No. 24-889

IN THE

Supreme Court of the United States

HIKMA PHARMACEUTICALS USA INC., *ET AL.*,

Petitioners,

v.

AMARIN PHARMA, INC., *ET AL.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF AMICUS CURIAE PUBLIC CITIZEN IN SUPPORT OF PETITIONERS

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INTEREST OF AMICUS CURIAE[1]

Public Citizen is a nonprofit consumer advocacy organization with members and supporters in every state. Public Citizen advocates before Congress, administrative agencies, and courts on a wide range of issues, including ensuring that patients' and consumers' interests are protected in the resolution of legal and regulatory issues posed by prescription drugs and medical devices. A central concern of Public Citizen, embodied in Public Citizen's Global Access to Medicines program, is protecting and expanding access to affordable medicines both domestically and globally.

Among the key strategies that Public Citizen advocates for making medicines more affordable is the adoption of policies that facilitate regulatory approval and marketing of generic drugs that compete with expensive brand-name drugs. Competition from generic drug manufacturers plays a critical role in checking the excessive prescription-drug prices that drain consumers' pocketbooks, impair the health of those who cannot afford to pay those prices, and harm federal and state governments by massively increasing the costs of government health-care programs. Accordingly, Public Citizen has long supported the Hatch-Waxman Amendments—the landmark legislation that created the legal framework for introduction and regulation of generic medications in the United States. Among other things, Public Citizen has sought to ensure that the courts' resolution of antitrust and patent litigation involving generic and brand-name manufacturers is consistent with the Hatch-Waxman

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[1] This brief was not authored in whole or part by counsel for a party. No one other than amicus curiae made a monetary contribution to preparation or submission of the brief.

Amendments' provisions that promote the introduction of generic drugs while respecting valid patent rights of name-brand drug manufacturers.[2]

Public Citizen submits this brief to explain that the lower court's opinion in the case disregards the language and structure of the Hatch-Waxman Amendments, is likely to cause significant harm to consumers, and runs counter to the strong federal policy of promoting the availability of generic medications as a means of lowering costs for patients.

SUMMARY OF ARGUMENT

The proper functioning of the statutory scheme created by the Hatch-Waxman Amendments is critical to the national goal of increasing public access to affordable prescription medications. Formally titled the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, the Hatch-Waxman Amendments amended various provisions of the Food, Drug, and Cosmetic Act (FDCA) and the patent laws to enhance patent protections in certain respects, while allowing streamlined marketing approval of generic versions of prescription drugs that do not violate valid patents.

Among the many innovations of the Hatch-Waxman Amendments were the provisions, at issue here, that permit a generic drug manufacturer to obtain

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[2] Public Citizen, through its Litigation Group, submitted amicus curiae briefs in this Court on behalf of former Rep. Henry Waxman, the architect of the generic drug provisions of the Hatch-Waxman Act, in *FTC v. Schering-Plough Corp.*, No. 05-273, and *FTC v. Actavis, Inc.*, No. 12-416, supporting the FTC's ultimately successful efforts to subject pay-for-delay agreements between brand-name and generic manufacturers to antitrust scrutiny.

approval to market a generic version of a drug even if the drug still has methods of use that are protected by valid patents, if the generic manufacturer does not seek approval to market the drug for those uses and carves them out from the labeling of the generic version. *See* 21 U.S.C. § 355(j)(2)(A)(viii). The resulting regulatory approval of the generic drug permits the generic manufacturer to market the drug for the unpatented uses specified in what is commonly called a "skinny label." As the statute's terms make clear, Congress understood that drug manufacturers may have patent protection limited to specific uses of their products, and it provided that, in that circumstance, the Food and Drug Administration (FDA) may authorize generic manufacturers to produce and market generic versions for unpatented uses.

Staying within the bounds of that authorization should protect a generic manufacturer from patent liability even when doctors predictably prescribe the generic version of the drug for uses that are not included in the approved skinny label because they remain subject to the brand-name manufacturer's patents. The Federal Circuit, however, holds that the approved label, combined with innocuous statements by the manufacturer that say no more than the label does to alert doctors to the possibility of additional uses, may suffice to constitute inducement of infringement, threatening generic drug manufacturers with immense liability if they use skinny labels to obtain marketing approval. The Federal Circuit's holdings are impossible to square with the Hatch-Waxman Amendments' language, structure, and context.

The Federal Circuit's decisions threaten serious damage to the successful operation of the regulatory regime created by the Hatch-Waxman Amendments.

The Amendments' provisions facilitating and expediting the introduction of generic drugs have been singularly successful, saving consumers and governments hundreds of billions of dollars and making it possible to achieve more health benefits with less money. And they have done so in an environment where nearly every other category of health care expense—and especially the cost of brand-name drugs—has continued to escalate, threatening the well-being of all Americans. The unwarranted imposition of patent liability on generic manufacturers will discourage them from seeking to market generic versions of any drug that still has patent protection for any common use—a consequence that will have tremendous impact given the propensity of brand-name drug manufacturers to seek to extend patent monopolies by repeatedly patenting additional uses of their products. Unless the decision below is reversed, the aims of the Hatch-Waxman Amendments will be thwarted, and the goal of reining in excessive health care costs will be even further out of reach.

ARGUMENT

I. The Hatch-Waxman Amendments do not permit patent liability to be imposed on generic manufacturers who play by the rules when marketing drugs approved with skinny labels.

The Hatch-Waxman Amendments were designed to balance two important objectives: first, providing incentives for innovation in the development of new drugs; and second, holding down drug prices by fostering competition with already-approved brand-name drugs from generic equivalents. The Amendments advance the first objective by extending the term of

pharmaceutical patents to account for delays in the FDA approval process that would otherwise eat into the value of the patents; establishing procedures to ensure that generic drugs approved by the FDA do not infringe existing patents; and providing a period of market exclusivity for innovative new drugs regardless of whether they are patented. The Amendments pursue the second objective by allowing generic drugmakers to manufacture and use patented drugs for purposes of preparing an application for FDA approval of a generic equivalent, and by establishing accelerated procedures for approval of generic drugs to allow them to enter the market as soon as possible without infringing brand-name manufacturers' patents and statutory exclusivity rights. Together, the Amendments' provisions seek to achieve a "fundamental balance … that assures consumers of more low-cost generic drugs when a valid patent expires and the drug industry of sufficient incentive to develop innovative pharmaceutical therapies." 130 Cong. Rec. 24426 (Rep. Waxman) (Sept. 6, 1984).

In a nutshell, the Hatch-Waxman Amendments provide that "the FDA cannot authorize a generic drug that would infringe a patent," while "facilitat[ing] the approval of generic drugs as soon as patents allow." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S,* 566 U.S. 399, 405 (2012). The latter objective, moreover, is not limited to allowing generic entry after all patent protection for a brand-name drug has expired. Rather, even when a brand-name drug is protected by unexpired patents, the Amendments provide two main routes by which a generic manufacturer can expedite access to the market. First, if the generic manufacturer believes the patents are invalid or unenforceable, it may so certify in its application for approval,

and the validity of the patents may then be litigated immediately, with approval of generic entry following if the generic manufacturer prevails.

The second avenue for generic entry in the face of unexpired patents, at issue here, comes into play if a brand-name manufacturer has *valid* patents that protect only some of the approved uses of its drug. The Amendments allow for approval and marketing of generic equivalents in those circumstances, if the generic manufacturer certifies that it does not seek approval of the drug for a use claimed by any unexpired method-of-use patent. When the FDA approves a generic drug subject to such a certification, it also approves labeling for the generic drug that excludes those portions of the approved labeling of the brand-name drug that the brand-name manufacturer has identified as describing a use claimed by an unexpired patent. *See* 21 C.F.R. § 314.94(a)(8)(iv). Otherwise, however, the labeling must, like generic drug labeling more generally, be identical to that of the brand-name drug. *See id.* The statutes and regulations that provide for approval with labeling that excludes patented uses—referred to colloquially as a "skinny label"—simultaneously promote competition and protect patent rights by "allow[ing] the generic company to place its drug on the market … but only for a subset of approved uses—i.e., those not covered by the brand's patents." *Caraco Pharm.*, 566 U.S. at 406.

The clear import of this statutory scheme is that marketing a generic drug using approved labeling that carves out any remaining patented uses of the drug does not in itself violate the brand-name manufacturer's patent rights. This Court succinctly made the point in *Caraco Pharmaceutical*:

> [A]s Congress understood[,] a single drug may have multiple methods of use, only one or some of which a patent covers. … The Hatch-Waxman Amendments authorize the FDA to approve the marketing of a generic drug for particular unpatented uses; and section [355(j)(2)(A)(viii)] provides the mechanism for a generic company to identify those uses, so that a product with a label matching them can quickly come to market. The statutory scheme, in other words, contemplates that *one patented use will not foreclose marketing a generic drug for other unpatented ones*.

Caraco Pharm., 566 U.S. at 415 (emphasis added). In short, establishing "that a method of use is unpatented … allows the FDA to authorize a generic drug." *Id.*

Any construction of the Hatch-Waxman Amendments must be consistent with the basic proposition that a generic manufacturer may lawfully market an approved generic version of a brand-name drug for unpatented uses notwithstanding that still-patented uses of the drug are excluded from the skinny label. This Court recognized as much in *Caraco Pharmaceuticals*, when it held that the Hatch-Waxman Amendments' clear authorization of "approval of non-infringing generic drugs under section [355(j)(2)(A)(viii)]," *id.* at 417, provides the "statutory context" for construction of other provisions of the law, *id.* at 414.

The same point applies to construction of the patent laws in the context of the marketing of generic drugs with skinny labels. The Hatch-Waxman Amendments, after all, amended not only the FDCA, but also the patent laws, and the evident purpose of such enactments is to create a "symmetrical and

coherent regulatory scheme." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (citation omitted). Faced with different federal statutory provisions "touching on the same topic," courts should strive for "harmony" among them. *Epic Sys. Corp. v. Lewis*, 584 U.S. 497, 511, 512 (2018); *see Brown & Williamson*, 529 U.S. at 133.[3]

Construing the patent laws to impose liability on a generic drug manufacturer for doing what the provisions added to the FDCA by the Hatch-Waxman Amendments expressly permit—that is, marketing the generic version of a drug for unpatented uses described in a skinny label—would be anything but harmonious. Doing so would amount to "conclu[ding] that Congress enacted a self-defeating statute," *Pugin v. Garland*, 599 U.S. 600, 607 (2023) (citation omitted), and conflict with the maxim that an "act cannot be held to destroy itself." *AT&T Mobility LLC v. Concepcion*, 563 U.S. 333, 343 (2011).

To be sure, if a generic manufacturer expressly encourages the use of its drug for an indication that was omitted from its skinny label to protect the brand-name manufacturers' patent rights, imposing liability for inducing patent infringement does not conflict with the Hatch-Waxman provisions that authorize the FDA's approval for marketing of the generic version: The Hatch-Waxman Amendments do not authorize marketing for the patented use and hence are not frustrated if patent liability is imposed for such unauthorized marketing.

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[3] *See also* A. Scalia & B. Garner, *Reading Law* 252 (2012) ("Hence laws dealing with the same subject—being *in pari materia* (translated as 'in a like matter')—should if possible be interpreted harmoniously.").

Marketing a generic drug under a skinny label, however, cannot in itself be considered active encouragement of patent infringement, even if physicians are likely to prescribe the generic for patented indications excluded from the skinny label. After all, this Court "assume[s] that Congress is aware of existing law when it passes legislation." *Miles v. Apex Marine Corp.*, 498 U.S. 19 (1990). Congress presumptively knew when enacting the Hatch-Waxman Amendments of the longstanding consensus that the FDCA permits doctors to prescribe drugs for off-label uses. *See United States v. Evers*, 643 F.2d. 1043, 1049 (5th Cir. 1981).[4] Holding that marketing a generic pursuant to a skinny label "induces" infringement because doing so implicitly informs doctors that they can prescribe the generic for patented uses would effectively make marketing the generic as authorized by the Hatch-Waxman Amendments unlawful, contradicting the balance Congress struck in enacting the statute.

II. The Federal Circuit's decisions upset the balance drawn by the Hatch-Waxman Amendments.

The Federal Circuit's decision in this case and its earlier opinion in *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320 (2021), do not hold that marketing a generic drug using a skinny label *by itself* constitutes inducement to infringe, but they

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[4] Former Representative Waxman has confirmed that Congress was aware of the obvious possibility that prescriptions for patented uses may be filled by generics marketed with skinny labels. *See* Brief of Amicus Curiae Former Congressman Henry A. Waxman in Support of Petition for Rehearing En Banc, at 8–9, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, Nos. 18-1976 & 18-2023 (Fed. Cir. Dec. 30, 2020).

come dangerously close. The court's decisions are sharply at odds with the appropriate limits on liability for induced infringement in two important respects. First, they allow the required terms of the skinny labeling itself to be used as *evidence* of inducement. Second, they allow liability for inducement to infringe to be based on the use of innocuous, truthful descriptions of the generic drug—such as calling it the "generic version" or "generic equivalent" of the brand-name drug—that add no information beyond what is inherent in the approval of a generic drug with a skinny label. The court's decisions thus create a threat of ruinous liability for marketing a generic drug in compliance with the terms of the Hatch-Waxman Amendments—a threat incompatible with the clear commands of the legislation.

A. Under any reasonable reading of the Hatch-Waxman Amendments, the *terms* of an approved skinny label itself cannot constitute evidence of inducement to infringe. The patent-holder itself is required to identify all portions of its product labeling that describe patented uses, *see Caraco Pharm.*, 566 U.S. at 405–06, and the FDA must direct that the generic manufacturer exclude those portions while using the remainder of the labeling. The generic manufacturer, in turn, is *required* to market the drug using the brand-name drug's labeling as modified in this manner, *see PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), including all indications that the brand-name manufacturer has not designated as patented. Because the generic manufacturer is stuck with the labeling, holding that the terms of the labeling itself induce infringing uses, or are evidence of inducement, would effectively preclude the generic manufacturer from marketing the drug. Treating the description of non-

infringing indications as inducements to infringe patented uses not addressed in the labeling would also allow the brand-name manufacturer to sandbag the generic manufacturer by claiming infringement based on parts of the labeling that the manufacturer earlier certified to the FDA did *not* describe patented uses of the drug.

The Federal Circuit nonetheless takes the view that a skinny label, despite its omission of all parts of the brand-name drug's labeling that the brand-name manufacturer has designated as describing patented uses, can, "*in combination* with [the generic manufacturer's] public statements and marketing materials," be considered evidence of inducement to infringe. Pet. App. 17a–18a; *see GlaxoSmithKline*, 7 F.4th at 1334. Indeed, in this case, the court allowed Amarin to proceed with allegations of inducement based in part on the skinny label while at the same time acknowledging that the label "does not provide an implied or express instruction to prescribe the drug for [a patented] indication." Pet. App. 16a.

The Federal Circuit's approach places all generic drugs marketed with skinny labels at risk. In every case, a generic manufacturer will be required by the terms of its FDA approval to use the skinny label. And the skinny label, read together with the brand-name drug's label, can always be said in some sense to "teach," Pet. App. 16a, that the generic could be prescribed for the patented indications excluded from it. Thus, under the Federal Circuit's approach, whenever a generic drug is marketed under a skinny label there is evidence of inducement to infringe that, in combination with other factors, may support liability.

As the judges who dissented from denial of rehearing in *GlaxoSmithKline* observed, the use of the skinny label as part of the evidence to support a finding of inducement to infringe is impossible to square with the structure of the Hatch-Waxman Amendments. *See GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 25 F.4th 949, 955 (2022) ("Congress enacted the skinny-label provisions as a way for generics to avoid inducement liability—and thus litigation itself. … When a generic plays by the skinny-label rules, the FDA-required label can't be evidence of intent.") (Prost, J., dissenting from denial of rehearing); *id.* at 959 ("Canons of statutory construction demonstrate that the more specific and later-enacted provisions of the Hatch-Waxman Act override the general infringement provisions of the Patent Act.") (Dyk, J., dissenting from denial of rehearing).

The features of the skinny label that Amarin has pointed to in this case demonstrate just how problematic reliance on the label as "evidence" of inducement to infringe can be. Amarin, and the panel below, pointed to the absence from the skinny label of a "Limitation of Use" statement that appeared in the brand-name labeling before the drug was approved for the patented use of treatment to reduce cardiovascular risk. But by the time the skinny label was approved, Hikma *could not* have included that statement because it was not part of the then-current labeling for the brand-name drug. The skinny label provisions authorize "omission" of language referring to patented uses, 21 C.F.R. § 314.94(a)(8)(iv), not *addition* of language to prohibit patented uses. Moreover, the language that Amarin insists should have been part of the label was not just a statement that a particular use was not authorized; it was a *factual* statement

that the effect of the drug on cardiovascular mortality and morbidity "has not been determined." Pet. App. 3a. And that statement is no longer true: Amarin now has authority to market Vascepa for treating cardiovascular risk because it has been determined to be safe and effective for that use.

Amarin's argument about the label, which formed part of the basis for the Federal Circuit's ruling that it had "plausibly state[d] a claim for induced infringement," Pet. App. 18a, amounted to the assertion that a generic drug manufacturer's failure to add to the skinny label an unauthorized and false disclaimer of effectiveness for a patented use is evidence of intent to induce infringement. That assertion cannot be squared with the text, structure, and context of the Hatch-Waxman Amendments.

B. Although the Federal Circuit has indicated that the prescribed terms of a skinny label "standing alone" may be insufficient to state a claim for inducement of infringement, Pet. App. 17a; *see also H. Lundbeck A/S v. Lupin Ltd.*, 87 F.4th 1361, 1370 (Fed. Cir. 2023), the kinds of statements that the court has found sufficient to state a claim "*in combination*" with the label, Pet. App. 18a, are as troubling as its reliance on the label itself. Both in the decision below and in *GlaxoSmithKline*, the court relied principally on isolated, innocuous phrases in public statements describing the generic drug—statements that do not mention patented uses and do nothing more to encourage the prescription of the drug for such uses than does the FDA's approval of the generic drug and its skinny label.

In particular, both below and in *GlaxoSmithKline*, the court placed primary reliance on statements by the generic manufacturer that its newly approved

drug is the "generic version" and the "generic equivalent" of the brand-name drug. Pet. App. 18a; *GlaxoSmithKline*, 7 F.4th 1324, 1336. But those statements are truisms that describe *every* generic approval under Hatch-Waxman, which *requires* that the generic drug be the equivalent of a specific, previously approved drug, *see GlaxoSmithKline*, 7 F.4th at 1353 (Prost, J., dissenting), of which the approved generic drug is by definition a "generic version." 21 U.S.C. § 353d(a)(3) ("The term 'generic version' means a drug approved under section 355(j) of this title whose reference listed drug is a covered drug."). Indeed, Amarin itself, in its SEC 10-Q filings, characterizes Hikma's drug as a "generic version of VASCEPA."[5] On Amarin's reasoning, its own 10-Q filing actively encouraged doctors to infringe its patents.

Of course, *neither* party's use of the anodyne term "generic version" or "generic equivalent" actively encouraged infringement. Such statements do not provide any more encouragement to doctors to infringe the brand-name manufacturer's patents than does the FDA's own approval of the generic drug and its skinny label. The skinny label already lets doctors know that the generic is bioequivalent to the brand-name drug, and it effectively tells them that the reason certain indications for which the brand-name drug is approved are not on the label is that they are patented. That information provides ample reason for a doctor inclined to disregard (or ignorant of) the brand-name manufacturer's patent rights to prescribe the generic for a patented use or, where allowed or required by

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[5] https://www.sec.gov/Archives/edgar/data/897448/000156459021021572/amrn-10q_20210331.htm#ITEM_1_LEGAL_PROCEEDINGS 25 (Apr. 29, 2021).

state law, for a pharmacist to substitute the generic when filling a prescription for the drug. Public statements about the drug that do no more than the label itself to inform doctors of the possibility of prescribing the generic version for patented indications do not show that a generic manufacturer has actively encouraged infringement. If the skinny label itself cannot constitute inducement to infringe, such statements cannot do so either.

The FDA's approval letter in this case, for example, specifically stated that the approval was based on the determination that Hikma's drug is "bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Vascepa Capsules."[6] Moreover, the FDA's letter (*unlike* the press releases on which the court below relied) specifically refers to the patented uses for which the drug has not been approved solely because they were excluded from Hikma's application for approval pursuant to 21 U.S.C. § 355(j)(2)(A)(viii). That information provides everything a doctor needs to know if he or she wishes to prescribe the generic version for a use that is off-label because of patent protection. The generic manufacturer's accurate descriptions of the drug as the "generic version" of or "generic equivalent" to the brand-name drug (which are essential to inform doctors and pharmacists that the generic drug can be substituted for the brand-name version for the approved uses) provide no encouragement, beyond what is intrinsic in the system created by the Hatch-Waxman Amendments, to prescribe the generic version for patented uses not included in its labeling.

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[6] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/209457Orig1s000ltr.pdf (May 21, 2020).

If intent to encourage infringement can be conjured up by combining statements using inoffensive terms like "generic version" or "generic equivalent" with the FDA-mandated labeling that carves out patented uses identified by the brand-name manufacturer, then, as Judge Prost stated in *GlaxoSmithKline*, "no skinny-label generic is safe." 25 F.4th at 955 (dissenting from denial of rehearing). "[I]f left untouched, the [Federal Circuit's decisions] may reasonably be read to mean that companies … may be held liable for induced infringement despite demonstrated compliance with the statutory and regulatory requirements to carve out everything from a skinny label that the patent owner … itself designated as covered by its patent." *Id.* at 960 (Reyna, J., dissenting from denial of rehearing).

Indeed, even if a generic manufacturer sought to protect itself by warning against patented uses in every public communication that referred to its generic version of a brand-name drug, it still would not be safe: The brand-name manufacturer would undoubtedly point to those references to the patented uses as indications that the generic manufacturer was tacitly attempting to provide doctors with a roadmap showing how to violate the patents through off-label prescriptions. The Federal Circuit's decision thus puts generic manufacturers in a no-win position.

To be sure, some doctors aware of the existence of the generic version of a drug will inevitably prescribe the generic for patented uses (with or without knowledge that those uses remain subject to patent). And in light of state laws permitting or requiring pharmacists to substitute generic drugs for brand-

name ones,[7] prescriptions written based on patented uses of the drug may often be filled by the generic version unless the doctor specifies that they may not be. But that outcome is not the result of active encouragement by the generic manufacturer. It is an inherent consequence of the Hatch-Waxman Amendments' authorization of generic competition for drugs that have both patented and unpatented uses. Imposing liability on generic manufacturers for following the Hatch-Waxman Amendments' path to approval cannot be squared with Congress's balancing of the interests at stake.

III. The Federal Circuit's decisions threaten serious harm to the consumer-protection and public-health goals of the Hatch-Waxman Amendments.

The consequences of imposing patent liability on generic drug manufacturers for marketing drugs approved with skinny labels underscore the importance of restoring the balance struck by the Hatch-Waxman Amendments by reversing the Federal Circuit's decision. When a generic manufacturer faces multimillion-dollar patent liability for marketing a product using its FDA-mandated skinny label, the result is not likely to be limited to deterrence of *infringing* uses of the drug. Rather, the consequence is likely to be that generic competitors will be deterred from entering the market at all when an indication remains patented, even after one or more uses are no longer patented, because it may be impossible to market a generic

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[7] *See* Yan Song & D. Barthold, *The effects of state-level pharmacist regulations on generic substitution of prescription drugs*, 27 Health Econ. 1717 (2018) (Table 1 and Figure 1), https://pmc.ncbi.nlm.nih.gov/articles/PMC6172151/#R24.

version without incurring liability. Indeed, in cases such as this one, it is hard to imagine what a generic manufacturer could do to avoid infringement on the theory accepted by the Federal Circuit, short of remaining out of the market altogether. And the threat of patent liability will be an especially potent deterrent to marketing generic drugs that have patented uses, because the damages for patent infringement (measured by lost profits at the inflated prices typical of brand-name drugs) are likely to dwarf the revenues to be gained from selling a lower-priced generic version. In the *GlaxoSmithKline* case, for example, the $234 million damages award based on the brand-name manufacturer's lost profits was more than three times the total revenue generated by the generic manufacturer's competing sales. *See GlaxoSmithKline*, 25 F.4th at 955 (Prost, J., dissenting from denial of rehearing).

The unavailability of generic drugs for unpatented and patented uses alike that will result from driving skinny-label generics off the market will be very costly for consumers, as well as for government-funded health programs. For example, after generic versions of carvedilol, the drug at issue in the *GlaxoSmithKline* case, appeared in 2007, 20 million patients benefited from their use. The generic versions cost two cents a dose; the brand-name version went for $4.81—about 24,000% higher. The cost to consumers if generic competitors had been unable to enter the market for carvedilol alone would have been enormous.[8]

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[8] The figures in this paragraph are taken from M. Carrier, C. Duan & S. Tu, *Prevent a legal catch-22 that could push thousands of generic drugs off the market*, L.A. Times (Sept. 21, 2022).

The costs of the Federal Circuit's legal error, of course, are likely to be much higher. As this case illustrates, what one brand-name manufacturer can succeed in doing, others will surely attempt. And if those attempts have the predictable results of deterring generic competition for the many brand-name drugs that have unexpired method patents covering approved uses, the great benefits that the Hatch-Waxman Amendments have achieved over the past four decades will be substantially impaired.

The availability of generic drugs attributable to the Hatch-Waxman Amendments has saved consumers and government health programs literally trillions of dollars since the legislation's passage in 1984. Before Hatch-Waxman, generic drugs accounted for only 19% of prescriptions filled in the United States;[9] today, that figure is about 90%.[10] The resulting savings are truly staggering. The 90% of prescriptions filled by generic drugs account for only about 12% of prescription drug costs because generic drugs are so much less expensive.[11] Throughout the history of Hatch-Waxman, the costs of brand-name medications, like other medical expenses, have continued to rise at rates much higher than the overall rate of inflation, while overall costs of generic drugs have *decreased*. For the five

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[9] FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, at i (2002) (*FTC Study*), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf.

[10] Ass'n for Accessible Medicines, *The U.S. Generic & Biosimilar Medicines Savings Report*, at 10 (Sept. 2025) (*Savings Report*), https://accessiblemeds.org/wp-content/uploads/2025/09/AAM-2025-Generic-Biosimilar-Medicines-Savings-Report-WEB.pdf.

[11] *Id.*

years between January 2014 and December 2019, for example, brand-name drug prices increased by 70.5%, more than seven times the overall inflation rate, while generic drug prices *fell* by 40.9%.[12] More recently, generic drug prices have continued to fall even as consumer prices overall have inflated and brand-name drug prices have ballooned even more.[13]

As a result, generic drug approvals in the six years from 2018 through 2023 were estimated to save $17.8 billion, $24.8 billion, $10.7 billion, $16.6 billion, $18.9 billion, and $18.6 billion, respectively, just in the first year after approval.[14] Total savings from generic drugs for 2024 alone are estimated at over $467 billion, and savings for the entire decade from 2015 to 2024 add up to $3.4 *trillion*.[15]

Preserving the integrity of the Hatch-Waxman regime that has yielded these extraordinary benefits is

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[12] P. Minemyer, *Express Scripts reveals drug classes that are driving spending growth* (Feb. 18. 2020), https://www.fiercehealthcare.com/payer/express-scripts-drug-classes-are-driving-spending-growth.

[13] *See Savings Report,* at 3.

[14] FDA, *Estimating Cost Savings from New Generic Drug Approvals in 2018, 2019, and 2020*, at 3 (2022), https://www.fda.gov/media/161540/download; FDA, *Estimating Cost Savings from New Generic Drug Approvals in 2021*, at 2 (2023), https://www.fda.gov/media/172608/download; FDA, *Estimating Cost Savings from New Generic Drug Approvals in 2022*, at 2 (2024), https://www.fda.gov/media/182435/download#:~:text=Estimates%20show%20that%20generic%20drugs,approval%20cohorts%20are%20shown%20below; FDA, *Estimating Cost Savings from New Generic Drug Approvals in 2023*, at 2 (2025), https://www.fda.gov/media/189635/download#:~:text=In%202023%2C%20the%20FDA%20granted,approval%20cohorts%20are%20shown%20below.

[15] *Savings Report*, at 10.

a matter of national importance. Americans pay too much for medical care, including prescription drugs, and medical costs continue to increase, threatening the health and solvency of individuals and straining the budgets of governments. In 2024, national health expenditures grew 7.2%, to $5.3 trillion, accounting for 18% of the nation's gross domestic product (GDP). Health expenditures are projected to continue increasing at a 5.8% average annual rate for the 10 years from 2024–2033, exceeding the rate of GDP growth. The federal government bears the largest share of overall health expenditures, 31%, with private households coming in second at 28%, private businesses accounting for 18%, and state and local governments 16%. Prescription drug expenditures totaled $467 billion in 2024, and they, too, are increasing significantly year-over-year: Prescription drug spending increased by 7.9% in 2024 after growing by 10.8% in 2023.[16]

In light of the burdens created by these ever-increasing costs, holding down the rate of increase while preserving and expanding access to and quality of care is a paramount interest for both consumers and the federal government. The Hatch-Waxman Amendments provide a rare example of a program that has achieved huge successes on all these counts, dramatically reducing costs while expanding public access to medications of the highest quality. Altering the Hatch-Waxman balance in a way that reduces availability of generic drugs for non-patented uses threatens to roll back those savings, place life-saving medications beyond the reach of low-income and elderly

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[16] All figures in this paragraph are from CMS, *NHE Fact Sheet* (2026), https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet.

consumers, increase costs to Medicare, Medicaid, and other critically important government programs—and further exacerbate the serious national problem of excessive and increasing medical costs.

For these reasons, protection of the Hatch-Waxman balance against legal challenges from brand-name manufacturers whose profits are threatened by competition has long been a priority of the federal government. The FTC, for example, has long recognized the important role of the Hatch-Waxman Amendments in fostering beneficial competition in the pharmaceutical industry and "taken an active role in ensuring that consumers benefit from [that] competition."[17] In particular, the FTC has directed antitrust enforcement efforts against attempts by brand-name manufacturers to preserve their monopolies by paying generic manufacturers to delay entry. *See FTC v. Actavis, Inc.*, 570 U.S. 136 (2013). The FTC also suggested amendments to Hatch-Waxman, which were ultimately adopted in 2003, to ensure that generic drug manufacturers could challenge false claims by brand-name manufacturers that particular uses of approved drugs were covered by patents, allowing Hatch-Waxman's provisions permitting generics to carve patented indications out of their labels to function effectively.[18] In *Caraco Pharmaceutical*, 566 U.S. 399, this Court held that the 2003 amendments must be read consistently with the Hatch-Waxman Amendments' structure to facilitate approval of generic drugs with labels carving out patented uses.

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[17] *FTC Study*, at i.

[18] *See FTC Study*, at v.

The Department of Health and Human Services has similarly recognized the important role of the Hatch-Waxman Amendments in the federal government's efforts to address high drug prices. Indeed, in its 2021 report on the subject, the Department noted that the ability of generic manufacturers to carve out patented uses from their labeling benefits patients and the federal government:

> Both the biosimilar and generic drug marketing pathways created by Congress provide important flexibility for biosimilars and generic drugs to seek approval for fewer than all of the brand product's conditions of use, and, accordingly, to exclude or "carve-out" certain uses from their labeling, including those that are protected by patents for the brand product. Biosimilar and generic drug manufacturers can thus seek timely approval of and market their products for non-protected uses, even when other uses of the brand product remain patent protected. This practice, sometimes described as "skinny labeling," may result in decreased costs to patients and to the federal government, including reducing spending on Medicare and Medicaid.[19]

The provisions allowing generic manufacturers to carve out patented uses of a drug whose formulation is no longer protected by a patent and that has approved, unpatented uses are critically important to the balance struck by the Hatch-Waxman

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[19] HHS, *Comprehensive Plan for Addressing High Drug Prices: A Report in Response to the Executive Order on Competition in the American Economy*, at 21 (Sept. 9, 2021), https://aspe.hhs.gov/sites/default/files/2021-09/Drug_Pricing_Plan_9-9-2021.pdf.

Amendments and its goal of ensuring that generic drugs marketed for unpatented uses "quickly come to market." *Caraco Pharm.* 566 U.S. at 415. Absent the authority to approve a label that carved out patented uses, the FDA would be unable to approve a generic drug for unpatented uses as long as a single approved use of the brand-name drug remained under patent.

That consequence would drastically undermine the objectives of the Amendments, because patents claiming new uses for old drugs—and thus keeping patent protection alive for the brand-name drug—are ubiquitous: A 2017 study found that 78% of drugs associated with new pharmaceutical patents reported to the FDA between 2005 to 2015 were existing drugs, not new ones; that 70% of the roughly 100 best-selling drugs had patent protection extended by new patents at least once in that period, and 50% had their protection extended more than once; that almost 40% of all drugs available on the market received additional protection from new patents; and that pharmaceutical companies that used this strategy tended to be repeat players, with 80% using it more than once.[20]

Not surprisingly, then, generic entrants frequently must use skinny labels as a means to obtain marketing approval for drugs whose brand-name manufacturers have outstanding patents covering only some of multiple approved uses for the drugs. A recent study showed that 43% of the generic versions approved for such drugs between 2015 and 2019 used skinny

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[20] R. Feldman, *May your drug price be evergreen*, 2018 J.L. & Bioscis. 1, 7–8 (2018). https://repository.uclawsf.edu/cgi/viewcontent.cgi?article=2711&context=faculty_scholarship

labels.[21] That trend continued in the years immediately preceding the Federal Circuit's decision in *GlaxoSmithKline*, but in 2023, soon after that decision, skinny label approvals, and the associated savings, fell off markedly.[22]

The improper threat of patent liability for generic drug manufacturers that use skinny labels to obtain marketing approval threatens the balance struck by the Hatch-Waxman Amendments, and the resulting benefits to consumers, patients, federal and state governments, and public health. This Court should put an end to that threat.

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[21] B. Walsh, *et al.*, *Frequency of First Generic Drug Approvals With "Skinny Labels" in the United States*, JAMA Intern. Med. Research Letter (Mar. 29, 2021), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2777965.

[22] T. Ziaks, *et al.*, *Frequency of first generic drugs approved through "skinny labeling," 2021 to 2023*, 31 J. Manag. Care Spec. Pharm. 343 (2025), https://pubmed.ncbi.nlm.nih.gov/40152800/.

CONCLUSION

The Court should reverse the judgment of the court of appeals and remand with instructions to affirm the district court's dismissal with prejudice of Amarin's complaint.

Respectfully submitted,

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