A New Wave of Agency Challenges to Pharmaceutical Patent Holders: A Survey of Novel and Reinvigorated Tools

Elyssa Lacson Wenzel, Megan Hackett, and Will Lavery

Introduction

Do patents promote or hinder innovation? This question highlights the existing tension between antitrust and patent law, particularly in the pharmaceutical sector. Patents can do both—on one hand, they can incentivize financial investment in innovation by enabling investors to recoup those investments and prevent free riding. On the other hand, patent holders have an obvious incentive to protect their investments in valuable assets, which has led the agencies to challenge alleged patent misuse in multiple ways.

To address this tension, the U.S. antitrust agencies are dusting off traditional tools and rolling out novel actions against alleged patent activity that, at least according to them, may have anti-competitive effects in the pharmaceutical industry. For example, the Federal Trade Commission ("FTC") has pursued recent actions targeting so-called "patent thickets," Orange Book[1] listings, and has taken other actions intended to target alleged patent misuse. However, many practitioners and other industry experts remain skeptical about whether these agency interventions will effectively address the complexities of patent law without stifling legitimate innovation.

Despite the many avenues currently available to challenge patents, the FTC contends that the current process is "slow and inefficient, discouraging entry by rivals or generics confronted with large thickets, or chilling investment in those areas."[2] Consequently, the federal antitrust agencies (particularly the FTC) are stepping in and increasingly using what they say are more efficient and resource-saving means to invalidate patents.[3] This marks a particularly significant antitrust era as the FTC has publicly ramped up its use of Section 5 of the FTC Act, leveraging its broad authority to prosecute unfair methods of competition. The Department of Justice ("DOJ") has likewise increased its efforts. However, some critics argue that the agencies' measures might inadvertently create new obstacles for genuine innovators and life-saving drugs. This article examines the U.S. regulatory framework and surveys the new and revitalized tools utilized by the FTC and the DOJ to address alleged patent misuse in the pharmaceutical sector.

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[1] The Orange Book is a list of drugs and pharmaceuticals that the FDA has approved as both safe and effective.

[2] Comment, Fed. Trade Comm'n, Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights at 16 (Feb. 6, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/2024.02.06March-InRightsComment.pdf.

[3] Report, Fed. Trade Comm'n, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy at 6 (Oct. 2023), https://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf.

Historical Background

Executive Order 14036. President Biden's sweeping Executive Order 14036 issued on July 9, 2021 (Executive Order),[4] along with his leadership appointments at the antitrust agencies, ushered in a period of increasingly aggressive antitrust enforcement in the United States. The Executive Order called for a whole-of-government approach to enhance competition across multiple industries, including health care and pharmaceuticals. It encouraged federal agencies to think creatively and reassess existing practices that may have hindered rather than promoted competition.

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On the pharmaceutical front, President Biden called on several federal agencies to address patent matters specifically. The Executive Order attributed the high cost of prescription drugs in the United States to the misuse of patents that inhibit or delay entry of generics and biosimilars. One directive to the Commerce Department's National Institute of Standards and Technology (NIST) asked the agency to "consider not finalizing any provisions on march-in rights[5] and product pricing in the proposed rule."[6] Additionally, the Executive Order directed the Secretary of Health and Human Services (HHS) to ensure that the existing patent system incentivizes innovation while "not also unjustifiably delay[ing] generic drug and biosimilar competition beyond that reasonably contemplated by applicable law."[7] Overall, the Executive Order empowered the DOJ and FTC to vigorously enforce the antitrust laws and work cooperatively with other federal agencies. These directives spotlighted complex, decades-old legislation and incumbent frameworks, providing support for the current antitrust leadership to pursue new theories of harm in inventive ways.

Hatch-Waxman. Addressing the current framework of pharmaceutical patents and potential anticompetitive behavior is no small feat. The Patent and Trademark Office ("PTO") grants patents to pharmaceutical manufacturers, the Food and Drug Administration ("FDA") oversees registered pharmaceutical and biologic product patents, and the FTC enforces related antitrust laws. However, the current process for challenging patent misuse is resource intensive and time consuming.

The U.S. framework for generic entry is governed largely by the Drug Price Competition and Patent Term Restoration Act of 1984[8] (the "Hatch-Waxman Act").[9] This law is aimed at promoting innovation by providing pathways for potential generic entrants to enter the market by challenging patents covering branded prescription drugs before the patents expire, typically due to invalidity or non-infringement. These challenges are specific to the patents of the reference listed drug (RLD), which are administered by the FDA in the "Orange Book."[10] Patents listed in the Orange Book are limited to three categories: i) active ingredient; ii) drug product (formulation and composition); and iii) method-of-use patents. A potential generic entrant must challenge one of the RLD's

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4 Joseph R. Biden, Jr., *Executive Order on Promoting Competition in the American Economy*, White House (July 9, 2021), https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/.

5 *See infra* article section "Supporting March-in Rights (Bayh-Dole Act)" for more information on march-in rights.

6 Biden, *supra* note 4.

7 *Id.*

8 For a more thorough treatment of the Hatch-Waxman challenge process, *see generally* Cong. Rsch. Serv., *The Role of Patents and Regulatory Exclusivities in Drug Pricing* (updated Jan. 30, 2024) (hereinafter CRS Report), https://crsreports.congress.gov/product/pdf/R/R46679.

9 While this article focuses on the Hatch Waxman Act, the pathway for biosimilar market entry was created by the Biologics Price Competition and Innovation Act (BPCIA). The biosimilar register equivalent to the Orange Book is known as the "Purple Book."

10 The Orange Book was nicknamed such because of its launch on Oct. 31, 1980, or Halloween. Podcast, Am. Bar Ass'n Our Curious Amalgam, Episode #247: Throwing the Book at Orange Book Listings? The FTC's Views on the Antitrust Implications of Listing Patents in the Orange Book (posted on Jan. 22, 2024).

patents to access a regulatory pathway for generic entry. Once challenged, the incumbent drug manufacturer can then sue for infringement, triggering an abbreviated intellectual property litigation under the parameters of the relevant statutes.

Under the Hatch-Waxman framework, the filing of a patent infringement suit by the branded drug manufacturer triggers an automatic 30-month stay on FDA approval of the generic drug, preventing market entry by the generic challenger while the litigation proceeds.[11] If successful, the generic challenger can enter the market and enjoy a period of market exclusivity. Historically, the first generic entrant rapidly gains market share, leading to a significant price drop for the drug. The generic challenger plays a crucial role in initiating the long path to market entry, needing to successfully challenge each patent covering a specific drug or biological product. The cost of an Orange Book listing challenge, which is estimated to be around $5 million,[12] combined with the presence of multiple patents, can be expensive for potential generic entrants.

Theories of Anticompetitive Harm Arising from the Hatch-Waxman Framework. The Hatch-Waxman Act litigation framework has spurred numerous allegations of anticompetitive conduct by pharmaceutical manufacturers attempting to purportedly game the system to delay competitive entry, including allegations of "reverse payment" settlements[13] and "sham" patent litigations,[14] which the FTC has challenged for over a decade.

More recently, private plaintiffs have alleged anticompetitive harm arising from the sheer number of patents held by pharmaceutical patent holders on a given drug, which they have deemed "patent thickets."[15] However, case law is clear that it is not inherently illegal for a company to protect its (often considerable) investment with legitimate patents. *In re Humira* is a notable example of the courts grappling with alleged "patent thickets" and ruling in favor of the patent holder.[16] There, the Seventh Circuit affirmed the district court's view that even acquiring a large number of patents (well over 100 in that case) does not itself represent an antitrust violation under the established case law on this issue. However, the antitrust agencies do not appear deterred in their pursuit of exploring this and other novel strategies.

Survey of Agency Tools

Policing the Orange Book. The FTC's recent actions in policing the Orange Book have stood out as one of the most novel public-facing efforts by the agency involving pharmaceutical patents

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[11] Note that the BPCIA has no comparable stay on biosimilar entry, *i.e.*, suing a would-be biosimilar competitor does not stay FDA approval of the biosimilar drug.

[12] CRS Report at 49 (indicating that costs can be compounded if there are several patents at issue).

[13] Reverse payment settlement agreements, also referred to as "pay-for-delay" agreements, are a type of settlement in which a brand-name drug maker sues a generic firm for patent infringement and then settles the suit by paying the generic firm to agree not to enter the market until a negotiated date. *See* FTC v. Actavis, 133 S. Ct. 2223 (June 17, 2013) (holding that reverse payment settlement agreements should be evaluated under the rule of reason).

[14] Sham litigation occurs when a patent owner uses litigation or another government process with the intent to cause anticompetitive harm. In the patent content, a sham petition could take the form of pre-suit communications concerning the alleged infringement, a patent infringement lawsuit (or a series of such lawsuits), and petitioning activity before a government agency. *See* FTC v. AbbVie Inc., 976 F.3d 327 (3d Cir. 2020) (holding that the biopharma company's patent infringement suit was a sham litigation).

[15] The FTC has characterized instances where pharmaceutical companies use large patent portfolios to protect a single treatment as "patent thickets." Comment, Fed. Trade Comm'n, Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights at 15 (Feb. 6, 2024).

[16] In re Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811 (N.D. Ill. 2020), *aff'd*, Mayor and City Council of Baltimore v. AbbVie Inc., 42 F. 4th 709, 716 (7th Cir. 2022).

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since the Executive Order. In September 2023, the FTC put all pharmaceutical drug patent holders on notice that it intends to use its Section 5 powers to "scrutinize improper Orange Book listings to determine whether these constitute unfair methods of competition [and] illegal monopolization."[17] Specifically, the agency called out the practice of submitting patents for listing in the Orange Book that "claim neither the [RLD] nor a method of using it." The agency argues that improper patents "disincentivize investments in developing a competing product and increase the risk of delayed generic and follow-on product entry."[18] Some within the agency appear to consider this low-hanging fruit that, if successful, would provide impact without expending enormous time, energy, and resources. For example, getting drug manufacturers to de-list certain patents from the Orange Book would remove the basis for the 30-month stay under the Hatch-Waxman Act and potentially encourage more generic entry. But many question whether these measures will significantly impact the overall dynamics of pharmaceutical innovation and competition.

Since issuing the Orange Book policy statement, the FTC has embarked on two rounds of patent challenges. In November 2023, the FTC issued warning letters to drug manufacturers for over 100 patents related to asthma and other inhalers, and epinephrine autoinjectors.[19] The second wave of challenges in April 2024, also in the form of warning letters, disputed over 300 patents for drugs targeting diabetes, weight loss, asthma, and other indications.[20] Some effects were immediate; since the November 2023 warning letters, at least 14 patents across six RLDs have been de-listed from the Orange Book. However, this is only a fraction of the patents identified in the Orange Book warning letters, and it remains to be seen whether the FTC will follow through on its threat of legal challenge in district court. Further, de-listing a patent does not affect the validity of the patent itself, which will still have to be resolved through expensive litigation. Critics argue that this approach might lead to increased legal battles, creating further uncertainties for patent holders.

FTC Amicus Brief in Private Litigation. Another method of challenging patent holders involves the agencies' reinvigorated use of amicus briefs in private litigations, allowing them to extend their influence without expending enormous resources. The FTC has recommitted itself to involvement where a private suit may have broader implications for the FTC's competition mission. This article highlights a recent amicus brief filed by the FTC.

In 2022, the FTC filed an amicus brief in *Jazz Pharmaceuticals v. Avadel CNS Pharmaceuticals*.[21] The private litigation was brought by a generic challenger to Jazz Pharmaceuticals' brand drug Xyrem, a potent narcolepsy drug under a Risk Evaluation and Mitigation Strategy (REMS) program, which is an FDA-mandated process to mitigate the safety risk in the prescription of certain dangerous drugs. Because Xyrem had been approved decades earlier, Jazz Pharmaceuticals no longer held the patent for the drug product, but was able to successfully patent its central pharmaceutical

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[17] Fed. Trade Comm'n, Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book at 5-6 (Sept. 14, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf.

[18] *Id.* at 4.

[19] FTC Press Release, FTC Challenges More Than 100 Patents as Improperly Listed in the FDA's Orange Book (Nov. 7, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-challenges-more-100-patents-improperly-listed-fdas-orange-book.

[20] FTC Press Release, FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs (April 30, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-expands-patent-listing-challenges-targeting-more-300-junk-listings-diabetes-weight-loss-asthma.

[21] See Mem. of Law for Fed. Trade Comm'n as Amicus Curiae, Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC, Case No. 1:21-cv-00691-GBW (D. Del. Nov. 10, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/P163500JazzPharmaAmicusBrief.pdf.

distribution of Xyrem due to its REMS status. Jazz used its distribution patent to block Avadel CNS Pharmaceuticals' introduction of a generic form of Xyrem; consequently, Avadel sued Jazz to have its patent removed from the FDA's Orange Book. Jazz Pharmaceuticals claimed the validity of the patent as a method-of-use patent. The FTC filed an amicus brief to support Avadel and argued that distribution systems should not be patent protected because it is not a change or innovation in the drug itself or a method of using the drug. Specifically, the agency argued that a method of distribution is distinct from "selection, prescription, dosing, and administration" which are valid bases of method-of-use patents; method-of-distribution patents should be de-listed.[22] In February 2023, the Federal Circuit affirmed the district court's granting of Avadel's motion to have Jazz's distribution patent removed from the Orange Book.[23]

Scrutinizing the Patent Application Process. Antitrust enforcers have also turned to the patent application process itself. On October 4, 2022, in response to the Executive Order, and spurred by a letter from senators troubled by pharmaceutical companies creating "patent thickets," the FDA and PTO embarked on several initiatives, one of which was a request for information (RFI) on current patent prosecution practices.[24]

In February 2023, the DOJ submitted a comment supporting the PTO's efforts to reconsider continuation and obvious-type double patenting, both of which can grant the holder additional patents and potentially lead to duplicative patents. In its comment, the DOJ shone a light on the accuracy of patent applications, particularly the discovery of false or inconsistent statements made to different agencies during the patent process. The agency claims that through these allegedly false or inconsistent statements, "firms can exploit regulatory arbitrage between the patenting rules and the drug approval process."[25] The DOJ went further to state that "misrepresentations to the PTO can form the basis of antitrust liability," citing the *Walker Process*[26] case for fraud on the PTO.[27] Lastly, the DOJ encouraged the PTO to collaborate with the U.S. Department of Agriculture, based on the latter's knowledge and data in various industries.

At first glance, the agencies appear poised to engage in *Walker Process* based litigation.[28] However, these claims, traditionally used as counterclaims to patent infringement allegations by private parties, may be difficult for agencies like the FTC to pursue effectively. Although the Federal Circuit's ruling in *Ritz Camera*[29] allows injured parties to bring standalone *Walker Process* claims, it is unclear if the FTC can claim to represent the American public as an injured party. Moreover, pursuing such claims could strain the FTC's resources and challenge its capacity to manage complex litigation.

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[22] *Id.* at 7.

[23] Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC, 60 F.4th 1373 (Fed. Cir. 2023).

[24] Letter from Sen. Patrick Leahy et al to the U.S. Patent and Trademark Office (June 8, 2022), https:/fingfx.thomsonreuters.com/gfx/legaldocs/gdpzyeojjvw/IP*20PATENTTHICKETS*20letter.pdf__;JSU!!A-8UxJjp!JSpSd09d3JnQ-qDC0SWy1b2Z_CQwPLiTAo8qV2oUX-oXWWI26nRWEJ0sHrn5PrysVwa5DChgU7j1Z9CbTGmg3z3yI2g$"https://fingfx.thomsonreuters.com/gfx/legaldocs/gdpzyeojjvw/IP%20PATENTTHICKETS%20letter.pdf.

[25] Comment of the U.S. Dep't of Just. at 15, In the Matter of Initiatives to Ensure the Robustness and Reliability of Patent Rights, Docket No. PTO-P-2022-0025-0134 (Feb. 28, 2023) (hereinafter DOJ PTO Comment).

[26] Walker Process Eqpt., Inc. v. Food Mach. Corp., 382 U.S. 172 (1965) (holding that the enforcement of a patent procured by fraud on the PTO may violate Section 2 of the Sherman Act, provided all other elements to establish a Section 2 monopolization charge are proved).

[27] Comment of the U.S. Dep't of Just. at 15, In the Matter of Initiatives to Ensure the Robustness and Reliability of Patent Rights, Docket No. PTO-P-2022-0025-0134 (Feb. 28, 2023) (hereinafter DOJ PTO Comment).

[28] A *Walker Process* claim is a legal action taken by someone accused of infringing on a patent. The claim is grounded in antitrust law and seeks to prove the patent is invalid because the person who owns it lied or cheated when they applied for it.

[29] Ritz Camera & Image, LLC v. SanDisk Corp., No. 2012-1183 (Fed. Cir. 2012).

This is not the only PTO proposal in play. On June 18, 2024, the FTC filed a comment supporting the PTO's proposed rulemaking, issued via Federal Register Notice on April 19, 2024, to modify the rules of post-grant review proceedings before the Patent Trial and Appeal Board (PTAB) to align more closely with the FTC and DOJ's enforcement work.[30] In its comment, the FTC pushed for the uniform disclosure (and filing) of all patent settlement agreements made in connection with the termination of an America Invents Act proceeding,[31] even if the settlement occurs before the commencement of a PTAB proceeding. It remains to be seen if and how the PTO will consider the FTC's recommendations.

Supporting March-in Rights (Bayh-Dole Act). The Patent and Trademark Act Amendments of 1980,[32] also known as the Bayh-Dole Act, allows inventors to retain patent rights for inventions funded or partially funded by the federal government, in turn spurring innovation, private-sector development and commercialization of federally funded research. One provision, however, addresses so-called march-in rights, which would allow the U.S. government royalty-free use of the invention and the ability to mandate the licensure of the relevant patents under certain conditions.[33] Within this provision, the four illustrated scenarios include instances where the subject invention has not been applied in a reasonable timeframe, where health and safety needs are not reasonably satisfied, where there are requirements for public use by the federal regulations, or where the inventor did not comply with a stated preference for domestic manufacturing of the subject invention.[34]

The comments submitted appear to demonstrate a split between groups on the issue of whether a product's high price could justify the use of march-in rights.

While certain federal agencies have been petitioned to use their march-in rights, particularly to stabilize drug prices, none of the agencies so far have opted to exercise those rights. In December 2023, spurred by the Executive Order to revisit the provision, the NIST issued a proposal for public comment addressing conditions under which the federal agencies should exercise march-in rights. For funding agencies considering using their march-in rights, the NIST's proposed framework encouraged them to consider the practical and potential impact the use of march-in would have by providing three guideline questions: i) whether the Bayh-Dole Act applies to the invention(s) at issue; ii) whether any of the four statutory criteria for exercising march-in rights (including health and safety) applies under the circumstances; and iii) whether the exercise of march-in rights would support the policy and objectives of Bayh-Dole.[35] The results of the RFI are pending, however, the tens of thousands of comments sent to the NIST show the keen interest that organizations, companies, and citizens have in this potential federal enforcement tool.

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[30] Comment of the Fed. Trade Comm'n at 2, Patent Trial and Appeal Bd. Rules of Practice for Briefing Discretionary Denial Issues, and Rules for 325(d) Considerations, Instituting Parallel and Serial Petitions, and Termination Due to Settlement Agreement, Docket No. PTO-P-2022-0025-0134 (June 18, 2024).

[31] In an American Invents Act proceeding, a third party who is not the patent owner may challenge the validity of the claims in an issued patent.

[32] https://www.congress.gov/bill/96th-congress/house-bill/6933.

[33] 35 U.S.C. § 203(a).

[34] 35 U.S.C. § 203(a)(1)-(4).

[35] NIST Press Release, NIST Releases for Public Comment Draft Guidance on March-In Rights (Dec. 7, 2023), https://www.nist.gov/news-events/news/2023/12/nist-releases-public-comment-draft-guidance-march-rights.

After the NIST released its proposed framework regarding march-in rights for comment in late 2023, it received well over 50,000 comments, including a statement in support by the FTC.[36] The comments submitted appear to demonstrate a split between groups on the issue of whether a product's high price could justify the use of march-in rights. Regarding pharmaceutical products, detractors state that threatening to march-in on patents based solely on the high cost of a drug would be too expansive and will ultimately discourage innovation. Ironically, they point out, march-in rights may cause a decrease in federal funding for research and development, which would lead to the unintended consequence of increased corporate funding (i.e. influence) for the subject invention.

Supporters, including the antitrust agencies, recommend that the funding agency (the National Institutes of Health) exercise march-in rights in instances where prices unreasonably limit the public's access to drugs protected by federally funded patents. Specifically, the FTC notes that march-in rights would "reactivate an important check on companies charging Americans high prices for drugs that taxpayers funded."[37] The comment goes on to note that the U.S. government directly or indirectly funded 210 new molecular entities approved between 2010 and 2016 and spent $187 billion for basic or applied research related to 356 drugs approved between 2010 and 2019. In its comment, the FTC touted the NIST's proposed framework as "appropriately expansive and flexible since the reasonableness inquiry by the statute is deeply fact-intensive."[38] Critics argue that the FTC's endorsement may oversimplify complex market dynamics and potentially stifle genuine innovation.

Practically, the exercise of march-in rights may not be the panacea that supporters hope for. The drugs and biologics mentioned in the comments submitted to the NIST are covered by multiple patents, only some of which are federally funded. While unlikely to succeed as a standalone strategy, however, march-in rights could be considered a powerful new tactic to ebb away at the group of patents protecting the highest cost pharmaceuticals.

While the public awaits the NIST's next steps, President Biden doubled down on this approach to high drug costs and launched the Strike Force on Unfair and Illegal Pricing in March 2024, noting that drug manufacturers are "artificially inflating the price" of their products. The DOJ and FTC are tasked to co-head the initiative, of which little is publicly known on its structure, resources, or future targets. The accompanying press release references both the FTC's comment to the NIST on march-in rights as well as prior agency efforts such as the 2021 Multilateral Pharmaceutical Merger Task Force and recent 6(b) study issued to the six largest pharmaceutical benefit managers (PBMs).[39] President Biden also recommends more probes into drug pricing in the near term. However, some industry observers remain skeptical about the effectiveness of these measures and their potential to create unintended consequences.

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[36] *See* Notice, Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, (Dec. 8, 2023), https:/www.regulations.gov/document/NIST-2023-0008-0001__;!!A-8UxJjp!JSpSd09d3JnQ-qDC0SWy1b2Z_CQwPLiTAo8qV2oUXoXWWI26nRWEJ0sHrn5PrysVwa5DChgU7j1Z9CbTGmgnRKnA8Q$"https://www.regulations.gov/document/NIST-2023-0008-0001.

[37] *Id.* at 2.

[38] *Id.* at 9.

[39] White House Press Release, FACT SHEET: President Biden Announces New Actions to Lower Costs for Americans by Fighting Corporate Rip-Offs (Mar. 5, 2024), https://www.whitehouse.gov/briefing-room/statements-releases/2024/03/05/fact-sheet-president-biden-announces-new-actions-to-lower-costs-for-americans-by-fighting-corporate-rip-offs/.

Conclusion

Under the guidance of the Executive Order, U.S. antitrust agencies have been extremely active in enforcing the competition laws in the pharmaceutical patent sector. The agencies have firmly established their stance and launched a multifaceted assault on what they perceive to be improper patents through various means. These include issuing Orange Book warning letters, filing amicus briefs in private litigations, supporting march-in rights for federally funded patents, pursuing allegedly anticompetitive behavior in key stages of pharmaceutical development, and threatening *Walker Process* claims. While the success or failure of these myriad challenges remains uncertain, the agencies show no signs of relenting in their pursuit of novel challenges to patents.

What could be next? It's not clear at this point. Many practitioners predict another Section 5 action from the FTC to ban reverse-payment settlements (or at least did prior to the Supreme Court's recent decisions in *Loper Bright*[40] and *Jarkesy*[41]), with heightened scrutiny on evergreening,[42] continuation patents,[43] termination disclaimers,[44] *Walker Process* claims, compulsory licensing under 28 U.S.C. § 1498,[45] or even advocating for laws mimicking the European Union's regulations against excessive pricing and disparagement. The agencies have many options, and it will be important to see where these efforts will lead. Ultimately, the challenge will be balancing rigorous enforcement with fostering an environment that still encourages pharmaceutical innovation and development. ●

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[40] Loper Bright Enterprises v. Raimondo, 144 S.Ct. 2244 (2024).

[41] SEC v. Jarkesy, 144 S.Ct. 2117 (2024).

[42] Evergreening is a term used to describe when pharmaceutical companies patent slight modifications of older drugs.

[43] A continuation patent allows a patent applicant to pursue patent claims based on the same specification and drawings as previously filed pending parent applications.

[44] A termination disclaimer overcomes the non-statutory double patenting rejection (i.e., a rejection is issued when the claimed invention of a later-filed application is not patentably distinct from the claimed invention of an earlier patent). Once a termination disclaimer is filed, the rejection is overcome pursuant to the provisions of the disclaimer, and if the application has no other grounds for rejection, then the application becomes a granted patent.

[45] 28 U.S.C. § 1498 allows patent owners to sue the federal government for compensation when the government (or someone authorized by the government) practices their patents without permission.