BIOSIMILAR DEVELOPMENT

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How Will Trump's New FTC/DOJ Reporting Requirements Impact Biosimilars?

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On Oct. 10, 2018, President Trump signed into law the Patient Right to Know Drug Prices Act, which, among other things, amends the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (also known as MMA, the Medicare Modernization Act) to require that certain biosimilar applicants and reference product sponsors involved in patent disputes file their settlement agreements with the Federal Trade Commission (FTC) and the Department of Justice (DOJ). The amendment intends to impose on biologic and biosimilar makers the same reporting obligation currently in place for branded and generic drug makers. While the new law itself is unlikely to have a significant impact on the biosimilar industry as it merely makes it easier for the FTC to access patent settlement agreements and is not applicable to all biosimilar settlements, it indicates that these deals are drawing more antitrust scrutiny.

This article summarizes the key provisions of the new law and discusses its limitations. I then look at the FTC's practice in evaluating "reverse payment" settlements in Hatch-Waxman litigations and discuss why similar antitrust analyses of biosimilar settlements will likely be more complex.

Key Provisions Of Reporting Requirement

Under the amendment, a branded biologics company and a biosimilar applicant that has submitted an abbreviated biologic license application (aBLA) and provided "a statement under section 351(*l*)(3)(B)(ii)(I) of the Public Health Service Act" (also known as the Paragraph 3(B)(ii)(I) statement, which is a detailed statement of noninfringement, invalidity, and/or unenforceability with respect to patents allegedly covering the reference product) that enter into an agreement regarding the following enumerated subject matters must each file the agreement with the FTC and DOJ:

- the manufacture, marketing, or sale of the branded reference product;
- the manufacture, marketing, or sale of the biosimilar product for which an aBLA was submitted; or
- the one-year commercial marketing exclusivity afforded to first biosimilar product approved as interchangeable for the reference product.

Biosimilar applicants that have provided Paragraph 3(B)(ii)(I) statements for the same reference product and entered into an agreement with one another regarding the one-year commercial marketing exclusivity must also each file the agreement.

The parties must file with the FTC and DOJ — within 10 business days of execution and before the commercial launch of the biosimilar product — the text of any such agreement, unless the agreement solely concerns purchase orders for raw material supplies; equipment and facility contracts; employment or consulting contracts; or packaging and labeling contracts.

If a covered agreement has not been reduced to text, written descriptions of such agreement sufficient to disclose all the terms and conditions of the agreement must be filed. In addition, the parties must file any ancillary agreements that are contingent on, provide a contingent condition for, or are otherwise related to a covered agreement within 10 business days of execution. Any party who fails to comply with the reporting requirement is liable for a civil penalty up to $11,000 per day of noncompliance.

Limited Impact Of The New Reporting Requirement On Biosimilar Applicants

The reach of the new law on biosimilar settlements is more limited compared to the reach of its predecessor counterpart under MMA on generic settlements. Unlike generic drug makers that filed an abbreviated new drug application (ANDA), not all aBLA applicants that contest the validity or infringement of the brand's patents are subject to the reporting requirement under the new law. This is because the framework for patent dispute

resolution under the Biologics Price Competition and Innovation Act of 2009 (BPCIA) is very different than under the Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the Hatch-Waxman Act).

The reporting obligation for a brand-generic settlement is triggered by the generic drug applicant's inclusion in its ANDA a certification that one or more patents listed in the Orange Book by the branded drug company as covering the listed drug are invalid or will not be infringed (known as the "Paragraph IV certification"). Unlike generic drug applicants that, under the Hatch-Waxman Act, must consult the Orange Book and include a certification with respect to each relevant U.S. patent in their ANDA applications,[1] there is no parallel requirement for aBLA filings under BPCIA. The Purple Book, while commonly viewed as analogous to the Orange Book, does not list patents for biologic products. Instead, patent information and related contentions are exchanged under the private "patent dance" scheme set out in BPCIA, which a biosimilar applicant is free to opt out of, either entirely or at any point during the dance.

Under the patent dance scheme, after the biosimilar applicant provides a copy of the aBLA and relevant manufacturing information to the reference product sponsor (RPS), the RPS has 60 days to identify a list of patents for which it believes a claim of patent infringement could reasonably be asserted. The biosimilar applicant then has another 60 days to provide a response as to each listed patent, in the form of either a statement that the biosimilar applicant does not intend to begin commercial marketing of the biosimilar product before the patent expires, or a detailed statement that describes the factual and legal basis of the biosimilar applicant's opinion that the patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biosimilar product. The latter, known as the Paragraph 3(B)(ii)(I) statement, triggers the reporting obligation of settlement agreements under the new law.

Biosimilar applicants that settle patent disputes without a Paragraph 3(B)(ii)(I) statement are not subject to the mandatory reporting requirement under the new law. Using the Humira settlements as an example, the mandatory reporting requirement would not have applied to Abbvie's settlement with Samsung Bioepis, reached more than five months before Samsung Bioepis' aBLA filing, or its settlement with Mylan, which has yet to file for approval of a Humira biosimilar in the U.S. In both cases, the parties settled without the involvement of a Paragraph 3(B)(ii)(I) statement. On the other hand, the requirement would have applied to Abbvie's settlements with Amgen and Sandoz, as they followed lawsuits filed after completion of the patent dance.

Moreover, where applicable, the new reporting requirement simply makes it easier for the FTC to access and review biosimilar patent settlements without changing the scope or substance of the investigation or the antitrust laws. The settlements need not be approved by the FTC or DOJ; nor is there a waiting period similar to that required for mergers.

However, the new law, enacted on the heels of Senators Grassley (R-Iowa) and Klobuchar (D-Minnesota) urging the FTC to investigate the Humira settlements, signals that increased antitrust scrutiny of biosimilar settlements is imminent. Although settlements without a Paragraph 3(B)(ii)(I) statement need not be voluntarily reported, the FTC may still investigate them through administrative subpoenas.

What Can We Learn From The FTC's Review Of ANDA Settlements?

The FTC's review of ANDA settlements has been primarily focused on "reverse payment" or "pay for delay" arrangements that delay the entry of generic drugs. In *FTC v. Actavis, Inc.*, issued in June 2013, the U.S. Supreme Court ruled that reverse-payment settlements in patent litigation could sometimes violate the antitrust laws. The court held that "a reverse payment, where *large and unjustified*, can bring with it the risk of significant anticompetitive effects[.]" (Emphasis added.) Legitimate justifications may include situations where the reverse payments "amount to no more than a rough approximation of the litigation expenses saved through the settlement" or "reflect compensation for other services that the generic has promised to perform[.]" Whether a reverse-payment arrangement violates antitrust laws is determined under a "rule of reason" approach, where its procompetitive features are measured against its anticompetitive effects. As the Supreme Court explained, "the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification."

The FTC has reported a decrease in reverse-payment deals since the issuance of the *Actavis* decision. For fiscal year 2015, the FTC identified 14 final settlements — out of 170 — as potentially involving "pay for delay" because they "contain both explicit compensation from a brand manufacturer to a generic manufacturer and a restriction on the generic manufacturer's ability to market its product in competition with the branded product." Excluding the nine agreements in which compensation was solely in the form of a cash payment of $7 million or less in litigation fees — which the FTC has okayed for ANDA settlements in recent stipulated orders for permanent injunction with Endo and Teikoku — the remaining five included compensations in the forms of a cash payment of greater than $7 million in litigation fees and/or a brand manufacturer's promise not to market an authorized generic (AG) for some period of time. The FTC also identified 10 additional

final settlements as containing "possible compensation" because "it is not clear from the face of each settlement agreement whether certain provisions act as compensation to the generic challenger." These included agreements with a declining royalty structure tied to the brand's launch of an AG product.

In suits or administrative complaints filed by the FTC concerning ANDA settlements, the agency has alleged the following as constituting unjustified "reverse payments" from the brand to the generic: (1) cash payments that exceed litigation expenses saved; (2) no-AG commitments and/or AG deals for other products; (3) cash payments for co-development, co-promotion, and/or manufacturing deals that have little benefit to the brand; (4) royalties for patent licenses that the brand does not need; (5) supply branded products to the generic or its partner at no cost for resale; (6) purchase active ingredients from the generic or its partner at prices substantially higher than paid to existing suppliers; and (7) settling unrelated patent litigation on terms favorable to the generic. In evaluating whether a side deal is "justified," the FTC often considers a number of factors, including:

- whether the deal was entered into simultaneously with the patent settlement;
- whether there was any significant discussion about the deal prior to patent settlement negotiations;
- whether the brand received anything meaningful from the deal;
- whether the deal is inconsistent with the brand's usual policies; and
- whether the generic had tried but failed to enter into similar deals with others.

The FTC is likely to apply the same antitrust analyses to biosimilar patent settlements, focusing on the amount of reverse compensation and restrictions on biosimilar entry. However, identification and calculation of the "compensation," as well as assessing whether it qualifies as a "large" and "unjustified" payment under *Actavis*, will likely be much more complex for biosimilar settlements. Compared to Hatch-Waxman litigation, BPCIA patent litigation is still in its nascent stage and there is not enough comparable data to determine what amounts to reasonable litigation expenses in a specific case (although it is likely to be a higher amount than Hatch-Waxman litigation given that with the patent dance and two phases of litigation, the BPCIA patent resolution mechanism is more protracted by design). Moreover, the patent dance adds another seven and a half months to the district court litigation — compared to 45 days to lawsuit in Hatch-Waxman litigation — giving the parties more time to negotiate and come up with creative ways to structure the settlement. The line between biosimilars and branded biologics companies is more blurred compared to the traditional line between branded and generic drug companies, affording the biologics/biosimilars companies more opportunities to meaningfully partner with each other. Efforts to educate the FTC on what are "justified" expenses in the biologics/biosimilars arena are well warranted.

About the Author:

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[1] Under the Hatch-Waxman Act, an ANDA applicant must make one of the four certifications: (I) no patent is listed for the reference listed drug; (II) the listed patent already expired; (III) it will not commercially market the generic drug before the listed patent expires; or (IV) the listed patent is invalid or will not be infringed. The last certification is often referred to as the "Paragraph IV certification." After receiving notice of a Paragraph IV certification, the branded drug manufacturer has 45 days to file a patent infringement suit in order to stay FDA's approval of the generic drug.