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Update on Pending Legislation: Three New Bills Have the Potential to Affect Generic Pharmaceutical Companies

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In the first month of the 116th Congress, three bills have been introduced (or re-introduced) that have potential to impact generic pharmaceutical companies.

Hatch-Waxman Integrity Act of 2019

On January 30, 2019, Sen. Thom Tillis (R-NC) and Rep. Bill Flores (R-TX) introduced the Hatch-Waxman Integrity Act of 2019 (H.R.990 and S.344, respectively) with the goal of foreclosing ANDA, 505(b)(2) and biosimilar applicants from petitioning for inter partes review or post-grant review of patents covering the reference listed drug or biologic drug.

The Act would amend the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)(2)) by requiring a 505(b)(2) or ANDA applicant to certify that it will not institute IPR or PGR as to any Orange Book-listed patent, and that it will not "rely[] in whole or in part" on any PTAB IPR or PGR decision. Similarly, the bill requires biosimilar applicants to certify that the applicant will not petition to institute IPR or PGR with respect to a patent that covers a reference product or a method of its use and that has been so identified by way of marking or other public notice.

This is not the first time this legislation has been introduced. In June 2018, then-Senator Orrin Hatch introduced the Hatch-Waxman Integrity Act of 2018 as an amendment to the Creating and Restoring Equal Access to Equivalent Samples Act (CREATES Act). Sens. Hatch and Tillis, along with Rep. Flores then introduced the Act again in December 2018 prior to Sen. Hatch's retirement at the end of the 115th Congress.

According to Sen. Tillis and Rep. Flores, the proposed legislation seeks to prevent "alternative procedures for challenging drug patents [from] tilt[ing] the playing field contrary to *Hatch-Waxman's* design." Press Release, Sen. Thom Tillis, Tillis & Rep. Flores Introduce Bill to Restore Balance and Integrity to the Patent System (Feb. 6, 2019). "[The Hatch-Waxman Integrity Act of 2019] restores an effective balance between the interests of brand-name and generic drug manufacturers so that innovation and competition will continue to flourish," said Rep. Flores. *Id.*

Notably, former Rep. Henry Waxman, a cosponsor with Sen. Hatch of the 1984 legislation commonly referred to as the Hatch-Waxman Act, has been vocal in his criticism of

the bill as introduced in 2018. According to former Rep. Waxman, "The IPR process is one of several key policy mechanisms for encouraging competition and reducing prices in the pharmaceutical markets. Efforts to undermine this process—such as the proposed Hatch amendment—will likely undermine current efforts to ease the burden of high drug costs on American consumers by allowing brand-name manufacturers to extend monopoly pricing." Henry Waxman et al., "Proposed CREATES Amendment Could Impede the Availability of Affordable Generic Drugs," *To the Point,* Commonwealth Fund, July 17, 2018.

BLOCKING Act

On January 31, 2019, Reps. Kurt Schrader (D-OR) and Earl L. "Buddy" Carter (R-GA) introduced the Bringing Low-Cost Options and Competition while Keeping Incentives for New Generics Act (BLOCKING Act) (H.R. 938), with the stated intent of preventing generic first filers from "parking" applications and delaying the start of their 180-day generic exclusivity.

The BLOCKING Act would amend the FDC Act (35 U.S.C. § 355(j)(5)(B)(iv)) to effectively add an additional set of circumstances that would trigger the start of the first filer's 180-day exclusivity. Specifically, FDA would be able to approve a second or subsequent filer "on the date that is 180 days after the earlier of" the date of first commercial marketing of the first applicant (as before), or the "applicable date." The "applicable date" is the date "on which each of the following conditions is met":

> (aa) The approval of such an application could be made effective, but for the eligibility of a first applicant for 180-day exclusivity under this clause.
>
> (bb) At least 30 months have passed since the date of submission of an application for the drug by at least one first applicant.
>
> (cc) Approval of an application for the drug submitted by at least one first applicant is not precluded under clause (iii).
>
> (dd) No application for the drug submitted by any first applicant is approved at the time the conditions under items (aa), (bb), and (cc) are all met, regardless of whether such an application is subsequently approved.

According to Rep. Schrader, the current law allows "some manufactures to 'park' the exclusivity before receiving final approval, blocking competition for more than the 180 days intended by the law," an option the BLOCKING Act seeks to eliminate by starting the 180-day exclusivity period where the specified conditions are met. Press Release, Rep. Kurt Schrader, Schrader, Carter Introduce Bipartisan Bill to Keep Drug Costs Down (Jan. 31, 2019).

Whether the BLOCKING Act will be effective to address those stated concerns is the subject of dispute, given the perception that it will diminish the 180-day exclusivity period as an incentive for companies to pursue development of generic drugs, as well as the fear that it would introduce complications and uncertainty with a low likelihood of effectiveness.

CREATES Act

On February 5, 2019, Sen. Patrick Leahy (D-VT) and Rep. David N. Cicilline (D-RI) re-introduced versions of the Creating and Restoring Equal Access to Equivalent Samples Act (CREATES Act) (S. 340, H.R. 965, respectively), aimed at facilitating quicker market entry of generic drug products.

The CREATES Act, in relevant part, proposes two changes. First, it would allow a generic or biosimilar applicant to bring a civil action against a brand drug company in the event the brand refuses to make sufficient drug product samples available for testing. Generic applicants require testing of brand samples in order to support their applications. Refusal to provide samples (or sufficient quantities of samples) is one way brand companies can attempt to stymie efforts by generic applicants to seek approval. The CREATES Act would curtail such attempts by allowing a biosimilar or generic-drug applicant to sue the brand in Federal court for an order to provide the needed samples.

Second, the CREATES Act would give FDA the authority to approve alternative Risk Evaluation and Mitigation Strategy programs if a generic or biosimilar and brand are not able to cooperate to use a single shared REMS program. REMS programs may be required by FDA for certain drugs with serious safety concerns to reduce the frequency and/or severity of adverse events of a drug. Often, a single shared REMS program pertains to a

product or class of products and generic equivalents. The inability to incorporate generic applicants into a single shared REMS program can delay approval and entry into the market. The CREATES Act would expressly permit FDA to approve alternative REMS programs to facilitate approval of generic applicants.

The CREATES Act was previously introduced in 2016 and again in 2018. Although it has enjoyed broad bipartisan support, it has been previously unable to reach a vote amidst opposition from pharmaceutical companies.

For More Information

For more information about the status of this pending legislation and how it may affect business opportunities for generic pharmaceutical companies, please contact the authors or your Polsinelli attorney.

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