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

I. For too long,

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]

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),

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 adr -22ue Statemo.32 0 Tdinp320 Td[(ad)3 (on)16-4 (t)-6o (,)-147.66 0 -4 (ef)N (T)-13arednt[(m)-26 (o)-ind[(b)-essc-4 (ef)-

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. Tf397 Tw [(a)-24 (os)5.6 (e)-6 7 (ct)2.7 (

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

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-

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]

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%20 Industry%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] rmmivat s hateorhmrc .7 (o)6 (r)t6 (r)50.7 (h)emtierOnhd es ch tor

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*.").