Executive Order on Promoting Competition in the American Economy: A Focus on Patent and Drug Law to Reduce Health Care Spending

Each year, Americans spend more than $1,500 per person on prescription drugs. Critics calling for measures to lower prescription drug costs often cast blame on alleged abuses of patent and competition laws. To address these perceived abuses, President Biden issued an “Executive Order on Promoting Competition in the American Economy” focused on increasing competition in several industries, including the pharmaceutical and biotechnology industries. In response, executive agencies and members of Congress have recently issued reports and letters addressing the concerns and directives presented in President Biden’s executive order.

This Jones Day White Paper outlines: (i) President Biden’s executive order and documents issued in response; (ii) proposed changes to the U.S. patent and drug regulatory regimes; and (iii) potential effects of those proposals on the pharmaceutical and biotechnology industries.
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As part of an overall strategy to reduce health care spending, the Biden administration continues past proposed regulatory reform that is focused on increasing the availability of generic drugs and biosimilars. Pharmaceutical and biotechnology innovators likely will face increased scrutiny of their research and development, patenting, litigation settlement, and pricing practices, as well as streamlined regulatory processes for the approval of competing generic and biosimilar products. This administration also has signaled its focus on driving significant statutory and regulatory changes impacting the pharmaceutical industry.

EXECUTIVE ORDER ON PROMOTING COMPETITION IN THE AMERICAN ECONOMY

On July 9, 2021, President Biden issued an “Executive Order on Promoting Competition in the American Economy” (“Competition EO”). The Competition EO set forth a statement of the Biden administration’s policy goals, established a White House Competition Council, and directed executive agencies to adopt rules, issue reports, and consider other actions to redress perceived deficiencies in competition across the economy.

The Competition EO emphasized that the Biden administration aims to “enforce the antitrust laws to combat the excessive concentration of industry, the abuses of market power, and the harmful effects of monopoly and monopsony.”

A significant portion of the Competition EO targeted the pharmaceutical/biotech and health care sectors, including directing:

- The Federal Trade Commission (“FTC”) to consider rule-making related to “unfair anticompetitive conduct or agreements in prescription drug industries, such as agreements to delay the market entry of generic drugs or biosimilars” (also known as “reverse-payment settlements” or “pay-for-delay” agreements).

- The Department of Health and Human Services (“HHS”) to “clarify and improve the approval framework for generic drugs and biosimilars” and to support “biosimilar product adoption by providing effective educational materials and communications to improve understanding.”

- The Administrator of the Centers for Medicare & Medicaid Services (“CMS”) to “prepare for Medicare and Medicaid coverage of interchangeable biological products.”

- The Commissioner of FDA to “work with States and Indian Tribes that propose to develop section 804 Importation Programs” to permit those entities to import eligible prescription drugs from Canada.

- The Director of the National Institute of Standards and Technology (“NIST”) to “consider not finalizing any provisions on march-in rights and product pricing” in rules proposed in January 2021 (which included language that “[m]arch-in rights shall not be exercised exclusively based on the business decisions of the contractor regarding the pricing of commercial goods and services arising from the practical application of the invention”).

The Competition EO also ordered FDA to write a letter to the Patent and Trademark Office (“PTO”) describing any FDA concerns about the patent system “unjustifiably” delaying generic and biosimilar competition “beyond that reasonably contemplated by applicable law.” Similarly, the Competition EO ordered HHS to submit a report “with a plan to continue the effort to combat excessive pricing of prescription drugs and enhance domestic pharmaceutical supply chains, to reduce prices paid by the Federal Government for such drugs, and to address the recurrent problem of price gouging.”

As discussed below, since the issuance of the Competition EO, FDA and HHS have issued the requested documents, and members of Congress separately have sent letters to the PTO setting forth their own views.

LETTERS TO THE PTO

On September 10, 2021, the Acting Commissioner of Food and Drugs, Janet Woodcock, M.D., issued the ordered letter (“FDA letter”) on behalf of FDA, to Mr. Andrew Hirshfeld, who is currently performing the functions and duties of the Under
The FDA letter enumerated several "areas of concern" related to uses of the patent system that allegedly "inappropriately impede competition from generic, biosimilar and interchangeable biological products":

1. **Patent Thickets.** FDA identified "the practice of filing 'continuation' patent applications" as allowing companies to create "patent thickets" (referring to multiple patents covering the same product) that potentially increase litigation burdens and delay the approval of generics and biosimilar products.

2. **Evergreening.** FDA conveyed concerns about patent "evergreening," described as "the practice of patenting 'post-approval' or 'secondary' changes to previously approved drug products such as new formulations of the same drug, new delivery systems, or patents claiming various additional methods of use," with the alleged purpose of extending the period of exclusivity.

3. **Product-hopping.** Finally, FDA described the practice of switching the market to a modified drug product, covered by additional patents (referred to as "product-hopping"), as having the "effect of forestalling competition notwithstanding the fact that the prior product (for which generic, biosimilar, or interchangeable competition has become available) remains safe and effective."

To address these concerns, FDA offered the following ideas to the PTO for consideration:

- **Engagement Between FDA and PTO.** FDA proposed increased engagement between the two agencies by offering training to examiners on FDA's public information and databases and "provid[ing] information on the scope and nature of FDA approvals to support PTO's ability to accurately and fairly grant patent extensions, and to grant them only in instances where such extensions are appropriate."

- **Possible Misuse of the Patent System.** FDA requested the PTO's perspective on practices that allegedly misuse the patent system ("such as brand use of the patent continuation process to create patent thickets, product hopping, and evergreening") and whether the PTO "is considering means of limiting such practices."

- **Adequate Time and Resources for PTO Examiners.** FDA questioned whether PTO examiners have adequate time and resources to strike "the right balance of rewarding innovation and facilitating competition" in assessing patentability.

- **The Patent Trial and Appeal Board (‘PTAB’).** FDA requested data on the impact of post-grant review (‘PGR’) and inter partes review (‘IPR’) proceedings on Orange-Book listed patents and patents covering biological products.

- **Information Exchange.** FDA requested thoughts from the PTO on areas of information/experience that may be exchanged between the two agencies to "enhance our respective efforts to address the need for an appropriate balance between innovation and patient access to medicines."

Separately, Senators Leahy and Tillis, Chairman and Ranking Member of the U.S. Senate Judiciary Subcommittee on Intellectual Property, in a letter addressed to Mr. Hirshfeld, express support for creation of a regular channel of information between the PTO and other federal agencies. Their concern is that "some patent applicants may, in certain circumstances, make significantly different statements in submissions to other federal agencies." For example, "inconsistent statements submitted to the Food and Drug Administration … to secure approval of a product—asserting that the product is the same as a prior product that is already on the market—can then be directly contradicted by statements made to the PTO to secure a patent on the product." The senators believe this lack of inter-agency coordination "dilute[s] patent quality and stifle[s] competition" and could be cured by requiring patentees to disclose to the PTO statements made to other agencies and by establishing a "smooth, predictable, and regular channel of information" from other agencies to the PTO to ferret out any contradictory statements.

On September 16, 2021, 11 members of Congress, in a letter addressed to Mr. Hirshfeld, also expressed concern that the patent system, while incentivizing innovation, has "allowed drug companies to engage in anti-competitive practices that drive up the cost of drugs and keep competitors from entering
the market.” This letter focused on discretionary denials of
copyrights for IPR, claiming the “disturbing” rise in this prac-
tice since the Apple v. Fintiv decision “robs generic drug and
biosimilar companies of a key venue to challenge the validity
of brand manufacturer patents.” This letter described IPRs as
“one of the few tools available that can help address the root
cause of high prescription drug prices” and further claimed
that, “[w]ithout a sufficiently strong IPR system to serve as a
check against questionable patents, brand manufacturers will
continue to wield patent thickets that are nearly impossible to
challenge and engage in product hopping, further burdening
the American people with needlessly high drug prices.”

COMPREHENSIVE PLAN FOR ADDRESSING HIGH
DRUG PRICES

Pursuant to the Competition EO, HHS Secretary Xavier Becerra
and other HHS officials prepared a report to the White
House Competition Council titled “Comprehensive Plan for
Addressing High Drug Prices” (“HHS report”). Similar to the PTO
letters, the HHS report expressed a number of concerns about
the effect of the patent system, settlement of patent litigations,
and FDA regulatory approval processes on prescription drug
prices and access. Secretary Becerra also expressed con-
cern about rising drug prices and high out-of-pocket costs
for beneficiaries.

Guiding Principles
In discussing the “guiding principles” of the Biden administra-
tion’s drug pricing plan, the HHS report heavily focused on
increasing the availability of biosimilar and generic drugs and
making drug prices more affordable and equitable. Stated
goals included reducing regulatory barriers to approval of
generics and biosimilars, streamlining the licensure process
for biologics, and promoting the use of approved biosimilars
and generics. In particular, the report recommended stream-
lining the approval of generic versions of “complex drugs.” The
HHS report also directed FDA to work with the Chair of the FTC
to “reduce gaming by brand manufacturers” by “identify[ing]
and address[ing] any efforts to impede generic drug and bio-
similar competition, including but not limited to false, mislead-
ing, or otherwise deceptive statements about the safety or
effectiveness of generic drug or biosimilar products.”

Like FDA Acting Commissioner Woodcock’s letter to the
PTO discussed above, the HHS report singled out the patent
system for increasing drug costs, pointing to alleged “pat-
ent thickets,” “evergreening,” and “pay-for-delay” agreements
as sources of anticompetitive effects. The administration will
target companies that allegedly “invest in product develop-
ment aimed at extending the monopolies of already-approved
products” rather than investing in “innovation that will have the
largest impact on health” through drug-pricing reform that will
purportedly “better align[] incentives for companies to focus
on innovations with the greatest health impact.”

In line with its guiding principles, the HHS report set out a
series of proposed legislative and administrative actions. The
proposals outlined a number of areas for potential future
action but did not identify any specific pending legislative
measures or articulate contemplated statutory or regulatory
provisions. However, HHS is expected soon to release a notice
requesting information to inform the development of rulemak-
ing that would implement prescription drug reporting require-
ments by group health plans and health insurance companies
offering group and individual health plans.

Legislative Proposals
The HHS report’s legislative proposals are multifaceted and
include actions to promote the prompt approval of generics,
provide federal support for drug development by nonprofit
generic drug manufacturers, reassess the optimal period of
exclusivity for biological products, clarify regulatory standards,
and stem rising drug prices:

• Prohibiting Reverse Payment Settlements (“Pay-for-Delay”
Agreements). The administration envisions “bipartisan
approvals that would designate as ‘anti-competitive’ any
agreements between branded and generic drug manufac-
turers in which Abbreviated New Drug Application (ANDA)
holders commit to forgo research and development activi-
ties, manufacturing, marketing, or sales in exchange for
economic compensation.”

• Introducing Conditions on the First-to-File ANDA
Exclusivity Period. For example, to limit the ability to
“park” generic exclusivity by settling ANDA litigation, HHS
proposes legislation “specifying that exclusivity does not
block approval of subsequent applications until a first
applicant begins commercial marketing of the drug, or
expanding the circumstances in which the 180-day exclu-
sivity period may be forfeited by first applicants who fail to
market their products within specified timeframes.”
• Eliminating Certain Regulatory Requirements. The administration envisions approaches that would speed the approval of biosimilars, such as exempting biological products from the U.S. Pharmacopeia, or USP, monograph standards and providing greater flexibility in including data from animal studies. Theoretically, this will increase the speed and flexibility of the biosimilar/generic product review process.

• Requiring Disclosure of Inactive Ingredients. The HHS report proposes amending rules to require branded drug manufacturers to disclose full information about their products’ inactive ingredients in the product label. FDA could then provide generic drug sponsors with the names and amounts of the inactive ingredients in a reference listed drug to facilitate approval of the generic drug product.

• Citizen Petitions and REMS. HHS suggests curtailing the practice of submitting allegedly “sham” citizen petitions or purportedly exploiting “Risk Evaluation and Mitigation Strategy” (“REMS”) in an alleged attempt to slow FDA approval of generics.

• Price Negotiations for Medicare Part B and D. The report recommends adopting legislation that would allow HHS to negotiate prices with brand manufacturers for Medicare. The administration envisions that this benefit could extend to private insurer coverage.

• Redesigning Medicare Part D. The report proposes that there be an out-of-pocket cap for beneficiaries and a decrease in Medicare liability in the catastrophic phase of coverage, while increasing manufacturer and insurer Medicare liability.

• Excise Tax. HHS suggests imposing an excise tax when branded drug manufacturers raise the price of their products faster than the rate of inflation.

Administrative Proposals
In addition to the above legislative proposals, the HHS report provided recommendations for administrative actions to promote competition and reduce drug prices, and identified related efforts already in progress or recently completed:
• CMS will consider value-based payment models for prescription drugs and biologics.

• CMS will use information collected to “improve transparency in the prescription drug industry, including a better understanding of which drugs are driving the increase in U.S. prescription drug spending, the impact of prescription drug rebates, trends in prescription drug utilization, and the impact of prescription drug rebates on premiums and out-of-pocket costs.”

**ON THE HORIZON**

All of the foregoing echoes legislative reform efforts and initiatives of other administrations, but also signals that the Biden administration may be willing to advance aggressive executive, legislative, and regulatory action related to drug pricing. Although the tenor of the Competition EO in this regard is clear, it remains to be seen how significant or effective these actions will be in practice or whether such reform measures will focus exclusively on patenting reforms or a combination of regulatory exclusivity, government-directed pricing, and IP-limitation reform measures.

Some of the proposals, while theoretically possible, are predicated on past reform proposals in one form or another that have been rejected, or would potentially lead to significant and undesirable knock-on effects. For example, in 2007, the PTO attempted to limit the number of continuing applications that an applicant could pursue but rescinded the rule after the Federal Circuit determined the PTO had exceeded its rule-making authority. Curtailing the ability of the PTAB to decline to decide cases already pending before a district court judge or the ITC also has the potential to increase litigation costs and complexity. Similarly, prohibiting any form of economic compensation in settlement of Hatch-Waxman litigation could also serve as a major deterrent to settlement of litigations that often permit generics to enter the market before expiration of the patents. Involving FDA in the otherwise *ex parte* prosecution of pharmaceutical and biotech patents would subject those patents to a unique level of scrutiny not seen in other industries and not provided for by statute, and could effectively heighten patentability requirements in a manner that discourages innovation and disclosure. Finally, reducing regulatory requirements for generic drugs, particularly “complex” drugs, increases risks to consumers that some have argued are already too high. It is therefore difficult to predict how these and other proposed measures may ultimately be implemented.

Nevertheless, it is clear the administration intends to use antitrust enforcement as a mechanism to address its perceived and alleged flaws and abuses in the current pharmaceutical patent regime or by pharmaceutical patentees. As such, patentees may anticipate increased scrutiny of settlement agreements with generics and biosimilars and increased review of other practices related to potential generic or biosimilar entrants to the market. In addition, the Competition EO called on the FTC to consider rulemaking related to alleged “agreements to delay market entry of generic drugs or biosimilars,” which, if implemented, could likewise have significant impacts on such settlement agreements.

Finally, although not a direct outcome of the Competition EO or associated administrative actions, any of the suggested statutory changes to the Hatch-Waxman generic exclusivity and forfeiture provisions would have a significant impact on both innovator and generic product development, litigation, and settlement strategies. The Hatch-Waxman Act has been touted as a delicate balancing of the interests of many stakeholders in the U.S. prescription drug market, and these suggested changes would tilt that balance in favor of earlier entry of generic drugs.
Miguel A. Alvarez, an associate in the San Diego Office, assisted in the preparation of this White Paper.

ENDNOTES


2 See Belcher Pharm., LLC v. Hospira, Inc., 2020-1799, 2021 WL 3889810, at *1 (Fed. Cir. Sept. 1, 2021) (holding that a patent was invalid after Belcher withheld material prior art during prosecution when it told the PTO that a certain aspect of its invention was novel, while telling FDA it was known).


4 See GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 7 F.4th 1320, 1326 (Fed. Cir. 2021) (finding, despite the use of a “skinny label,” Teva’s marketing and advertising of the generic drug were sufficient to establish inducement and “substantial evidence supports a jury finding that the patented use was on the generic label at all relevant times and that, therefore, Teva failed to carve out all patented indications.”).

5 See Tafas v. Doll, 559 F.3d 1345 (Fed. Cir. 2009).