1)(i)(A)(*4*) or § 314.94(a)(12)(i)(A)(*4*) that the relevant patent is invalid, unenforceable, or will not be infringed, and complies with the requirements of § 314.52 or § 314.95, the 505(b)(2) application or ANDA may be approved immediately upon submission of documentation of receipt of notice of paragraph IV certification under § 314.52(e) or § 314.95(e). The 45-day period provided for

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[35] 21 C.F.R. § 314.107(b)(3)(i).

[36] There was no basis for Apotex to be excused from the patent certification obligation under the provisions in FDA's regulations governing untimely filed patent information. *See* 21 C.F.R. § 314.53(d)(3); 21 C.F.R. § 314.94(a)(12)(vi), (viii).

in section 505(c)(3)(C) and (j)(5)(B)(iii) of the Federal Food, Drug, and Cosmetic Act does not apply in these circumstances.[37]

Section 314.107(b)(2) does not provide a basis for withholding a 30-month stay where, as here, the NDA holder satisfied the prerequisites for a stay that are set forth in the statute and 21 C.F.R. § 314.107(b)(3)(i)(A). These prerequisites would not be satisfied under the circumstances in which FDA intended for section 314.107(b)(2) to preclude a stay; for example, for patents that are issued after approval of the NDA. It would be unreasonable and contrary to the statute for FDA to rely upon 21 C.F.R. § 314.107(b)(2) to deny a 30-month stay on the different set of facts at issue here; i.e., where Bayer submitted the required patent information on Forms 3542a with the NDA, but Apotex may have submitted its ANDA before Bayer timely made the post-approval submission of patent information for the same patents on Forms 3542.

In short, FDA should apply a 30-month stay to ANDA 216421 because the statutory prerequisites are satisfied. The requirement that patent information be submitted before submission of the original ANDA is satisfied by Bayer's submission of Forms 3542a with the NDA. Even in the event that Bayer's timely post-approval submission of Forms 3542 pursuant to section 505(c)(2) of the FDCA occurred after Apotex submitted ANDA 216421, there would be no legal basis for FDA to withhold the 30-month stay because the eligibility requirements have been met.

B. <u>It would be contrary to the legislative purpose for FDA to interpret the statute in a way that withholds a 30-month stay as to ANDA 216421.</u>

The MMA added, as a prerequisite for a 30-month stay, the requirement that patent "information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application) . . . was submitted."[38] The legislative history makes clear that Congress added this provision to prevent NDA holders from obtaining successive 30-month stays as to an ANDA by submitting information about newly issued patents, with the effect of delaying generic entry. Nothing in the legislative history suggests that Congress sought to deny a single 30-month stay to an NDA holder like Bayer that submitted the required patent information with the original NDA, even if an ANDA applicant submitted its original ANDA before the NDA holder made its timely post-approval submission of patent information.

Congress added the prerequisite regarding the relative timing of submission of patent information and the ANDA in an effort to make only a single 30-month stay available in most

[37] 21 C.F.R. § 314.107(b)(2).

[38] MMA § 1101(a), *supra* note 21.

cases, as FDA has acknowledged.[39] During early discussions of the MMA, Senator Collins noted that "the brand manufacturer's ability to stack multiple and sequential automatic 30-month stays during patent litigation in order to keep generics off the market and extend their market exclusivity indefinitely" was "one of the primary abuses that [the] proposal would end."[40] Members of Congress continued to raise this specific concern over the course of the bill's history. For example, while discussing a draft of the MMA, Senator Hatch stated that "[a] key component of the bipartisan agreement codif[ies] the recent regulation that limits drug manufacturers to one and only one 30-month automatic stay in patent infringement litigation involving a generic drug application."[41]

Members of Congress referenced a 2002 report issued by the Federal Trade Commission (FTC) report, titled *Generic Drug Entry Prior to Patent Expiration: An FTC Study*[42] (FTC Report) as an important motivating factor behind the bill. The FTC Report examined generic drug entry prior to patent expiration and identified two provisions governing such entry that, in the FTC's view, were susceptible to strategies that would delay or deter consumer access to low-cost generic drug products.[43] One of these two provisions was the 30-month stay, about which the FTC Report noted that "[t]he history thus far of multiple 30-month stays caused by the filing of later-issued patents appears problematic."[44] Specifically, the FTC Report noted that "[m]ultiple 30-month stays prevented FDA approval of the generic applicants' ANDAs for 4 to 40 months *beyond* the initial 30-month period" and that FDA approval for these drugs may have occurred more quickly in the absence of these multiple stays.[45] To prevent the use of this provision to delay generic entry, the FTC Report recommended that the FDCA "[p]ermit only one automatic 30-month stay per drug product per ANDA."[46] Senator Hatch referred to the

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[39] *See* Letter from Janet Woodcock, M.D., FDA, to Gerald F. Masoudi, Covington & Burling LLP, re: Docket No. FDA-2010-P-0223, at 5-6 (Oct. 19, 2010) (attached hereto as Exhibit 15).

[40] 148 Cong. Rec. 13,039 (2002) (statement by Sen. Collins) (attached hereto as Exhibit 16). *See also id.* at 13,023 ("Schumer-McCain closes the evergreen loophole by permitting only one 30-month stay to apply to each generic drug.") (statement by Sen. Kennedy).

[41] 149 Cong. Rec. 30,951 (2003) (statement by Sen. Hatch) (attached hereto as Exhibit 17).

[42] FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002) (attached hereto as Exhibit 18).

[43] *Id.* at i, iv.

[44] *Id.* at iv.

[45] *Id.* at iv.

[46] *Id.* (emphasis omitted).

FTC Report in stating that he "[could] only believe that the factual presentation, analysis, and recommendations contained in the FTC report and subsequent public notice and comment process surrounding the recently-issued FDA final rule on patent listings and the application of the statutory 30-month stay both played a constructive role in helping to form the basis of the Gregg-Schumer legislation."[47] Similarly, Senator Kennedy noted that the proposed bill would "stop the multiple, successive 30-month stays that the Federal Trade Commission identified as having delayed approval of generic versions of several blockbuster drugs and cost consumers billions of dollars."[48]

Nothing in the legislative history of the MMA suggests that Congress sought to deny a single 30-month stay where an NDA applicant submitted Form 3542a with the original NDA and a generic applicant submits an ANDA before the NDA holder timely submits patent information a second time on Form 3542 following approval of the NDA. Instead, Congress sought to prevent the effect that multiple 30-month stays with respect to a single ANDA could have on the timing of generic entry. The MMA attempted to achieve this goal by requiring the submission of patent information—but not FDA's listing of those patents in the Orange Book—before the original ANDA is submitted. In light of the approach that Congress adopted, the fact that FDA publishes in the Orange Book patent information submitted on Form 3542, but not Form 3542a, is not a valid basis for disregarding patent information submitted on Form 3542a for purposes of assessing eligibility for a 30-month stay.[49]

Moreover, the legislative history of the Orange Book Transparency Act of 2020, which amended section 505(c)(2) to require the post-approval submission of patent information (in addition to the submission of patent information with the NDA as required by section 505(b)), contains no suggestion that Congress intended to alter the eligibility requirements for a 30-month stay—and certainly not in a way that would withhold a single 30-month stay from an NDA holder that meets all the prerequisites set forth in the statute and FDA's regulations.[50]

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[47] 149 Cong. Rec. 16,690 (2003) (statement by Sen. Hatch) (attached hereto as Exhibit 19).

[48] 149 Cong. Rec. 31,783 (2003) (statement by Sen. Kennedy) (attached hereto as Exhibit 20).

[49] *See, e.g.*, 80 Fed. Reg. at 6836, 6838 (contrasting the "determination of a 505(b)(2) or ANDA applicant's patent certification obligations and the availability of a 30-month stay based on patent information in FDA's possession" to the evaluation of the validity of a paragraph IV notice for purposes of assessing first applicant eligibility, which turns on "the actual date of publication of the patent information in the Orange Book"), *supra* note 17.

[50] *See* 165 Cong. Rec. H3486-88, H3491 (daily ed. May 8, 2019) (attached hereto as Exhibits 21, 22); 166 Cong. Rec. S7242-43, S7244-45 (daily ed. Dec. 7, 2020) (attached

Congress thus intended the MMA amendments to limit eligibility for a 30-month stay in an effort to address the effect that successive 30-month stays for later-issued patents could have on the timing of generic entry. These concerns are not present here. It therefore would be inconsistent with the legislative purpose of the MMA amendments for FDA to interpret them in a way that would deny a single 30-month stay as to ANDA 216421.[51]

Such an interpretation also would be contrary to the legislative purpose of the 30-month stay; i.e., to enable the parties to litigate a patent dispute before the ANDA applicant begins marketing its product.[52] The stay thus allows patent litigation to be resolved before the ANDA applicant would be liable for damages, thereby reducing the complexity of litigation, allowing patent suits to be resolved in a bench (rather than jury) trial, and enabling litigation to proceed in an orderly fashion with a reduced likelihood of the need for the parties and courts to address a request for preliminary relief (i.e., a temporary restraining order (TRO) or preliminary injunction (PI)) to prevent an impending launch of the generic product. To deny a stay on the

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hereto as Exhibits 23, 24); 166 Cong. Rec. H7130-31 (daily ed. Dec. 10, 2020) (attached hereto as Exhibit 25).

[51] *Cf.* 81 Fed. Reg. at 69,582 ("implementing . . . restrictions on submission of certain types of changes in an amendment or supplement to a 505(b)(2) application or ANDA in a manner that is consistent with the statutory text and preserves a meaningful opportunity for a single 30-month stay" (emphasis added)), *supra* note 8.

[52] *See* H.R. Rept. No 98-857, pt. 1, at 28 (1984) (stating that the stay "permits the commencement of a legal action for patent infringement before the generic drug maker has begun marketing. The Committee believes this procedure fairly balances the rights of a patent owner to prevent others from making, using, or selling its patented product and the rights of third parties to contest the validity of a patent or to market a product which they believe is not claimed by the patent.") (attached hereto as Exhibit 26); 130 Cong. Rec. 24,425 (1984) (statement by Rep. Waxman) (explaining that the length of the stay was lengthened from 18 months (in an earlier version of the bill) to 30 months to "increase[] the likelihood that . . . patent litigation will be concluded before the generic drugmaker begins marketing") (attached hereto as Exhibit 27). FDA has acknowledged this purpose of the 30-month stay. *See* 81 Fed. Reg. 69,582, *supra* note 8; 80 Fed. Reg. 6805, *supra* note 17; *see also* 54 Fed. Reg. 28,872, 28,894 (proposed July 10, 1989) ("It serves the public interest to permit a prudent ANDA holder in that situation to stay off the market until the litigation is resolved, thereby minimizing potential damages.") (attached hereto as Exhibit 28); *Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions*, 59 Fed. Reg. 50,338, 50,352 (Oct. 3, 1994) (referring to an applicant who delays marketing until patent issues have been resolved on appeal as a "prudent applicant.") (attached hereto as Exhibit 29).

facts present here—where Bayer has done everything required under the statute and FDA's regulations to timely submit patent information and initiate litigation as prerequisites for a 30-month stay—would expose the parties and the courts to the type of disruption that Congress sought to avoid.

More broadly, an interpretation by FDA that the submission of patent information on Form 3542a before the submission of an original ANDA does not fulfill one of the prerequisites for a 30-month stay would create significant uncertainty about the availability of the stay for certain types of products. For those products for which an ANDA may be submitted soon after NDA approval—in particular, those for which bioequivalence data are not needed (e.g., due to a waiver of *in vivo* bioequivalence data[53])—an NDA holder might not have the full 30-day period following NDA approval, as provided in the statute and FDA's regulations, to submit patent information on Form 3542. These types of products thus will be at significant risk of facing an ANDA submission before the Form 3542 is submitted. If FDA considers such an ANDA submission before submission of the Form 3542 to disqualify such products from eligibility for a 30-month stay—even if the NDA holder submitted patent information on Form 3542a with the NDA—the holders of NDAs for these types of products will lack a meaningful opportunity for a single 30-month stay. Patent litigation involving these products would be less likely to be concluded before the launch of generic products, with the attendant disruption to the parties and courts—an outcome that would be contrary to the legislative purpose for the 30-month stay.

III. Conclusion

For the reasons stated above, Bayer requests that FDA confirm that the Agency will stay the final approval of ANDA 216421 until the expiration of the 30-month period beginning on the date when Bayer received Apotex's paragraph IV notice, absent any event specified in FDCA § 505(j)(5)(B)(iii) that would cause the stay to be shortened, lengthened, or terminated.

C. Environmental Impact

The actions requested herein are subject to categorical exclusion under 21 C.F.R. §§ 25.30 and 25.31.

D. Economic Impact

Pursuant to 21 C.F.R. § 10.30(b), an economic impact statement will be submitted only upon the request of the Commissioner.

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[53] *See* 21 C.F.R. § 320.22(b).

E. Certification

I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: March 17, 2022. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: I am making these representations on behalf of Bayer HealthCare LLC as part of my responsibilities as an employee of Bayer; I am not being separately compensated for submitting this petition. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.

Respectfully submitted,

Jeremy R. Jessen

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