UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

FEDERAL TRADE COMMISSION,
STATE OF CALIFORNIA,
STATE OF ILLINOIS,
STATE OF MINNESOTA,
STATE OF NEW YORK,
STATE OF WASHINGTON
and
STATE OF WISCONSIN,

Plaintiffs,

v.

AMGEN INC.
and
HORIZON THERAPEUTICS PLC,

Defendants.

Case No. 1:23-cv-03053

Judge John F. Kness

MOTION OF THE BIOTECHNOLOGY INNOVATION ORGANIZATION, ILLINOIS MANUFACTURERS ASSOCIATION, CHICAGOLAND CHAMBER OF COMMERCE, AND ILLINOIS BIOTECHNOLOGY INNOVATION ORGANIZATION TO FILE A BRIEF AS AMICUS CURIAE IN OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

The Biotechnology Innovation Organization ("BIO"), Illinois Manufacturers Association ("IMA"), Chicagoland Chamber of Commerce ("CCC"), and Illinois Biotechnology Innovation Organization ("iBIO"), all not-for-profit membership associations, respectfully submit this Motion for Leave to File a Brief as Amicus Curiae in this matter. For the reasons set forth below, BIO, IMA, CCC, and iBIO request that this Court grant the motion and permit the filing of the

amicus brief attached as Exhibit A.[1] Amici have consulted with Plaintiffs (both the Federal Trade Commission and the States) who declined to take a position on the motion without first having reviewed the brief.[2]

1. BIO is the world's largest life sciences trade association, representing nearly 1,000 biotechnology companies (including Amgen and Horizon Therapeutics), academic institutions, state biotechnology centers, and related organizations across the United States and abroad. BIO's members are involved in the research and development of innovative biotechnology products that will help to solve some of society's most pressing challenges, such as sustainably growing nutritious food, improving animal health and welfare, enabling manufacturing processes that reduce waste and minimize water use, and advancing the health and well-being of our families. In particular, BIO advocates for innovation in biotechnology in the healthcare space, to bring treatments and cures to patient populations in the U.S. and throughout the world.

2. Founded in 1893, the IMA is the oldest, and one of the largest, state manufacturing trade associations in the United States. The IMA represents nearly 4,000 member companies and facilities, including biopharmaceutical companies, that employ approximately 650,000 workers directly and contribute the single largest share of the Gross State Product. The biopharmaceutical sector has a $59 billion economic impact in Illinois and supports more than 100,000 jobs directly and indirectly. The IMA advocates for the needs of its members by championing strong economic and regulatory policies.

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[1] No counsel for Plaintiffs or Defendants authored this brief in whole or in part, and no entity or person, aside from amicus curiae, its members, or its counsel, made any monetary contribution intended to fund the preparation or submission of this brief. See Fed. R. App. P. 29(a)(4)(E).

[2] In the experience of Counsel for Amici, who themselves are alumni of the FTC (and, in one case, DOJ), it is unusual for the government to request to see an advance copy of an amicus brief as a condition for consent.

3. CCC represents more than 1,000 businesses from all major industries. Its members employ approximately 500,000 people in the greater Chicagoland area and create more than $30 billion in local annual revenues. The CCC advocates on behalf of its members to promote economic development in Illinois, improve technology, entrepreneurial, and innovation infrastructure, build the region's workforce, and maintain Chicago's status as a global hub for infrastructure. The CCC also promotes policies that advance a diverse, equitable, and inclusive economy and opportunities for Minority and Women owned businesses and disadvantaged business enterprises. The life sciences and biopharmaceutical sectors are critical industries in Chicago and the Chicagoland region, employing nearly 100,000 Illinois workers and driving the regional economy. The industries are targeted key growth sectors for the region and are expected to play a critical role in long-term regional economic development.

4. iBIO is a life sciences industry association that represents the 85,000 life sciences employees at member companies, universities, service providers and venture firms. iBIO promotes the industry's value to the public and policymakers; connects innovators to investment and talent; stimulates collaboration; and fosters the next generation of innovators and entrepreneurs to transform patient lives through groundbreaking research. iBIO also works to grow the Illinois economy.

5. BIO, the IMA, CCC, iBIO, and their members have numerous interests in this lawsuit, which threatens the biopharmaceutical industry's basic business model. The biopharmaceutical industry depends on dynamic merger and acquisition ("M&A") activity to allocate risk, to raise and deploy capital, to develop and test new drugs, to obtain regulatory approval, and to produce approved drugs in sufficient quantities to meet consumer demand in the U.S. and throughout the world. In 2021, biopharmaceutical companies engaged in 196 M&A transactions worth $152

billion in total, more than any other U.S. industry.[3]

6. Although the Federal Rules of Civil Procedure neither prohibit nor expressly permit amicus participation in the district courts, in other cases, this Court has accepted amicus briefs in cases that affect the public concern. *See Bost v. Illinois State Board,* 2022 WL 6750940 (N.D. Ill.).

7. In their amicus brief, BIO, the IMA, CCC, and iBIO explain how the FTC's lawsuit would chill biopharmaceutical mergers to the detriment of patients and the public writ large. In the present case, in seeking to enjoin the proposed transaction, the FTC moves beyond the longstanding focus on competitive overlaps in biopharmaceutical markets and the bipartisan consensus on pro-competitive efficiencies, thereby threatening innovation, and chilling investment in an industry that brings treatments and cures to patients. The amicus brief explains that the FTC's resistance to the merger, if accepted, would chill pro-competitive mergers across the industry and beyond.

8. The amicus brief also discusses the lawsuit in the context of broader antitrust law. The FTC's legal theory breaks sharply from a focus on traditional antitrust theories involving overlapping markets and pro-competitive efficiencies. For four decades, FTC has evaluated mergers based on demonstrable harm to consumers, concentration within a market, and competitive overlaps, while also taking into account the pro-competitive aspects of specific transactions.

WHEREFORE, amici BIO, the IMA, CCC, and iBIO respectfully request that this Court grant leave to file the brief attached hereto as Exhibit A.

[3] Giglio and Micklus, *Biopharma Dealmaking in 2022,* NATURE (Jan. 11, 2023), at https://www.nature.com/articles/d41573-023-00012-0.

Dated: August 24, 2023

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Exhibit A

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES iii

INTRODUCTION 1

I. Biopharmaceutical Mergers and Acquisitions Promote Innovation and Expand Output and Benefits for Patients 2

II. The FTC's Unnecessary Expansion of the Enforcement Framework Will Block or Chill Pro-competitive Biopharmaceutical Mergers 6

III. The FTC's Recent Rejections of Proposed Remedies Will Also Block or Chill Pro-competitive Biopharmaceutical Mergers 11

CONCLUSION 15

TABLE OF AUTHORITIES

Page(s)

CASES

FTC. v. Meta Platforms,
No. 22-cv-04325-EJD, 2023 WL 2346238 (N.D. Cal. Feb. 3, 2023).....8, 9

FTC. v. Microsoft Corp.,
No.23-cv-2880-JSC, 2023 WL 4443412 (N.D. Cal. Jul. 10, 2023).....9, 10, 12, 13

In the Matter of Illumina, Initial ALJ Decision 199 (Sept. 9, 2022) 13

United States v. AT&T,
310 F. Supp. 3d 161 (D.D.C. 2018).....12

OTHER AUTHORITIES

BIO, Clinical Development Success Rates 2006-2015 (June 2016).....3

BIO, *Comments on the FTC's Request for Information on Merger Enforcement* (Apr. 15, 2022).....3, 4, 5

Cong. Budget Off., Research and Development in the Pharmaceutical Industry (Apr. 2021).....4

Christine Wilson, FTC Comm'r, Keynote Address, *There's Nothing New Under the Sun: Reviewing Our History to Foresee the Future* (Oct. 7, 2021).....10

Christine Wilson, Remarks for the Joint Conference on Precautionary Antitrust, *Marxism and Critical Legal Studies Walk into the FTC: Deconstructing the Worldview of Neo-Brandeisians* (Apr. 8, 2022) 10

Christine Wilson, *Why I'm Resigning as an FTC Commissioner*, WALL ST. J. (Feb 14, 2023). 9, 10

David Michaels & Joseph Walker, *FTC Moves to Block Amgen's $27.8 Billion Deal for Horizon Therapeutics,* WALL ST. J. (May 16, 2023).....14

David Michaels and Ryan Tracy, *Wall Street Deal Making Faces Greater Scrutiny, Delays Under FTC's Lina Khan,* WALL ST. J (Aug. 15, 2022).....11

David J. Ravenscraft & William F. Long, *Paths to Creating Value in Pharmaceutical Mergers*, MERGERS AND PRODUCTIVITY (2000).....5

D. Daniel Sokol, *Antitrust Mergers and Regulatory Uncertainty,* (Working Paper, 2023) 11

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Michael S. Ringel and Michael K. Choy, *Do large mergers increase or decrease the productivity of pharmaceutical R&D,* DRUG DISCOV. TODAY (2017).....5

Org. for Econ. Co-operation & Dev., Conglomerate effects of mergers – Note by the United States, (June 4, 2020) 5, 6, 7

Patricia Giglio & Amanda Micklus., *Biopharma Dealmaking in 2022,* NATURE (Jan. 11, 2023*)*.....2

Robert H. Bork, THE ANTITRUST PARADOX: A POLICY AT WAR WITH ITSELF (1978).....7

Sean Heather, The FTC's Objection to Microsoft-Activision Merger: A Bridge Too Far, Even for Europe, U.S. Chamber (June 13, 2023).....14

Shuxun Wang et al., *Acquisition for innovations? M&A intensity and intra-firm innovation reallocations*, 62 RSCH. IN INT'L BUS.(2022) 5

Ted W. Love, *New attacks on the drug industry would have made my breakthrough sickle cell treatment impossible,* STAT (July 23, 2023).....3

Timothy J. Muris, Neo-Brandeisian Antitrust: Repeating History's Mistakes (Am. Ent. Inst. Working Paper No. 2023-02, 2023) 11

I. Introduction

The biopharmaceutical industry depends on dynamic merger and acquisition ("M&A") activity to innovate, to distribute risk and capital, and to develop and bring cutting-edge treatments and cures to patients globally. Over the past four decades, the Federal Trade Commission ("FTC," "Agency," or "Commission") has pursued an approach to antitrust merger enforcement that not only permits, but encourages and values, this activity.[4] Unfortunately, recent cases – including this one – suggest that the Commission is inexplicably diverting from its time-tested focus on competitive overlaps and evidence of consumer harm. Amici worry that such an abrupt and unnecessary shift in merger enforcement, combined with an unwillingness to negotiate reasonable remedies, will discourage beneficial transactions and chill investment, with predictable and unwelcome results for innovation and drug development.

The Commission's request to enjoin the current merger, pending an administrative trial, should be rejected. Because there is no horizontal competition between the merging companies in the relevant market, post-merger relief will not need to "unscramble" any material mixing of productive assets. Because there is no upstream-downstream relationship between those companies and competitors in the relevant market, and no prospect of early entry into the relevant markets, no possible future competitors would be foreclosed pending the result of an administrative trial. On the other hand, an injunction would continue to delay the merger's potential benefits and, more broadly, chill transactions that support the distribution of innovative pharmaceutical products for the benefit of patients in the U.S. and throughout the world. Amici

[4] Enforcement of the antitrust laws is a core element of the FTC's mission. BIO acknowledges that actual anticompetitive conduct by firms should be the subject of scrutiny and challenge, whether by the Agency or by private parties. However, both over-enforcement and misdirected enforcement by the Agency impose significant costs of their own, particularly in the biotech sector. It is this type of enforcement that is the focus of BIO's brief.

Biotechnology Innovation Organization ("BIO"), Illinois Manufacturers Association ("IMA"), Chicagoland Chamber of Commerce ("CCC"), and Illinois Biotechnology Innovation Organization ("iBIO") believe that the FTC's actions are already chilling beneficial mergers and that this suit, if successful, would cripple the industry's innovation ecosystem, which has demonstrated success for four decades under the existing rubric for analysis of competitive threats.

II. Biopharmaceutical Mergers and Acquisitions Can Promote Innovation and Expand Output and Benefits for Patients

Today, mergers and acquisitions help define much of the biopharmaceutical innovation ecosystem. In 2021, biopharmaceutical companies engaged in 196 M&A transactions worth $152 billion in total, more than any other U.S. industry.[5] In a typical deal, a large firm acquires a smaller company that has developed promising drug candidates, even as the acquired company often has no or few drugs that have received approval from the Food & Drug Administration ("FDA"). After the acquisition, the large firm uses its resources to conduct the expensive "Phase 3" trials that test a promising drug's efficacy and, ideally, obtain the FDA's approval. Alternately, a smaller company may conduct a Phase 3 trial in collaboration with a larger company, and then partner with the larger company, via licensing or merger, to manufacture and distribute the drug globally. In either case, if all goes well, the large company uses its resources to facilitate the testing, manufacturing, and distribution of the medicine, helping to reach patients in need of these treatments and cures much more quickly.

This ecosystem allows the various industry participants to play to their strengths. In the early stages of drug development, smaller companies have a comparative advantage in terms of flexibility and a willingness to absorb the risks of experimenting with new molecules. Based on

[5] Patricia Giglio and Amanda Micklus, *Biopharma Dealmaking in 2022,* NATURE (Jan. 11, 2023), https://www.nature.com/articles/d41573-023-00012-0.

decades of experience, small biotechnology companies have a "secret sauce" that large companies often cannot replicate, namely, nimble cultures that enthusiastically explore new ideas in the early stages of identifying promising molecules. Indeed, post-acquisition, small biotechnology companies often continue to exist as subsidiaries to preserve their cultures and to empower their founders and staff.[6]

Given the right circumstances, a large biopharmaceutical company can bring other assets to the ecosystem. In the later stages of drug development, larger firms have the expertise and resources to manage the process, such as unequalled reach to patients for therapeutic candidates. Larger companies also can command established marketing and distribution capacity and capabilities from having successfully commercialized other treatments. By combining complementary assets and expertise, the combined firm may create new therapies more quickly and then produce those drugs in sufficient quantities, and distribute those drugs more efficiently, to meet global demand. For instance, one such acquisition allowed a small company to expand production and distribution enough to reach patients in poorer countries suffering from sickle-cell disease.[7]

Large companies, as well as private venture capital firms, also can bring with them both necessary capital and a higher capacity to absorb the risks of late-stage development. In drug trials, usually all does not go well. According to one study, a drug's aggregate probability of receiving FDA approval is only 20.9% for non-oncology programs, and even worse, only 3.4%,

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[6] *See generally*, BIO, *Comments on the FTC's Request for Information on Merger Enforcement* (Apr. 15, 2022) ("BIO Merger Comments"), http://www.regulations.gov/comment/FTC-2022-0003-1784.

[7] Ted W. Love, STAT, *New attacks on the drug industry would have made my breakthrough sickle cell treatment impossible* (July 23, 2023), https://www.statnews.com/2023/07/31/global-blood-therapeutics-oxbryta-pfizer-ira-small-molecules/?mkt_tok=NDkwLUVIWi05OTkAAAGNSzydZu2PV2OVJe0UGzN_ycgjiz4m4RgJc9b4HPJkY6IXvsHWSVX6d-teICRKrixj-px6HSLjKObGI7aDGvfMVta4jnMTDUhFFPZe3LB9H0XmOQ.

for oncology programs.[8] Moreover, as the FTC itself acknowledges, "The preclinical and clinical trials can cost hundreds of millions of dollars to complete, all without a guarantee of success. The Department of Health and Human Services estimates that it can take $300-500 million or more, and 14 years on average, to develop and bring a drug to market." Am. Cmplt. ¶ 82. Other estimates are even higher. According to the Congressional Budget Office, "The expected cost to develop a new drug—including capital costs and expenditures on drugs that fail to reach the market—has been estimated to range from less than $1 billion to more than $2 billion."[9] Few ongoing concerns can afford expensive failures almost 80% of the time, and almost 97% of the time for oncology drugs. Nevertheless, in 2020, private venture capital invested $17.9 billion, and large biopharmaceutical companies invested $15.9 billion, in upfront payments to emerging biotechs.[10]

With large and diversified revenue streams, perhaps only these firms can afford to gamble on numerous unsuccessful molecules in the hope that a handful will succeed. Based on centuries of history dating to the 1800s, no bank, traditional financial institution, or government entity has shown the willingness or ability to risk these sums of capital tied to high probabilities of failure. Although the return on investment of a successful therapeutic can offset the sunk costs of failures and the rising costs of drug development and approval, historically this strategy works best for large firms and investors who maintain a broad portfolio of biotech products.

This innovation ecosystem, typically centered on M&A or licensing between a large

[8] Other estimates differ slightly. According to one study, the overall likelihood of approval from Phase I for all developmental candidates was 9.6%, and 11.9% for all indications outside of oncology. BIO, Clinical Development Success Rates 2006-2015 (June 2016), https://www.bio.org/sites/default/files/legacy/bioorg/docs/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf.

[9] Cong. Budget Off., Research and Development in the Pharmaceutical Industry (Apr. 2021), https://www.cbo.gov/publication/57126#_idTextAnchor000.

[10] BIO Merger Comments at 3 (citing Lo et al, "Estimation of clinical trial success rates and related parameters," Biostatistics (2018)).

company and smaller one, has proven more successful than anyone could reasonably hope. In the U.S., this model produces more new drugs each year than the rest of the world combined, including new gene therapies, vaccines, and biologics.[11] Today, most commercial drugs originated with smaller firms that were bought or licensed by larger pharmaceutical firms who continued to develop the drugs and bring them to market.[12] Output continues to increase as measured by both R&D spending and the number of new molecular entities that target previously untreated rare and orphan diseases.[13]

Numerous studies confirm that biopharmaceutical mergers can promote competition, particularly where, as here, there is no competitive overlap between the companies' products. One study found that "recent large pharmaceutical mergers are associated with statistically significant increases in R&D productivity."[14] Other studies concluded that mergers can effectively help firms allocate innovation resources to acquired companies[15] and that "biopharmaceutical firms can successfully outsource R&D through acquisitions."[16] In a case study, scholars concluded that the hostile acquisition of a smaller company by a larger company (GlaxoSmithKline) reduced costs via economies of scale, and improved output via expanded global reach, broader product lines,

[11] *See* McKinsey & Co., *The UK biotech sector: The path to global leadership* (Dec. 3, 2021) (noting that the UK continues to lag behind the U.S. on many metrics), https://www.mckinsey.com/industries/life-sciences/our-insights/the-uk-biotech-sector-the-path-to-global-leadership.
[12] *E.g.*, Katasayna Smietana, et.al., NATURE, *The fragmentation of biopharmaceutical innovation* (Apr. 29, 2019), at https://www.nature.com/articles/d41573-019-00046-3.
[13] BIO Merger Comments at 15 (citing McKinsey, *supra*).
[14] Michael S. Ringel and Michael K. Choy, *Do large mergers increase or decrease the productivity of pharmaceutical R&D?,* 22 DRUG DISCOV. TODAY 1749-1753 (2017), https://pubmed.ncbi.nlm.nih.gov/28646641/.
[15] Shuxun Wang et al, *Acquisition for innovations? M&A intensity and intra-firm innovation reallocations*, 62 RSCH. IN INT'L BUS. (2022)
[16] Matthew John Higgins & Dan Rodriguez, *The outsourcing of R&D through acquisitions in the pharmaceutical industry*, 80 J. OF FIN. ECON., 352-383 (2006), https://www.sciencedirect.com/science/article/abs/pii/S0304405X05001807.

expanded use of future technologies, and the sharing of skills.[17]

Finally, the antitrust enforcement agencies themselves have recognized that "[m]ergers are one means by which firms can improve their ability to compete."[18] To be sure, Amici do not contend that every merger is necessarily pro-competitive, particularly where the merging parties compete in overlapping markets. Still, in a policy statement from just a few years ago, the FTC agreed that mergers can promote innovation:

> [I]n dynamic sectors characterized by high R&D costs, firms with broad scale and scope may have unique incentives and capabilities to invest in innovation. For example, where a firm can exploit synergies across product lines or earn returns on research and development projects across multiple geographies, it may have greater incentives to make investments in such projects than firms with more limited operations.[19]

As detailed below, the FTC's behavior in the current case breaks sharply from this approach, despite the FTC's own analysis that recognized biotech acquisitions drive innovation. Instead, the Commission now places all M&A activity under a cloud of suspicion. This is especially problematic when the innovation is measured in terms of lives saved and diseases prevented.

III. The FTC's Unnecessary Expansion of the Enforcement Framework Will Block or Chill Pro-competitive Biopharmaceutical Mergers

Over decades, the FTC has challenged scores of mergers involving pharmaceutical firms. The Agency resolved almost all of them with narrow, negotiated remedies that addressed any genuine competitive concerns, such as consent orders requiring divestiture of one or more competing products, or commitments to provide or allow access to critical inputs to competitors.[20]

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[17] David J. Ravenscraft & William F. Long, *Paths to Creating Value in Pharmaceutical Mergers*, MERGERS AND PRODUCTIVITY 287 (2000).
[18] OECD, Conglomerate Effects of Mergers – Note by the United States to the Organisation for Economic Co-operation and Development (June 4, 2020) at 5, https://www.ftc.gov/system/files/attachments/us-submissions-oecd-2010-present-other-international-competition-fora/oecd-conglomerate_mergers_us_submission.pdf.
[19] *Id*. at 8.
[20] *See* Federal Trade Commission, Overview of FTC Actions in Pharmaceutical Products and Distribution

The FTC adopted this view, at least in part, because the economic evidence showed that most mergers promoted competition so long as they did not involve horizontal competitors or otherwise result in anticompetitive business practices, and because the preceding few decades demonstrated that more aggressive antitrust enforcement stifled economic dynamism -- and proved unworkable in practice. *See generally*, Robert H. Bork, THE ANTITRUST PARADOX: A POLICY AT WAR WITH ITSELF (1978).

As part of this approach, and at least since the mid-1970s, the Commission and the Department of Justice both abandoned theories of harm arising from conglomerate mergers – mergers that, like this one, involve a combination of firms that are not in either a horizontal or vertical relationship. During that time, neither agency ever alleged harm, in any industry, from a combination of firms that were neither competitors (a horizontal merger) nor in an upstream-downstream relationship (a vertical merger). According to the antitrust enforcement agencies themselves, "[c]onglomerate mergers that raise neither vertical nor horizontal concerns are unlikely to be problematic under U.S. merger law."[21] Notably, for conglomerate mergers, "no [presumption of harm] is available because such mergers do not involve an increase in market concentration."[22]

In an international policy statement from just a few years ago, the agencies explained that such mergers, involving "conglomerate effects," could promote vigorous competition:

28-80 (2021), https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_of_ftc_actions_in_pharmaceutical_products_and_distribution.pdf (discussing challenges to mergers involving pharmaceutical products and the distribution of pharmaceutical products).

[21] OECD, Conglomerate Effects of Mergers – Note by the United States to the Organisation for Economic Co-operation and Development (June 4, 2020) at 2, https://www.ftc.gov/system/files/attachments/us-submissions-oecd-2010-present-other-international-competition-fora/oecd-conglomerate_mergers_us_submission.pdf.

[22] *Id*. at 4.

> The "entrenchment" doctrine, in particular, condemned mergers if they strengthened an already dominant firm through greater efficiencies or [by giving] the acquired firm access to a broader line of products … thereby making life harder for smaller rivals [of the acquired firm]. *This approach is no longer viewed as valid under U.S. law or economic theory*. … It is now recognized that efficiency and aggressive competition benefit[s] consumers, even if rivals that fail to offer an equally "good deal" suffer loss of sales or market share.[23]

Notwithstanding this history, the Commission now proposes to block a transaction in its entirety, not based on any concrete concerns about harm to consumers due to horizontal or vertical competition analysis, but out of an unreasonable and unnecessary denial of the strength of this enforcement consensus regarding potential pro-competitive benefits. Ignoring the many immediate and tangible ways in which mergers promote innovation by efficiently distributing risk, capital, and expertise, the FTC is disrupting the M&A space by blocking and chilling biopharmaceutical mergers based on a general hostility to mergers. The problem with the Commission's actions is that, by dramatically increasing the number of deals potentially subject to antitrust challenge, it creates an investment-suppressing cloud of regulatory uncertainty. The FTC's complaint, in short, is regrettably a bridge too far.

Unfortunately, this case is not the first in which the Commission has challenged a transaction without a factual basis for the feared harm. Two recent merger matters are instructive. In the first, in 2022, the Commission alleged that Meta's proposed acquisition of Within Unlimited would eliminate potential competition from Meta in the market for virtual reality ("VR") dedicated fitness apps in the United States. *FTC v. Meta Platforms*, No. 22-cv-04325-EJD, 2023 WL 2346238, *20 (N.D. Cal. Feb. 3, 2023). The Commission argued that, although Meta was not a current participant in this market, the transaction would lessen competition by depriving the market of the competition that would have arisen from Meta's independent entry. *Id*. at *20.

[23] *Id*. at 4-5 (emphasis added).

In reviewing the Commission's theory, the court evaluated whether it was "reasonably probable that Meta would have entered the VR dedicated fitness app market de novo if it was not able to acquire Within." *Id*. at *22. In a scathing review, the court found little or no basis to conclude that Meta would have entered the market absent the acquisition: Meta lacked "certain capabilities that are unique and critical to the VR dedicated fitness app market," "the capability to create fitness content," and "the necessary studio production capabilities." *Id*. at *23-24. Instead, the evidence showed "that Meta's capability and incentives … did not result in Meta ever seriously contemplating … building its own VR fitness app." *Id*. at *27. Although the FTC "implied that the Court may infer that Meta would have entered the market de novo … using 'available feasible means' unbeknownst to the parties or the Court," the district court rightly rejected the FTC's request for a preliminary injunction pending administrative litigation. *Id*. at *27, 33.

In a second recent matter, the Commission sought to preliminarily enjoin Microsoft's proposed acquisition of Activision, on the theory that post-merger Microsoft would refuse to license Activision's popular video game *Call of Duty* to Microsoft's rivals. *FTC v. Microsoft Corp.*, No.23-cv-2880-JSC, 2023 WL 4443412 at *1 (N.D. Cal. Jul. 10, 2023). The district court refused. *Id*. at *13-15. As the court explained, "notwithstanding the overwhelming evidence of the combined firm's lack of incentive to pull *Call of Duty* from [rivals], the FTC insists it is probable the combined firm will do so." *Id*. No evidence supported the FTC's theory: "[d]espite the completion of extensive discovery in the FTC administrative proceeding, including production of nearly 1 million documents and 30 depositions, the FTC has not identified a single document which contradicts Microsoft's publicly stated commitment to make *Call of Duty* available [to rivals]." *Id*. at *14, 15. The Court found "to the contrary, the record evidence points to more consumer access to *Call of Duty* and other Activision content." *Id*. at *22.

The FTC's newfound hostility to mergers is raising concerns with antitrust enforcers. FTC Commissioner Christine Wilson, who has since left the Agency,[24] observed that the FTC has now repudiated the merger review standards applied across presidential administrations over the past forty years, during which "roughly 95 percent of deals have been viewed as benign or beneficial."[25] As she noted, the FTC's dismissal of merger efficiencies "is reminiscent of the state of the law decades ago." *Id*.

Commissioner Wilson further explained that the FTC has been abusing legal processes to chill and block mergers. For instance, she explained that the Commission was "ignoring" its statutory timing obligations and using reporting requirements "frequently and punitively to increase the cost of future deals." *Id*. Commissioner Wilson worried that the FTC's antagonistic attitude would chill pro-competitive mergers: "FTC leadership has abused the merger review process to impose a tax on all mergers, not only those that hinder competition. … Abuse of regulatory authority now substitutes for unfulfilled legislative desires."[26] Ultimately, Commissioner Wilson noted, the FTC's current approach would harm consumers:

> Inevitably, these process changes will impact not just harmful deals, but beneficial ones as well. Of course, it is not clear to me that the current FTC majority views any deals as beneficial. But I believe a premise that M&A activity tends to be anticompetitive is flawed. Indeed, as the Department of Justice recognizes, "most mergers are not anticompetitive and may benefit consumers."[27]

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[24] Christine Wilson, *Why I'm Resigning as an FTC Commissioner,* WALL ST. J. (Feb 14, 2023), https://www.wsj.com/articles/why-im-resigning-from-the-ftc-commissioner-ftc-lina-khan-regulation-rule-violation-antitrust-339f115d.

[25] Christine Wilson, FTC Comm'r., Keynote Address, *There's Nothing New Under the Sun: Reviewing Our History to Foresee the Future* (Oct. 7, 2021), https://www.ftc.gov/system/files/documents/public_statements/1597798/gcr_merger_control_keynote_final.pdf.

[26] Wilson, WALL ST. J., *supra*, n. 21.

[27] Christine Wilson, Keynote Address, *supra*, n. 22 (citing U.S. DEP'T OF JUST., MERGER REMEDIES MANUAL 1 (Sept. 2020)).

Summing it up in another speech, Wilson opined that the new view "that mergers are evil may explain the many process and policy shifts undertaken by the FTC."[28]

In addition to Commissioner Wilson, many other antitrust observers have voiced concerns that the FTC's hostility to mergers could harm innovation. Former FTC Chairman Timothy Muris, for instance, pointed out that the FTC now "rejects the economics-driven antitrust policies of the past 40 years."[29] In a survey of antitrust practitioners, the USC Gould School of Law found that "[b]oth [the FTC and DOJ] are perceived as less transparent, less fair, and more combative in their interactions with merging parties" as compared to prior administrations. Two-thirds of practitioners (66%) responded that the FTC's current merger enforcement practices degrade efficiency and harm competition and innovation.[30]

The FTC's current challenge, if successful, could permanently damage the biopharmaceutical innovation ecosystem. In addition to licensing and other important factors, this ecosystem relies on private venture capitalists and larger companies acquiring smaller firms with a few promising drug candidates, so that the biopharmaceutical industry can effectively deploy capital and expertise with the goal of efficient and effective development and distribution of new medicines. Based on the FTC's implicit and ill-informed logic, however, virtually every

[28] Christine Wilson, Remarks for the Joint Conference on Precautionary Antitrust, *Marxism and Critical Legal Studies Walk into the FTC: Deconstructing the Worldview of Neo-Brandeisians* (Apr. 8, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Marxism%20and%20Critical%20Legal%20Studies%20Walk%20into%20the%20FTC%20Deconstructing%20the%20Worldview%20of%20the%20Neo-Brandeisians.pdf.

[29] Timothy J. Muris, *Neo-Brandeisian Antitrust: Repeating History's Mistakes* (Am. Ent. Inst., Working Paper No. 2023-02, 2023), https://www.aei.org/wp-content/uploads/2023/01/Muris-Neo-Brandeisian-Antitrust-WP.pdf?x91208.

[30] D. Daniel Sokol et al., *Antitrust Mergers and Regulatory Uncertainty* (Working Paper, Dec. 2022), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4295283.

transaction would raise competitive concerns. In the FTC's eyes, therefore, virtually every biopharmaceutical merger or acquisition would – or could – run afoul of the antitrust laws.[31]

IV. The FTC's Recent Rejections of Proposed Remedies Will Also Block or Chill Pro-competitive Biopharmaceutical Mergers

Competitive concerns in mergers are often remedied by structural relief (divestiture) or contractual or behavioral commitments (binding promises to do, or not do, something). Here, however, the FTC has rejected the parties' remedy offer, despite the fact that it appears to address the agency's concerns. This rejection of reasonable remedies, if accepted, would serve as an additional obstacle to biopharmaceutical mergers while adding little or no competitive value.

The FTC's position is both inexplicable and inconsistent with past practice. *See, e.g.*, FTC, *The FTC's Merger Remedies 2006-2012: A Report of the Bureaus of Competition and Economics* (Jan. 2017), at Table 1 (showing the Commission accepted non-structural remedies in 100% of their challenges to non-horizontal mergers). The Commission considers its remedies successful if they maintain or restore competition in the relevant market. All non-structural remedies in non-horizontal merger matters reviewed for the report were, in fact, considered successful. *Id.* at 1-2.

In many cases, courts have found that non-structural remedies address any genuine competitive concerns. In *United States v. AT&T*, for example, the district court properly incorporated Turner Broadcasting's irrevocable offers of no-blackout arbitration agreements into its analysis of the potential anticompetitive effects of the vertical merger of AT&T (distribution) and Time-Warner (content). 310 F. Supp. 3d 161 (D.D.C. 2018), *aff'd* 916 F.3d 1029 (D.C. Cir

[31] Although this merger does not involve private venture capital, the FTC is also likely to treat private equity deals with deep skepticism. In recent years the FTC has expressed open hostility to private equity financing. *E.g.*, Dave Michaels and Ryan Tracy, *Wall Street Deal Making Faces Greater Scrutiny, Delays Under FTC's Lina Khan* WALL ST. J. (Aug. 15, 2022) (noting that the FTC "has targeted stricter oversight of private equity"), at https://www.wsj.com/articles/bidens-regulators-take-a-harder-look-at-wall-street-deals-11660555801.

2019). The government alleged the combined firm would threaten to withhold content from AT&T's competitors, but the court found that Turner Broadcasting's "irrevocable offers of no-blackout arbitration agreements means the merger is unlikely to afford Turner Broadcasting increased bargaining leverage." 916 F.3d at 1042-1043.

Likewise, in the Microsoft-Activision case, the court found that Microsoft's proposal resolved the FTC's competitive concerns, even though the Commission had rejected Microsoft's proposed behavioral remedy – to license Call of Duty for ten years. *FTC v. Microsoft*, Case No. 23-cv-02880-JSC, 2023 WL 4443412 (N.D.Cal. July 10, 2023).

Contrary to these court decisions, the Commission recently rejected another behavioral remedy, this time in the diagnostics and life sciences space. In the Illumina-Grail case, which is ongoing, the merging companies committed to an open offer that would grant rivals access to certain Illumina technology for a period of twelve years. In that case, the FTC's own Administrative Law Judge found that this behavioral remedy would resolve any competitive concern. However, the Commission was not satisfied and, on appeal, rejected the proposed remedy. The case is now before the Fifth Circuit.[32]

Until recently, the Commission has regularly accepted contractual/behavioral remedies in non-horizontal mergers (and in monopolization cases based on exclusionary conduct), provided that they are easily administrable. For example, in *Northrop Grumman-Orbital ATK*, the Commission required Northrop to commit to non-discrimination provisions in its dealing with

[32] *In the Matter of Illumina*, Initial ALJ Decision (Sept. 9, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/D09401InitialDecisionPublic.pdf, *rev'd*, Docket No. 9401 (Mar. 31, 2023), at https://www.ftc.gov/system/files/ftc_gov/pdf/d09401commissionfinalopinion.pdf, *stayed pending appeal*, https://www.ftc.gov/system/files/ftc_gov/pdf/d09401commissionordergrantingstay.pdf (Apr. 24, 2023) (in *Microsoft*, the court called into question the Commission's reasoning in rejecting Illumina's proposed remedy, at 39).

competitors to Orbital. Decision and Order at § II, *In the Matter of Northrop Grumman Corp. & Orbital ATK, Inc.*, Docket No. C-4652 (F.T.C. Dec. 3, 2018). In *Valero-Kaneb*, the Commission alleged that Valero's post-merger operation of certain Kaneb refined petroleum product terminals would give Valero, a bulk supplier of refined petroleum products, an incentive and ability to foreclose access by its competitors to Kaneb's terminals. To address its concerns, the Commission entered into a consent order with Valero requiring that it, among other things, operate the terminals in a reasonable and non-discriminatory way. Decision and Order at § VI, *In the Matter of Valero, L.P.*, Docket No. C-4141 (F.T.C. July 22, 2005).

The FTC has also accepted narrow behavioral remedies in the biopharmaceutical space. In *Teva-Allergan*, a transaction with both horizontal and vertical aspects, the Commission had concerns that the combined firm would have the incentive and ability to withhold supply of active pharmaceutical ingredients from current or future competitors. As a narrow remedy, the FTC required Teva to enter into supply agreements with respect to all users of any of eight active pharmaceutical ingredients, at pre-acquisition pricing, in commercial quantities, with related services provided consistent with past practice. Decision and Order at § IV, *In the Matter of Teva Pharma. Indus. & Allergan PLC*, Docket No. C-4589 (F.T.C. Sept. 7, 2016).

The FTC's sudden hostility to behavioral remedies, if endorsed by this Court, would further hamstring the biopharmaceutical industry's innovation ecosystem. Biopharmaceutical companies regularly agree to remedies, particularly partial divestments, to resolve competitive concerns.[33] If the FTC is allowed to reject reasonable, manageable behavioral remedies, this case could sharply reduce M&A activity in the biopharmaceutical space.

[33] Dave Michaels and Joseph Walker, *FTC Moves to Block Amgen's $27.8 Billion Deal for Horizon Therapeutics,* WALL ST. J. (May 16, 2023), at https://www.wsj.com/articles/ftc-poised-to-block-amgens-27-8-billion-deal-for-horizon-therapeutics-a9c1b499.

Indeed, although Amici's primary interest is the biotech industry and its patients, the potential harm from the FTC's approach is by no means so limited. Beyond the biopharmaceutical sector, the Commission's actions in tech, aerospace, microchips, the metaverse (Meta-Within), and cloud gaming (Microsoft-Activision) have also involved challenges to mergers in the absence of horizontal overlap and without actual evidence of competitive harm.[34] In most of these cases, the FTC also did not acknowledge that the merging parties could address conceivable harms through behavioral remedies.[35] To date, the FTC has lost every one of these challenges that has proceeded to litigation. But this should not be misunderstood as suggesting that the Commission's action has had no impact. The FTC's misdirected and arguably over-zealous enforcement likely has already chilled pro-competitive deals.

By moving beyond the bipartisan consensus on merger enforcement that has been in place for the past forty years, the FTC is endangering the innovation ecosystem, an inherent part of which is acquisition of small innovators by larger companies. The FTC's approach will burden small innovators, increase regulatory uncertainty, chill investment, and inhibit distribution of lifesaving treatments and cures, all of which will result in less innovation and poorer health outcomes for patients.

CONCLUSION

For these reasons, amici BIO, the IMA, CCC, and iBIO respectfully encourage this Court to reject Plaintiffs' motion for a preliminary injunction.

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[34] *E.g.*, Sean Heather, *The FTC's Objection to Microsoft-Activision Merger: A Bridge Too Far, Even for Europe,* U.S. Chamber, (June 13, 2023), https://www.uschamber.com/finance/antitrust/the-ftcs-objection-to-microsoft-activision-merger-a-bridge-too-far-even-for-europe.

[35] *E.g.*, Sean Heather, Why FTC's Lawsuit Against Meta is Concerning for the Entire Business Community, U.S. Chamber (Aug. 31, 2022), https://www.uschamber.com/finance/antitrust/why-ftcs-lawsuit-against-meta-is-concerning-for-the-entire-businesses-community.

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CERTIFICATE OF SERVICE

I hereby certify that on August 24, 2023, I electronically filed this Brief with the Clerk of the United States District Court for the Northern District of Illinois, Eastern Division, using the CM/ECF system, which will provide notice to all registered parties.

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