Biden's executive order targets pay-for-delay

Many aspects of IP including drug pricing, patent ownership and FRAND addressed in executive order

US President Joseph Biden is calling on leading US antitrust agency the Federal Trade Commission to ban pay-for-delay agreements between pharmaceutical companies.

The call is part of an expansive executive order issued on 9 July to increase competitiveness in the US economy.

In the White House fact sheet about the order, it says that US citizens pay more than 2.5 times as much for the same prescription drugs as peer countries and sometimes much more.

Price increase continues to surpass inflation and the White House says that these high prices are the result in part because of a lack of competition between among drug manufacturers.

It adds that pay-for-delay agreements, in which brand-name drug manufacturers pay generic manufacturers to stay out of the market, has raised drug prices by $3.5bn per year, and research also shows that pay for delay and similar deals between generic and brand name manufacturers reduce innovation – reducing new drug trials and R&D expenditures.

In the order, the president:

- Encourages the FTC to ban "pay-for-delay" and similar agreements by rule.
- Directs the Health and Human Services Administration (HHS) to increase support for generic and biosimilar drugs, which provide low-cost options for patients.
- Directs HHS to issue a comprehensive plan within 45 days to combat high prescription drug prices and price gouging.
- Directs the Food and Drug Administration to work with states and tribes to safely import prescription drugs from Canada, pursuant to the Medicare Modernization Act of 2003.

Other IP

The order includes 72 initiatives by more than a dozen federal agencies to tackle some of the most pressing competition problems across the US economy. It has sections covering not just healthcare but the labour market, transportation, internet, technology, agriculture and banking and consumer finance.

The order impacts many aspects of IP: in relation to the agrisector, it calls on the director of the US Patent and Trademark Office to submit a report to the chair of the White House Competition Council, on how to tackle reduced competition in seed and other input markets.

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Fair, reasonable and non-discriminatory (FRAND) licensing is also discussed, with the Attorney General and the Secretary of Commerce "encouraged" to revise their position on the intersection of IP and antitrust laws. They are asked to consider whether to "revise the Policy Statement on Remedies for Standards-Essential Patents Subject to Voluntary F/RAND Commitments issued jointly by the Department of Justice, the United States Patent and Trademark Office."

The Secretary of Commerce, acting through the Director of the National Institute of Standards and Technology, is also asked to consider not finalising any provisions on march-in rights and product pricing in the proposed rule "Rights to Federally Funded Inventions and Licensing of Government Owned Inventions."

Principal in McKool Smith Nick Matich said, "Many products in the pharmaceutical industry are covered by patents that were developed with government funds, so the executive order's provision calling on the Department of Commerce not to finalise the currently proposed Bayh-Dole regulations could have a significant impact in the bio-pharma space. HHS Secretary Becerra has previously indicated his desire to exercise march-in-rights on these patents to compel companies lower drug prices.

"It's at least an open legal question whether the government can do that, with or without the proposed regulations, and it will be interesting to see how the industry responds to that part of the order. I would expect to see at least some companies mount challenges to any attempt to use the march-in-rights in that way."

Maura O'Malley is editor at *IPM*.