Antitrust Byte: FDA and FTC Join Forces to Promote Biosimilars

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- Intellectual Property
- All Federal

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The U.S. Food and Drug Administration (“FDA”) and the Federal Trade Commission (“FTC”) (collectively, the “Agencies”) have a long history of teaming up to ensure that advertising and other promotional communications for products subject to FDA oversight and FTC enforcement are truthful and non-misleading. According to the Agencies, “Truthful and non-misleading advertising and promotional communications help foster a competitive market by allowing purchasers to compare products, prices, and benefits.”

The most recent collaboration between the FDA and FTC focuses on the advancement of competition in the biologic marketplace. In their joint statement issued February 3, 2020, the Agencies noted that biosimilars (much like their generic counterparts) are generally priced 15 to 35 percent lower than the biologic reference product. However, according to the Agencies, the introduction and promotion of biosimilars has been hampered by efforts to “game” the system through, among other things, false and misleading advertising and other efforts to delay competition. As a result, in an effort to support appropriate adoption of biosimilars,
deter false and/or misleading statements about biosimilars, and deter anticompetitive behaviors in the industry, the FDA and the FTC are teaming up to:

1. coordinate future public outreach, including sponsoring public meetings to discuss competition for biologics;

2. identify and deter tactics used to prevent or impede access to samples of the reference product needed for testing to be licensed as a biosimilar or interchangeable biosimilar;

3. address false or misleading comparisons between reference products and a biosimilar; and

4. review patent agreements (already under the FTC’s authority pursuant to the Patient’s Right to Know Drug Prices Act) that might include reverse payments that slow or defeat the introduction of lower-priced medicines, including biosimilars.

Enforcing truth in advertising and promotional communications is to be applauded. However, whether the Agencies have sufficiently identified the root cause behind the slow adoption of biosimilars, and whether this collaborative effort will successfully address that cause, is unclear.

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