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WHITE PAPER

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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.[1] 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 rulemaking 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") and FTC to identify and address "false, misleading, or otherwise deceptive statements about generic drug or biosimilar products and their safety or effectiveness" and to "promptly issu[e] Covered Product Authorizations" to allow generic and biosimilar developers to obtain brand samples for drugs subject to Risk Evaluation and Mitigation Strategies with elements to ensure safe use.

- 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

Secretary of Commerce for Intellectual Property and Director of the PTO.

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."[2] 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 petitions for IPR, claiming the "disturbing" rise in this practice since the *Apple v. Fintiv*[3] 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 concern about rising drug prices and high out-of-pocket costs for beneficiaries.

Guiding Principles

In discussing the "guiding principles" of the Biden administration'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 streamlining 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 biosimilar competition, including but not limited to false, misleading, 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 "patent thickets," "evergreening," and "pay-for-delay" agreements as sources of anticompetitive effects. The administration will target companies that allegedly "invest in product development 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 rulemaking that would implement prescription drug reporting requirements 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 manufacturers in which Abbreviated New Drug Application (ANDA) holders commit to forgo research and development activities, 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 exclusivity 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:

- FDA finalized guidance documents to modernize biological product regulations drafted before the passage of the Biologics Price Competition and Innovation Act of 2009.

- FDA issued draft guidance regarding approval of interchangeable biosimilar products without requiring a clinical immunogenicity study. Pharmacists may prescribe these interchangeables, rather than the reference product, without consulting the prescriber ("pharmacy-level substitution").

- FDA will customize regulatory requirements to fit difficult-to-develop complex generic drug products with "forthcoming product-specific guidance."

- HHS is committed to protecting labeling "carve-outs," which HHS views as a critical practice that merits protection from questions raised in recent patent infringement litigation.[4]

- FDA is developing guidance on covered product authorizations, a mechanism created by the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 to enable generic drug developers to "obtain timely access to the samples of certain brand products."

- Pursuant to the Competition EO and section 804 of the federal Food, Drug, and Cosmetic Act, FDA is inviting states and Indian Tribes to develop prescription drug importation programs, allowing importation of certain prescription drugs from Canada.

- Pursuant to the Bayh-Dole Act, the HHS, National Institutes of Health, and other agencies will continue to give due consideration to petitions for licenses to use intellectual property arising from government funding without permission of the rights-holder.

- HHS will support the FTC in combatting "patent settlements [that] increasingly favor non-cash business transactions that continue to serve as pay-for-delay agreements."

- FDA is working to enhance the patent information listed in the Orange Book and "has issued guidance on Orange Book processes, held related public educational events, and sought public comment on future changes."

- 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 rulemaking authority.[5] 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.

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ENDNOTES

1 *See* U.S. Dep't of Health and Hum. Servs., Off. of the Assistant Sec'y for Plan. and Evaluation, "A Report in Response to the Executive Order on Competition in the American Economy" 2 (2021).

2 *See Belcher Pharms., 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).

3 IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020, designated as precedential May 5, 2020).

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).