Hatch-Waxman Integrity Act of 2018

In 1984, Congress enacted the *Drug Price Competition and Patent Term Restoration Act* (the "*Hatch-Waxman Act*"), which carefully balanced incentives for both pharmaceutical innovation and drug affordability. To incentivize innovation by branded drug manufacturers, the *Hatch-Waxman Act* included various protections for patent terms and data exclusivity. But to incentivize market entry of low-cost generic drugs, the *Hatch-Waxman Act* also amended the *Food, Drug, & Cosmetic Act* ("FD&C Act") by creating two abbreviated drug approval pathways—Sections 505(b)(2) and 505(j)—and by clearly delineating a pathway for challenging drug patents.

Congress has also enacted rules comparable to the *Hatch-Waxman Act* for biologic products. In 2009, Congress enacted the *Biologics Price Competition and Innovation Act* ("BPCIA") to both provide incentives for biologic innovation and create an abbreviated pathway—Section 351(k) of the *Public Health Service Act* ("PHS Act")—for market entry of lower-cost biosimilar products.

In 2012, Congress enacted the *America Invents Act* to fix a problem unrelated to drug/biologic innovation and drug/biologic affordability; it created the inter partes review ("IPR") and post-grant review ("PGR") processes to combat the growing problem of patent trolls.

Even though Congress did not intend to upset its drug/biologic-specific Hatch-Waxman and BPCIA procedures with the enactment of the IPR and PGR processes, generic drug and biosimilars manufacturers have increasingly used the IPR process to circumvent the *Hatch-Waxman Act* and BPCIA patent challenge processes while nonetheless taking advantage of their abbreviated processes for drug entry.[1] Moreover, hedge funds with no interest in manufacturing or marketing drugs have filed IPR challenges against drug patents with the goal of profiting from stock market declines triggered by the IPR filings—a type of market manipulation.

The *Hatch-Waxman Integrity Act of 2018* would close the loophole unintentionally created by the *America Invents Act*. To restore the careful balance of the *Hatch-Waxman Act* and the BPCIA, and to prevent the IPR or PGR processes from undercutting them, the FD&C Act and the PHS Act would be amended to prevent using IPR (or PGR) challenges to circumvent the specific patent-challenge processes for drugs and biologics painstakingly created by Congress. In addition, the federal securities rules would be clarified to indicate that filing IPR patent challenges and profiting from resulting stock price changes is a form of prohibited market manipulation.

Section-By-Section Analysis

Section 5(a). Short Title

Section 5(a) of the amendment establishes the amendment's short title: "Hatch-Waxman Integrity Act of 2018."

[1] *See* Joanna Shepherd, *Disrupting the Balance: The Conflict Between Hatch-Waxman and Inter Partes Review*, 6 N.Y.U. J. OF INTELL. PROP. & ENT. LAW 15 (2016).

Sections 5(b)–(d). Brand Name Drugs; Generic Drugs; Biosimilar Drugs

Sections 5(b)–(d) create a new certification requirement for three forms of drug applications: (1) New Drug Applications ("NDAs") submitted to FDA pursuant to § 505(b)(2) of the FD&C Act; (2) Abbreviated New Drug Applications ("ANDAs") submitted to FDA pursuant to § 505(j) of the FD&C Act; and (3) Biosimilar Applications submitted to FDA pursuant to § 351(k) of the PHS Act. These modifications are aimed at preventing such applicants, and related entities, from taking advantage of both the specific drug/biologic patent procedures (created by the *Hatch-Waxman Act* and the BPCIA) and the IPR or PGR procedures (created by the *America Invents Act*).

i. Section 5(b). Brand Name Drugs

Section 5(b) of the amendment modifies the certifications required in an NDA submitted to FDA pursuant to section 505(b)(2) of the FD&C Act. A 505(b)(2) application is a new drug application "that contains full reports of investigations of safety and effectiveness, where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use."[2] In submitting a 505(b)(2) application, the applicant must certify with respect to each patent claiming the reference listed drug that either: (i) the patent information has not been filed in the Orange Book; (ii) the patent information was submitted to the Orange Book but the patent has expired; (iii) the patent in the Orange Book has not yet expired, but the applicant is not looking to market its product prior to the patent expiring; or (iv) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

Section 5(b) amends the FD&C Act to require that an NDA submitted under section 505(b)(2) include a certification, in addition to the existing certification requirement noted above, that neither the NDA applicant nor any party in privity has filed, or will file, a petition to institute an IPR or PGR challenge of any patent claiming the reference listed drug. In short, if the 505(b)(2) applicant wants to take advantage of the abbreviated pathway created by the *Hatch-Waxman Act*, the applicant must certify that it has not utilized (and will not in the future utilize) the IPR or PGR process. Section 5(b) further requires a certification that, in making a certification under section 505(b)(2)(A), the applicant is not relying, in whole or in part, on any decision issued by the Patent Trial and Appeal Board ("PTAB") in an IPR or PGR proceeding. In practice, this would typically be a certification that the applicant is not relying on an IPR or PGR determination in its certification that the relevant listed patent is "invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the [505(b)(2)] application is submitted."[3]

[2] U.S. FOOD & DRUG ADMIN., *Guidance for Industry: Determining Whether to Submit an ANDA or a 505(b)(2) Application* (Oct. 2017).
[3] 21 U.S.C. § 355(b)(2)(A)(iv).

ii. Section 5(c). Generic Drugs

Section 5(c) of the amendment modifies the certifications required in an ANDA submitted to FDA pursuant to section 505(j)(2) of the FD&C Act. An ANDA is an application for a generic drug, i.e., "for a duplicate of a previously approved drug product…that relies on [the FDA's] finding that the previously approved drug product (the reference listed drug) is safe and effective."[4] In submitting a 505(j) application, the applicant must certify with respect to each patent claiming the reference listed drug that either: (i) the patent information has not been filed in the Orange Book; (ii) the patent information was submitted to the Orange Book but the patent has expired; (iii) the patent in the Orange Book has not yet expired, but the applicant is not looking to market its product prior to the patent expiring; or (iv) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

Section 5(c) amends the FD&C Act to require that an ANDA submitted under section 505(j) include a certification, in addition to the existing certification requirement noted above, that neither the ANDA applicant nor any party in privity has filed, or will file, a petition to institute an IPR or PGR challenge of any patent claiming the reference listed drug. In short, if the 505(j) applicant wants to take advantage of the abbreviated pathway created by the *Hatch-Waxman Act*, the applicant must certify that it has not utilized (and will not in the future utilize) the IPR or PGR process. In addition, section 5(c) requires a certification that, in making the certifications required under section 505(j)(2)(A)(vii), the applicant is not relying, in whole or in part, on any decision issued by the PTAB in an IPR or PGR proceeding. Similar to 505(b)(2), in practice, this would usually be a certification that the applicant is not relying on an IPR or PGR determination in making a certification that the relevant listed patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the [ANDA] is submitted."[5]

iii. Section 5(d). Biosimilar Drugs; Evaluation by the Secretary

Section 5(d) of the amendment modifies the information that must be included in a biosimilar application under section 351(k) of the PHS Act. A biosimilar application permits "a manufacturer that shows its proposed biosimilar product is highly similar to and has no clinically meaningful differences from the FDA-approved reference product [to] rely in part on FDA's previous determination of safety and effectiveness for the reference product for approval."[6]

Section 5(d) amends the PHS Act to require that applications submitted to FDA under 351(k) of the PHS Act include, with respect to any patent that is, or that could be, included in the list of potentially infringed patents to be supplied by the reference product sponsor, a certification that neither the biosimilar applicant nor any party in privity has filed, or will file, a petition to institute an IPR or PGR challenge of that patent. Section 5(d) also requires that the Secretary of

[4] U.S. FOOD & DRUG ADMIN., *Guidance for Industry: Determining Whether to Submit an ANDA or a 505(b)(2) Application* (Oct. 2017).
[5] 21 U.S.C. § 355(j)(2)(A)(vii)(IV).
[6] U.S. FOOD & DRUG ADMIN., *Biosimilar Product Regulatory Review and Approval Factsheet* (Oct. 2017).

Health and Human Services make a determination that the biosimilar application fully complies with the above certification requirement, prior to licensing the product that is the subject of the application.

Section 5(e). Preventing Manipulative and Deceptive Use of Inter Partes Review

Under the *Securities Exchange Act of 1934*, it is "unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce or of the mails or of any national securities exchange…[t]o use or employ in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, or any securities-based swap agreement any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [Securities and Exchange] Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors."[7]

Section 5(e) of the amendment modifies the *Securities Exchange Act* to consider a person as using a manipulative or deceptive device if the person (or an affiliate) files a petition to institute an IPR proceeding with respect to a patent and the person (or an affiliate), during a 180-day period spanning 90 days before and 90 days after filing that challenge, engages in a short sale of any publicly traded security of the owner of the patent that is the subject of the petition.

This section is intended to address the relatively novel practice of hedge funds, and similar entities, short selling stock of a company and filing an IPR challenge against a patent held by that company in an effort to crash the company's stock and thereby create a profit for the short seller. Under section 5(e) of the amendment, such activities would be treated as a manipulative or deceptive device, as prohibited by section 10 of the *Securities Exchange Act*.

[7] 15 U.S.C. § 78j(b).