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President Biden's Executive Order on Competition Signals Potential Changes Affecting Patents in the Healthcare Sector

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On July 9, 2021, President Biden issued "Executive Order on Promoting Competition in the American Economy" (the "Executive Order"). The Executive Order was billed by the White House as "historic" and comparable to Teddy Roosevelt's trust-busting and Franklin Roosevelt's "supercharged antitrust enforcement". Asserting that a "fair, open, and competitive marketplace has long been the cornerstone of the American economy," the Executive Order sets forth 72 initiatives across over a dozen federal agencies.

Notably, a number of these initiatives focus on the healthcare sector, among them, a direction to the Secretary of Health and Human Services to:

1. "**lower the prices of and improve access to prescription drugs and biologics, [and] continue to promote generic drug and biosimilar competition**," including by: (a) clarifying the approval framework for generic drugs and biosimilars, and the standards for interchangeability of biological products; (b) "supporting biosimilar product adoption;" (c) facilitating "the development and approval of biosimilar and interchangeable products;" and (d) "identifying and addressing any efforts to impede generic drug and biosimilar competition, including but not limited to false, misleading, or otherwise deceptive statements about generic drug and biosimilar products and their safety or effectiveness;"
2. "**ensure that the patent system, while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition**," and, by August 23, 2021, "write a letter to the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office enumerating and describing any relevant concerns;" and
3. "**support the market entry of lower-cost generic drugs and biosimilars**."

As part of the effort to address competition matters in the healthcare space, the Executive Order also "encourage[s]" the Attorney General and the Secretary of Commerce to "consider whether to revise their position on the intersection of the intellectual property and antitrust laws." It further instructs the Federal Trade Commission to exercise its statutory rulemaking authority with respect to "anticompetitive conduct or agreements in the prescription drug industries, such as agreements to delay the market entry of generic drugs or biosimilars."

Although the Executive Order is potentially significant, its impact will depend on the extent and timing of concrete actions that the affected agencies ultimately take. Indeed, by its own terms, the Executive Order does not "create any right or benefit, substantive or procedural, enforceable at law or in equity." With respect to the patent system, more will be known once the Secretary of Health and Human Services releases his letter to the Under Secretary of Commerce for Intellectual Property and Director of the USPTO on or before August 23, 2021. Industry stakeholders should monitor this space for updates, including opportunities to provide public comments on any proposed rules and regulations.

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