

No. 24-889

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IN THE  
**Supreme Court of the United States**

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HIKMA PHARMACEUTICALS USA INC., *et al.*,

*Petitioners,*

*v.*

AMARIN PHARMA, INC., *et al.*,

*Respondents.*

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ON WRIT OF CERTIORARI TO THE  
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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**BRIEF OF THE PUBLIC INTEREST  
PATENT LAW INSTITUTE AS *AMICUS  
CURIAE* IN SUPPORT OF NEITHER PARTY**

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**INTEREST OF THE *AMICUS CURIAE*<sup>1</sup>**

Amicus Public Interest Patent Law Institute (“PIPLI”) is a nonprofit, nonpartisan organization dedicated to ensuring the patent system promotes innovation and access for the public’s benefit. PIPLI conducts and publishes research, provides pro bono assistance to people seeking to create and access technology, and shares the perspective of innovators and consumers with policymakers.

Many Americans contribute to and depend on advances in medicine, science, and technology but do not participate directly in the patent system. These constituencies include consumers, patients, research scientists, small business owners, and health care providers, none of whom are parties to this case, but all of whom will be affected by its outcome.

A robust market for generic drugs properly achieves Congress’s intent in the Hatch-Waxman amendments: to strike the right balance between incentivizing companies to develop new products and protecting consumers’ economic interests and access to healthcare. Amicus has a strong interest in this case because its outcome will affect both the economic opportunities available to consumers and their access to healthcare within the American drug market.

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1. Pursuant to Rule 37, counsel for *amicus curiae* represent that no counsel for any party authored this brief in whole or in part. No entity or person, aside from *amicus curiae* or their counsel, made a monetary contribution to the preparation or submission of this brief.

## SUMMARY OF ARGUMENT

The United States has long been the world’s leading healthcare innovator, thanks to a robust system of incentives embedded within federal law. Congress designed those laws not merely to reward invention, but to ensure that medical innovation ultimately reaches patients through affordable access to medicines. Our patent and drug-regulatory regimes therefore reflect a carefully calibrated balance between encouraging pharmaceutical innovation and ensuring timely public access to lower-cost medicines. We respectfully urge the Court to preserve that balance and Congress’s prescribed intent in § 271(b) of the Patent Act, especially in light of the “far-reaching social and economic consequences of a patent.” See *Precision Instrument Mfg. Co. v. Automotive Co.*, 324 U.S. 806, 816 (1945).

This case concerns whether Congress’s carefully calibrated balance will continue to function as Congress intended. Section 271(b)’s specific-intent requirement plays a critical role in preserving that balance. Inducement liability has long required purposeful encouragement of infringement, not mere awareness that infringement might occur through lawful commerce. See *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003). When Congress enacted the Hatch-Waxman Amendments and created the Section viii “skinny label” pathway, it relied on this settled understanding. See *Takeda Pharms. U.S.A. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015). Section viii permits generic manufacturers to market drugs for unpatented uses even where some off-label infringing use may foreseeably result. *Id.* Proper application of § 271(b) therefore

safeguards conduct Congress expressly authorized to facilitate timely generic entry.

Treating lawful Section viii marketing, truthful competitive statements, or FDA-required disclosures as evidence of inducement collapses the specific-intent requirement into mere foreseeability. Generic manufacturers may face liability for engaging in lawful competition. Faced with unpredictable exposure, manufacturers may delay or abandon carved-out approvals altogether—undermining Congress’s chosen mechanism for introducing lower-cost medicines while patients on discrete uses remain in force.

Secondary method of use patents tend to require less innovation and provide limited benefits to patients; they should not be further strengthened. In practice, such patents are frequently deployed strategically to delay competition. Robust Section viii entry under the Hatch-Waxman Act, by good faith actors, should be preserved. To do otherwise risks entrenching monopoly practices and rendering the statutory provision effectively meaningless.

Uncertainty regarding the usage of “skinny labels” under Section viii produces harmful market effects. Ambiguity about what constitutes permissible statements of therapeutic equivalence or market context burdens providers, pharmacists, and patients. The lack of clarity raises compliance costs for marketers of generic drugs, which ultimately trickles down to taxpayers and consumers. When routine marketing communications or statements of therapeutic equivalence may later be characterized as inducement, firms rationally curtail entry or lawful speech. This chilling effect may reduce

substitution, increase compliance costs, and deprive pharmacists, providers, and patients of clear information necessary to facilitate affordable treatment choices.

A restricted generic drug market uniquely harms American patients. Reduced availability of generics drives up drug prices, while limits on communication about therapeutic equivalence and market information further distort competition and inflate costs. Americans already pay more for prescription drugs than patients in any other nation, effectively subsidizing pharmaceutical innovation for the rest of the world. We respectfully ask the Court to reject any rule that would further burden the public by limiting access to affordable medicines, suppressing competition, and creating uncertainty in the marketplace.

## ARGUMENT

### **I. Section 271(b)'s Specific-Intent Requirement Safeguards Conduct Authorized by Section viii.**

The Federal Circuit has repeatedly held that “mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven.” *Warner-Lambert*, 316 F.3d at 1364 (citing *Manville Sales Corp. v. Paramount Sys.*, 917 F.2d 544, 553 (Fed. Cir. 1990)). Inducement liability attaches only where a manufacturer purposefully encourages infringing conduct, not where it engages in lawful marketing and competition for unpatented indications permitted under Hatch-Waxman. *See H. Lundbeck A/S v. Lupin*, 87 F.4th 1361, 1372 (Fed. Cir. 2023). This Court has emphasized that inducement liability attaches only to “purposeful, culpable expression and

conduct,” not rules that “compromise legitimate commerce or discourage innovation having a lawful promise.” *Metro-Goldwyn-Mayer Studios v. Grokster*, 545 U.S. 913, 915–16 (2005) (drawing on patent-law inducement principles to articulate the standard for copyright inducement liability).

Congress enacted Section 505(j)(2)(A)(viii) (hereinafter, “Section viii”) of the Federal Food, Drug, and Cosmetic Act (codified as 21 U.S.C § 355(j)(2)(A)(viii)) under the longstanding patent-law principle that inducement requires purposeful encouragement of infringement, not mere knowledge that infringement may occur. Congress sought to expressly permit the marketing and sale of generic drugs for non-patented uses even where such sales “would result in some off-label infringing uses.” *Takeda Pharms. U.S.A.*, 785 F.3d at 631; *see also Warner-Lambert*, 316 F.3d at 1359 (explaining § 271 was not intended “as a sword” against any competitor’s Abbreviated New Drug Application “seeking approval to market an off-patent drug for an approved use not covered by the patent”).

Treating Section viii marketing conduct, unaccompanied by clear culpable intent, as sufficient to establish inducement would collapse the statutory requirement of specific intent into mere foreseeability, which could deter generics from using Section viii as broadly as Congress intended. As a practical matter, generic manufacturers must describe the market in which they compete and distinguish their products from branded counterparts to sell drugs for approved, carved-out indications. If competitive statements or references to sales data were sufficient to establish inducement, the Section viii pathway could be substantially narrowed in

practice. See *GlaxoSmithKline v. Teva Pharms. U.S.A.*, 7 F.4th 1320, 1326 (Fed. Cir. 2021) (acknowledging that “generics could not be held liable for merely marketing and selling under a ‘skinny’ label omitting all patented indications, or for merely noting (without mentioning any infringing uses) that FDA had rated a product as therapeutically equivalent to a brand-name drug”) (internal quotations omitted).

Proper application of § 271(b)’s intent requirement ensures that inducement liability remains tethered to culpable conduct rather than lawful competition authorized by Congress. Expanding inducement liability to encompass conduct consistent with a Section viii carve-out would contravene Congress’s intent to promote carve-out labels, facilitate timely access to generics, and preserve incentives to invest in new therapeutic uses. It would also threaten to undermine public access to medicines after patents covering a drug compound or approved indications have expired. Predictable legal frameworks are essential to allow both innovative and generic manufacturers to make the investment and timing decisions necessary to develop and launch their products. When the specific-intent requirement of § 271(b) is diluted or rendered unpredictable, generic manufacturers may delay or forgo development rather than risk liability based on conduct Congress expressly permitted.

## **II. The Hatch-Waxman Regime Combined with Limits on Statutory Inducement Strikes the Proper Balance Between Innovation and Affordable Health Care.**

### **A. The Statutory Purpose of Hatch-Waxman Requires Balancing Competing Policy Interests, and Section viii is Central to Achieving That Balance.**

The Hatch-Waxman Amendments reflect a deliberate legislative balancing of “two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.” *Andrx Pharms. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

To advance these two interests, Congress created the Abbreviated New Drug Application (“ANDA”) pathway. This framework allows a generic manufacturer to rely on the safety and efficacy findings of a previously-approved branded drug rather than repeating costly clinical trials, provided the generic demonstrates bioequivalence and satisfies applicable patent requirements. *See Caraco Pharm. Labs. v. Novo Nordisk A/S*, 566 U.S. 399, 404–05 (2012). Congress made this purpose explicit in the legislative history, explaining that Title I of the Bill, which authorizes the ANDA process, was intended “to make available more low-cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962.” *Warner-Lambert*, 316 F.3d at 1358 (citing H.R. Rep. No. 98–857(I), at 14–15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647–48). Hatch-Waxman thus facilitates healthcare access by allowing generic

manufacturers to resolve patent issues before launch and thus enter the market with little risk of liability.

Congress intended the Hatch-Waxman framework to encourage generic drug entry even in an already heavily patented area. Section viii, integral to the ANDA framework, ensures generics can “quickly come to market” without waiting for all patents of a branded drug to expire. *Caraco*, 566 U.S. at 415. By submitting a Section viii statement, ANDA applicants seek approval for only those indications or methods of use that are not claimed in a listed patent, while “carving out” patented uses in its “skinny label.” *See id.* at 406. “The statutory scheme, in other words, contemplates that one patented use will not foreclose marketing a generic drug for other unpatented ones.” *Id.* at 415.

The Hatch-Waxman Act has significantly increased the availability of generic substitutes at lower prices for consumers. *See* Wendy H. Schacht & John R. Thomas, Cong. Rsch. Serv., RL30756, *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 (“The Hatch-Waxman Act”)* (2000). Prior to 1984, less than 20% of prescription purchases were for generic drugs. U.S. Food & Drug Admin., *40th Anniversary of the Generic Drug Approval Pathway*, <https://www.fda.gov/drugs/cder-conversations/40th-anniversary-generic-drug-approval-pathway> (last visited Feb. 11, 2026). Today, over 90% of prescription purchases are for generic drugs. *Id.* Cost savings from this pro-competitive legacy are at risk if induced-infringement theories are expanded in ways that discourage manufacturers from utilizing the carve-out pathway to bring lower-cost drugs to market.

## **B. Secondary Method of Use Patents Already Have Limited Policy Justifications.**

Drug developer firms often obtain a slew of patents at varying timepoints to cover a variety of aspects of the drug. *See* Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, 1 *Innovation Pol’y & Econ.* 119, 120 (2000). Even if original compound and original method patents expire, firms may obtain further patents. *See* 21 U.S.C. § 355(j), (b)(1)(A) (viii)(II) (referencing method of use patents in reference to drug applications). These so-called ‘secondary method of use’ patents cover *only* narrow, additional methods of using a drug, including additional clinical indications.

Secondary method of use patents require reduced levels of innovation compared to those required for original compound or method patents and should not be further strengthened. *See Addressing Anticompetitive Conduct and Consolidation in Health Care Markets: Hearing Before the H. Comm. on the Judiciary, Subcomm. on Antitrust, Com., & Admin. L., 117th Cong. 4* (2021) (written testimony of Professor Robin Feldman, Univ. of Cal. Hastings Coll. of Law) (“When a company makes a secondary change to a drug — such as adjusting a drug’s dosage — the R&D investment is generally far less than required for the drug’s initial innovation.”). Patents are meant to incentivize innovation, but the public cost of exclusivity via secondary method patents may not be justified. Secondary method of use patents grant exclusivity to pharmaceutical firms for the claimed indication and maintain that monopoly for the full twenty years of the patent’s lifetime. 35 U.S.C. § 154(a)(2). That indication may be novel to the market. However, the underlying drug has already been discovered.

Patients do not significantly benefit from secondary method of use patents. Grants of secondary method of use patents do not result in lower prices, because pharmaceutical pricing is not based on actual development cost or patentability, but on market willingness to pay. See Aaron S. Kesselheim, Jerry Avorn & Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858, 863 (2016). For example, blockbuster drug prices often continually increase even with exclusivity beyond initial patent term. See Alfred Engelberg, *Unaffordable Prescription Drugs: The Real Legacy of the Hatch-Waxman Act*, STAT News (Dec. 16, 2020), [statnews.com/2020/12/16/unaffordable-prescription-drugs-real-legacy-hatch-waxman-act/](https://www.statnews.com/2020/12/16/unaffordable-prescription-drugs-real-legacy-hatch-waxman-act/). Squeezing a little more ‘juice from the lemon’ does little good for patients. “From society’s standpoint, one might be better off with incentives that drive scientists back to the bench to look for advances of greater significance,” rather than incremental secondary methods of use. Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & Biosciences 590, 637 (2018). Patent jurisprudence should not incentivize additional patenting that has limited public benefit.

Section viii fights high drug prices by easing generic entry. See Ryan Conrad & Randall Lutter, U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*, at 2 (Dec. 2019). Allowing generic manufacturers to enter while still carving out space for secondary method of use patents was part of Congress’s statutory balancing. 21 U.S.C. § 355(j), (b)(1)(A)(viii)(II). The present case puts that balance under threat by elevating the risk tolerance threshold associated with Section viii usage.

**C. Restricting Good Faith Uses of Section viii Threatens to Entrench Monopolistic Practices.**

Some manufacturers have used method of use patents to effectively entrench monopolies on drugs. Secondary method of use patents are often sought as part of an explicit extension and “anti-generic” strategy by branded drug manufacturers to prolong the life of an initial drug’s invention. Olga Gurgula, *Strategic Patenting by Pharmaceutical Companies—Should Competition Law Intervene?*, 51 IIC – Int’l Rev. Intell. Prop. & Competition L. 1062, 1074 (2020).

Section viii defends against these monopolies by protecting good faith uses of “skinny labels.” The widespread good faith use of “skinny labels” enables efficient pharmaceutical innovation. See Kevin J. Hickey, Cong. Rsch. Serv., IF12700, “*Skinny Labels*” for Generic Drugs Under Hatch-Waxman (2026). Imposing additional liability based on a wide-sweeping analysis of “skinny label” users’ statements will force firms out, limiting the pathway to only risk tolerant generics manufacturers, if any. This would render Section viii “insignificant, if not wholly superfluous,” contrary to the clear meaning of the statute. See *Caraco*, 566 U.S. at 421 (referencing *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001)).

The Court should seek to protect good faith uses of Section viii by examining parties’ differing purposes. As the Court elaborated in *Precision Instrument*, “[t]he far-reaching social and economic consequences of a patent therefore give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct, and that

such monopolies are kept within their legitimate scope.”  
324 U.S. at 816.

### **III. Uncertainty Over Equivalence and Marketing Statements Raises Compliance Costs and Creates Confusion, Resulting in a Chilling of the Marketplace.**

Generic manufacturers require clear guidance regarding what forms of promotion and commercial communication are permissible when a product is approved with a carved-out label. The Court should adopt a rule that provides sufficiently definite standards so that manufacturers can structure their conduct in advance.

#### **A. Uncertainty for Generic Drug Marketers Increases Marketing, Insurance, and Other Costs, and Discourages Future Investments.**

Uncertainty in marketing standards will increase the costs of promoting generic drugs. Marketing activities would need to be vetted against complex and evolving legal standards governing inducement, raising compliance costs and exposing manufacturers to heightened litigation risk, thereby increasing insurance expenses. Those concerns are particularly acute in the pharmaceutical industry, where development and launch decisions must be planned out years in advance. Generic manufacturers base their research, development, and launch strategies on assumptions about which patent rights will remain in force, as well as how they may lawfully market their products at different points in time. If manufacturers cannot be certain whether routine marketing using a carved-out label, or references to FDA therapeutic-

equivalence ratings, may give rise to inducement liability, manufacturers cannot reliably determine when entry is feasible, or what commercial conduct is permissible.

Legal ambiguity regarding carved-out labeling or the boundaries of permissible marketing practices may also undermine reliable forecasting and discourage investment across the generics industry. The Court has repeatedly emphasized the importance of clear, predictable limits on patent rights. *See, e.g., Kimble v. Marvel Ent.*, 576 U.S. 446, 451–53 (2015). Patent laws must be judicially construed to prevent restrictions that impede public access to inventions that are no longer patented or were never patentable. *Id.*

**B. Ambiguity Surrounding Equivalence and Marketing Statements Creates Consumer and Pharmacist Confusion.**

Clear communication regarding equivalence is central to the Hatch-Waxman framework, which relies on therapeutic-equivalence determinations to facilitate substitution and price competition. *See Caraco*, 566 U.S. at 415. If generic manufacturers are deterred from making statements about their products' relationship to branded drugs, substitution may be reduced, undermining the statute's goal of expanding access to affordable medicines. That chilling effect would not merely affect manufacturers, but also leave pharmacists and consumers with less guidance, increasing the likelihood of confusion about substitutability, approved uses, or the reasons certain labeling differences exist.

The problem is particularly acute because both branded and generic drugs frequently serve specific and medically

defined patient populations. If inducement liability may arise whenever a patent claims only a subgroup of patients within a broader approved population, manufacturers would effectively be barred from communicating with the very patients and healthcare providers for whom their products are intended. Manufacturers cannot meaningfully market or provide accurate product information while attempting to avoid any reference that might reach overlapping patient subgroups defined only by patent claims.

When communication about equivalence becomes uncertain or constrained, substitution rates may decline, price competition may weaken, and patients may face higher costs. Preventing manufacturers from speaking clearly about approved uses and therapeutic equivalence would thus impair the careful balance Hatch-Waxman strikes between patent protection and patient access. Clarity in this area serves both economic and public-health interests. Pharmacists and prescribers must be able to rely on consistent, accurate information in making dispensing and treatment decisions.

**C. Elevated Cost of Market Entry and Uncertainty Chills Marketing, Raising First Amendment Concerns.**

Absent clarity, generic drugmakers may respond by curtailing ordinary, lawful marketing practices—such as press releases, product descriptions, and communications regarding therapeutic equivalence—out of concern that *routine* commercial speech could later be characterized as evidence of inducement. As the Court noted in

*Grokster*, there is a “need to keep from trenching on regular commerce or discouraging the development of technologies with lawful and unlawful potential.” 545 U.S. at 937.

Uncertainty surrounding permissible advertising and promotional language raises First Amendment concerns. Finding inducement liability, absent clear expressions encouraging infringing uses, would dramatically increase uncertainty surrounding protected commercial speech. The Court should not adopt a “totality of the circumstances” standard for liability that cobbles together instances of otherwise individually protected speech. Such a ruling would impermissibly chill commercial speech (including equivalency statements and market sales data) that is truthful, non-misleading, and valuable to healthcare providers and patients. *See Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 367 (2002) (finding that commercial speech is protected by the First Amendment unless it concerns unlawful activity or is misleading).

The fact that the chilling effect arises from uncertainty is immaterial. The Court should not undermine the effective dissemination of medical information. *See id.* Further, there is a *strong* interest in pharmacists and physicians obtaining complete, accurate, and true medical information regarding drugs they furnish for patients. *See Sorrell v. IMS Health Inc.*, 564 U.S. 552, 578 (2011) (emphasizing how the First Amendment preferences the uninhibited and free flow of medical information). The Court should uphold that strong interest.

#### **IV. Increased Costs for Generic Manufacturers Will Ultimately Trickle Down to Consumers.**

##### **A. The Availability of Generics Directly Affects Drug Prices.**

Patients and taxpayers suffer when generics are unavailable or delayed. *See* Chintan V. Dave et al., *Estimating The Cost Of Delayed Generic Drug Entry To Medicaid*, 39 Health Affs. 1011, 1012 (2019). For just four top drugs, generic delays of between seven to thirteen months cost Medicare more than \$3.5 billion cumulatively. Dongzhe Hong et al., *Estimating Costs of Market Exclusivity Extensions for 4 Top-Selling Prescription Drugs in the US*, 6 JAMA Health F., 2025, at 1.

On the other hand, drug prices are lower for consumers when there are *more* generic options available. Both initial generic entry and continuing incremental competition from generics are essential for the affordability of drugs throughout the healthcare system. U.S. Food & Drug Admin., *Estimating Cost Savings from New Generic Drug Approvals in 2023*, at 2 (Nov. 2025). The FDA's most recent report found that generic drug approvals from 2023 generated \$18.6 billion in cost savings in the year following approval by disrupting monopolies and inducing price reductions. *Id.* Their analysis concluded that these savings “directly enhance affordability at the patient level” and “provide meaningful financial relief for Americans.” *Id.*

While competition between generic and brand-name drugs is crucial in driving down prices, competition within the market for generics drives down prices even further.

Greater competition *among* generic drug makers is directly associated with lower generic drug prices. Ryan Conrad & Randall Lutter, U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*, at 2 (Dec. 2019). A study on competition within generic markets found that in markets with three competitors, prices eventually declined by about 20%. U.S. Dep't of Health & Hum. Servs., Off. of the Assistant Sec'y for Plan. & Evaluation, *Drug Competition Series: Analysis of New Generic Markets: Effect of Market Entry on Generic Drug Prices: Medicare Data 2007–2022*, at 10 (2025). In markets with at least 10 competitors, prices eventually declined by over 70%. *Id.* at 11. A review of multiple studies found that prices declined by about 15% to 40% in markets with three to five competitors and by 60% to 90% in markets of ten or more competitors. *Id.* at 2.

**B. Disincentivizing Equivalence Statements May Reduce Market Competition and Increase Drug Prices for Consumers.**

Many consumers have mixed or negative perceptions about generics when compared to brand-name drugs. Mohamed A. A. Hassali et al., *Consumers' Views on Generic Medicines: A Review of the Literature*, 17 *Int'l J. Pharmacy Prac.* 79, 86 (2009); Jennifer N. Howard et al., *Influencers of Generic Drug Utilization: A Systematic Review*, 14 *Res. Soc. & Admin. Pharm.* 619, 626 (2018). Consumers often cite concerns over the safety and efficacy of generic drugs, which leads to fewer generic drug substitutions. Hassali et al., 17 *Int'l J. Pharmacy Prac.* at 87; Howard et al., 14 *Res. Soc. & Admin. Pharm.* at 626.

Improving consumer confidence in generic drugs through a better understanding of brand-name equivalency is key to addressing this issue. Howard et al., 14 Res. Soc. & Admin. Pharm. at 619. An analysis of twenty studies on consumer views of generic drugs concluded that “better communication among patients and health care professionals regarding the equivalency between most branded and generic products should increase the use of generic medications.” Hassali et al., 17 Int’l J. Pharmacy Prac. at 87. Also, studies assessing generic uptake strategies have found that meeting the public’s “informational needs about generic drugs” is necessary to maximize generic drug use. Howard et al., 14 Res. Soc. & Admin. Pharm. at 619. By clearly communicating to patients that a drug is the generic version of a brand-name drug, equivalency statements are helpful in reducing patients’ uncertainty and increasing their willingness to accept the substitution.

If disincentivized from using equivalency statements, generic drug manufacturers may have greater difficulty communicating with many patients, especially skeptical and uncertain patients, leading to increased costs and worse health outcomes. Generic drug manufacturers unable to properly communicate with potential patients could lose market share to brand-name manufacturers, and all consumers may consequently experience increased drug prices. Additionally, the harms will compound for people who need both medical care *and* accessible information. For example, patients in underserved and lower income communities exhibit higher rates of distrust in generic drugs across the board. A study of generic drug utilization concluded that specific patient groups, including male patients, low-income patients, and minority patients,

are less likely to accept generic drugs and would benefit the most from more information and targeted educational materials. Howard et al., 14 Res. Soc. & Admin. Pharm. at 626–27. Thus, imposing liability on the provision of medical information—or, as in this case, on the failure to withhold medical information—may disproportionately impact the health of these patients, their families, and our nation.

**C. Limiting Section viii Would Allow U.S. Drug Companies to Raise Prices for American Consumers.**

Americans already pay outsized costs for pharmaceuticals, effectively subsidizing other nations' drugs. See Kate Ho & Ariel Pakes, *Policy Options for the Drug Pricing Conundrum*, 122 Proc. Nat'l Acad. Sci., 2025, at 4. Major political branch leaders recognize this major problem. *E.g.*, Exec. Order No. 14,297, *Delivering Most-Favored Nation Prescription Drug Pricing to American Patients*, 90 Fed. Reg. 20,749 (May 12, 2025). U.S. prices for drugs are, on average nearly three times that of thirty-three other OECD countries. Andrew W. Mulcahy et al., RAND Corp., *International Prescription Drug Price Comparisons*, at 26 (Feb. 1, 2024).

The permissiveness of extant patent statutes in the United States contributes to this price disparity. Legal precedent should not exacerbate it. U.S. patent statutes allow much broader method of treatment patents than those of many other countries. Compare Convention on the Grant of European Patents art. 82, Dec. 13, 2007 (17th ed. Nov. 2020) [hereinafter European Patent Convention art. 82], with 35 U.S.C. §§ 101–103. While

we do not argue for the Court to alter this regime—that is for Congress alone—we note that these secondary patents, typically of lower legal “quality,” nonetheless persist in prolonging exclusivity. The United States Patent and Trademark Office allows “broad latitude for routine modifications, such as adjusting dosages or combining known treatments, often requiring a specific ‘motivation to combine’ to reject a claim as obvious.” Pub. Int. Pat. L. Inst., *White Paper: Comparing Patentability Requirements for Pharmaceuticals, Biologics, and Medical Methods in the U.S. and Europe*, at 7 (May 26, 2025). By contrast, the European Patent Office (“EPO”) limits similar methods-only approaches and requires a means of treatment coupled with a compound, as to form a “single general inventive concept.” European Patent Convention art. 82. When evaluating the application, the EPO also “takes a different approach when determining if known elements would be obvious to combine,” effectively limiting patents for uses which may have been elucidated by a firm’s prior research work. Pub. Int. Pat. L. Inst., *White Paper: Comparing Patentability Requirements for Pharmaceuticals, Biologics, and Medical Methods in the U.S. and Europe*, at 4 (May 26, 2025).

This patentability evaluation determines the scope of liability. Any ruling broadening patentability and distancing the U.S. from other jurisdictions risks entrenching pharmaceutical monopolization, decreasing the availability of generic drugs. Fewer drug options will increase costs for American patients and exacerbate the disparity between American and other nations’ drug prices.

**CONCLUSION**

For the foregoing reasons, the Court should delineate a clear threshold for inducement liability to preserve innovation and access to generic drugs as Congress intended.

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