

No. S283862

IN THE SUPREME COURT OF THE STATE OF CALIFORNIA

GILEAD TENOFOVIR CASES

GILEAD SCIENCES, INC.,
Petitioner,

v.

SUPERIOR COURT OF THE CITY AND COUNTY OF SAN FRANCISCO,
Respondent;

and

PLAINTIFFS IN JCCP No. 5043,
Real Parties in Interest.

Review of a Decision from the Court of Appeal,
First Appellate District, Division Four, No. A165558

San Francisco County Superior Court No. CJC-19-005043
Hon. Andrew Y.S. Cheng

**APPLICATION FOR PERMISSION TO FILE AMICUS
CURIAE BRIEF IN SUPPORT OF RESPONDENT AND
REAL PARTIES IN INTEREST; AMICUS CURIAE BRIEF
OF JUSTICE CATALYST**

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**APPLICATION FOR PERMISSION FOR JUSTICE
CATALYST TO FILE BRIEF AS AMICUS CURIAE**

Pursuant to California Rules of Court, rule 8.520(f), Justice Catalyst respectfully requests permission to file the attached amicus curiae brief in support of Respondent and Real Parties in Interest.

Justice Catalyst Law is a national public interest legal advocacy organization and nonprofit law firm that develops high-impact legal strategies. Justice Catalyst Law's advocacy and litigation have led to major industry reforms in areas of high complexity. Justice Catalyst Law also conducts critical research, campaigns, and participates as an amicus in cases involving social, economic, and consumer justice, corporate and state accountability, and civil rights and access to justice.

Justice Catalyst presents the accompanying brief in support of its goal of furthering the rights of persons to be protected by an effective and equitable tort system. Because Justice Catalyst believes the accompanying brief would assist the Court in its resolution of the issues this case presents, Justice Catalyst respectfully requests this Court's permission to file it.

More broadly, no party, attorney for a party, or judicial member drafted this brief or participated in our decision to file it. Other than Justice Catalyst, no person or entity, including any party or party's counsel, made a monetary contribution intended to fund the preparation or submission of this brief.

November 4, 2024

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BRIEF OF AMICUS CURIAE

INTRODUCTION

The laws and regulations that apply to the pharmaceutical industry are many and varied, but they all have one common characteristic. When each new rule of law was first adopted, it came in the face of predictions of disaster. Each products liability rule was prophesied to be the end of all research, the end of new products, the end of innovation, and a catastrophe for public health. All limitations on exclusivity under patents and all laws that would encourage competition from generic products were met with similar threats of doom and disaster. And so here, in this case. Defendant Gilead and its various amici each suggest that if this Court were to affirm the thoughtful ruling of the Court of Appeal, that this would strike a crippling blow to innovation, and to America's public health.

The problem with these often-predicted disaster scenarios is that they repeatedly have not come true. Again and again, as new bodies of law were developed, the pharmaceutical industry has remained exceptionally profitable. Investment in research has repeatedly increased and new drug applications have flourished. Decisions by this Court and by the U.S. Supreme Court that were supposedly going to lead to catastrophe did not begin to do so. So, when this Court hears hyperventilated threats of disaster, it should see these for what they are: exaggerated predictions that are not going to pan out.

This brief also addresses another point. To hear Gilead and its amici tell it, the American legal system has never imposed any

liability upon any conduct by a manufacturer or pharmaceuticals for manipulating the availability of a product to extend the time that the product is under patent, with a single exception: when the product is defective. Outside of defective products, however, Gilead says that the American legal system has always been silent, without any rules relating to patent manipulation. This is also exaggerated. In fact, there are several ways where liability has fastened in such settings. This brief will give one instructive example of an analogous area of law—the limitations that the antitrust laws have sometimes placed on “product hopping,” which is a different, but related, kind of practice to Gilead’s behavior here. Under Gilead’s theory, since the conduct at issue in product hopping harms people but does not involve a defective product, it cannot possibly be illegal. But many courts and regulatory agencies have disagreed, for good and important reasons. So, the invisible limitation claimed by Gilead here—that manipulation of patents is always acceptable except when involving a defective product—is also illusory and wrong.

ARGUMENT

I. The Court should reject the pharmaceutical industry’s tired refrain that proper regulation will stifle innovation.

Like a boy who cries wolf, Gilead recycles an argument that has echoed through the decades whenever virtually any type of legal regulation over the pharmaceutical industry has been proposed, no matter how large or small: that innovation will be “diminish[ed]”, “undermine[d]”, “chill[ed],” and “disincenvitiz[ed]” if the Court does not do what Gilead wants. Gilead Pet. for Review

at 34, 37, 50, 56. These arguments are repeated by Gilead’s amici. But the only difference from that timeless fable here is that there isn’t a real wolf at the end of the story. The Court should discredit this classic *ipse dixit*.

a. Courts and legislators have been hearing about this parade of horrors for at least 60 years.

For many years, the pharmaceutical industry and its allies have repeated the illusory truth¹ that any manner of legal liability or oversight will chill innovation.² In 1961, when addressing the legislative proposal that ultimately became the 1962 Kefauver-Harris Amendments to the Federal Food, Drug, and Cosmetic Act, the pharmaceutical industry complained that amendments caused a so-called “drug lag” harming U.S. innovation, whereby “innovative compounds reached markets in Europe long before the U.S. market.”³

In the decades that followed, the industry has repeated this threat ad nauseum, seeking to obtain the same result with no regard to whether there is any logical connection between lessened innovation and a particular proposal. The major Drug Price

¹ The illusory truth effect describes the phenomenon by which statements begin to be perceived as more true merely because of how often they are repeated. See Emma L. Henderson, et al., *The Trajectory of Truth: A Longitudinal Study of the Illusory Truth Effect*, 4(1) J. COGNITION 29, 1–23 (2021).

² See Michael A. Carrier & Genevieve Tung, *The Industry that Cries Wolf: Pharma and Innovation*, STAT (Sept. 26, 2019) <https://www.statnews.com/2019/09/26/innovation-boy-cried-wolf-pharma-industry/>.

³ See Jeremy A. Greene & Scott H. Podolsky, *Reform, Regulation, and Pharmaceuticals — The Kefauver–Harris Amendments at 50*, 367,16 NEW ENGL. J. MED. 1481 (2012), <https://doi.org/10.1056/NEJMp1210007>.

Competition and Patent Term Restoration Act of 1984, better known as the Hatch-Waxman Act, is generally regarded as a compromise whereby generic manufacturers could obtain expedited approval for generic drugs, while brand manufacturers could extend their patents for time lost during the approval process. It sought to strike “a balance between two potentially competing policy interests—inducing pioneering development of pharmaceutical formulations and methods and facilitating efficient transition to a market with low-cost, generic copies of those pioneering inventions at the close of a patent term.” *Novo Nordisk A/S v. Caraco Pharm. Lab’ys, Ltd.*, 601 F.3d 1359, 1360 (Fed. Cir. 2010). But before its enactment, the pharmaceutical industry threatened that under Hatch-Waxman, “[i]nnovation will dry up” and “you get what you pay for.”⁴ Of course, even under Hatch-Waxman, the pharmaceutical industry has seen its profits and drug prices continue to increase. *See supra* Section I(b).

More recent legislative efforts have been no different, with industry representatives consistently warning that any attempt at reform will stifle innovation. The Pharmaceutical Research and Manufacturers of America (“PhRMA”) has led the charge. In 2013 it opposed efforts to curb the misuse of patent enforcement and legislation targeting pay-for-delay settlements; in 2019 it opposed government “march-in rights” compelling the grant of a patent license if the patent was procured through government-funded

⁴ *Drug Price Competition Act, Hearings Before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce*, 98th Cong., 1st Session, Serial No. 98-67, p. 131 (July 25, 1983).

research; and most recently, it opposed federal government negotiation of Medicare prescription drugs under the Inflation Reduction Act of 2022.⁵

These industry threats have permeated the courts as well. Even the amici supporting Gilead in this appeal have repeated this stale argument in countless cases about whether the pharmaceutical industry can or should be subject to tort liability. For example, in the lead-up to the landmark *FTC v. Actavis* decision, where the U.S. Supreme Court held that a reverse-payment patent settlement (a so-called “pay for delay” agreement) could constitute an antitrust violation, the brand-name pharmaceutical defendants argued to the Eleventh Circuit that reverse-payment agreements fit perfectly within the Hatch-Waxman framework and to outlaw them would result in an “undercutting of the reward for innovation.”⁶ The industry’s fears did not stop the U.S. Supreme Court from holding that reverse payment settlements are not immune from antitrust liability. *See FTC v. Actavis*, 570 U.S. 136 (2013).

⁵ *See* Carrier, *supra* note 2; *Government Price Setting Has Potentially Devastating Consequences for Patients*, PHRMA, <https://phrma.org/en/pricesetting> (last visited Oct. 28, 2024); *see also* Lynn Paramore, *Experts: Negotiating Big Pharma’s Prices Won’t Stifle Innovation—They Don’t Use the Money to Innovate!*, INST. FOR NEW ECON. THINKING (Mar. 14, 2024), <https://www.ineteconomics.org/perspectives/blog/experts-negotiating-big-pharmas-prices-wont-stifle-innovation-they-dont-use-the-money-to-innovate>.

⁶ Br. for Appellees Unimed Pharmaceuticals, LLC, Abbott Products, Inc., and Watson Pharmaceuticals, Inc., *FTC v. Watson Pharms., Inc.*, No. 10-12729-DD, 2010 WL 5064781, at *51 (11th Cir. 2010).

In *Wyeth v. Levine*, the U.S. Supreme Court held that federal regulatory approval of a medication does not shield the manufacturer from state tort liability. *Wyeth v. Levine*, 555 U.S. 555 (2009). Supporting Wyeth, both PhRMA and the Biotechnology Innovation Organization (“BIO”) argued that “the growth in state-law tort suits challenging FDA-approved labeling has posed an increasingly serious threat to public health” and that “[s]tate-law tort suits can deprive doctors and patients of critical medicines by inhibiting drug development or driving beneficial drugs from the market.”⁷ The Supreme Court was apparently not convinced and certainly did not hold that state tort law should not apply to drug manufacturers. The landmark decision in *Wyeth* was handed down 15 years ago, but none of the disaster scenarios prophesized by PhRMA have eventuated.

And in *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299 (2019), a case where the Court clarified *Wyeth*, PhRMA and BIO argued the Third Circuit’s decision had “hamper[ed] innovation and harm[ed] public health” by “discounting the rigorous FDA-supervised process manufacturers undertake to bring a medicine to market and encouraging civil litigation.”⁸ The U.S. Chamber of Commerce similarly argued that “[a]llowing failure-to-warn claims to proceed under the varying tort laws of the fifty states despite a preponderance of the evidence that FDA

⁷ Br. for PhRMA and BIO as Amici Curiae Supporting Pet’r, *Wyeth v. Levine*, No. 06-1249, 2008 WL 2322236, at *14, *18 (U.S. 2008).

⁸ Br. of Amici Curiae Pharmaceutical Research and Manufacturers of America and Biotechnology Innovation Organization in Support of Pet’r at 34, *Merck Sharp & Dohme Corp. v. Albrecht*, No. 17-290 (U.S. 2018).

would not have approved the proposed warnings would impose significant and unpredictable defense and liability costs on manufacturers, and thereby reduce their willingness to invest in drug development.”⁹

Here in California, the industry and its allies have repeated the same old story. In *T.H. v. Novartis Pharms. Corp.*, a case filed against a brand name drug company on behalf of twins who were injured in utero after a label failed to warn that the drug can cause fetal brain damage, industry-aligned amici warned that to impose liability “could rapidly pose an existential threat to legitimate high-technology businesses”¹⁰ and “will make California a magnet for novel lawsuits against manufacturers, thereby hurting California’s economy and costing manufacturing jobs.”¹¹ This Court rejected the industry’s parade of horrors, holding that brand-name manufacturers can be sued for negligently misrepresenting the dangers of generic drugs. *T.H. v. Novartis Pharms. Corp.*, 4 Cal. 5th 145, 165 (Cal. 2017).

To no one’s surprise, these same fears have been stoked again here and in the Court of Appeal by both Gilead and the amici

⁹ Br. of the Product Liability Advisory Council, Inc. and the Chamber of Commerce of the United States of America as Amici Curiae in Support of Pet’r at 34, *Merck Sharp & Dohme Corp. v. Albrecht*, No. 17-290 (U.S. 2018).

¹⁰ Appl. of Product Liability Advisory Council, Inc. for Permission to File Amicus Curiae Br. and Proposed Amicus Curiae Br. Supporting Def. and Resp’t Novartis Pharmaceuticals Corp., *T.H. v. Novartis Pharms. Corp.*, No. S233898, 2016 WL 7245262, at *26 (Cal. 2016).

¹¹ Amici Curiae Br. of National Association of Manufacturers and American Tort Reform Association in Support of Def./Resp’t, *T.H. v. Novartis Pharms. Corp.*, No. S233898, 2016 WL 11713479, at *24 (Cal. 2016).

supporting it.¹² They ring hollower now than they ever have. Just as it did in *Novartis*, this Court should reject this tired, slippery-slope argument and focus on the merits of this appeal.

b. The pharmaceutical industry’s fears about innovation are not just repetitive; they are also wrong.

Gilead insists that the pharmaceutical industry’s fear of liability for negligence will result in disastrous policy consequences and widespread societal harm—stymied innovation, a refusal to develop new drugs, and ironically, “diminished consumer safety.” Reply at 9; Opening Br. at 10, 50–51. As shown above, these are recycled talking points, resurfacing each time a legal change may impact the pharmaceutical industry. *See infra* at Section II(a).

They are also untrue. Empirical research has shown that regulation has not devastated the industry, that competition drives innovation, and that American drug manufacturers have enjoyed record profits and robust growth in innovation over the past several decades, despite the industry outcry that each regulatory shift will result in its collapse.

i. The pharmaceutical industry is more profitable than ever.

Between 1979 and 2018, publicly traded U.S. pharmaceutical companies doubled their sales revenue—from

¹² *See, e.g.*, Gilead Opening Br. at 54, 63; Gilead Reply Br. at 8, 36; Gilead Pet. for Review at 34, 37, 50, 56; Letter Brief of Amici Curiae ALLvanza, et al. in Support of Pet. for Review at 1, 4; Letter Br. of Amici Curiae Viasat, Inc., et al., in Support of Pet. for Review at 2–5; Letter Br. of Amicus Curiae Product Liability Advisory Council, Inc., in Support of Pet. for Review at 4–5; Br. of PhRMA, et al. in Support of Gilead Sciences, Inc. at 27–34, *Gilead Sciences, Inc. v. Cal. Super. Ct. S.F. Cty.*, No. A165558 (Cal. Ct. App. 2022).

\$139 billion in 1979 to \$321 billion in 2018 (both numbers in 2018 dollars)—and more than tripled their profits.¹³ Profits increased from 15.3% of sales revenue in 1979 to 23.4% in 2018.¹⁴ Today, the industry has the highest average profit margins of any sector in the U.S., exceeding the energy and financial sectors.¹⁵

In fact, the U.S. pharmaceutical industry has been outperforming other industries for decades. Empirical research comparing the profitability of large public pharmaceutical companies to large public companies across ten other sectors from 2000 to 2018 shows that pharmaceutical companies are the most profitable by significant margins.¹⁶ A 2017 Government Accountability Office (GAO) report on the worldwide pharmaceutical industry confirms this: between 2006 and 2015, the average profit margin among the largest 25 drug companies significantly outpaced that of the largest 500 companies across all sectors.¹⁷

¹³ John (Xuefeng) Jiang, et al., *How Did the Public U.S. Drugmakers' Sales, Expenses, and Profits Change Over Time?*, EVIDENCE BASE (Nov. 5, 2021), <https://healthpolicy.usc.edu/evidence-base/how-did-the-public-u-s-drugmakers-sales-expenses-and-profits-change-over-time/>.

¹⁴ *Id.*

¹⁵ Luke Hawksbee, et al., *Don't worry about the drug industry's profits when considering a waiver on covid-19 intellectual property rights*, BMJ (Jan. 31, 2022), <https://doi.org/10.1136/bmj-2021-067367>.

¹⁶ Fred D. Ledly, et al., *Profitability of Large Pharmaceutical Companies With Other Large Public Companies*, 323(9) JAMA NETWORK 834, at 841 (2020).

¹⁷ Gov't Accountability Off., *Drug Industry Profits, Research and Development Spending, and Merger and Acquisition Deals*, REP. TO CONG. REQUESTERS, Nov. 2017, at 19, <https://www.gao.gov/assets/gao-18-40.pdf>.

Alongside Big Pharma's unparalleled profits is the industry's unmatched expenditures in lobbying. The pharmaceutical industry is considered one of the most effective lobbying groups in Washington, D.C.¹⁸ In 2022, the industry spent \$373.7 million in lobbying, outspending all other industries.¹⁹ But despite the lobbyists' familiar refrains each time a regulatory change is proposed, the empirical data demonstrates that the industry reaps record profits. In fact, the pharmaceutical industry could experience an 11 percent profit reduction and still achieve the highest returns of any market sector, while maintaining robust investment in the research and development that fuels innovation.²⁰

ii. The pharmaceutical industry is more innovative than ever.

The pharmaceutical industry has seen robust innovation in the prevention and treatment of disease over the past several decades. Between 1980 and 2022, pharmaceutical companies introduced a growing number of new drugs to the U.S. market each year—and did so increasingly quickly.²¹ Investment in

¹⁸ SEAN DICKSON & JEROMIE BALLREICH, HOW MUCH CAN PHARMA LOSE? A COMPARISON OF RETURNS BETWEEN PHARMACEUTICAL AND OTHER INDUSTRIES 4 (2019), https://westhealth.org/wp-content/uploads/2023/11/WHPC_White-Paper_How-Much-Can-Pharma-Lose_FINAL-November-2019 (last visited Nov. 1, 2024).

¹⁹ *Industry Profile: Pharmaceuticals/Health Products: 2022*, OPEN SECRETS, <https://www.opensecrets.org/federal-lobbying/industries/summary?cycle=2022&id=H04> (last visited Nov. 1, 2024).

²⁰ DICKSON, *supra*, at 10.

²¹ Enrique Seoane-Vazquez, et al., *Analysis of U.S. Food and Drug Administration new drug and biologic approvals, regulatory pathways, and review times, 1980-2022*, 14 SCI. REPS. 3325 (Feb. 9, 2024), <https://doi.org/10.1038/s41598-024-53554-7>.

pharmaceutical research and development (R&D) expanded during this time period, with the industry spending over \$83 billion on R&D in 2019—which, when adjusted for inflation, is approximately ten times what the industry spent each year in the 1980’s.²²

Over the last two decades, drug companies have filed an increasing number of new drug applications with the Food and Drug Administration (FDA) each year and the FDA has approved an increasing number of new drugs.²³ Between 2010 and 2019, an average of 38 new drugs were approved by the FDA annually, which represents a 60 percent increase from the previous decade.²⁴ This number continues to increase. In 2023, the FDA approved 55 new drugs.²⁵ Over the past ten years alone, the pharmaceutical industry has developed hundreds of drugs to treat diseases such as cancer, diabetes, and cardiovascular disease.²⁶

²² CONG. BUDGET OFF., RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY (2021), <https://www.cbo.gov/publication/57126>.

²³ Angelica Battam, et al., *Trends in FDA drug approvals over last 2 decades: An observational study*, 9 J. FAM. MED. & PRIMARY CARE 105 (Jan. 28, 2020) <https://pmc.ncbi.nlm.nih.gov/articles/PMC7014862/>.

²⁴ CONG. BUDGET OFF., *supra*.

²⁵ Beatriz G. de la Torre & Fernando Albericio, *The Pharmaceutical Industry in 2023: An Analysis of FDA Drug Approvals from the Perspective of Molecules*, 29 MOLECULES 585 (2024), <https://pmc.ncbi.nlm.nih.gov/articles/PMC10856271/>; see also *Novel Drug Approvals for 2023*, FDA, <https://www.fda.gov/drugs/novel-drug-approvals-fda/novel-drug-approvals-2023> (last visited Nov. 1, 2024).

²⁶ *Novel Drug Approvals for 2022*, FDA, <https://www.fda.gov/drugs/novel-drug-approvals-fda/novel-drug-approvals-2022> (last visited Nov. 1, 2024); see also Seoane-Vazquez, *supra*.

The United States remains a leader in the launch of new prescription drugs globally, with more than half of new drugs launched first in the United States in 2022.²⁷ Today, American pharmaceutical companies have thousands of new products in clinical development targeting high-needs therapeutic areas such as cancer and nervous system disorders like Alzheimer’s disease and Parkinson’s. The over 700 new drugs approved by the FDA over the past two decades have contributed to a range of new treatment options for patients across the country.

iii. Innovation is driven by competition, not deregulation.

Regulation in the pharmaceutical industry not only discourages corporate misconduct²⁸— it also promotes innovation. To be sure, regulations such as those implemented by the FDA protect patients from products that may be hazardous, discouraging fraudulent marketing of drugs, prosecuting the manipulation of clinical trials, and reducing other types of corporate misconduct.²⁹ But by certifying drug safety and effectiveness, FDA regulations also increase the value and expected returns on drugs that hit the market, incentivizing innovation.³⁰ These regulations require scientifically rigorous

²⁷ ANDREW W. MULCAHY, COMPARING NEW PRESCRIPTION DRUG AVAILABILITY AND LAUNCH TIMING IN THE UNITED STATES AND OTHER OECD COUNTRIES (2024), https://www.rand.org/pubs/research_reports/RRA788-4.html.

²⁸ Richard C. Ausness, *Corporate Misconduct in the Pharmaceutical Industry*, 71 DePaul L. Rev. 1, 10, 45 (2021).

²⁹ *Id.*

³⁰ Ariel Katz, *Pharmaceutical Lemons: Innovation and Regulation in the Drug Industry*, 14 MICH. TELECOMM. & TECH. L. REV. 1 (2007), <https://ssrn.com/abstract=964664>.

clinical trials and promote the investment in R&D that fuels innovation.³¹

Laws that temper the ability of drug manufacturers to engage in anticompetitive behavior have been empirically shown to increase incentives to innovate.³² For example, restricting the ability of drug manufacturers to engage in pay-for-delay agreements causes incumbent drug manufacturers to implement increasing numbers of new drug trials.³³ Conversely, consolidation in the pharmaceutical industry stifles innovation. Merged drug companies spend proportionally less on R&D than their non-merged competitors.³⁴ The data show that, in the periods following waves of mergers in the pharmaceutical industry, the industry has generated fewer new molecular entities each year.³⁵ In sum, the standard story that regulation negatively affects incentives to innovate does not fully capture the role that regulation plays in the pharmaceutical industry.³⁶

³¹ Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345 (2007), <https://repository.law.umich.edu/mttlr/vol13/iss2/1/>.

³² Zuelin Li & Richard Thakor, *How pay-for-delay affects competition and innovation in the pharmaceutical industry*, VOXEU COLUMN (Aug. 11, 2021), <https://cepr.org/voxeu/columns/how-pay-delay-affects-competition-and-innovation-pharmaceutical-industry>.

³³ *Id.*

³⁴ Robin Feldman, *Drug companies keep merging. Why that's bad for consumers and innovation.*, WASH. POST: MADE BY HIST., Apr. 6, 2021, <https://www.washingtonpost.com/outlook/2021/04/06/drug-companies-keep-merging-why-thats-bad-consumers-innovation/>.

³⁵ *Id.*

³⁶ Katz, *supra*.

II. There is nothing unprecedented about holding pharmaceutical companies liable for unreasonably manipulating their drug portfolio.

Gilead characterizes the liability theory advanced by the plaintiffs and embraced by the Court of Appeal here as wholly without precedent. It argues that there will be disastrous consequences from this supposedly one-of-a-kind cause of action, including upsetting a fragile “equilibrium” protecting manufacturers. See Gilead Reply at 8–9, 31–41. According to Gilead and its amici, a manufacturer of any product may never be held liable for manipulating the availability of its product, even when the manipulation causes substantial harm, unless the product is proven to be defective. This argument is unwound by the existence of a comparable (albeit not exactly analogous) theory of liability in antitrust law—product hopping. Further, despite some successful government enforcement actions and private suits against product hopping, none of the doomsday consequences Gilead describes have come to pass.

a. Pharmaceutical companies are subject to liability under the antitrust laws for product hopping.

Product hopping is a maneuver that pharmaceutical companies have used to subvert the expiration of drug patents by “hopping” patients over to other drugs. *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 643 (2d Cir. 2015). A company executes a product hop when its patent on a drug is soon to expire. *Id.* at 642. If the company does nothing, it will lose market share as its patent expires, generic alternatives enter the market, and patients are automatically switched to the generics. *Id.* at 642–43. From the perspective of a competitive market, the

ideal is that the manufacturer will lower its price, still making a profit but no longer at the dizzying heights of monopoly pricing.

There is, however, a loophole in this system: pharmacists acting under state law will generally only automatically switch a patient to a generic if there is an *exact* generic version of the branded drug they take. *Id.* at 644–45. A drug company can exploit this loophole by developing a new version of its drug that is functionally identical but different enough to receive its own patent. *Id.* at 642–43. For example, if a pill form of a drug has a patent that is about to expire, a company can get a new 30-year patent on a functionally identical version of the drug in the form of dissolving strips. Next, the company executes a “product hop” by moving patients from the pill form of the drug to the strip form. If it successfully executes this hop, the company will neither lose market share nor lower its prices to competitive levels when the pill form of the drug expires. Patients on the dissolving strip form of the drug will continue taking that form and will not be automatically switched to the generic alternative.

The U.S. Court of Appeals for the Second Circuit upheld a preliminary injunction against Actavis PLC for attempting to execute a product hop on an Alzheimer’s drug. *Id.* at 643. Actavis’s patent on Namenda Instant Release, a twice-daily Alzheimer’s pill, was set to expire in 2015. *Id.* at 647. Generics were poised to enter the market, at which point state laws would cause patients to be automatically switched away from the brand-name drug, ending Actavis’s monopoly. *Id.* at 649. To avoid this outcome, Actavis introduced Namenda Extended Release, a drug with no medical

benefits that had a patent lasting until 2029. *Id.* at 642. Actavis spent substantial sums of money promoting the new drug to doctors, caregivers, patients, and pharmacists. *Id.* at 648. They also sold the new drug at a discount and provided rebates to encourage switching. *Id.* These efforts to persuade the market to switch to a new drug before generic entry are called a “soft hop.”

When Actavis’s efforts at executing a soft hop were unsuccessful, Actavis took a more dramatic approach known as a “hard hop.” Actavis’s “internal projections estimated that only 30% of” users would switch in time based on the soft hop strategies. *Id.* at 648. To retain even more market share, Actavis initiated plans to remove the Instant Release drug from the market entirely. *Id.* This would force Namenda users to switch to the new, Extended Release, formulation before generic entry. *Id.* at 649. As a result, Namenda patients (all of whom would be using Extended Release) would not automatically be switched to generic alternatives and Actavis would maintain its monopoly. *Id.*

According to Gilead and its amicus, Actavis should have an unlimited right to manipulate the availability of its products so long as they are not defective. But Actavis’s conduct was unlawful, and it was punished accordingly. The state of New York sued to stop Actavis from pulling the Instant Release version from the market. *Id.* at 643. A preliminary injunction was granted by the U.S. District Court for the Southern District of New York and upheld by the Second Circuit. *Id.* And multiple class action suits were filed on behalf of injured drug purchasers seeking treble damages. *In re Namenda Direct Purchaser Antitrust Litig.*, No. 15-

cv-7488 (CM)(RWL) (S.D.N.Y.); *In re Namenda Indirect Purchaser Antitrust Litig.*, No. 15-cv-6549 (CM)(RWL) (S.D.N.Y.). One of those suits resulted in a \$750 million settlement. Op. & Order Approving the Settlement, *In re Namenda Direct Purchaser Antitrust Litig.*, No. 15-cv-7488 (CM)(RWL) (S.D.N.Y. May 27, 2020).

Courts and regulators have scrutinized and taken action against product hops in a range of contexts. *See, e.g., Abbott Lab's v. Teva Pharms. USA, Inc. (TriCor)*, 432 F. Supp. 2d 408, 422 (D. Del. 2006) (rejecting defendants' bid for immunity on product hopping claim in high-triglyceride treatments); *In re Suboxone Antitrust Litig.*, 64 F. Supp. 3d 665 (E.D. Pa. 2014) (scrutinizing efforts to move patients from opioid addiction tablets to film); Final Order & Stipulated Permanent Inj., *FTC v. Warner Chilcott Holdings Co. III, Ltd.*, No. 1:05-cv-02179 (D.D.C. Oct. 23, 2006); FTC, REPORT ON PHARMACEUTICAL PRODUCT HOPPING (2022), https://www.ftc.gov/system/files/ftc_gov/pdf/p223900reportpharmaceuticalproducthoppingoct2022.pdf (last visited Nov. 1, 2024) (describing FTC product hop enforcement actions).

b. While not perfectly analogous, product hopping law shows that attaching liability to Gilead is not unprecedented.

Product hopping liability provides an instructive analog to the theory of liability here. This is not a product-hopping case, so naturally there are notable differences between the two approaches. For example, product hopping involves removing a drug from the market whereas here Gilead faces liability for intentionally delaying TAF's release to the market in the first

instance. But there are also critical similarities and lessons that can be drawn from the product hopping context.

First, product hop law shows that liability in this case is not so unprecedented as Gilead and its amici insist. Gilead argues that ruling for plaintiffs would create a wholly novel “cycle of liability, transforming every product-development decision into a potential lawsuit over the path not taken[.]” Gilead Opening at 10. Gilead repeatedly asserts that it must be immune from scrutiny over how it manages the “complex decisions” it makes about its drug portfolio. *Id.* at 57. But drug companies already face legal liability for their boardroom decisions about what drugs they develop, market, and sell. Product hop law scrutinizes companies’ decisions about drug development, marketing, and sales. For both hard hops (which are the most likely to be subject to liability) and Gilead’s conduct, courts condemn decisions that unreasonably reduce customer choice and cause harm.

Legal liability plays a critical role in ensuring that pharmaceutical companies’ decisions do not have immense social consequences. In the product hop context, the social consequence to be avoided is allowing companies to unfairly coopt market power. Here, the social consequences—mass human suffering due to avoidable side effects—are far more dire. Incentivizing corporations to act reasonably when deciding between comparable alternatives is the animating premise of much of tort law. Carving out an exception for the conduct here is wrong. Pharmaceutical company’s boardroom decisions are not so sacrosanct that they are never subject to liability.

Second, product hopping shows that liability is appropriate even when it implicates decisions about resource allocation. Gilead repeatedly argues that its decisions about allocating “finite resources” must never be impinged by potential liability. *Id.* at 10, 57. Gilead’s argument is that by forcing it to expend resources, it will be precluded from using resources for other goals, like new drug development. *Id.* But that argument would preclude liability for product hopping as well. The injunction in *Actavis* required the company to keep selling the Instant Release formula instead of pulling it from the market. This required substantial resource investment in manufacturing, quality assurance, shipping, and more. Nevertheless, courts have not shied away from attaching liability when companies engage in illegal product hops.

Third, despite similarities to the liability here, product hop law has not wrought catastrophic consequences on the pharmaceutical industry. Gilead’s arguments would suggest that even the threat of liability in a product hop context would stymie innovation and put a substantial drag on the pharmaceutical industry. But the opposite is true. The pharmaceutical industry has been wildly innovative and successful in the decades since Herbert Hovenkamp defined the concept of a “product hop” and courts began to sustain product hop actions. *Actavis*, 787 F.3d at 643 n.2; *see supra* Section I(b). Instead, both Gilead’s liability and product hop law ensure that pharmaceutical companies are incentivized to continue innovating, competing, and acting reasonably on behalf of patients.

The central lesson from product hop law for this litigation is that pharmaceutical companies' decisions about drug portfolios are not, and should not be, immune from liability when they act unreasonably.

CONCLUSION

The parade of horrors warned of by Gilead and its amici will not come to pass. Identical concerns have been raised by the industry for decades and comparable liability schemes have arisen. Nevertheless, pharmaceutical profits, innovation, and drug prices have all risen precipitously. The decision of the Court of Appeal should be affirmed.

November 4, 2024

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Orrick, Herrington & Sutcliffe LLP		d666b248-700a-4db1-910c-da2639672ea9	
Daniel R. Adler	dadler@gibsondunn.com	e-Serve	11-04-2024 6:14:09 PM
Gibson, Dunn & Crutcher LLP		df918951-50df-4a0c-bc9a-11850c5726d8	
Lawrence Ebner	lawrence.ebner@atlanticlegal.org	e-Serve	11-04-2024 6:14:09 PM
Atlantic Legal Foundation		6ad1349c-1d6e-47a1-b30e-cf4e74053ff0	

TrueFiling created, submitted and signed this proof of service on my behalf through my agreements with TrueFiling.
The contents of this proof of service are true to the best of my information, knowledge, and belief.
I declare under penalty of perjury that the foregoing is true and correct.

11-04-2024

Date

/s/F. Paul Bland

Signature

Bland, F. Paul (298635)

Last Name, First Name (Attorney Number)

Berger Montague PC

Firm Name