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FTC and FDA Announce Plans to Combat Anticompetitive Practices in the "Biologic Marketplace"

February 2020

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On February 3, 2020, the Federal Trade Commission ("FTC") and the Food and Drug Administration ("FDA") issued a joint statement and plan seeking to advance biosimilar competition and combat deceptive and anticompetitive practices in the "biologic marketplace." As discussed below, the FTC and FDA are targeting a broad range of conduct, including alleged restrictions on access to biologic drug samples, false and misleading marketing practices, and certain patent litigation settlements between biologic and biosimilar drug manufacturers.

Background

A biologic drug is generally a pharmaceutical whose active ingredient is a large, complex molecule that is produced using biotechnology in a living system, such as a microorganism, plant cell, or animal cell.[1] "The nature of biological products, including the inherent variations that can result from the manufacturing process, can present challenges in characterizing and manufacturing these products that often do not exist in the development of small molecule drugs."[2] Unlike small molecule drugs, it is impossible to exactly copy a biologic medication. Thus, in contrast to a generic drug approved using the Abbreviated New Drug Application process under the Hatch-Waxman Act, a biosimilar drug is not identical to the reference product and subject to different approval standards.

In 2009, Congress passed the Biologics Price Competition and Innovation Act to provide an abbreviated FDA approval pathway for biosimilar versions of a biologic drug.[3] To receive FDA approval, the biosimilar manufacturer must demonstrate that its proposed biosimilar is "highly similar" to the reference biologic and has "no clinically meaningful differences from the reference product in terms of safety, purity, and potency

1 FDA, Biological Product Definitions at 1 (last viewed Feb. 7, 2020), https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf.

2 *Id.*

3 Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010).

(safety and effectiveness)."[4] An interchangeable biosimilar drug may be substituted for its corresponding reference biologic drug without the prescriber's involvement.[5]

To date, FDA has approved 26 biosimilars that range in indication from cancer to arthritis related treatments.[6] According to the FTC and FDA, biosimilars are "typically launched with initial list prices 15 to 35 percent lower than the list prices of the reference products," and are "essential for improving patient access to medicines and potentially reducing health care costs."[7]

Recent Initiatives to Increase Biosimilar Competition and Potential Antitrust Concerns

In the last few years, the FTC and FDA have increasingly focused on promoting biosimilar competition and reducing allegedly anticompetitive practices. For example, in July 2018, the FDA published a Biosimilars Action Plan that includes four key initiatives seeking to increase biosimilar competition.[8] One of those initiatives is to reduce "gaming of FDA requirements or other attempts to unfairly delay competition" by coordinating with the FTC and working with legislatures to close so-called loopholes.[9] The FTC and FDA have suggested that such anticompetitive conduct may include "anticompetitive reverse payment agreements, abusive repetitive regulatory filings, or misuse of restricted drug distribution programs."[10]

Additionally, effective October 10, 2018, Congress extended reporting requirements under the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA"), requiring that "agreements between brand and biosimilar drug manufacturers regarding the manufacture, marketing, and sale of biosimilar versions of reference drug products" be filed with the FTC and the DOJ, as well as certain agreements between biosimilar manufacturers for the same reference drug.[11] The FTC has used this reporting process to scrutinize patent litigation settlements for unlawful "reverse payments" and other potential anticompetitive terms.[12]

In September 2019, the FDA also published its final guidance for the industry addressing "certain types of citizen petitions intended to delay FDA action on a generic or other abbreviated application."[13] Under this guidance, the FDA intends to reallocate resources when the petition is "likely to obstruct entry of generic and biosimilar medications," and the "FDA will also refer to FTC and highlight in FDA's annual report to Congress its determinations of petitions submitted with the primary purpose of delaying an approval."[14]

Finally, private plaintiffs have also pursued antitrust suits against biologic manufacturers. In 2017, a biosimilar manufacturer filed a complaint alleging, for instance, that the defendants employed a "multifaceted scheme" to

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4 FDA, Biosimilar and Interchangeable Products (Oct. 23, 2017), https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products.

5 FDA, Biological Product Definitions at 2 (last viewed Feb. 7, 2020), https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf.

6 FDA, Biosimilar Product Information, FDA-Approved Biosimilar Products (Nov. 15, 2019), https://www.fda.gov/drugs/biosimilars/biosimilar-product-information.

7 Joint Statement of the Food & Drug Administration and the Federal Trade Commission Regarding a Collaboration to Advance Competition in the Biologic Marketplace at 2 (Feb. 3, 2020) ("Joint Statement"), https://www.ftc.gov/system/files/documents/public_statements/1565273/v190003fdaftcbiologicsstatement.pdf.

8 FDA, Biosimilars Action Plan: Balancing Innovation and Competition at 5-9 (July 2018), https://www.fda.gov/media/114574/download.

9 *Id.* at 5, 8.

10 Joint Statement at 3.

11 FTC, Pharmaceutical Agreement Filing Procedures Updated, Modernized with Electronic Filings and Updated for Agreements Related to Biologics (June 6, 2019), https://www.ftc.gov/news-events/press-releases/2019/06/pharmaceutical-agreement-filing-procedures-updated.

12 *See* Eric Grannon & Adam M. Acosta, FTC Publishes Annual MMA Report and Updated Filing Procedures (June 10, 2019), https://www.whitecase.com/publications/alert/ftc-publishes-annual-mma-report-and-updated-filing-procedures.

13 Joint Statement at 3 (citing FDA, Docket No. FDA-2009-D-008, Final Guidance for Industry: Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act (Sept. 2019), https://www.fda.gov/media/130878/download).

14 Joint Statement at 3.

thwart biosimilar competition for the biologic drug Remicade through imposing exclusionary contracts on certain health insurers and healthcare providers.[15] In a separate set of biosimilar suits filed in early 2019, class-action plaintiffs filed antitrust complaints concerning the biologic drug Humira, which is presently the bestselling prescription drug in the world with more than US$130 billion in estimated total sales. The complaint alleges that the biologic originator for Humira impaired biosimilar competition by employing a "patent thicket"—defined by plaintiffs as "an unlawful scheme whereby [the biologic manufacturer] secured over 100 patents designed solely to insulate Humira from any biosimilar competition"—and then entered into illegal market division agreements.[16] Both of these cases are still pending.

The FTC and FDA's February 2020 Joint Statement to Advance Biosimilar Competition

On February 3, 2020, the FTC and FDA announced in a joint statement their latest initiative to advance biosimilar competition. The statement explains that the agencies "are collaborating to support appropriate adoption of biosimilars, deter false or misleading statements about biosimilars, and deter anticompetitive behaviors in this industry."[17] The agencies announced four joint goals to further this mission. While the first goal focuses on collaboration related to public outreach and education efforts, the other three goals focus on combating allegedly deceptive and anticompetitive conduct in what the agencies refer to as the "Biologic Marketplace."[18]

A. Impeding Biosimilar Manufacturers From Accessing Samples of Biologic Drugs

The FTC and FDA plan to "collaborate to identify and deter tactics used to prevent or impede access to samples of the reference product that the prospective biosimilar applicant needs for testing to be licensed as a biosimilar or interchangeable biosimilar."[19] In particular, the FDA's Risk Evaluation and Mitigation Strategies ("REMS") program subjects certain medications with serious safety risks to additional safety requirements to help ensure the benefits of the medication outweigh its risks. In July 2018, the FTC called for legislative and regulatory action to combat the potential misuse of REMS, under which certain drug manufacturers allegedly have withheld drug samples.[20] The FDA has also released a list of "access inquiries" from generic drug manufacturers who were seeking to develop a generic version of a reference listed drug, but were unable to obtain samples due to programs like REMS.[21]

Furthermore, in a recent REMS antitrust case (although not one involving a biologic), a generic drug manufacturer sued a brand drug manufacturer for allegedly withholding samples of the cancer drugs Thalomid and Revlimid under the REMS program.[22] In October 2018, a US District Court granted summary judgment for the brand manufacturer in part as to some REMS-related conduct while permitting other REMS-related conduct to proceed to trial.[23] The case later settled in July 2019 for US$62 million.

B. False and Misleading Communications Concerning Biologics and Biosimilars

The FTC and FDA also "intend to take appropriate action against false or misleading communications about biologics, including biosimilars, within their respective authorities."[24] The agencies have expressed concerns

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15 Complaint, *Pfizer, Inc. v. Johnson & Johnson*, No. 2:17-cv-4180 (E.D. Pa. Sept. 20, 2017), ECF No. 1.

16 Complaint, *UFCW Local 1500 Welfare Fund v. AbbVie*, No. 1:19-cv-1873 (N.D. Ill. Mar. 8, 2019), ECF No. 1.

17 Joint Statement at 4.

18 *Id.* at 4-5.

19 *Id.* at 4.

20 FTC Press Release, FTC Submits Statement to HHS on Its Blueprint to Lower Drug Prices (July 17, 2018), www.ftc.gov/news-events/press-releases/2018/07/ftc-submits-statement-hhs-its-blueprint-lowerdrug-prices.

21 FDA, Reference Listed Drug (RLD) Access Inquiries (Sept. 24, 2019), https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/reference-listed-drug-rld-access-inquiries.

22 Complaint, *Mylan Pharms. Inc. v. Celgene Corp.*, No. 2:14-cv-02094 (D.N.J. Apr. 3, 2014), ECF No. 1.

23 Opinion, *Mylan Pharms. Inc. v. Celgene Corp.*, No. 2:14-cv-02094 (D.N.J. Oct. 3, 2018), ECF No. 287.

24 Joint Statement at 4.

about how false or misleading "comparisons of reference products and biosimilars may constitute unfair or deceptive practices that undermine confidence in biosimilars."[25]

The FTC intends to use the FTC Act to address unfair or deceptive acts or practices that are not subject to FDA jurisdiction.[26] The FTC defines "deceptive" practices as "involving a material representation, omission or practice that is likely to mislead a consumer acting reasonably in the circumstances."[27] And according to the FTC, an act or practice is "unfair" if it "causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition."[28]

The FDA, on the other hand, intends to use the Food, Drug, and Cosmetic Act to curb false or misleading communications about biologics and biosimilars, particularly those communications that "have the potential to impact public health."[29] Also in February 2020, the FDA issued a draft guidance on Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products. The draft guidance addresses how to present data and information concerning biologic and biosimilar products in promotional materials to help reduce inaccurate and misleading communications.[30] The FDA is accepting public comments on the draft guidance until April 6, 2020.

C. Patent Litigation Settlements Between Biologic and Biosimilar Manufacturers

Finally, the "FTC will review patent settlement agreements involving biologics, including biosimilars, for antitrust violations."[31] As discussed above, effective October 2018, Congress extended the MMA reporting requirements to certain patent litigation settlements between Biologic and Biosimilar companies, which the FTC continues to scrutinize.

The US Supreme Court's decision in *FTC v. Actavis, Inc.*, 570 US 136 (2013) opened a floodgate for more than 25 separate antitrust cases that have been filed or revived under the Supreme Court's rule of reason approach to reverse payment claims announced in that decision. Reverse payment claims generally allege that an innovator pharmaceutical company provided financial inducement to a potential generic or biosimilar competitor to settle patent litigation concerning the innovator's drug product, or to obtain a later settlement entry date than the generic or biosimilar company otherwise would have accepted, absent the innovator's financial inducement.

Actavis expressly delegated to the lower courts the task of figuring out how to apply the rule of reason to alleged reverse payment settlements, and in the years since, we have seen conflicting district court decisions, the first jury verdict, the first appellate decisions, and record-setting settlements.[32] As case law developments continue to evolve, the US Court of Appeals for the Fifth Circuit is the latest appellate court poised to rule on a pending appeal concerning the FTC's chief administrative law judge's recent bench-trial opinion finding that an alleged reverse payment for the drug Opana was not unlawful.

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25 *Id.* at 3.

26 *Id.* at 4-5.

27 FTC, A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority (Oct. 2019), https://www.ftc.gov/about-ftc/what-we-do/enforcement-authority.

28 *Id.* (citing 15 U.S.C. § 45(n)).

29 Joint Statement at 4-5.

30 FDA, Draft Guidance, Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products at 2 (Feb. 2020), https://www.fda.gov/media/134862/download.

31 Joint Statement at 5.

32 *See* Eric Grannon & Adam M. Acosta, et al., United States: Pharmaceutical Antitrust, Global Competition Review (2020), https://www.whitecase.com/sites/default/files/2019-09/gcr-united-states-pharmaceutical-antitrust-2020.pdf.

Conclusion

With biologics reportedly comprising one of the fastest growing segments of prescription medicine spending, with an estimated US$125.5 billion annually spent by public and private insurers, biologic and biosimilar competition will likely continue to face increasing scrutiny.[33] The FDA, in collaboration with the FTC, plans to hold a public workshop on many of these issues at the FDA's office in Silver Spring, Maryland on March 9, 2020.

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[33] *See* Joint Statement at 1.