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FTC and FDA intensify efforts to promote biologics competition

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On 9 March 2020 the Federal Trade Commission (FTC) and the U.S. Food and Drug Administration (FDA) (collectively the Agencies) held a public workshop to discuss competition issues concerning biologics.[1] The workshop, along with the Agencies' recent Joint Statement Regarding Collaboration to Advance Competition in the Biologic Marketplace, signals a new priority on efforts to promote competition between biologics and biosimilars. Below are some key takeaways from the workshop.

Background: biologics and biosimilars

Biologics are protein-based therapeutic drugs derived from living matter or produced in a living system using biotechnology. In contrast to the chemically-synthesized small molecules used in most drugs, the therapeutic proteins that form the basis of biologics are larger and more complex. Biologics are playing an increasing role in the treatment of many serious illnesses, including rare genetic disorders, autoimmune diseases, and cancer, and make up the fastest growing segment of prescription medicine spending in the United States.[2] They are also one of the most expensive, with annual treatment costs often running in the tens of thousands of dollars.

In an effort to encourage and facilitate the development of biosimilars that compete with biologics, in 2009 Congress enacted the Biologics Price Competition and Innovation Act, which created "an abbreviated pathway for biological products demonstrated to be biosimilar or interchangeable with an FDA-licensed reference product" – analogous to the Hatch-Waxman Act for generic drugs. The FDA approved the first biosimilar in the United States in 2015, and as of today, there are 26 FDA-approved biosimilars, 15 of which are currently being marketed. Biosimilars are generally priced 15 to 35 percent lower than reference biologics.[3]

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[1] U.S. Food and Drug Administration, Public Workshop: FDA/FTC Workshop on a Competitive Marketplace for Biosimilars (9 March 2020) available at https://www.fda.gov/drugs/news-events-human-drugs/public-workshop-fdaftc-workshop-competitive-marketplace-biosimilars-03092020-03092020.

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

[3] *Id.*

Scrutiny on marketing and potentially anti-competitive conduct is likely to increase

Although there has been little antitrust enforcement to date in the biologics area, antitrust scrutiny is likely to increase. The FTC has been focused on the importance of competition from biosimilars for some time, including issuing a report on the topic in 2009 drawing on the agency's extensive experience in the area of generic competition.[4] At the workshop, representatives from the FDA and FTC stressed they intend to work closely together to enhance competition from biosimilars. They identified joint efforts in two key areas. First, the Agencies are taking steps to police companies' efforts to inhibit the development and approval of biosimilars. This includes, for example, vigilance with respect to restrictions on biosimilar companies' access to samples, patent abuse, which could include unlawful use of so-called "patent thickets,"[5] and abuse of the citizen petition process. It also includes scrutiny on reverse payment patent settlements involving biologics. Under the Patient Right to Know Drug Prices Act, the FTC and Department of Justice (DOJ) obtain patent settlement agreements between reference biologic products and biosimilar manufacturers. The FTC is well-positioned to bring enforcement actions against anticompetitive biologic-biosimilar agreements as a result of its significant experience with brand-generic pharmaceutical patent settlements.

Second, the Agencies are paying close attention to practices that may increase barriers to the effective marketing of biosimilar products. Both Agencies emphasized their efforts to ensure that healthcare professionals receive truthful, non-misleading information about biologics and biosimilars, as robust competition in the marketplace depends on consumers and prescribers receiving reliable and truthful representations. Misleading statements could include: (1) advertising that creates an impression of clinically meaningful differences between biologics and biosimilars, and (2) advertising that states or suggests biosimilars are of a lower quality than biologics. FDA representatives explained that both of these types of assertions would be likely to mislead because biosimilars cannot be marketed unless there are no material differences between the biosimilar and the reference biologic, and the regulatory pathway for approval of a biosimilar is as rigorous as that for biologics. Other barriers to competition could include exclusionary contracting practices, rebate traps,[6] or formulary or reimbursement restrictions.

The Agencies will use all their tools to promote competition

The FTC can bring claims against misleading or deceptive statements through its Bureau of Consumer Protection by enforcing FTC Act § 5's prohibition of unfair and deceptive acts or practices and § 12's prohibition on false advertisement of food, drugs and services, or through the Bureau of Competition by enforcing § 5's prohibition of unfair methods of competition.

The FDA monitors advertisements and promotional labeling for prescription drugs and works to ensure that prescription drug information is truthful, balanced, and accurately communicated. The FDA's Office of Prescription Drug Promotion works with the DOJ to enforce compliance with FDA regulations. In addition, in February 2020, the FDA issued Draft Guidance: Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar

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[4] Federal Trade Commission, Emerging Health Care Issues: Follow-on Biologic Drug Competition (June 2009) available at https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf.

[5] At least one private case has challenged the accumulation and assertion of numerous patents as an unlawful "patent thicket" strategy designed to prevent the entry of biosimilars. *See UFCW Local 1500 Welfare Fund v. Abbvie, Inc. et al*, C.A. No. 1:19-cv-01873 (N.D. Ill). Plaintiffs' allegations are subject to a pending motion to dismiss.

[6] A "rebate trap" is the practice of established brands offering volume-based rebates to insurers or pharmacy benefit managers to incentivize them to provide coverage for brand-name drugs. This can result in insurers declining to provide coverage – or requiring a larger copay – for generic or biosimilar alternatives.

Products[7] covering promotional issues involving both reference products and biosimilars. The guidance states that advertising and promotional labeling must be truthful and non-misleading, and convey information about a drug's efficacy and risks in a balanced manner. The FDA is currently soliciting comments on the draft guidance.

Looking ahead

With the Agencies having clearly stated their commitment to use their resources to promote robust and fair competition in the biologics market, we are likely to see greater scrutiny in this area in the near future. Industry participants with questions or concerns about complying with FTC and FDA regulations related to biologics development, marketing and sales should consider contacting experienced outside counsel.

[7] U.S. Food and Drug Administration, Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products Questions and Answers Guidance for Industry (February 2020), available at https://www.fda.gov/media/134862/download.

Contacts

Edith Ramirez
Partner, Washington, D.C., Los Angeles
T +1 202 637 5509 (Washington, D.C.)
T +1 310 785 4600 (Los Angeles)
edith.ramirez@hoganlovells.com

Chuck Loughlin
Partner, Washington, D.C.
T +1 202 637 5661
chuck.loughlin@hoganlovells.com