UNITED STATES DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights	Docket No.: 230831-0207

COMMENT OF

THE UNITED STATES FEDERAL TRADE COMMISSION

February 6, 2024

I. Introduction

For too long, Americans have been paying soaring prices for prescription drugs[1]—often paying more than double the average price in many other countries.[2] Nearly three in ten Americans report rationing or even skipping doses of their prescribed medicines due to these high costs.[3] The United States Federal Trade Commission ("FTC") commends the National Institute of Standards and Technology ("NIST") and the Interagency Working Group for Bayh-Dole on their new efforts to reactivate an important check on companies charging Americans high prices for drugs that taxpayers funded.

Specifically, the FTC welcomes the *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights,*[4] which makes operational previously unutilized statutory provisions within the University and Small Business Patent Procedures Act of 1980, also known as the "Bayh-Dole Act"[5]—a statute designed to safeguard public health needs against patent holders' private interests. The FTC submits this comment supporting the Proposed Framework and the use of march-in rights, among other tools, to promote a competitive U.S. pharmaceuticals market and to ensure that taxpayer-funded innovations are accessible and affordable to the public. Given the FTC's longstanding expertise in pharmaceutical markets, the FTC principally focuses this comment on the Bayh-Dole Act's application to prescription drugs.

---

[1] Total inflation-adjusted drug expenditures grew from $522 billion in 2017 to $618 billion in 2022, an 18.4% increase. However, there was only a 1.9% increase in the number of prescriptions, suggesting that spending per prescription, rather than drug usage per patient, is the primary driver of costs. U.S. DEP'T OF HEALTH AND HUMAN SERVICES, OFF. OF THE ASSIS. SECRETARY FOR PLANNING AND EVAL., COMPETITION IN PRESCRIPTION DRUG MARKETS, 2017-2022 1, 7 (2023), *available at* https://aspe.hhs.gov/sites/default/files/documents/1aa9c46b849246ea53f2d69825a32ac8/competition-prescription-drug-markets.pdf.

[2] Andrew W. Mulcahy et al., *International Prescription Drug Price Comparisons, Current Empirical Estimates and Comparisons with Previous Studies*, RAND CORP. (2021), *available at* https://www.rand.org/pubs/research_reports/RR2956 html (reporting U.S. gross drug prices to be 256% of the average price in 32 OECD comparison countries in 2018); *see also* Rebecca Robbins & Christina Jewett, *Six Reasons Drug Prices Are So High in the U.S.*, N.Y. TIMES (Jan. 17, 2024), https://www nytimes.com/2024/01/17/health/us-drug-prices.html?smid=nytcore-ios-share&referringSource=articleShare ("Research has consistently found that drug prices in America are significantly higher than those in other wealth countries" for reasons including that "[p]atent gaming keeps prices high longer."); Evan D. Gumas, *How Prices for the First 10 Drugs Up for U.S. Medicare Price Negotiations Compare Internationally*, THE COMMONWEALTH FUND (Jan. 4, 2024), https://www.commonwealthfund.org/publications/2024/jan/how-prices-first-10-drugs-medicare-negotiations-compare-internationally?check_logged_in=1; Robert Hart, *Americans Spend More On Top Drugs Than Every Other Country Combined —And It's Not Because They're Buying More*, FORBES (Sep. 30, 2021), https://www.forbes.com/sites/roberthart/2021/09/30/americans-spend-more-on-top-drugs-than-every-other-country-combined--and-its-not-because-theyre-buying-more/?sh=1f99aa931bec.

[3] *See* Lunna Lopes et al., *Americans' Challenges with Health Care Costs*, KFF POLLING (Dec. 21, 2023), https://www.kff.org/health-costs/issue-brief/americans-challenges-with-health-care-costs/ ("About one in five adults (21%) say they have not filled a prescription because of the cost while a similar share say they have instead opted for over-the-counter alternatives. About one in ten adults say they have cut pills in half or skipped doses of medicine in the last year because of the cost"); Ashley Kirzinger et al., *Public Opinion on Prescription Drugs and Their Prices*, KFF POLLING (Aug. 21, 2023), https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/ ("[a]bout three in ten adults report not taking their medicines as prescribed at some point in the past year because of the cost."); *see also infra* notes 59–60.

[4] 88 Fed. Reg. 85593 (Dec. 8, 2023) [hereinafter *Proposed Framework*].

[5] 35 U.S.C. §§ 200–212.

A. Background.

Congress enacted the Bayh-Dole Act ("Bayh-Dole" or the "Act") to promote the use, commercialization, and public availability of inventions arising from federally funded research.[6] Congress designed the Act to use the U.S. patent system to facilitate collaboration between private industry and nonprofit entities to more fully commercialize taxpayer-funded inventions and to ensure that these inventions are available to the public. Congress also sought to ensure that taxpayer-funded inventions "are used in a manner to promote free competition and enterprise."[7] In exchange for private entities receiving federal funding and retaining ownership of resulting inventions, the Act reserves to federal agencies the right to "march in" on patents arising from taxpayer funds. These march-in rights allow government agencies to require patent holders to license certain federally funded patents to responsible applicants—including to license a competitor to produce the taxpayer-funded invention. March-in rights therefore safeguard against the "nonuse or unreasonable use of" patents obtained from federally funded research.[8]

The funding agency—such as the National Institute of Health ("NIH")—may exercise march-in rights under the specific circumstances enumerated in the Act.[9] In brief, these statutory criteria are:

> (1) "the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention";
>
> (2) "health or safety needs . . . are not reasonably satisfied by the contractor, assignee, or their licensees";
>
> (3) "requirements for public use specified by Federal regulations . . . are not reasonably satisfied by the contractor, assignee, or licensees"; or
>
> (4) domestic manufacturing requirements set forth in § 204 are not satisfied.[10]

To date, the federal government has never exercised march-in rights—despite the high price of taxpayer-funded inventions like prescription drugs and despite Congress's express intent that patents obtained under the Bayh-Dole Act be used in a manner that promotes competition

---

[6] *Id.* § 200 ("It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor.").

[7] *Id.*

[8] *Id.* §§ 200–03.

[9] *Id.*

[10] *Id.* § 203.

and that march-in rights provide a check on nonuse or unreasonable use of such patents.[11] The Proposed Framework marks an important turning point in recognizing and operationalizing the longstanding but previously unused authority of the federal government to ensure taxpayer-funded inventions are accessible and affordable to the public.

B. The FTC's interest.

The FTC is a law enforcement agency charged by Congress with protecting the public from unfair methods of competition as well as from deceptive or unfair trade practices. The FTC exercises primary responsibility for federal antitrust enforcement in the pharmaceutical industry and has significant expertise in analyzing pharmaceutical markets.[12] The FTC Bureau of Competition has two divisions that focus on pharmaceuticals.[13] The Mergers I Division

[11] There is no organized government-wide repository of information regarding march-in petitions and determinations. The NIH has published its responses to several march-in requests, including the denial of at least six petitions from 1980-2016 and a 2021 rejection of a petition involving Astellas Pharma, Inc., and Pfizer Inc.'s prostate cancer drug Xtandi (enzalutamide). *See, e.g.*, March-In Determination in the Case of CellPro, Inc (Mar. 3, 1997) (march in requested where CellPro's device was the only FDA-approved product on the market but had been found to infringe government-funded patent), https://www.techtransfer nih.gov/sites/default/files/documents/policy/cellpro-marchin.pdf; March-In Determination in the Case of Fabrazyme (Dec. 1, 2010) (march in requested where patentee's manufacturing difficulties caused critically short supply of drug used to treat neurological disorder); https://www.techtransfer.nih.gov/sites/default/files/documents/policy/March-In-Fabrazyme.pdf; March-In Determination in the Case of Norvir (July 2, 2004) (march in requested after 400% overnight price increase); https://www.techtransfer nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf; March-In Determination in the Case of Norvir (Nov. 1, 2013) (march in requested where drug price in the United States was greater than other high-income nations), https://bayhdolecoalition.org/wp-content/uploads/2023/05/March-In-Norvir2013.pdf; March-In Determination in the Case of Xalatan (Sept. 17, 2004), https://www.techtransfer.nih.gov/sites/default/files/documents/policy/March-in-xalatan.pdf (march in requested where drug price was two to five times higher in the United States than the prices in 13 other high income countries); Letter from Sylvia M. Burwell, Sec'y., U.S. Health Hum. Servs. to Andrew Goldman, Counsel, Knowledge Ecology International Declining to Exercise March-In Rights for Xtandi (June 20, 2016) (march in requested where drug sold at an average wholesale price of $129,269 per year, which was much higher than in other high-income countries), https://www.techtransfer.nih.gov/sites/default/files/documents/policy/pdfs/Final_Response_Goldman_6.20.2016.*pdf*; Letter from Lawrence A. Tabak, Dir., Nat'l Inst. Health to Clare M. Love & Robert Sachs, Cancer Patients Denying Petitioner's Request that the U.S. Dep't of Health & Hum. Servs. Exercise March-In Rights for Xtandi (Mar. 12, 2023), https://www keionline.org/wp-content/uploads/NIH-rejection-Xtandi-marchin-12march2023.pdf (march in requested where drug was three to five time more expensive in the United States than in other high income countries); *see also* Letter from Xavier Becerra, Ca. Att'y Gen. et al. to Alex M. Azar, Sec'y., U.S. Health Hum. Servs., Dr. Francis S. Collins, Dir., Nat'l Inst. Health, & Stephen Hahn, Comm'r, U.S. Food & Drug Admin. Regarding Petitioner Gilead Sciences, Inc. Request to Exercise March-In Rights for Remdesivir (Aug. 4, 2020) (march in requested where patentee was unable to assure sufficient supply of Covid-19 treatment during pandemic crisis), https://www.oag.ca.gov/system/files/attachments/press-docs/Remdesivir%20Letter%2020200804.pdf; *see generally* JOHN R. THOMAS, CONG. RSCH. SERV., R44597, MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT 8–10 (2016) (describing petitions).

[12] Additionally, the FTC along with the U.S. Department of Justice, offices of state attorneys general, and international enforcement partners formed the Multilateral Pharmaceutical Merger Task Force in 2021 to consider how to address the varied competitive concerns that pharmaceutical mergers and acquisitions raise. *See* Press Release, Fed. Trade Comm'n, Event: The Future of Pharmaceuticals: Examining the Analysis of Pharmaceutical Mergers (June 14, 2022), https://www ftc.gov/news-events/events/2022/06/future-pharmaceuticals-examining-analysis-pharmaceutical-mergers.

[13] For a summary of the FTC's actions in the pharmaceutical industry, see FED. TRADE COMM'N, OVERVIEW OF FTC ACTIONS IN PHARMACEUTICAL PRODUCTS AND DISTRIBUTION (Oct. 2023), https://www.ftc.gov/system/files/ftc_gov/

investigates potentially anticompetitive mergers involving pharmaceuticals, medical devices, and life sciences products. In the mid-1970s, the FTC formed the Health Care Division within its Bureau of Competition, which works to investigate and challenge anticompetitive conduct in pharmaceutical and health care markets.

Protecting competition in pharmaceutical markets promotes lower prices and spurs innovation in the discovery and development of drugs. The Commission is using the full breadth of its tools to target anticompetitive conduct that can raise prescription drug prices and reduce innovation. The FTC recently achieved numerous major victories enforcing the antitrust laws against anticompetitive mergers, including:

- unwinding Illumina's acquisition of Grail, which threatened competition and innovation in the market for cancer detection tests; [14]
- bringing suit prompting Sanofi to abandon its proposed acquisition of an exclusive license to Maze Therapeutics' pipeline drug for Pompe disease. The FTC alleged the drug posed a nascent competitive threat to Sanofi's monopoly over Pompe therapies, which cost patients over $750,000 for an annual course of treatment; [15]
- blocking IQVIA's proposed acquisition of Propel Media in order to protect competition in the emerging health care programmatic advertising market and help lower health care costs; [16]
- preventing Amgen from leveraging its large portfolio of blockbuster drugs to pressure insurance companies and pharmacy benefit managers into favoring Horizon Therapeutics' two monopoly products—Tepezza and Krystexxa—disadvantaging rivals.

---

pdf/Overview-Pharma.pdf. For a summary of the FTC's actions involving health care services and products, see FED. TRADE COMM'N, OVERVIEW OF FTC ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS (Oct. 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Overview-Healthcare.pdf.

[14] *Illumina, Inc. v. Fed. Trade Comm'n*, 88 F.4th 1036, 1048, 1059 (5th Cir. 2023) (holding that the vertical transaction was likely to substantially lessen competition in U.S. market for research and development of multi-cancer early detection tests and remanding to Commission to consider whether supply agreement offered to rivals sufficiently mitigated merger's effect); Press Release, Fed. Trade Comm'n, Statement Regarding Illumina's Decision to Divest Grail (Dec. 18, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/12/statement-regarding-illuminas-decision-divest-grail.

[15] Compl., In the Matter of Sanofi/Maze Therapeutics, Inc., FTC File No. 2310091 (Dec. 11, 2023) (alleging that Sanofi's proposed acquisition of an exclusive license to Maze Therapeutics' developmental Pompe therapy would have eliminated a nascent competitor to Sanofi's monopoly) [hereinafter *Sanofi Complaint*]; Press Release, Fed. Trade Comm'n, Statement Regarding the Termination of Sanofi's Proposed Acquisition of Maze Therapeutics' Pompe Disease Drug (Dec. 13, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/12/statement-regarding-termination-sanofis-proposed-acquisition-maze-therapeutics-pompe-disease-drug.

[16] Order Granting Complaint Counsel's Motion for Preliminary Injunction, In the Matter of IQVIA Holdings/Propel Media, FTC File No. 2210196 (Dec. 29, 2023) (alleging that the merger would have increased IQVIA's incentive to withhold key information to prevent rival companies and potential entrants from effectively competing); Press Release, Fed. Trade Comm'n, Statement on FTC Win Securing Temporary Block of IQVIA's Acquisition of Propel Media (Jan. 3, 2024), https://www ftc.gov/news-events/news/press-releases/2024/01/StatementonFTCWinSecuring TemporaryBlockofIQVIA%E2%80%99sAcquisitionofPropelMedia.

According to securities filings, Horizon charged about $350,000 for a six-month course of treatment for Tepezza and around $650,000 for an annual supply of Krystexxa.[17]

In addition to successfully stopping illegal mergers, the FTC has taken action against anticompetitive conduct that raises prescription drug prices, including:

- banning Martin Shkreli for life from the pharmaceutical industry for his role in enacting an anticompetitive scheme to impede competition for the lifesaving drug Daraprim, in which his company raised the drug's list price from $17.60 to $750 per tablet;[18]
- returning nearly $60 million to consumers from a product-hopping scheme involving Suboxone, a patented opioid treatment drug;[19]
- successfully challenging reverse payment patent settlements that impede entry of cheaper generics;[20]
- barring Surescripts from engaging in exclusionary conduct that led to higher prices, stifled innovation, and reduced customer choice in e-prescription markets.[21]

---

[17] Agreement Containing Consent Order, In the Matter of Amgen, Inc. and Horizon Therapeutics plc, FTC File No. 2310037 (Dec. 13, 2023) (alleging that the acquisition would enable Amgen to leverage its large portfolio of drugs to pressure insurance companies and PBMs into favoring Horizon's monopoly products or disadvantaging rivals); Press Release, Fed. Trade Comm'n, FTC Approves Final Order Settling Horizon Therapeutics Acquisition Challenge (Dec. 14, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/12/ftc-approves-final-order-settling-horizon-therapeutics-acquisition-challenge; Press Release, Fed. Trade Comm'n, FTC Sues to Block Biopharmaceutical Giant Amgen from Acquisition That Would Entrench Monopoly Drugs Used to Treat Two Serious Illnesses (May 16, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/05/ftc-sues-block-biopharmaceutical-giant-amgen-acquisition-would-entrench-monopoly-drugs-used-treat.

[18] Press Release, Fed. Trade Comm'n, States to Recoup Millions in Relief for Victims Fleeced by 'Pharma Bro' Scheme to Illegally Monopolize Life-Saving Drug Daraprim (Dec. 7, 2021), https://www ftc.gov/news-events/news/press-releases/2021/12/ftc-states-recoup-millions-relief-victims-fleeced-pharma-bro-scheme-illegally-monopolize-life-saving; *see also* Fed. Trade Comm'n, Concurring Statement of Comm'r Rebecca Kelly Slaughter In the Matter of Fed. Trade Comm'n and State of New York v. Vyera Pharmaceuticals, LLC; Phoenixus AG; Martin Shkreli; and Kevin Mulleady (Jan. 27, 2020), https://www.ftc.gov/system/files/documents/public_statements/1564517/2020_01_27_final_rks_daraprim_concurring_statement.pdf (supporting an additional claim of violation of the FTC Act's prohibition on unfair acts or practices, where the price hike of off-patent drug was not attributable to increases in production or manufacturing costs, nor was it due to a change in supply or demand).

[19] Press Release, Fed. Trade Comm'n, FTC Returns Nearly $60 Million to Those Suffering from Opioid Addiction Who Were Allegedly Overcharged in Suboxone Film Scheme (May 10, 2021), https://www.ftc.gov/news-events/news/press-releases/2021/05/ftc-returns-nearly-60-million-those-suffering-opioid-addiction-who-were-allegedly-overcharged.

[20] *See, e.g.*, *Impax Labs, Inc. v. Fed. Trade Comm'n*, 994 F.3d 484, 487 (5th Cir. 2021) (holding that substantial evidence supported FTC finding that reverse payment settlement threatened competition in violation of the antitrust law, and that a less restrictive settlement was viable); *Fed. Trade Comm'n v. Actavis, Inc.*, 570 U.S. 136 (2013) (applying rule of reason analysis to determine whether reverse payment pharmaceutical patent settlement violates the antitrust laws).

[21] Press Release, Fed. Trade Comm'n, FTC Reaches Proposed Settlement with Surescripts in Illegal Monopolization Case (July 27, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/07/ftc-reaches-proposed-settlement-surescripts-illegal-monopolization-case; Stipulated Order for Permanent Injunction and Equitable Relief, Fed. Trade Comm'n v. Surescripts, LLC (D.D.C. Aug. 14, 2023) (No. 1:19-cv-01080) (alleging that Surescripts

The FTC also provides policy guidance and conducts investigative studies into complex and opaque aspects of the pharmaceutical industry. As drug prices have soared and independent pharmacies have shuttered, the FTC has also ramped up its scrutiny of pharmacy benefit managers ("PBMs")—middlemen that manage prescription drug benefits on behalf of private health insurers, Medicare Part D drug plans, large employers, and other payers. The FTC withdrew outdated statements about PBMs that may not reflect the current reality of the marketplace,[22] and it issued a statement condemning exclusionary rebates and fees in the prescription drug industry.[23] In addition, the FTC is using its investigative authority under Section 6(b) of the FTC Act to examine the impact of PBM business practices on prescription drug access and affordability and to advise policymakers on industry reforms.[24]

The FTC is also scrutinizing patent abuse that delays or blocks generic manufacturers from entering the market, depriving millions of Americans of access to lower-cost medicines and drug products. The FTC recently issued a policy statement concerning brand drug manufacturers' improper listing of patents in the United States Food and Drug Administration's ("FDA") Orange Book,[25] filed amicus briefs addressing improper Orange Book listings,[26] and

---

employed illegal vertical and horizontal restraints to maintain its monopolies over two electronic prescribing markets); Press Release, Fed. Trade Comm'n, FTC Reaches Proposed Settlement with Surescripts in Illegal Monopolization Case (Jul. 27, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/07/ftc-reaches-proposed-settlement-surescripts-illegal-monopolization-case.

[22] Press Release, Fed. Trade Comm'n, FTC Votes to Issue Statement Withdrawing Prior Pharmacy Benefit Manager Advocacy (July 20, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/07/ftc-votes-issue-statement-withdrawing-prior-pharmacy-benefit-manager-advocacy; Fed. Trade Comm'n, Statement Concerning Reliance on Prior PBM-Related Advocacy Statements and Reports That No Longer Reflect Current Market Realities (July 20, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/CLEANPBMStatement7182023%28OPPFinalRevisionsnoon%29.pdf.

[23] Press Release, Fed. Trade Comm'n, FTC to Ramp Up Enforcement Against Any Illegal Rebate Schemes, Bribes to Prescription Drug Middleman That Block Cheaper Drugs (June 16, 2022), https://www ftc.gov/news-events/news/press-releases/2022/06/ftc-ramp-up-enforcement-against-illegal-rebate-schemes; Fed. Trade Comm'n, Policy Statement on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products, FTC Matter No. P221201 (June 16, 2022), https://www.ftc.gov/legal-library/browse/policy-statement-federal-trade-commission-rebates-fees-exchange-excluding-lower-cost-drug-products.

[24] Press Release, Fed. Trade Comm'n, FTC Launches Inquiry Into Prescription Drug Middlemen Industry (June 7, 2022), https://www ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry.

[25] Press Release, Fed. Trade Comm'n, FTC Issues Policy Statement on Brand Pharmaceutical Manufacturers' Improper Listing of Patents in the Food and Drug Administration's "Orange Book" (Sept. 14, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/09/ftc-issues-policy-statement-brand-pharmaceutical-manufacturers-improper-listing-patents-food-drug; Federal Trade Commission, Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book, FTC. File No. P233900 (Sept. 14, 2023), https://www.ftc.gov/legal-library/browse/federal-trade-commission-statement-concerning-brand-drug-manufacturers-improper-listing-patents.

[26] Press Release, Fed. Trade Comm'n, FTC Amicus Brief Challenges Abuse of FDA "Orange Book" Listing Procedures to Block Drug Competition (Nov. 10, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/11/ftc-amicus-brief-challenges-abuse-fda-orange-book-listing-procedures-block-drug-competition; Brief for Fed. Trade Comm'n as Amici Curiae, *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, 1:21-cv-00691 (D. Del. Nov. 10, 2022) (No. 222-3); Press Release, Fed. Trade Comm'n, FTC Files Amicus Brief Outlining Anticompetitive Harm Caused by Improper Orange Book Listings (Nov. 20, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-files-amicus-brief-outlining-anticompetitive-harm-caused-improper-orange-

challenged the accuracy of Orange Book patent listings with the FDA.[27] As a result, several companies recently removed improper patent listings on asthma inhalers and epinephrine autoinjection products from the Orange Book, removing a major barrier to generic competition on critical lifesaving drugs.[28]

Protecting and promoting fair competition in pharmaceutical markets is enormously beneficial for the American public. For example, increasing competition among generic drug manufacturers generates increasingly lower prices. According to a 2019 FDA Report, generic firms' average manufacturer prices are 39% lower than the brand price after initial generic entry, 54% lower with two generic competitors, 79% lower with four generic competitors, and 95% lower with six or more generic competitors.[29] The appropriate exercise of march-in rights under Bayh-Dole provides a pathway to further promote competition in drug markets and lower drug prices.

II. The FTC Supports an Expansive and Flexible Approach to March-In Rights, Including on the Basis of Price

A. The FTC supports NIST's expansive and flexible approach to march in.

The recent Proposed Framework from NIST provides important guidance as to agency decision making in exercising march-in rights for patented inventions. Consistent with the spirit of the whole-of-government approach described in President Biden's Executive Order on Promoting Competition in the American Economy,[30] the Proposed Framework considers the commercial circumstances surrounding the invention and access across the supply chain,[31] as well as impact on end users and the public at large.[32] Specifically, the Proposed Framework provides that agencies should assess three overarching questions: (1) whether Bayh-Dole applies to the invention(s) at issue; (2) whether any of the four statutory criteria for exercising march in

---

book-listings; Brief for Fed. Trade Comm'n as Amici Curiae, *Mylan Pharm. v. Sanofi-Aventis LLC*, 2:23-cv-00836 (W.D. Pa Nov. 20, 2023) (No. 61-3).

[27] Press Release, Fed. Trade Comm'n, 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.

[28] Leah Nylen & Nacha Cattan, *GlaxoSmithKline Pulls Back Inhaler Patents After US FTC Warning Letter*, BLOOMBERG (Dec. 20, 2023), https://www.bloomberg.com/news/articles/2023-12-20/glaxosmithkline-pulls-back-inhaler-patents-after-us-ftc-warning-letter?accessToken=eyJhbGciOiJIUzI1NiIsInR5cCI6IkpXVCJ9.eyJzb3VyY2UiOiJTdWJzY3JpYmVyR2lmdGVkQXJ0aWNsZSIsImlhdCI6MTcwMzEwMjc1NywiZXhwIjoxNzAzNzA3NTU3L CJhcnRpY2xlSWQiOiJTNVo3MkVEV0xVNjgwMCIsImJjb25uZWN0SWQiOiI1Nzk3RERGRDdEMkE0M0JCOT c0OTEwMkRFOTQyMDUxNiJ9.C9TMeQmFF9vVNeOnOUZ4l2QJ_jBGFYJNLZIs3j_Owuo.

[29] U.S. FOOD & DRUG ADMIN., GENERIC COMPETITION AND DRUG PRICES: NEW EVIDENCE LINKING GREATER GENERIC COMPETITION AND LOWER GENERIC DRUG PRICES 2-3 (Dec. 2019), *available at* https://www fda. gov/media/133509/download.

[30] *See* Exec. Order No. 14,036, 86 Fed. Reg. 36987 (July 14, 2021).

[31] *See, e.g.*, Proposed Framework, Fed. Reg. 85598–99 (Criterion 1, III, VI).

[32] *Id.* at 85599 (Criterion 1, VI A, C, D) (*see also* Criterion 3; explanation of specific case and broader context as overarching consideration 3).

applies under the circumstances; and (3) whether the exercise of march-in rights would support the policy and objectives of Bayh-Dole.[33]

The Proposed Framework for exercising march-in rights benefits from being appropriately expansive and flexible since the reasonableness inquiry required by the statute is deeply fact-intensive.[34] Agencies should be wary of imposing categorical limitations on the factors that can be considered for march in, such as price. For example, price can be a critical determinant of a drug's subsequent availability to patients,[35] and high prices can thus undermine the ultimate utility of the drugs developed with taxpayer funds. In factoring price into the march-in analysis, funding agencies may consider the size of the patent holder's private investment, the *ex ante* uncertainty of return on that investment, and the degree to which it has been recouped. Funding agencies may also consider that the utility of marching in may be greater or lesser depending on what the government-funded patents cover and whether the drug is also covered by privately funded patents that could block the use of the invention.[36] A flexible, fact-dependent inquiry allows agencies to consider these and other potentially relevant circumstances. As discussed further below, the FTC supports the exercise of march-in rights where prices unreasonably limit the public's access to drugs protected by federally funded patents.

B. Under the plain text of the statute, price may be an appropriate basis for marching in.

The Proposed Framework's elaboration of Bayh-Dole's first statutory criterion, effective steps to achieve practical application, includes price as a consideration. The Proposed Framework explains:

> "If the contractor or licensee has commercialized the product, but the price or other terms at which the product is currently offered to the public are not reasonable, agencies may need to further assess whether march-in is warranted. Whether action may be needed to meet the needs of the Government or protect the public against nonuse or unreasonable use of the subject invention may include consideration of factors that unreasonably limit availability of the invention to the public, including the reasonableness of the price and other terms at which the product is made available to end-users."[37]

The statutory text reflects that price is an appropriate consideration in the march-in analysis. The Bayh-Dole Act includes language stating that march-in rights may be exercised when "action is

---

[33] *Id.* at 85596.

[34] *Id.* at 85597 ("When reviewing this framework, it is important to remember that march-in considerations are extremely fact-dependent and any decision to exercise march-in will be made based on the totality of all circumstances.").

[35] *See infra* § III.

[36] Proposed Framework at 85600 (noting that "if only one of several patents necessary to produce a product is subject to march-in, that likely weighs against march-in, since other licensees would need separate permission to use several other patents before they could make the product").

[37] *Id.* at 85598–99 (Criterion 1, VI, D; Criterion 2, V); *id.* at 85603–04 (Scenarios 5 & 6).

necessary . . . to achieve practical application of the subject invention."[38] "Practical application" is defined in 35 U.S.C. § 201(f), which requires that the invention be "available to the public on reasonable terms."[39] As multiple scholars have explained, the plain meaning of "on reasonable terms" has been interpreted to include price as a term.[40] Reading "reasonable terms" to exclude the ability to exercise march-in rights based on price would defy the plain text of the statute and remove this important check on unreasonable use of taxpayer-funded patents.

C. March-in rights represent a tradeoff for private entities to gain public subsidies in return for providing benefits to the public.

Prior to enactment of the Bayh-Dole Act in 1980, the U.S. government generally retained the rights to inventions developed with public funding, and few third parties sought licenses to employ such technology. It has been estimated that only 5% of the 30,000 federally owned patents that existed before 1980 were ever licensed to industry, and even fewer were commercialized in products or services that benefited consumers.[41]

Bayh-Dole changed this paradigm by allowing entities that receive federal funding to patent their inventions after giving notice to the government. Such entities could then license the patents for further development and broader use. In other words, the Act uses patent ownership to incentivize private-sector development and commercialization of federally funded research. The Act established march-in rights as an essential counterbalance, enabling the funding agency to "march in" in case of a patent holder's poor stewardship of an invention. These express

---

[38] 35 U.S.C. § 203(a)(1).

[39] *See also* 45 CFR § 650.4(a)(3).

[40] *See* Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed Upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 TULANE L. REV. 631, 644 n.69, 649–53 (2001) (explaining that the ordinary meaning of the words "'reasonable terms' have uniformly been interpreted to include price" in contexts including as a remedy to monopolistic markets); *see also* Jennifer Penman & Fran Quigley, *Better Late than Never: How the U.S. Government Can and Should Use Bayh-Dole March-In Rights to Respond to the Medicines Access Crisis*, 53 WILLAMETTE L. REV. 1, 7–12 (2017) (finding "an abundance of evidence that the Bayh-Dole Act's march-in provisions were devised to ensure that federally funded inventions be available to the public at reasonable prices"); Nicholas Bagley, *Pushing back on exorbitant drug prices*, INCIDENTAL ECONOMIST (Sept. 21, 2015), https://theincidentaleconomist.com/wordpress/pushing-back-on-exorbitant-drug-prices/ (affirming it is a "powerful and straightforward argument that the federal government could conclude that a drug is 'not available on reasonable terms' if its price is exorbitant"); Thopher Sipro et al., *Enough Is Enough The Time Has Come to Address Sky-High Drug Prices*, CENTER FOR AM. PROGRESS (Sept. 2015) (explaining that under Bayh-Dole, "rights apply when a drug company has not achieved 'practical application of the research' [and] [t]hus, if a drug company is not charging a reasonable price for a drug, or if its pricing harms public health by substantially restricting access to the drug"); David Halperin, *The Bayh-Dole Act and March-In Rights*, ESSENTIAL INVENTIONS.ORG 1, 6 (May 2001); *Cf. The University and Small Business Patent Procedures Act: Hearing on S. 414 Before the S. Comm. on the Judiciary*, 96th Cong. 2 (1979) 153–154 (testimony of Betsy Ancker-Johnson, Vice President, Gen. Motors Environmental, Activities Staff, Former Assistant Secretary of Commerce); *University Research and the Patent System: Hearing Before the S. Comm. on the Judiciary*, 110th Cong. (2007) (statement of Robert Weissman, Director, Essential Action).

[41] JORGE L. CONTRERAS, INTELLECTUAL PROPERTY LICENSING AND TRANSACTIONS THEORY AND PRACTICE 378 (2022) *available at* https://www.cambridge.org/core/books/intellectual-property-licensing-and-transactions/academic-technology-transfer/D87194AF210C7F9F2274C6772679AAC1#A-sec-208 (Chapter 14).

statutory provisions serve to ensure that the public shares a cut of the patent-benefits to which they contributed through tax dollars.

The terms of this "bargain" appeared favorable to both universities and industry. Indeed, many entities chose to invest in innovation, as evidenced by the large influx of new patents in the immediate aftermath of the Act's passage.[42] For example, human biology patents obtained by U.S. universities and hospitals increased 300% in the first five years after the Act became law.[43] In the 20 years after Bayh-Dole, universities produced ten times as many patents as they did in the similar period before the Act and—as collaborations between universities and the private sector grew[44]—created thousands of new companies designed to commercialize those discoveries.[45] According to a survey conducted by the Association of University Technology Managers, between 2005 and 2017, various measures of technology transfer activity all increased significantly, including issued patents, executed licenses, and annual new startup formation, as a direct result of Bayh-Dole.[46]

March-in rights can ensure that the public benefits from taxpayer-funded innovation. Even when march-in rights are not actually exercised, the fact that the government has such rights in an invention can be powerful leverage. The threat of march in during certain health crises has yielded tangible public benefits. For example, the government leveraged the threat of march in to persuade Bayer to ramp up production of patented anthrax antibiotics after the September 11 attacks. Similarly, the government convinced Roche to allow generic manufacturing of Tamiflu during the 2005 avian flu pandemic, in significant part due to the threat of march in.[47]

---

[42] Penman, *supra* note 40 at 16–17.

[43] *Id.* at 16; Peter Drahos & John Braithwaite, *Who Owns The Knowledge Economy: Political Organising Behind TRIPS*, CORNER HOUSE BRIEFING 32 (Sept. 30, 2004), *available at* http://www.thecornerhouse.org.uk/resource/who-owns-knowledge-economy.

[44] *See id.* at 16; Aaron S. Kesselheim, *An Empirical Review of Major Legislation Affecting Drug Development: Past Experiences, Effects, and Unintended Consequences*, 89 THE MILBANK QUARTERLY 450, 454, 460 (Sept. 2011), *available at* https://www ncbi.nlm.nih.gov/pmc/articles/PMC3214718/#b53; *see also The Role of the Bayh-Dole Act in Fostering Technology Transfer and Implications for Innovation*, PHRMA 3 & n.2 (Feb. 2020), https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/Bayh-Dole-Whitepaper-FINAL---21820.pdf ("Collaborations between universities and government-funded researchers and the private sector have proven to be a successful model to leverage complementary roles in basic research and applied development of medical innovations[.] Without . . . the economic incentive of exclusive licensing established under Bayh-Dole, private firms might not devote scarce resources to the highly uncertain development efforts" for medical therapies).

[45] Penman, *supra* note 40 at 16.

[46] *See* PhRMA, *The Role of the Bayh-Dole Act*, *supra* note 44 at 11; Douglas Hockstad et al., US Licensing Activity Survey: 2017, AUTM, *available at* https://autm.net/AUTM/media/SurveyReportsPDF/AUTM_2017_US_Licensing_Survey_no_appendix.pdf.

[47] Charles Duan, *Patents and the Common Good*, THE NEW ATLANTIS (2021), https://www.thenewatlantis.com/publications/patents-and-the-common-good ("[P]owers like march-in rights must be used judiciously, but they are not deadly to the Bayh–Dole Act; they are vital to it."); CONG. RSCH. SERV., INFLUENZA ANTIVIRAL DRUGS AND PATENT LAW ISSUES, SUMMARY (Aug. 16, 2007), *available at* https://www.everycrsreport.com/files/20070816_RL33159_6f5f7a4fa81ef47c80dc79eaa26ac77c0ecbf034.pdf ("In response to the heightened demand for the drug, as well as faced with threatened abrogation of its patent rights by U.S. politicians and government officials

The Proposed Framework serves to better achieve the Act's goals by providing more concrete guidance about when the government will exercise its march-in rights. Specifically recognizing that inflated prices can be a basis for exercising march-in rights is important to ensure taxpayer-funded patent holders do not receive lopsided benefits at the expense of the public. Clarity will also facilitate a more efficient allocation of limited government funds toward developing inventions that benefit the public.

III. The FTC Supports Utilizing March-In Rights as a Check on Inflated Pharmaceutical Prices

A. Pharmaceutical markets enjoy significant taxpayer investment in R&D.

Development of pharmaceutical products in the United States has long benefited from taxpayer support, with a substantial number of breakthroughs in drug development stemming from government-funded research. NIH funding directly or indirectly contributed to every one of the 210 new molecular entities ("NMEs") approved from 2010-2016.[48] Remarkably, this includes 84 "first in class" products, defined as NMEs that work through a novel mechanism of action or molecular target.[49]

NIH funding contributed to published research related to 354 of 356 new drugs approved by the FDA from 2010 to 2019.[50] In terms of dollars spent, NIH contributed $187 billion for basic or applied research related to the 356 drugs approved from 2010-2019.[51] Nearly all of the drugs that grew out of that research were subsequently launched by commercial biopharmaceutical companies under the provisions of the Bayh-Dole Act.[52] In light of the federal government's substantial investment in public health, Americans deserve to have affordable access to the prescription drugs that billions of taxpayer dollars paid to develop.

B. Pharmaceutical markets have characteristics that can facilitate inflated pricing, which may warrant the exercise of march-in rights in some instances.

Pharmaceutical markets are characterized by high barriers to entry, including intellectual property rights, regulatory approvals, and research and development costs. Each new drug is typically protected by numerous patents covering its core active ingredient, formulation, and

---

in other countries, Roche significantly boosted Tamiflu production in 2006 and 2007 by voluntarily signing licensing agreements with 19 external contractors in 9 different countries to manufacture the drug.").

[48] Ekaterina G. Cleary et al., *Contribution of NIH funding to new drug approvals 2010–2016*, 115 PROC. NAT'L ACAD. SCI. 2329, 2230 (Mar. 2018), *available at* https://www.pnas.org/doi/epdf/10.1073/pnas.1715368115.

[49] *Id.*

[50] Fred D. Ledley & Ekaterina G. Cleary, *NIH funding for patents that contribute to market exclusivity of drugs approved 2010–2019 and the public interest protections of Bayh-Dole*, 18 PLOS ONE 2 (July 2023), *available at* https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0288447.

[51] *Id.* at 2 & n.2; *see also* Ekaterina G. Cleary et al., *Government as the First Investor in Biopharmaceutical Innovation: Evidence From New Drug Approvals 2010–2019*, INST. FOR NEW ECON. THINKING, Working Paper Series No. 133 (2020), *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3731819.

[52] *Id.* at 2 (99.4% of these drugs). To provide additional reference, biopharmaceutical companies spent an estimated $1.03-1.4 billion per drug to develop these products. *Id.*

method of use to treat a particular condition. Some of these patents may serve to block competing generic, biosimilar, and branded drugs from coming to market for many years.[53] In addition, the FDA grants marketing exclusivity periods to new drug products.[54] For the duration of these exclusive periods—typically between 5-7 years for new brand name drug products[55]—the FDA will not accept or approve an application for a competing drug that relies on approval of the innovator drug or is considered to be the same drug (for the same use or indication).[56]

As a result of these entry barriers and the explicit statutory scheme, a branded drug in some cases faces limited or no competition for many years, enabling the manufacturer to market the drug at higher prices than it could if competitors were present. Pharmaceutical markets in which a branded drug faces no generic competition typically exhibit significantly higher pricing than those in which generics are present.[57] Pharmaceutical markets in which a branded drug faces limited or no competition even from other branded drugs may enable firms to charge monopoly-level prices.[58] In markets where there is only one or only a few approved products, the lack of alternative drug treatments means patients and health plans have few options. Patients often have no choice but to pay high prices for lifechanging or lifesaving drugs, forgo the drug treatment, or turn to inferior options.

High prices for prescription drugs can render these drugs unaffordable and inaccessible for many patients. For example, research by the Centers for Disease Control and Prevention and other studies have found evidence that high prices can interfere with patients' ability to access

---

[53] So-called patent thickets, where an incumbent manufacturer amasses a large number of patents related to a particular treatment, have become a significant entry barrier with respect to biologic medicines (which the FDA approves under a separate regulatory pathway from small molecule drugs). CONG. RSCH. SERV., DRUG PRICES: THE ROLE OF PATENTS AND REGULATORY EXCLUSIVITIES 51 (Feb. 2021), *available at* https://crsreports.congress.gov/product/pdf/R/R46679; *see also infra* § IV.

[54] *See* U.S. Food & Drug Admin., *Small Business Assistance: Frequently Asked Questions for New Drug Product Exclusivity*, https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-frequently-asked-questions-new-drug-product-exclusivity#:~:text=New%20Drug%20Product%20Exclusivity%20is,by%20its%20approved%20drug%20product (last updated Feb. 11, 2016) ("Exclusivity provides the holder of an approved new drug application limited protection from new competition in the marketplace for the innovation represented by its approved drug product.").

[55] *See* 21 C.F.R. § 314.108; *id.* § 316. 3, 21 U.S.C. §§ 355a, 355e. *But see* 42 U.S.C. § 262(k)(7)(A) (granting 12 years of exclusivity for biologic products).

[56] *Id.; see also* 21 U.S.C. §§ 355(c)(3)(E)(ii)-(iv), (j)(5)(F)(ii)-(iv); § 351(k)(7)(c) of the Public Health Services Act.

[57] For example, prices of drug products for which first generic approval occurred in 2021 declined up to 96% twelve months later. U.S. FOOD & DRUG ADMIN., ESTIMATING COST SAVINGS FROM NEW GENERIC DRUG APPROVALS IN 2021 9–10 (Sept. 2023), *available at* https://www fda.gov/media/172608/download?attachment#:~:text=Estimates%20show%20that%20generic%20drugs,estimates%20from%20previous%20approval%20years (61% of drug products declined 10-40%, while 25% declined 40-70%); *see also* U.S. GOV'T ACCOUNTABILITY OFF., GAO 18-40, DRUG INDUSTRY PROFITS, RESEARCH AND DEVELOPMENT SPENDING, AND MERGER AND ACQUISITION DEALS 47 (2017), *available at* https://www.gao.gov/assets/gao-18-40.pdf ("empirical studies we reviewed suggest that less competition—that is, a more highly concentrated market—is associated with higher drug prices, particularly for generic drugs").

[58] *See, e.g.*, Sanofi Complaint at 1 ("As a monopolist, Sanofi charges an average patient [with Pompe disease] over $750,000 for a course of annual treatment.").

medication at quantities necessary to follow appropriate treatment protocols,[59] and some recent polls report between 20-30% of U.S. adults skipping or abandoning prescribed treatments due to cost.[60] Further, for Medicare Part D beneficiaries without low-income subsidies, a recent study found that over 20% of new drug prescriptions for high-priced drugs were left unfilled, with even higher rates of failure to start filling prescriptions for drugs that treat severe conditions like cancer (30%), immune system disorders (over 50%), and hypercholesterolemia (over 60%).[61] These findings are in line with past assessments of the impact of highly inflated prices in pharmaceutical markets, which can broadly limit U.S. patients' access to innovative treatments and present further challenges for vulnerable populations dependent on patented lifesaving medications.[62]

Once a drug is on the market, the cost of manufacturing additional doses, particularly for small-molecule drugs, is often relatively low. Yet, when pharmaceutical firms are unconstrained by meaningful competition, they can charge prices far above their marginal production costs and earn very large profit margins.[63] Although industry members often claim such high drug prices fund research and development necessary for new drugs to become available, the fourteen leading drug companies' investment in research and development has fallen relative to their profits, stock buybacks, and dividends.[64] Additionally, prices for drug products are often more a

---

[59] *See generally* CENTERS FOR DISEASE CONTROL AND PREVENTION, NCHS DATA BRIEF NO. 470, CHARACTERISTICS OF ADULTS AGED 18-64 WHO DID NOT TAKE MEDICATION AS PRESCRIBED TO REDUCE COSTS: UNITED STATES, 2021 5 (June 2023), *available at* https://www.cdc.gov/nchs/data/databriefs/db470.pdf (reporting that the high cost of prescription drugs caused more than 9 million adults to skip doses of medication, take less medication than prescribed, or delay filling a prescription); *see also* CONG. BUDGET OFF., PRESCRIPTION DRUGS: SPENDING, USE, AND PRICES (2022), *available at* https://www.cbo.gov/publication/57050 ("[h]igh prices reduce consumers' access to such medications . . . [and] contribute to higher spending that strains budgets, including the federal budget").

[60] *See supra* note 3.

[61] Stacie B. Dusetzina et al., *Many Medicare Beneficiaries Do Not Fill High-Price Specialty Drug Prescriptions*, 41:4 HEALTH AFFAIRS 487, 492 (Apr. 2022), *available at* https://www healthaffairs.org/doi/10.1377/hlthaff.2021. 01742 (further noting that "noninitiation . . . was nearly twice as frequent among those without subsides versus with them").

[62] *See* Remarks of Chair Khan Regarding 6(b) Study on PBMs, Commission File No. P221200 at 1 (Feb. 17, 2022), https://www.ftc.gov/news-events/news/speeches/remarks-chair-lina-m-khan-regarding-6b-study-pharmacy-benefit-managers (citing Kaiser Family Foundation, Poll: Nearly 1 in 4 Americans Taking Prescription Drugs Say It's Difficult to Afford Their Medicines, including Larger Shares Among Those with Health Issues, with Low Incomes and Nearing Medicare Age, published Mar. 1, 2019).

[63] *See., e.g.*, Compl., Fed. Trade Comm'n v. Mallinckrodt ARD Inc. (f/k/a Questcor Pharmaceuticals, Inc.) (D.D.C. Jan. 25, 2017) (No. 1:17-cv-00120) at 7 ("Questcor has encountered no competitive constraint on its ability to repeatedly and profitably increase Acthar's price and earn extremely high margins.") [hereinafter *Mallinckrodt Complaint*].

[64] *See* U.S. HOUSE OF REP., COMM. ON OVERSIGHT AND REFORM, DRUG PRICING INVESTIGATION, INDUSTRY SPENDING ON BUYBACKS, DIVIDENDS, AND EXECUTIVE COMPENSATION 3 (July 2021), https://oversightdemocrats.house.gov/sites/democrats.oversight house.gov/files/COR%20Staff%20Report%20-%20Pharmaceutical%20Industry%20Buybacks%20Dividends%20Compared%20to%20Research.pdf ("From 2016 to 2020, the 14 companies examined spent over $577 billion on stock buybacks and dividends for investors, $56 billion more than they spent on R&D"); William Lazonick & Öner Tulum, *Sick with "Shareholder Value": US Pharma's Financialized Business Model During the Pandemic*, INST. FOR NEW ECON. THINKING (Dec. 2022), https://www.ineteconomics.org/perspectives/blog/sick-with-shareholder-value-us-pharmas-financialized-business-model-during-the-pandemic ("The $747 billion that the pharmaceutical companies distributed to shareholders was 13 percent greater than the $660 billion that these corporations expended on research & development over the decade.").

function of whether the drug faces competition than the drug's research and development or production costs.[65] One industry investor recently stated that large pharmaceutical firms operate more like marketing firms than scientific innovators.[66]

In past investigations into conduct and transactions in the pharmaceutical space, the FTC has encountered high prices and dramatic price increases for certain drugs. These instances often involved a company taking anticompetitive actions to establish or protect a monopoly position over a drug, leaving patients and payers no choice but to pay whatever price the company set or to forgo the medication entirely. In *FTC v. Lundbeck, Inc.*, the pharmaceutical company raised the price of its Indocin IV treatment for patent ductus arteriosus ("PDA"), a life-threatening heart condition affecting premature babies, from $77.77 to $1,614.44, after acquiring the U.S. rights to the only other available PDA treatment, which it priced at $1,522.50.[67] In *FTC v. Mallinckrodt*, the pharmaceutical company (which acquired the U.S. rights to a competing product) repeatedly increased the price of its H.P. Acthar Gel drug used to treat infantile spasms, nephrotic syndrome, and other serious diseases. On one occasion, Mallinckrodt raised the price overnight by 1,300%, to over $100,000 per course of treatment.[68] In *FTC v. Shkreli*, Vyera Pharmaceuticals increased overnight the price of its Daraprim treatment for toxoplasmosis, an acute, life-threatening infection, by over 4,000%, from $17.60 to $750 a tablet.[69] Vyera was able to maintain these prices by restricting the distribution of the drug and locking up viable sources of the active pharmaceutical ingredient in order to deter generic entry.[70] In *Sanofi/Maze*, the company charged in excess of $750,000 per year for its Pompe disease treatments and sought to acquire a competing drug to preserve its ability to charge these prices.[71] Once the FTC investigated these markets and determined it had reason to believe that these price levels were

---

[65] *See., e.g.*, Mallinckrodt Complaint at 2, 6–7 (detailing that Questcor acquired an on-market drug for a mere $100,000, incurring no research and development outlay, but still subsequently charged a supracompetitive price because it faced no competitive constraint).

[66] CNBC Television, *Blocking the Horizon-Amgen deal will be worse for pharma than for biotech, says Mizuho's Jared Holz*, YOUTUBE (May 18, 2023), https://www.youtube.com/watch?v=xglyNWjahgY ("The large cap pharma companies are really commercial entities. They're marketing machines[.]"); *see also* Aris Angelis et al., *High drug prices are not justified by industry's spending on research and development*, BMJ (Feb. 2023), https://www.bmj.com/content/380/bmj-2022-071710; Alexandra Pecci, *Do R&D costs justify the price of drugs? Nope, new study says*, PHARMAVOICE (Mar. 1, 2023), https://www.pharmavoice.com/news/rd-costs-justify-price-drugs-BMJ/643774/ (reporting companies spend "significantly more" on costs relating to selling, general, and administrative activities than on R&D, and that R&D spend may be inflated on activities "serving more as marketing strategies").

[67] *Fed. Trade Comm'n v. Lundbeck, Inc.*, 650 F.3d 1236, 1238 (8th Cir. 2011).

[68] Mallinckrodt Complaint at 2, 6 ("Questcor acquired Acthar from Aventis Pharmaceuticals, Inc. in 2001 for $100,000 plus modest royalties. At that time, the price of Acthar was $40 per vial. Questcor has since raised Acthar's price to over $34,000 per vial—an 85,000% increase.").

[69] *Fed. Trade Comm'n v. Shkreli*, 581 F. Supp. 3d 579, 601, 634 (S.D.N.Y. 2022) ("Vyera's agreements . . . closed off access to the two most viable suppliers of pyrimethamine for years."), *aff'd*, *Fed. Trade Comm'n v. Shkreli* (No. 22-728) 2023 WL 9346525 (2d Cir. Jan. 23, 2023).

[70] *Id.*

[71] Sanofi Complaint at 7 ("Sanofi has repeatedly and profitably raised Lumizyme's and Nexviazyme's prices without patients switching to any other treatment and without considering the price for any other treatment. The annual cost of treatment for either Lumizyme or Nexviazyme for a patient of average weight is over $750,000."); *see also supra* note 15.

being enabled or preserved via anticompetitive actions, the agency pursued antitrust enforcement actions.

In prescription drug markets where pricing is buoyed by a sponsor wielding patent rights over a government-funded invention, exercising march-in rights and enabling additional licensees to access federally funded inventions can foster competition and provide a necessary check on high drug prices that unreasonably limit public access.

IV. Further Actions Could Help Promote Licensing and Access to Patents Generated by Taxpayer-Funded Research

March-in rights are a valuable tool to address potential harms in the pharmaceutical industry. At the same time, the FTC also acknowledges broader challenges requiring government-wide solutions. One such challenge involves the trend of pharmaceutical companies using increasingly large patent portfolios—often described as a "patent thicket"—to protect a single treatment. For example, the 1980s blockbuster drug Cipro was covered by just one patent, whereas the present-day blockbuster Humira antibody is covered by over 130 patents. [72] In part, this trend reflects growth of the patent industry itself. [73] The patent industry has ballooned in recent decades; over 66,000 U.S. patents were granted in 1980 and by 2019 the number multiplied almost sixfold to over 391,000. [74]

Some claim that the pharmaceutical patent-thicket phenomenon may in part reflect the growing complexity of medical innovations. [75] However, research suggests that patent thickets do not necessarily reflect true innovation and pharmacological advancement. For example, some studies have found that the patents awarded in the decades after Bayh-Dole's enactment showed fewer clinically improved new drugs being offered than in the years leading up to the statute. [76] Moreover, especially in the biotechnology space, patent thickets often include large numbers of patents obtained after the initial round of patents covering an innovative active ingredient. As compared to the earliest innovative patents that cover a new compound, these "secondary patents" are more frequently invalidated in litigation. [77]

---

[72] Duan, *supra* note 47.

[73] *Id.*

[74] *Id.*

[75] *Id.*

[76] Penman, *supra* note 40 at 17 & n.96 (citing Donald W. Light & Antonio F. Maturo, *Good Pharma: The Public Health Model of the Mario Negri Institute* 197 (2015)).

[77] Michael A. Carrier & S. Sean Tu, *Why Pharmaceutical Patent Thickets Are Unique*, TEXAS INTELLECTUAL PROP. L. J. (Aug. 1, 2023), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4571486; S. Sean Tu & Mark A. Lemley, *What Litigators Can Teach the Patent Office About Pharmaceutical Patents*, 99 WASH. U. L. REV. 1673, 1675 (Aug. 11, 2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3903513. Many of these patents are directed toward methods of manufacturing, dosage formulations, combinations with known materials, or other improvements. Duan, *supra* note 47 ("These are essentially patents on *commercialization itself*.").

Dense patent thickets can impede competition and delay generic or biosimilar entry even where some component patents are ultimately determined to be invalid.[78] The process of challenging the validity of patents is often slow and inefficient, discouraging entry by rivals or generics confronted with large thickets, or chilling investment in those areas.[79] Patent thickets may also frustrate government efforts to use march-in rights to provide affordable public access to drugs, because drugs may be protected by patent thickets that include privately funded blocking patents in addition to government-funded patents subject to march-in rights. In other words, patent thickets may weaken the utility of march-in rights.

Accordingly, the FTC urges agencies to work collaboratively to address patent thickets in the pharmaceutical industry. The FTC applauds the U.S. Patent and Trademark Office's efforts to work with the FDA to stop patents from being improperly used to block or delay entry of cheaper competing drugs[80] and encourages the agencies to accelerate their efforts to address patent thickets as well. For example, as part of this work, the U.S. Patent and Trademark Office could revisit allowing the use of terminal disclaimers, which can impede entry of cheaper generic and biosimilar drugs.[81] The FTC stands ready to assist its sister agencies as appropriate.

---

[78] Alex Brill & Christy Robinson, *How Patent Thickets Constrain the US Biosimilars Market and Domestic Manufacturing*, MATRIX GLOBAL ADVISORS (May 2021), https://getmga.com/wp-content/uploads/2022/04/PatentThickets_May2021_FINAL.pdf; Rachel Goode & Bernard Chao, *Biological Patent Thickets and Delayed Access to Biosimilars, an American Problem*, 9 J. L. & BIOSCIENCES 1, 2 (2022), https://pubmed.ncbi.nlm.nih.gov/36072417/.

[79] Carrier, *supra* note 77.

[80] Kathi Vidal & Robert M. Califf, *The Biden Administration is acting to promote competition and lower drug prices for all Americans*, U.S. PATENT AND TRADEMARK OFFICE DIRECTOR'S BLOG (July 6, 2022), https://www.uspto.gov/blog/director/entry/the-biden-administration-is-acting.

[81] S. Sean Tu et al., *Biologic Patent Thickets and Terminal Disclaimers*, JAMA (Dec. 14, 2023), *available at* https://jamanetwork.com/journals/jama/article-abstract/2813272 (noting that "almost half all litigated patents on biologics over the past decade were continuation patents with terminal disclaimers" and that such patents "can trigger lengthy and costly litigation and add uncertainty for biosimilar manufacturers.") (also noting that "biosimilar entry is often delayed by expansive patent thickets").