Cooley

Agreements Involving Biosimilars Must Be Reported to FTC and DOJ Under New Law

October 19, 2018

Biologic drug makers will soon have to alert the Federal Trade Commission and Department of Justice of agreements, including patent litigation settlements, they reach with biosimilar applicants. The new reporting requirement is part of the **Patient Right to Know Drug Prices Act**, which President Trump signed into law on October 10, 2018.

The Patient Right to Know Drug Prices Act modifies the MMA – the Medicare, Prescription Drug, Improvement, and Modernization Act – which since 2004 has required pharmaceutical companies to file agreements reached with generic pharmaceutical applicants.

While the new law will similarly only require notification of agreements, and does not modify substantive antitrust law, the act may foreshadow increased scrutiny of patent settlements and other agreements involving biologics. Indeed, since the MMA reporting requirement was passed for agreements involving pharmaceuticals in 2004, the FTC has filed suit against more than a dozen companies challenging agreements between innovator and generic manufacturers under antitrust law on the theory they have delayed generic pharmaceutical entry and led to higher prices.

Why the need to report? Concerns regarding reverse payment settlements

For 20+ years, the FTC has targeted so-called reverse payment settlements of Hatch-Waxman litigation in the pharmaceutical industry, by which patent holders pay alleged infringers, and the alleged infringers agree to stay off the market for some period of time.

Debates continue regarding the competitive implications of deals for generic entry at a future date before patent expiration. The FTC views such payments as "payments for delay," arguing that the parties would have agreed to an earlier entry date in the absence of a payment. Antitrust defendants argue that absent the payment, there may have been no agreement, and if the innovator had prevailed in the patent litigation, the generic would have been kept off the market until the patent expired.

The FTC argues, "These anticompetitive deals cost consumers and taxpayers $3.5 billion in higher drug costs every year," and in recent years, has sought hundreds of millions of dollars in **disgorgement**. Under **Supreme Court precedent**, such challenges are subject to rule of reason analysis, with courts considering the size of any payment and whether it is "large" and "unexplained."

To permit the government to better monitor reverse payment settlements, the MMA has required that parties to certain agreements notify the FTC and DOJ of such agreements. The FTC tracks the agreements for potential impact on competition and generates annual reports summarizing key statistics, including how many agreements have been filed and how many include a cash payment, payment of litigation fees, debt forgiveness, side deals between innovator and generic firms and restrictions on marketing an authorized generic.

Recently, concerns about reverse payment settlements have been raised in the relatively nascent biologics industry. Like the Hatch-Waxman Act, the 2010 Biologics Price Competition and Innovation Act created an abbreviated timeline and approval process for biosimilar drugs, along with a mechanism to challenge patents held by approved biologics manufacturers. The law was intended to speed biosimilar entry but arguably also creates economic incentives for payments to delay biosimilar entry.

In a recent speech, the head of the FDA argued that building a market for safe, effective biosimilars is key to promoting access, reducing healthcare costs and advancing public health, noting that while the FDA has approved 11 biosimilars, only three are now marketed. He argued that PBMs, GPOs and distributors are splitting monopoly profits through rebates and bundles rather than embracing biosimilar competition, and litigation is delaying market access.

Biologics have caught the attention of Republicans as well as Democrats on Capitol Hill. Senators Chuck Grassley (R-IA) and Amy Klobuchar (D-MN), for example, have urged the FTC to "look into whether strategies to hinder or delay generics from entering the market – such as anticompetitive 'pay for delay' settlement agreements that have plagued generic pharmaceutical markets for years – may be utilized for settlements regarding biologic medicines." They asked the FTC specifically to examine agreements relating to Humira, a biologic that treats inflammatory diseases and is the world's top selling prescription drug with annual sales of $16 billion.

The law is in partial response to those concerns. Indeed, in signing the law, President Trump said the legislation "will lower the cost of prescription drugs," which he called "way out of whack."

In addition to requiring notification of agreements to the DOJ and FTC, the new law prohibits health plans and other middlemen from prohibiting pharmacists from telling customers they would be better off paying out of pocket rather than using their insurance plan – hence the name, the Patient Right to Know Drug Prices Act.

New law expands reporting obligation to biologics

The FTC and DOJ reporting provisions expand the MMA to agreements between a brand name biologic and a biosimilar biologic applicant or between biosimilar biologic applicants for the same product. The act requires the filing of certain agreements where a biosimilar biologic product applicant "has submitted a biosimilar biological product application for which a statement under section 351(l)(3)(B)(ii)(I) of the Public Health Service Act has been provided."

The law requires that companies meeting those criteria file agreements regarding the following topics, which are functionally identical to the reporting requirements for pharmaceuticals:

- "the manufacture, marketing or sale of … the reference product in the biosimilar biological product application involved"
- "the manufacture, marketing or sale of the … the biosimilar biological product for which the biosimilar biological product application was submitted" or
- "the one-year period referred to in section 351(k)(6)(A) of the Public Health Service Act as it applies to such biosimilar biological product application or to any other biosimilar biological product application based on the same brand name drug"

On the other hand, the law does not require filing of agreements that relate solely to:

- Purchase orders for raw material supplies
- Equipment and facility contracts
- Employment or consulting contracts
- Packaging and labeling contracts

The FTC has interpreted the MMA's statutory language broadly. For example, in 2011, the FTC found that parties violated the statute when they failed to submit a notification after they filed a stipulation to dismiss Hatch-Waxman patent infringement litigation, even though the generic had converted from a Paragraph IV certification to Paragraph III. The FTC reasoned that, on their face, the agreements fell within the MMA as they were agreements "regarding" the manufacture, marketing or sale of the ANDA product, and thus, that a filing was required.

Failure to file under the MMA can result in substantial penalties, currently of up to $14,666 per day of violation. In 2009, Bristol-Myers Squibb agreed to pay $2.1 million for failing to inform the FTC of an oral commitment not to launch an authorized generic.

What is actually submitted?

Parties to an agreement meeting the above criteria must file a cover sheet and a copy of the agreement with the FTC and DOJ within 10 days of execution and before commercialization of the relevant biosimilar biologic. Parties may also submit supplementary materials to assist the FTC in evaluating the transaction.

While the MMA does not have an approval mechanism – and there is no waiting period similar to that under the HSR Act for mergers and acquisitions – the information is used by the FTC to assess whether to pursue enforcement actions.

Consultation with antitrust counsel, both in structuring settlement agreements and in submitting filings, is therefore advisable.

Key Contacts

Megan Browdie Washington, DC	mbrowdie@cooley.com +1 202 728 7104
David Burns Washington, DC	dburns@cooley.com +1 202 728 7147
Howard Morse Washington, DC	hmorse@cooley.com +1 202 842 7852
