180-Day Generic Drug Exclusivity – Forfeiture

180-Day Exclusivity

- As an incentive for generic companies to further the statutory purpose of helping the public gain access to lower-cost drug products more expeditiously, the Hatch-Waxman Amendments grants a 180-day period of generic drug market exclusivity to the first ANDA applicant that submits a substantially complete application containing a Paragraph IV patent certification.

- 180-day exclusivity prevents the FDA from approving subsequently submitted ANDAs containing a Paragraph IV certification.

180-Day Exclusivity

- **Under amendments made to the FDC Act by the Medicare Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003), the first ANDA applicant that submits a substantially complete application containing a Paragraph IV patent certification can forfeit 180-day exclusivity eligibility for various reasons.**

- **180-Day exclusivity begins on the date of commercial marketing.**

Failure-to-Market

FDC Act 505(j)(5)(D)(i)(I)

Forfeiture Event

- **(I) Failure to market. The first applicant fails to market the drug by the later of -**
  - **(aa) the earlier of the date that is -**
    - **(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or**
    - **(BB) 30 months after the date of submission of the application of the first applicant; or**

Forfeiture Event

- (bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

Forfeiture Event

- (AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.
- (BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.
- (CC) The patent information submitted under subsection (b) or (c) is withdrawn by the holder of the application approved under subsection (b).

Withdrawal of Application

FDC Act 505(j)(5)(D)(i)(II)

Forfeiture Event

- **(II) Withdrawal of application.** **The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).**

Amendment of Certification

FDC Act 505(j)(5)(D)(i)(III)

Forfeiture Event

- **(III) Amendment of certification.** **The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.**

Failure to Obtain Tentative Approval

FDC Act 505(j)(5)(D)(i)(IV)

Forfeiture Event

- **(IV) Failure to obtain tentative approval.** **The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.**

Forfeiture Event

- **Congress clarified FDC Act 505(j)(5)(D)(i)(IV) in the 2007 FDAAA:**
  - **If "approval of the application was delayed because of a petition, the 30-month period under such subsection is deemed to be extended by a period of time equal to the period beginning on the date on which the Secretary received the petition and ending on the date of final agency action on the petition (inclusive of such beginning and ending dates) . . . ." (FDC Act 505(q)(1)(G)).)**
- **Further clarification in the 2012 FDASIA:**
  - **FDC Act 505(q) Citizen petitions – 150-day response timeframe**
  - **FDASIA 1133**

Agreement With Another Applicant

FDC Act 505(j)(5)(D)(i)(V)

Forfeiture Event

- **(V) Agreement with another applicant, the listed drug application holder, or a patent owner.** **The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 1 of the Clayton Act (15 USC 12), except that the term includes section 5 of the Federal Trade Commission Act (15 USC 45) to the extent that that section applies to unfair methods of competition).**

Expiration of All Patents

FDC Act 505(j)(5)(D)(i)(VI)

Forfeiture Event

- **(VI) Expiration of all patents. All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.**

First Interchangeable Biological Product Exclusivity

PHS Act 351(k)(6)

- **PHS Act § 351(k)(6), titled "Exclusivity for first interchangeable biological product," states that First Interchangeable Exclusivity ("FIE") prevents FDA from licensing another biosimilar biological product as interchangeable to the 351(a)-licensed "reference product" until the earlier of certain events.**

PHS Act 351(k)(6)

- **The Secretary shall not make approval as an interchangeable biological product effective with respect to an application submitted under this subsection that relies on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, until the earlier of—**
  - **(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;**

PHS Act 351(k)(6)

- (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).

First FDA FIE Letter Decision

- **FDA, FIE Letter Decision concerning BLAs 761058 and 761118 (Adalimumab) (Oct. 3, 2023), *available at* https://www.fda.gov/media/173749/download?attachment**
- **The Adalimumab FIE Letter Decision addresses the application of PHS Act 351(k)(6)(A)-(C) in determining the expiration of FIE when patent litigation is initiated under section 351(l)(6) in connection with an application for a proposed biosimilar biological product and ends prior to the submission of a supplement for interchangeability for the first interchangeable biosimilar biological product.**

First FDA FIE Letter Decision

- **“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.”**

First FDA FIE Letter Decision

- **"[W]e 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 for the first 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."**

First FDA FIE Letter Decision

- **"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."**