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 FOR THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS *AMICUS CURIAE* SUPPORTING PETITIONERS


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February 25, 2026

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## INTEREST OF *AMICUS CURIAE*[1]

*Amicus curiae* the Association for Accessible Medicines (AAM) is a nonprofit, voluntary association representing manufacturers and distributors of generic and biosimilar medicines and bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry. AAM's members provide patients with access to safe and effective generic and biosimilar medicines at affordable prices. AAM's core mission is to improve the lives of patients by providing timely access to safe, effective, and affordable prescription medicines.

Generic manufacturers play an invaluable role in the U.S. healthcare system. In 2024, for instance, the availability of generic and biosimilar medicines kept $467 billion in the pockets of patients and taxpayers, and that figure exceeded $3.4 trillion over the last decade.[2]

AAM regularly participates as an *amicus* in litigation of importance to the generic-pharmaceutical industry and to the American public that benefits from low-cost generic alternatives. AAM has filed *amicus* briefs in cases concerning the skinny-label provisions at issue here, which Congress created as part of the Hatch-Waxman Act to allow manufacturers to provide

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[1] No counsel for any party authored this brief in whole or in part, and no entity or person, aside from *amicus curiae*, its members, or its counsel, made any monetary contributions intended to fund the preparation or submission of this brief.

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

affordable generic drugs to the American public. AAM has a significant interest in this matter. The decision below is the second decision in three years from the Federal Circuit that has dramatically narrowed the skinny-label pathway. By putting generic drug manufacturers at risk of extraordinary liability when they follow Hatch-Waxman to the letter, the panel's decision makes the skinny-label pathway all but unusable. The harms will be felt not just by AAM's members, but by the patients who rely on generic manufacturers to produce affordable, life-saving medications.

## INTRODUCTION AND SUMMARY OF ARGUMENT

What keeps drug prices high? Mainly the lack of competition from generic alternatives. And as part of their strategy to avoid generic competition, brand-name drug companies can keep getting patents on different ways of using a single drug: consider a patent issued in 2011 for a new method of treatment involving a drug that has been in use for 3500 years, back to ancient Egypt.[3] If a single patent on a single way of using a drug could keep generics off the market, there would never be generics.

Enter Section viii, the statute at issue in this case—formally 21 U.S.C. § 355(j)(2)(A)(viii). Congress wrote Section viii as a specific, targeted exception to the general rule that a generic drug cannot be approved during the term of patents claiming the brand-name drug or methods of using it, at least not without

[3] *See* U.S. Patent No. 7,964,647; Georges El Hasbani et al., *Colchicine: An Ancient Drug with Multiple Benefits*, 27 Current Pharmaceutical Design 2917 (2021).

litigation over whether the patent is valid or not infringed. Under Section viii, the generic applicant can skip all that if the drug itself is not patented and the applicant is not "seeking approval" for the patented use—*i.e.*, if it will adopt a "skinny label" that "carves out" the instructions that would infringe the patent. The sole patented use of an unpatented drug may be a very small tail on a very large dog. And Congress determined that it would rather risk giving up the tail than get no dog.

So with a skinny label, a generic can get on the market immediately—no litigation, no delays, and under a correct view of the law, no fear that the skinny label will induce infringement. The results have been spectacular—hundreds of generic drugs on the market sooner, with billions of dollars in savings.[4]

But if the Federal Circuit's decision is not reversed, Section viii will plummet in significance. The Federal Circuit has opened the floodgates for litigation against generic manufacturers, allowing cases to get past the pleading stage merely by alleging conduct that is utterly commonplace in skinny-label launches. A reference to generic equivalence, some press releases aimed at investors, and a skinny label that carves out the patented use but makes some reference to cardiovascular disease in a warning—that is enough for the Federal Circuit. But under a correct understanding of the Section viii framework and the generic market, *none* of those allegations states a

[4] *See* Bryan S. Walsh et al., *Frequency of First Generic Drug Approvals with "Skinny Labels" in the United States*, 181 JAMA Internal Med. 995, 995 (2021); Doni Bloomfield et al., *Prescription Drug Method-of-Use Patent Protection, 1991-2018*, 41 J. Gen. Intern. Med. 261, 261 (2025).

plausible claim for actively inducing doctors to infringe Amarin's specific method-of-treatment patent. Active inducement of infringement is not supposed to include "ordinary acts incident to product distribution." *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 937 (2005). The Federal Circuit failed to follow that rule here. Allowing Amarin's complaint to proceed past the pleading stage risks closing off the skinny-label pathway for all generic drugs.

The Federal Circuit fundamentally misunderstood several key principles about Section viii and generic drug approval that should govern inducement in this context. (1) Section viii applies only to *method* patents. The sale (or offer for sale) of an unpatented *product* cannot induce infringement of a patent that claims only one way of *using* that product. (2) Skinny labels do not induce infringement of the carved-out patent. That is why the statute requires no notice to the brand and no pre-launch adjudication when the generic carves out the patent, whereas it does require notice and provides for pre-launch adjudication (and delayed FDA approval of the generic) when a generic challenges a patent as invalid. (3) True statements that a generic product is the "generic version" or "generic equivalent" of a brand product merely echo what the government itself says; they are characterizations of the (unpatented) product, not the labeled uses. (4) Generics generally do not market their products, because of state automatic-substitution laws, and because doctors do not specify which company's generic product will be used to fill a prescription. Press releases directed to investors, not doctors, have no bearing on doctors' prescribing decisions. Merely pointing to a statement in a press

release "to the marketplace" does not establish that the statement actively induced doctors to infringe. Adopting those principles would more than suffice to reverse the Federal Circuit's reliance on press releases and websites, statements of generic equivalence, and Hikma's FDA-approved skinny label.

This Court should reverse the Federal Circuit because the decision below makes the Section viii pathway untenable, harming patients, taxpayers, and generic manufacturers alike.

## ARGUMENT

The skinny-label statute has one job within the generic-drug regulatory framework: to make sure that generics can avoid infringing a patent on one *way* of using an unpatented *drug*. Under the Federal Circuit's overbroad approach to inducement, *no* manufacturer of a skinny-labeled generic can be sure it can avoid infringement. This Court should reject that approach and make Section viii usable again.

Congress understood what the Federal Circuit did not: For Section viii to operate, a skinny label cannot actively induce infringement of a patent on a carved-out use. Neither can the simple act of calling a generic equivalent a generic equivalent. Allowing either of those inducement theories past the pleading stage is not just a legal error, but also an existential threat to the operation of an important federal statute that fosters competition and lowers prices.

## I. The Plausibility of Amarin's Allegations Must Take Into Account Several Legal Principles Established by the Hatch-Waxman Act and State Laws.

Congress enacted Section viii as a targeted response to a specific problem, after extensive study of how generic drugs are developed and brought to market.[5] Congress made a clear choice: "that one patented use will not foreclose marketing a generic drug for other unpatented ones." *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 415 (2012). In other words, Section viii reflects Congress's judgment that patents on a specific *use* of an unpatented drug must not delay approval of a generic version of *the drug itself*, and its insight that removing the patented use from the label suffices to prevent inducement. *Id.* at 405.

Congress adopted the Section viii skinny-label regime against the backdrop of inducement liability—an aiding-and-abetting doctrine that requires an inducer to take "affirmative steps" "to encourage direct infringement" with the "affirmative intent that the product be used to infringe." *Grokster*, 545 U.S. at 936 (citation omitted); *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 760, 764 (2011). Section 271(b) had been on the books for thirty years by the time the Hatch-Waxman Act added Section viii in 1984. And because Congress limited Section viii to method patents, to speed approval of unpatented uses for unpatented products, Congress knew that inducement

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[5] U.S. Cong. Off. of Tech. Assessment, *Patent-Term Extension and the Pharmaceutical Industry* (Aug. 1981), https://www.princeton.edu/~ota/disk3/1981/8119/8119.PDF.

was the only realistic source of liability for manufacturers. It therefore structured Section viii—especially the labeling carve-out—so as to avoid creating inducement liability.

"Determining whether a complaint states a plausible claim for relief will, as the Court of Appeals observed, be a context-specific task." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009); *see Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 562 (2007). Here both the interpretation of Section viii and the context-specific interpretation of an inducement complaint must take account of several considerations about generic drug approval, sale, and dispensing that Congress knew well, but that the Federal Circuit has ignored. This crucial legal background demonstrates that Amarin has not stated a claim for inducement. All it has pleaded is conduct that, at best, is "more likely explained by" "lawful" behavior. *Iqbal*, 556 U.S. at 680. That is insufficient.

### A. Because Section viii applies only to patents on methods of using an unpatented drug, offering the drug for sale does not induce infringement of a carved-out method patent.

Section viii can only be used where "a method of use patent" claims an FDA-approved way of using the drug. The purpose of a skinny label is to permit generic companies to launch without delay when the drug itself is not patented, so a method-of-use patent is the only obstacle. Understanding that framework confirms that marketing the generic drug itself cannot be sufficient to induce infringement of the carved-out method of using the drug.

The generic manufacturer cannot use Section viii to get around any patents on the active ingredient or formulation itself; "[a] section viii statement is typically used when the brand's patent on the drug compound has expired and the brand holds patents on only some approved methods of using the drug." *Caraco*, 566 U.S. at 406. Section viii works to speed generic approval only when any patents on the compound or formulation itself have already expired or been invalidated or (in limited circumstances) successfully designed around.[6] That is because Congress recognized that there can be only one patent term on the active ingredient molecule[7]—but potentially many, many different patent terms on new ways to use that molecule.

By the time there is an unpatented molecule with at least one unpatented use, the brand manufacturer already will likely have enjoyed years of patent exclusivity on the compound and its original use. 35 U.S.C. §§ 154(a)-(b), 156 (patent term lasts for 20 years from filing, plus adjustments and extension for regulatory delays); Kevin J. Hickey, *"Skinny Labels" for Generic Drugs Under Hatch-Waxman*, Cong. Rsch. Serv. IF127000 (Jan. 28, 2026).[8] There are also several other forms of regulatory exclusivity that add

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[6] *See* 21 U.S.C. § 355(j)(2)(A)(vii)(III), (j)(5)(B)(ii) (approval permissible after patents expire); *id.* § 355(j)(2)(A)(vii)(IV), (j)(5)(B)(iii) (approval permissible after patents declared invalid or not infringed, or 30-month stay expires). The ability to design around is limited by the requirement that the generic formulation have the same active ingredient and be bioequivalent to the brand's. *Id.* § 355(j)(2)(A)(ii), (iv).

[7] *See, e.g.*, 35 U.S.C. § 102(a)(1) (no patent can issue on an invention that has previously been patented).

[8] https://www.congress.gov/crs-product/IF12700.

to or overlap with the protection for new drugs. *See* FDA, *Frequently Asked Questions on Patents and Exclusivity* (Feb. 5, 2020).[9]

Thus, the whole point of Section viii is to eliminate obstacles to approval based on a method of *using* an unpatented drug. It follows that merely selling or offering the *drug* cannot amount to indirect infringement of the carved-out method patent. The expiration (or invalidation) of patents on the drug means that the drug is in the public domain. *See, e.g.*, *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 153 (1989) (citing *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 231 (1964)). The patent owner's monopoly over the molecule is gone, and a patent on one use (out of many) does not restore it. That is precisely the purpose of the carve-out statute: to ensure that the owner of a patent on a single use of an unpatented drug cannot leverage that ownership to bar access to the drug entirely. *See, e.g.*, H.R. Rep. No. 98-857, at 21 (1984).

By definition, there is a "substantial noninfringing use" of any public-domain molecule that is FDA-approved for at least one unpatented use; selling such a drug therefore cannot be "contributory infringement" under 35 U.S.C. § 271(c). And late in a product's lifecycle, after being studied or sold for years, a patented use may be quite narrow (to avoid invalidation by prior art, sales, public use, or

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[9] https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#What_is_the_difference_between_patents_a. Most notably, securing FDA approval of a new chemical entity entitles the brand to five years of freedom from generic competition whether it has any patents or not. *See* 21 U.S.C. § 355(j)(5)(F)(ii).

obviousness, *see id.* §§ 102, 103). For example, in one of the Federal Circuit's carve-out cases, the drug had three FDA-approved indications, but the narrow patented method of use claimed only part of one of them—it required physicians to prescribe the drug product (i) in order to decrease mortality (ii) caused by congestive heart failure (iii) by administering a therapeutically acceptable amount of carvedilol (iv) in conjunction with one or more of three other drug products (v) as a maintenance dose (vi) for more than six months. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1324 (Fed. Cir. 2021). That is both narrow and relatively hard to induce.

Because a carved-out patent by definition claims only a method of *using* the product for some FDA-approved use, a manufacturer generally can infringe such a patent only indirectly, by inducing a provider or patient to practice the patented method. Carving the patented indication out of the FDA-approved label makes sure that the label itself does not induce any such infringement.

### B. Section viii does not trigger pre-launch infringement litigation because the carve-out itself offers immediate certainty: Skinny labels do not induce infringement.

The core innovation of Hatch-Waxman is the ability to get patent issues resolved with certainty *before* a generic launch. Congress recognized that even a small possibility of patent-infringement damages could well disincentivize generic manufacturers from even trying to market a product until after all patents expire. After all, generics

sometimes make just pennies per pill, but if found liable for infringement, they can be responsible for the brand's lost profits—at its *much* larger profit margins. So Congress created a process whereby generics and brands could obtain certainty about whether the brand's patents are valid, and whether the generic infringes them, *before* the generic launches—and becomes exposed to damages for the brand's lost profits. Just filing an application to market a generic before all patents expire (a so-called "Paragraph IV" certification) is deemed an act of infringement, triggering patent litigation. *See FTC v. Actavis, Inc.*, 570 U.S. 136, 143 (2013). In return, while that litigation proceeds, the brand gets certainty that the generic will not launch for at least 30 months (unless it wins the litigation before then). *Id.*

None of that happens in the Section viii process, which is not set up to "provok[e] litigation." *Caraco*, 566 U.S. at 407. The applicant does not have to submit a Paragraph IV certification, or provide notice to the brand company, because it is not "seeking approval" for the use that the brand's method patent claims. 21 U.S.C. § 355(j)(2)(A)(vii); *see id.* § 355(j)(2)(B) (Paragraph IV certification requires notice to the brand company). There is no artificial act of patent infringement. *See AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1377-78 (Fed. Cir. 2012) (citing *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1356-60 (Fed. Cir. 2003)). Indeed, when generics have tried to obtain patent certainty from a court before launching under a skinny-label, brand manufacturers have successfully defeated those claims by arguing that there is no statutory basis for them. *In re Entresto (Sacubitril/Valsartan) Patent Litig.*, 2022 WL

4482717, at *5 (D. Del. Sept. 27, 2022). Nor does the generic have to wait for the method patent to expire. Unlike with a Paragraph IV certification, there is not even a 30-month stay on approval: If the only patent is a carved-out method patent, the generic application can be approved immediately.

Given its focus on providing generics with certainty through pre-launch litigation, Congress plainly did not create Section viii as a font of *un*certainty. Rather, the reason Section viii does not provoke pre-launch litigation, or even require prompt notice from the generic to the brand, is because *it makes litigation unnecessary*: The carve-out from the label means that the label will not induce infringement. There is nothing to litigate.

Partly, this is because the skinny-label process favors brand manufacturers. Brands get to identify exactly what portions of their labeling they think are claimed by their method-of-use patents. *See* 21 C.F.R. § 314.53(b)(1) ("[T]he [brand-name company with an approved drug product] submitting information on the method-of-use patent must identify with specificity the section(s) and subsection(s) of the approved labeling that describes the method(s) of use claimed by the patent submitted."). In other words, they get to decide what words they believe generics must carve out in order to avoid even a "reasonabl[e]" claim of infringement. *Id.* Their claim is summarized in a "use code," which FDA publishes "in a fat, brightly hued volume called the Orange Book." *Caraco*, 566 U.S. at 405-06. And FDA will not second-guess their claim: It simply "will not approve" a generic application "if the generic's proposed carve-out label overlaps at all with the brand's use code.… [FDA] does not independently

assess the patent's scope or otherwise look behind the description authored by the brand." *Caraco*, 566 U.S. at 406.[10] This system therefore inherently favors brands from the outset.

So a generic that gets FDA's approval of a skinny label has, by definition, carved out everything that *the brand itself* has told FDA is necessary to avoid even a claim of infringement. That is why Congress did not set up a Section viii carve-out to trigger litigation—again, there is nothing to litigate.

### C. For important regulatory reasons, generic drugs are equivalent to brand drugs.

Generic drugs save patients and the healthcare system money precisely because they do not have to go through the same round of clinical trials for approval. Rather, FDA is able to find them safe and effective based on their close equivalence to already-approved drugs. A generic has the same active ingredient as the brand, it works on the human body in equivalent ways ("bioequivalence"), and it carries the same labeling[11]—except for any carve-out. *Caraco*, 566 U.S. at 406; *see* 21 U.S.C. § 355(j)(2)(A)(ii), (iv), (v). Generally speaking, however, the generic labeling can subtract

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[10] A generic's only recourse to an overbroad characterization by a brand company is a counterclaim in court to correct the Orange Book. *See Caraco*, 566 U.S. at 408-09.

[11] "[L]abeling" is defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). Labeling thus "embraces advertising or descriptive matter that goes with the package in which the articles are transported," in addition to any label that may be placed directly on a pill bottle. *Kordel v. United States*, 335 U.S. 345, 350 (1948).

aspects of the brand labeling, but cannot add to them. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 614-16 (2011). Thus, a generic label generally cannot include warnings or disclaimers that the brand label does not have; Section viii also does not allow a generic label to drop portions of the brand label that are not claimed in the carved-out patent(s).

Given this duty of sameness, FDA routinely describes generics as the therapeutic equivalents of brand products. Indeed, FDA publishes such determinations to the public in the Orange Book, and explains at length that bioequivalent products are "therapeutically equivalent" *to each other*. *See, e.g.*, FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* 2-1, 2-4 (46th ed. 2026), https://www.fda.gov/media/71474/download?attachment. That finding of equivalence is the basis of the entire system allowing generic products to be substituted for brand ones.

But that does not mean that representations about the equivalence *of the drug product* are akin to representations about how the drug product can or should be used. Therapeutic equivalence is a function of the product's composition, not the uses for which it is labeled. *See, e.g.*, 21 U.S.C. § 355(j)(8)(B); 21 C.F.R. § 314.94(a)(7). Products are bioequivalent if they result in the active ingredient being absorbed in the body at comparable rates, *id.*; bioequivalence is often tested in healthy subjects,[12] confirming that it has

[12] *See* FDA, *Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA Guidance for Industry, Draft Guidance* 3-4 (Aug. 2021), https://www.fda.gov/media/87219/download.

nothing to do with the prescribed indication.

Thus, every generic that FDA finds therapeutically equivalent to the brand drug is the subject of a government publication declaring that equivalence to the world. That is because describing the drugs as "equivalent" is both completely true and absolutely indispensable to the operation of the entire system. Generic drugs are determined to be safe and effective *as a result of* their equivalence.

It follows that for a manufacturer to repeat FDA's finding of equivalence accurately cannot be inducement of a method claim that encompasses only one use of an unpatented product. Just as selling the product cannot by itself be inducement, neither can correctly repeating this crucial regulatory judgment.

### D. Because of state automatic-substitution laws that operate at the pharmacy, generic companies do not market to doctors and doctors do not prescribe a specific manufacturer's generic drug.

Congress knew that most of the savings would be achieved at the pharmacy. Because FDA certifies brand and generic drugs as equivalent to one another, laws in effect in all 50 States (then and now) authorize pharmacies to substitute a generic product for a brand one. U.S. Cert. Amicus Br. 5; *see also PLIVA*, 564 U.S. at 628; *Inwood Lab'ys, Inc. v. Ives Lab'ys, Inc.,* 456 U.S. 844, 847 n.4 (1982). And prescribing physicians cannot prescribe a *particular* generic company's drug from among the available generic options (*e.g.*, Hikma's generic product over Apotex's or Teva's). Instead, doctors prescribe drugs by either their brand name or their non-proprietary name, Patrick J.

Skerrett, *Generic Drugs: Don't Ask, Just Tell*, Harvard Health Publ'g (Jan. 7, 2013),[13] and if there is more than one option that FDA has certified as therapeutically equivalent, the pharmacy can buy from the wholesaler whichever products it wants, and substitute whichever one it has in stock.

Indeed, the only *specific* manufacturer's drug product a physician can prescribe is the *brand* manufacturer's drug. Automatic substitution can be avoided if doctors specifically write the brand name on their prescription pad and then they (or sometimes their patients) direct the pharmacy to "dispense as written." U.S. Cert. Amicus Br. 6; *Inwood Lab'ys,* 456 U.S. at 847 n.4. That happens in only a small fraction of cases. William H. Shrank, et al., *The Consequences of Requesting "Dispense as Written,"* 124 Am. J. Med. 309, 309-10 (2011).

The automatic substitution system, along with generics' thin profit-margins, disincentivizes generic manufacturers from spending money to market directly to doctors (or patients). Generics do not maintain a sales force of tens of thousands of sales representatives the way that brand companies do. *See, e.g.*, *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 150 (2012). Generics sell their products to wholesalers, not to doctors and (given the need for a prescription) usually not to patients. Marketing might well result in sales to a competitor: Doctors do not decide which generic to fill a prescription with—pharmacies do. And pharmacies do not infringe method patents.

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[13] https://www.health.harvard.edu/blog/generic-drugs-dont-ask-just-tell-201301075766.

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These contextual points shape the plausibility of Amarin's allegations—or lack thereof. Congress well understood that generics would be equivalent medicines, both chemically and in the human body—and that it would be necessary for FDA, generics, and even brands to say so. But generics do not market their equivalence to doctors—they do not need to. The only place in which they give instructions that doctors might read is in the labeling. And that is precisely why the carve-out statute operates the way it operates: so that successfully carving out an indication from the labeling will eliminate the risk of inducing a doctor to practice that indication, and so that the carved-out patent will not delay the generic from coming on the market.

As the next section discusses, the Federal Circuit's treatment of both the label and other materials Amarin cited took no account of any of these important contextual points.

## II. Active Inducement Requires an Affirmative Encouragement of the Patented Use

Active inducement of patent infringement does not include "ordinary acts incident to product distribution." *Grokster*, 545 U.S. at 937. Accordingly, conduct basic to selling a skinny-labeled product cannot give rise to inducement liability. Manufacturers have to be able to sell the unpatented product, with the FDA-approved skinny label, and to describe it as a "generic equivalent" to a brand product, just as FDA does. Yet the Federal Circuit's decisions in this area treat that basic conduct as actionable inducement. Under the ordinary principles

of inducement, as informed by the generic drug regulatory framework and its history, those allegations cannot state a plausible claim of inducement. Amarin's complaint is insufficient because it does not plausibly plead that Hikma actively encouraged doctors to practice the specific patented method of use—the method carved out of Hikma's product label.

### A. Referring to a drug as a generic is not active inducement.

This Court should make clear that a truthful statement that one drug is the generic version of another cannot serve as the basis—in whole or in part—for alleging active inducement of infringement. The Federal Circuit recognized the point but failed to follow it—holding that such a statement can be actionable in combination with other matters. Pet. App. 21a. The court never identified how the "generic version" language could actively induce infringement, and it cannot. As explained above, a statement of generic equivalence accurately references the drug *product*—which, for skinny-labeled drugs, is *un*patented. Such statements are necessary to sell the product at all. And merely selling or offering the drug product cannot infringe a carved-out patent. *See* pp. 7-10, 14-15, *supra*. Indeed, *Congress itself* has used the precise terminology that the Federal Circuit found probative of inducement. *E.g.*, 21 U.S.C. § 353d(a)(3) ("The term 'generic version' means a drug approved under section 355(j) … whose reference listed drug is a covered drug."). So has Amarin. Pet. Br. 36.

Given that active inducement requires a "clear expression" or an "affirmative step[] taken to foster

infringement," *Grokster*, 545 U.S. at 936-37, active inducement to infringe a method patent requires, at minimum, a clear expression encouraging the recipient to practice every step of the specific patented method of use. Demanding anything less violates this Court's precedents, which have consistently explained that advertising a commercial product for uses that are not "necessarily infringing," even with "knowledge that some would use [the product] to infringe," is not sufficient for indirect infringement. *Id.* at 931.

Here there is no such clear encouragement. Hikma never stated that doctors or patients should use its product just like Vascepa for the still-patented CV indication. Hikma did not even point to Vascepa's patented uses in describing Hikma's product as Vascepa's generic equivalent. Pet. App. 35a. And the court did not even restrict itself to "generic equivalent" communications *directed to doctors or patients*—the class of people who could commit direct infringement of the carved-out claims. *See* pp. 22-23, *infra.*

The most the court could point to is that Hikma acknowledged obliquely that Vascepa *had* other indications on its label, by stating that Vascepa was approved "in part" for the unpatented SH indication. Pet. App. 18a. That is substantively no different than admitting that a label is a skinny label—*every* skinny-labeled product is the generic equivalent of a brand-name product with at least one patented indication that has been carved out of the generic label. The Federal Circuit's reasoning would make every skinny label self-defeating—the label's very skinniness would necessarily be deemed inducement. That reasoning is patently incorrect, because it comes nowhere close to active inducement to practice any patented method.

### B. A compliant skinny label cannot support a claim of active inducement.

This Court should also make clear that a compliant skinny label cannot support allegations of active inducement to infringe—again, in whole or in part. Here, too, the Federal Circuit's reasoning was opaque: It said that the label did not induce by itself, but plausibly did so in combination with other materials. Pet. App. 17a, 18a. The Hatch-Waxman framework precludes basing inducement of a carved-out patent on a label that has properly been through the carve-out process. *See* pp. 10-13, *supra*.

Hikma carved out everything it was required to. If it had not, FDA could not have approved the carve-out, and if FDA somehow misapplied the information that Amarin gave it, Amarin could have filed an APA action against the agency (rather than a damages action against Hikma). Indeed, the panel acknowledged that there is absolutely nothing infringing in the Indications & Usage section of the label—the first section, where Amarin lists the patented indication and Hikma's label omits it. Pet. App. 16a.

That should have been the end of the matter. Indeed, "[i]ndications or uses must not be implied or suggested in other sections of the labeling if not included in [the Indications and Usage] section." 21 C.F.R. § 201.57(c)(2)(iv). In the carve-out context, just alleging that doctors would read other sections as teaching "that the product could be prescribed to treat cardiovascular risk" is inadequate to state a plausible claim. Pet. App. 16a. Clever pleading cannot just disregard the countervailing evidence from the label: the conspicuous silence on that point *in the Indications*

*and Usage section*, the absence of any instruction to perform the steps of the method, and the absence of any encouragement to perform the patented method at all.

Because *every* skinny label is bound by the same-label requirement *except* for the carved-out portion, p. 13-14, *supra*, the Federal Circuit's decision is again a recipe to negate the skinny-label regime. Labels may often contain certain words or references that bear a relationship with a carved-out indication. *E.g.*, *Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 630 (Fed. Cir. 2015) (label discussing unpatented use, *preventing* gout flareups, mentioned but did not instruct patented use, *treating* gout flareups). That is no accident: Because of the duty of sameness, brands have substantial discretion to bury land mines in obscure corners of their labeling and force generics to copy them. As Judge Prost aptly noted, "because most skinny labels contain language that (with clever expert testimony) could be pieced together to satisfy a patent claim, essentially all of these cases will now go to trial." *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 25 F.4th 949, 955 (Fed. Cir. 2022) ("*GSK*") (Prost, J., dissenting from denial of rehearing en banc). This Court should not encourage that type of game-playing. A brand that owns a method patent must identify the language in the label to be carved out—the portion actually encouraging the performance of the patented method. Once that is carved out, the label cannot establish active inducement of the carved-out patent—that is the point of the carve-out statute.

Relatedly, the Federal Circuit erred in relying on Hikma's statement on a website that its drug is a

generic for the therapeutic category of "Hypertriglyceridemia": The court said that category *included* some infringing uses, but was not itself infringing. JA195; Pet. App. 18a. Hikma's drug *is* approved to treat severe hypertriglyceridemia. Pet. App. 4a-5a. That is not a "necessarily infringing" use. *Grokster*, 545 U.S. at 931. And nothing in this single word encourages actually practicing the patented method. Treating that as encouragement to infringe is wholly implausible. Some batted balls go fair, others go foul, but in context it would be wholly implausible to read "Go up to bat and make contact" as encouragement to hit a foul ball. Even encouragement to "take the product" (which is not what Hikma said), while in theory encompassing a large set of conduct that could include some infringing conduct, is not active inducement *of infringement*.

### C. Press releases directed to investors, containing market sales figures, do not show active inducement of doctors.

Finally, the Court should reject the Federal Circuit's reliance on Hikma's commercial websites and press releases not directed to doctors. A vague rule sweeping in any communication directed to "the marketplace," Pet. App. 18a, wrongly blurs the core inducement question: Did the defendant induce *a direct infringer* to infringe the relevant patent? Where the allegedly inducing statement appears in a press release directed to the investing public, not to doctors, the only plausible answer is no—certainly not without much more particularized factual allegations that Amarin did not make. Recall that generics generally do not advertise to doctors because doctors are not their customers and cannot even specifically prescribe

a particular generic company's product. *See* pp. 15-16, *supra*. Even if *a* doctor somehow spied a press release while day trading, and remembered it months later when Hikma's generic launched (it was no longer on the website), Amarin would have to explain why it is plausible and consistent with common sense to believe doctors would make their prescribing decisions on that basis. It did not. *See* U.S. Cert. Amicus Br. 18 (explaining the necessary chain of inferences).

And even if doctors *sometimes* made their prescribing decisions in that way, citing a brand's total sales data in an investor-directed press release does not plausibly allege a clear expression encouraging carved-out methods of use. Amarin argues that the straightforward citation of a brand's sales data *passively implies* an encouragement to infringe on its patented method of use. In other words, Amarin's theory is that by providing sales data for the entire brand product, and not differentiated sales data for the approved uses only, Hikma was hinting that its product could be used for all the brand's uses. That theory flunks for multiple reasons. First, it misapprehends the elements of *active* inducement. Second, the inference on which it rests is flawed. Amarin relies on speculation that differentiated sales data would have been available to Hikma and that a reader of the press releases would *expect* differentiation and thus rely on the lack thereof. The alternative, indication-by-indication data (which would still be an imperfect proxy for patented vs. unpatented) that the Federal Circuit thought Hikma should have used does not exist on the shelf. When such data has to be developed in litigation, it requires expert evidence—and "expert" does not mean

"scientific." In *GSK*, for example, the brand manufacturer hired an expert who proposed a figure for what share of prescriptions were infringing by calling 200 physicians, asking them for their "opinions" on what percentage of their carvedilol prescriptions were directed to patients who satisfied at least four claim elements over an eight-year period, and expressly instructing them not to consult any records before answering while reassuring them that there were "no right or wrong answers." C.A. App. at 5376-5381, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, Nos. 18-1976, 18-2023 (Fed. Cir. Mar. 27, 2019).

Hikma, a public company, sent press releases to investors based on important developments regarding a new product. It gave the figure it had: the size of Amarin's total market. But that does not mean that Hikma was representing that *it* expected to capture all of those sales and no more, or that it would bring in the same amount of revenue as Amarin if it did—the entry of generics can *expand* the market and lower the price. Providing the brand's sales data does not make a specific representation about how much market share the generic versions could take as a whole, much less the market share *a specific generic manufacturer* would take. And passive expectations of revenue from infringement would not be enough anyway: *Active* inducement requires the defendant to have actually encouraged the listener to infringe.

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Ultimately, the complaint relies on a speculative chain of hypotheticals: a doctor *might have* read a press release targeted toward investors, and *could*

*then* interpret sales figures describing a brand drug's total sales as an instruction to use the generic drug for a patented indication of use, and *could have* interpreted other true and anodyne statements about Hikma's generic drug as encouragement to use the product for a non-indicated use. Because none of these speculations rise to the level of a clear expression encouraging the use of Hikma's generic for Amarin's remaining patented method-of-use, Amarin fails to state a claim. *Twombly*, 550 U.S. at 555 ("Factual allegations must be enough to raise a right to relief above the speculative level.").

## III. The Federal Circuit's Ruling Renders Section viii Ineffective for Generic Market Entry.

The Federal Circuit's ruling has made Section viii unacceptably risky. Literally every skinny label launch could give rise to allegations like these. Any determined plaintiff can write a complaint that will survive a motion to dismiss under the low bar set by the Federal Circuit. And that will destabilize a crucial pathway for generic entry, one that has saved the U.S. healthcare market billions of dollars and avoided years of delay in generic competition.

Congress's goal for Section viii was "speed[ing] the introduction of low-cost generic drugs to market." *Caraco*, 566 U.S. at 405. That goal will not be achievable given the threat of liability— a first generic entrant could expect to pay hundreds of millions in lost-profits damages. That is far more than any generic can hope to make from a single product. Generic manufacturers operate on razor-thin profit margins, which makes launching a generic despite

massive post-launch risk an insupportable business decision. *See* HHS, *White Paper: Policy Considerations to Prevent Drug Shortages and Mitigation Supply Chain Vulnerabilities in the United States* 3 (Apr. 2, 2024).[14] Consider the situation in *GSK*, a precursor case to this one, in which "Teva's *revenues* (it made no profit) from selling carvedilol were $74 million, yet [after trial] it owe[d] GSK $234 million in lost-profit damages." 25 F.4th at 955 (Prost, J., dissenting from the denial of rehearing en banc).

Because of this post-launch liability risk, Section viii is now, perversely, the *riskiest* method of launching a generic. Instead of solving the problem of lengthy *pre-launch* litigation inherent in Paragraph IV certification, the Federal Circuit has created a pathway with ruinously high stakes and fraught with risk. The result is that Section viii now neither provides a method for pre-launch certainty, nor a reliable path to avoiding liability post-launch. "[I]f playing by the skinny-label rules doesn't give generics some security from label-based liability, generics simply won't play. And who could blame them? The risk is too great." *GSK*, 25 F.4th at 955 (Prost, J., dissenting from rehearing en banc).

Generic manufacturers cannot be expected to responsibly launch under these conditions, which means that even a narrow method patent can block generic entry altogether. Even if a generic is able to defeat the method patent through Paragraph IV litigation, that still means *at least* 30 months of

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[14] https://aspe.hhs.gov/sites/default/files/documents/bd863be8f0aaf5380dc801390440bc3d/HHS-White-Paper-Preventing-Shortages-Supply-Chain-Vulnerabilities.pdf.

litigation, millions of dollars in expense, and the risk of an uncertain outcome—and the penalty for losing a Paragraph IV case as to *even a single narrow patent* is to be kept off the market *completely* until that patent expires. *See* 35 U.S.C. § 271(e)(4)(A). Cutting off the Section viii process will therefore significantly harm patient access to generics.

The Hatch-Waxman scheme has been incredibly successful in increasing the availability of generics and bringing down drug prices for American patients. By 1996, generics already accounted for roughly 42.5% of all prescriptions dispensed—a huge victory for patients, as generics were roughly three times less expensive than their branded counterparts.[15] Today, generics make up an even larger percentage of all prescriptions dispensed,[16] while the median price of generics is a fraction of the price of branded drugs.[17] And across the United States, the robust market for generics has led to enormous financial and health benefits.[18]

Skinny labels have proven particularly important for generic competitors of blockbuster drugs, for which patent owners frequently seek to extend their monopolies by obtaining seriatim method-of-use

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[15] Kaiser Fam. Found., *Prescription Drug Trends: A Chartbook Update* 27, 36 (Nov. 2001), https://files.kff.org/attachment/report-prescription-drug-trends-a-chartbook-update.

[16] FDA, *Office of Generic Drugs 2021 Annual Report* 2 (Feb. 2022), https://www.fda.gov/media/156066/download?attachment.

[17] *See* FDA, *Generic Competition and Drug Prices* (last updated Nov. 17, 2025), https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices.

[18] *AAM 2025 Savings Report* 2.

patents.[19] Generic versions of no-longer-patented drugs with patented uses launch with a skinny label nearly 50% of the time,[20] saving patients (and the federal government) billions. For example, Crestor, a branded drug used to treat high cholesterol, cost patients and payors $6.2 billion annually before the entry of generics.[21] AstraZeneca's patent on the compound expired in 2016, but AstraZeneca had other method-of-use patents that would not expire until 2022.[22] Because the generics were able to omit those patented uses and obtain FDA approval of a skinny label, they were able to enter the market in 2016 rather than waiting until 2022.[23] Patients benefitted immediately from the introduction of generics—the savings were in excess of $8.4 billion in 2019 alone for just that one drug.[24]

In this and other cases, the use of skinny labels saved patients money and improved their access to

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[19] *See* Bloomfield 261 ("[T]he number of method-of-use patents per active ingredient quadrupled from 2001 to 2019"); *id.* ("In the past 30 years, brand-name drug manufacturers have increasingly sought to extend patent protection beyond their primary patents by obtaining method-of-use patents.").

[20] Walsh 995.

[21] Tracy Staton, *Top 10 Drug Patent Losses of 2014*, Fierce Pharma (Oct. 28, 2013), https://www.fiercepharma.com/special-report/top-10-drug-patent-losses-of-2014.

[22] Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., FDA, to Joseph A. Cash, Jr., AstraZeneca Pharms. 19 & n.59 (July 19, 2016), https://downloads.regulations.gov/FDA-2016-P-1485-0007/attachment_1.pdf.

[23] *Id.* at 1.

[24] Ass'n for Accessible Meds., *2020 Generic Drug & Biosimilars Access & Savings in the U.S. Report* 21 (2020), https://accessiblemeds.org/wp-content/uploads/2024/12/AAM-2020-Generics-Biosimilars-Access-Savings-Report-US-Web.pdf.

life-saving medications. FDA has estimated that "[g]eneric drugs approved between 2018 and 2020 ... have saved consumers more than $50 billion in the first 12 months of generic sales," and the approval of the first generic version of a brand-name drug, often with a carved-out condition of use, has reduced prices by more than 75%. U.S. Cert. Amicus Br. 19. But without a clear skinny-label pathway, generic manufacturers will be disinclined to use Section viii, allowing brand manufacturers to "maintain de facto indefinite exclusivity over a pharmaceutical compound by obtaining serial patents for approved methods of us[e]." *AstraZeneca*, 669 F.3d at 1380. Not only will patients be forced to pay higher brand prices for even longer, they may be deprived of access to life-saving alternatives altogether if a generic is never developed.

The Federal Circuit has effectively unraveled Congress's solution to the *precise* problem that Section viii was designed to remedy. Instead of a shield, as Congress intended, it has been forged into a sword to cut down generic manufacturers. Generics that seek to use carve-outs now face the inherent uncertainty of litigation and therefore a substantial risk of liability for damages, including brand plaintiffs' lost profits. This Court should reverse the Federal Circuit's mistaken rule, enforce the inducement standards that prevent patent owners from getting *in terrorem* litigation past the pleading stage, and restore skinny labels as a viable and predictable method of lawfully bringing generics to market and into the hands of patients.

## CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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February 25, 2026

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