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

BRIEF FOR THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

KARIN HESSLER
ASSOCIATION FOR ACCESSIBLE MEDICINES
601 New Jersey Avenue, NW, Suite 850
Washington, DC 20001
(202) 249-7100

MATTHEW S. HELLMAN
Counsel of Record
JONATHAN J. MARSHALL
JENNER & BLOCK LLP
1099 New York Avenue, NW, Suite 900
Washington, DC 20001
(202) 639-6000
mhellman@jenner.com

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

RULES

OTHER AUTHORITIES

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. Generic and biosimilar drugs constitute 90% of all prescriptions dispensed in the United States while accounting for just 13% of prescription-drug spending.[2] In 2023, for instance, the availability of generic and biosimilar medicines kept $445 billion in the pockets of patients and taxpayers, and that figure exceeded *$3 trillion* over the last decade.[3]

---

[1] Pursuant to this Court's Rule 37.6, *amicus* states that this brief was not authored in whole or in part by counsel for any party, and that no person or entity other than *amicus* and its counsel made a monetary contribution intended to fund the preparation or submission of this brief. Counsel of record for the parties received timely notice of the intent to file this brief pursuant to this Court's Rule 37.2.

[2] Ass'n for Accessible Meds., *The U.S. Generic & Biosimilar Medicines Savings Report* 2 (Sept. 2024), https://accessiblemeds.org/wp-content/uploads/2025/01/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf (*AAM 2024 Savings Report*).

[3] *Id.* at 7.

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 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 THE ARGUMENT

The opinion below is the latest, and most extreme, in a line of decisions by the Federal Circuit that have effectively nullified a key statutory protection allowing manufacturers to provide high-quality, affordable generic drugs to the American public. This Court's review is warranted.

Over forty years ago, Congress created the skinny-label process as part of the Hatch-Waxman Act. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 101, 98 Stat. 1585, 1586 (adding 21 U.S.C. § 355(j)(2)(A)(viii)). Congress's goal was simple: to ensure patient access to low-cost generic and biosimilar

medicines by protecting generic-drug manufacturers from patent-infringement lawsuits. And Congress's solution was elegant and effective. Generic manufacturers could come to market with a "skinny label," *i.e.*, a label that excludes uses that remain under patent. With skinny labels, patients would no longer have to pay branded-drug prices for uses that were not patented. That skinny-label regime has indisputably worked. In nearly 50% of cases where a drug is no longer patented and some (but not all) of its uses are patented, a generic version of the drug is brought to market with a skinny label.[4] And since its enactment in 1984, the section viii skinny-label process has saved the American public—both patients and taxpayers—*trillions* of dollars in unnecessary costs.[5]

But recent decisions by the Federal Circuit have eviscerated that skinny-label regime. What began as a shield, "a way for generics to avoid inducement liability—and thus litigation itself," has been transformed into a sword for branded manufacturers to wield against the very generics that Congress sought to protect. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 25 F.4th 949, 955 (Fed. Cir. 2022) (*GSK III*) (Prost, J., dissenting from the denial of the petition for rehearing en banc) (emphasis omitted).

Three years ago in *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021) (*GSK II*), the Federal Circuit held that a skinny label that properly carved out all still-patented uses of the drug

---

[4] Bryan S. Walsh et al., *Frequency of First Generic Drug Approvals with "Skinny Labels" in the United States*, 181 JAMA Internal Med. 995, 997 (2021).

[5] *AAM 2024 Savings Report, supra* note 2, at 7.

could still give rise to inducement liability based on label language pertaining to *unpatented* uses. *Id.* at 1328-31. That decision sounded alarm bells at multiple levels: several judges on the Federal Circuit issued dissents,[6] and the Solicitor General recommended that this Court grant certiorari to correct the Federal Circuit's distortion of the Hatch-Waxman scheme and inducement principles.[7]

Fast-forward to this decision, which goes even further in undermining the skinny-label regime. It is undisputed in this case that the generic drug's label "does not provide an implied or express instruction to prescribe the drug" for its patented use. Pet. App. 16a. Yet the Federal Circuit held that the branded manufacturer stated a claim for inducement simply because it alleged that the generic manufacturer (accurately) called its product a "generic" version of the branded drug and had referred to the total market size of the branded drug in marketing materials. *Id.* at 18a.

If those threadbare allegations state a claim, then every generic drug manufacturer who uses a skinny label is at risk for an infringement suit. The panel insisted that a generic manufacturer could ultimately prevail with "the benefit of fact discovery and expert testimony." Pet. App. 19a. But that is too late. Given the potential for ruinous

---

[6] *See GSK II*, 7 F.4th at 1342-61 (Prost, J., dissenting); *GSK III*, 25 F.4th at 953-58 (Prost, J., dissenting from the denial of the petition for rehearing en banc); *id.* at 958-59 (Dyk, J., dissenting from the denial of the petition for rehearing en banc); *id.* at 959-60 (Reyna, J., dissenting from denial of the petition for rehearing en banc).

[7] *See* Brief for the United States as *Amicus Curiae*, *Teva Pharms. USA, Inc. v. GlaxoSmithKline LLC*, No. 22-37 (U.S. Mar. 29, 2023) (U.S. *GSK* Br.).

lost-profits damages, no generic manufacturer could risk using a skinny label if it necessarily meant litigation before a factfinder. Congress intended the skinny-label regime to be a safe harbor; the Federal Circuit's decisions have made it a treacherous shoal.

The decision below is also flatly inconsistent with black-letter principles of secondary liability for intellectual-property infringement. This Court (not to mention Congress) has long made clear, in both the copyright and patent contexts, that induced infringement requires an *active* form of instruction, encouragement, or suggestion that third parties infringe. The allegations here are not of that sort. At most, the allegations are that the generic manufacturer provided truthful *information* that enabled third parties to infringe, and that has never been enough for inducement liability.

Ultimately, the true losers in this decision are American patients—and the American taxpayers who fund Medicare and Medicaid, which bear much of the country's drug expenditures. If generic manufacturers cannot bring generic drugs to market without being forced to litigate infringement suits to summary judgment and beyond, it is likely the generics will never be developed at all. Patients will thus be deprived of affordable generic alternatives for uses that, by definition, are not patented.

This Court should grant the petition and reverse.

ARGUMENT

I. THE DECISION BELOW EVISCERATES THE PROTECTIONS CONGRESS PROVIDED THROUGH THE SKINNY-LABEL PROCESS.

As this Court has repeatedly recognized, the Hatch-Waxman Act was "designed to speed the introduction of low-cost generic drugs to market." *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012); *see Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). Part of Congress's design was the section viii process, whereby a generic manufacturer can carve out infringing uses of an unpatented drug and thereby "avoid inducement liability." *GSK III*, 25 F.4th 949, 955 (Fed. Cir. 2022) (Prost, J., dissenting from the denial of the petition for rehearing en banc) (emphasis omitted).

The Federal Circuit's recent decisions in this area, however, all but wipe out the section viii process. In both *GSK* and this case, the Federal Circuit has endorsed broad theories of liability against generic manufacturers who "did everything right." *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 976 F.3d 1347, 1361 (Fed. Cir. 2020) (Prost, C.J., dissenting), *vacated on grant of reh'g*, *GSK II*, 7 F.4th 1320 (Fed. Cir. 2021).

Going forward, it will be near-automatic that a generic manufacturer who does "everything right" in bringing a drug to market with a skinny label will be sued for induced patent infringement under 35 U.S.C. § 271(b). But Section 271(b) should not be interpreted to negate Congress's efforts in the Hatch-Waxman Act, and respect for Congress's intent requires far more scrutiny of respondents' (Amarin's) complaint than it received below.

A. The Decision Below Provides a Roadmap for Branded Manufacturers to State a Claim for Induced Infringement in Every Skinny-Label Case.

If Amarin's complaint can defeat petitioners' (Hikma's) motion to dismiss, there is no reason to think that any generic manufacturer utilizing the skinny-label process will be safe.

All Hikma is alleged to have done wrong in this case is accurately describe its drug as a "generic equivalent" of the branded version and accurately present market data relating to the branded version's sales in a press release. Pet. App. 6a-7a. In fact, Hikma's press releases *also* clarified, in conformity with the skinny label, that the generic drug was approved only for a specific (unpatented) use and that the "product is not approved for any other indication for the" branded version. *Id.* at 7a. Essentially everything Amarin points to here—descriptions of a generic as "generic" and benign public statements about the market—will be present in every skinny-label case.

By holding that Amarin has stated a claim, the ruling below effectively eviscerates the section viii process and leaves generic manufacturers in the lurch. For obvious reasons, it is not realistic that a generic manufacturer would make no public statements whatsoever about its generic products—or that it could somehow refrain from even calling those products "generics." For one thing, federal securities laws mandate disclosure of material information—including information related to anticipated or completed products—to shareholders and the public. Yet, under the decision below, as soon as the manufacturer speaks about its generic product, the branded

manufacturer has enough to sue, and defeat a Federal Rule of Civil Procedure 12(b)(6) motion, by alleging that the generic manufacturer's communications—however innocuous sounding—were really a surreptitious effort to induce physicians to prescribe the generic drug for off-label, patented uses. In short, if simply calling a generic drug "generic" is enough to create a viable induced-infringement claim, no generic manufacturer utilizing the skinny-label process will avoid litigation.

Consider the allegations here. One of Hikma's alleged sins in this case was referring to its generic drug as the "generic equivalent" of the branded version. As Judge Prost recognized in *GSK*, "[e]ssentially *all*" generics approved through the abbreviated Hatch-Waxman application process "are the 'generic version' or 'generic equivalent' of a brand drug; the law *requires* them to be." *GSK II*, 7 F.4th at 1353 (Prost, J., dissenting). And as the petition explains, referring to the type of drug at issue as "generic" is a ubiquitous convention throughout the relevant statutes and regulations. *See* Pet. 27-29.

Nor is this case unusual due to the allegation that, when describing the revenues associated with Amarin's branded drug, Hikma included the *full* revenue for *both* patented and unpatented uses. Pet. App. 6a-7a, 18a. Naturally, in speaking to investors or the public about the potential marketability of a generic drug, the revenues associated with *both* patented and unpatented uses are relevant. That is because everyone knows that physicians remain free to prescribe off-label as they see fit. It would therefore not provide an accurate picture if generic manufacturers provided data relating only to prescriptions of the unpatented use—indeed, in most cases, this data *does*

not even exist (or will not be available to the generic manufacturer). Forcing generic manufacturers to suppress this information for fear of an induced-infringement suit simply runs them headlong into other legal problems. And even if the generic manufacturer avoids providing this specific datum about total market for the branded drug, there is no doubt the branded manufacturer will latch on to *whatever* public statement is made about the generic drug and allege that it induced physicians to infringe.

The Federal Circuit also faulted Hikma for calling its drug the "generic version" without always noting its "AB rating," suggesting that physicians might read the lack of an AB-rating notation as encouragement to prescribe the drug for a carved-out indication. Pet. App. 19a-20a. Yet the court of appeals said just the opposite in *GSK*, explaining that including "AB rated representations" was "affirmative evidence supporting" a finding of inducement. *GSK II*, 7 F.4th at 1335. This, too, underscores how a generic manufacturer cannot win under the Federal Circuit's precedent, no matter what it does or says (or omits).

The skinny-label process was meant to have the precisely opposite effect on the pharmaceutical industry: to make it *easier* for generics to enter the marketplace, compete with branded drugs, and provide patients with cheaper alternatives. *See Caraco Pharm. Lab'ys*, 566 U.S. at 405. It is directly contrary to Congress's judgment to subject a generic manufacturer to litigation based solely on utilizing the section viii process Congress created and making the sorts of statements that necessarily accompany the marketing of a new pharmaceutical product. If Amarin has stated a claim here, the branded

manufacturer in the next case will have no problem identifying a public statement that allegedly induced physicians to prescribe patented uses. Allowing Section 271(b) to defeat the Hatch-Waxman Act in this way is not, and cannot be, what Congress wanted.

B. By Opening Up the Litigation Floodgates, the Decision Below Destroys the Economics of the Skinny-Label Process and Vitiates Congress's Intent.

The Federal Circuit suggested that any concerns are overblown because, with the benefit of discovery, the generic manufacturer may prevail. *See* Pet. App. 14a. This is false comfort. These suits' ability to withstand Rule 12(b)(6) motions will inflate the costs of bringing lower-cost generic drugs to market. And because the branded manufacturer will typically be able to find an expert to agree with the allegations in the complaint, these cases can generally be expected to survive summary judgment, too. This will ultimately prevent those drugs from reaching the patients who need them—after all, "if playing by the skinny-label rules doesn't give generics some security from label-based liability, generics simply won't play." *GSK III*, 25 F.4th at 955 (Prost, J., dissenting from the denial of the petition for rehearing en banc).

As this Court has recognized, even the potential to come out victorious on summary judgment following a laborious discovery process is no true safeguard. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558-60 (2007). And given the Federal Circuit's low bar for what evidence can support a jury's finding of induced infringement, even a summary-judgment victory for the generic manufacturer in a meritless suit is far from guaranteed. And concerns

about litigation costs are already more serious in patent-infringement cases, in which discovery is particularly complex and costly, and which are often brought in the District of Delaware—where "judges rarely entertain" summary-judgment motions to begin with.[8]

With the average cost of defending a patent-infringement lawsuit hovering around $3.5 million,[9] even the expense of litigating through summary judgment will be a costly albatross around generic manufacturers' necks. And these manufacturers already "sell their products for considerably less than brands," so these inflated litigation costs may easily "dwarf whatever profits a generic could make." *GSK III*, 25 F.4th at 955 (Prost, J., dissenting from the denial of the petition for rehearing en banc). What is more, the Federal Circuit's assurances about summary-judgment resolution are difficult to swallow given the court's holding in *GSK* that a jury may properly find induced infringement *based on a section-viii-compliant skinny label mentioning only unpatented uses*. *See GSK II*, 7 F.4th at 1328-31. All this uncertainty and expense is exactly what section viii was meant to deter.

C. The Decision Below Will Also Undermine the Paragraph IV Process.

The decision below will also have the effect of undermining another aspect of the Hatch-Waxman scheme that

---

[8] Katherine Rhoades, *Do Not Pass Go, Do Not Stop for Summary Judgment: The U.S. District Court for the District of Delaware's Seemingly Disjunctive Yet Efficient Procedures in Hatch-Waxman Litigation*, 14 Nw. J. Tech. & Intell. Prop. 81, 95 (2016).

[9] Gregory Day & Steven Udick, *Patent Law and the Emigration of Innovation*, 94 Wash. L. Rev. 119, 125 (2019).

is supposed to ease the path of generic drugs to market. Under that scheme, generic manufacturers can file "paragraph IV certification[s]" in which they seek approval for *patented* methods of use and assert that these method-of-use patents are invalid or not infringed. *Caraco Pharm. Lab'ys*, 566 U.S. at 407-08; *see* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

It is common for a branded manufacturer to hold a large number of patents on a drug. For instance, as of July 2022, Amarin had 68 patents listed in FDA's Orange Book for the drug at issue in this case.[10] Generic manufacturers commonly challenge some patents—such as formulation and compound patents—through a paragraph IV certification, and utilize section viii statements for method-of-use patents that can be carved out. Under the decision below, however, the incentives for such paragraph IV challenges are distorted. If even *one* method-of-use patent remains as a basis for a damages claim after launch, the risk of litigation will remain untenably high, making it pointless to bring paragraph IV challenges in the first place. These challenges will dwindle, and—precisely contrary to Congress's intent—the scope of branded manufacturers' monopolies will expand.

The Federal Circuit's decisions also distort the relationship between the section viii skinny-label process and the paragraph IV certification process. When a generic manufacturer files an abbreviated new drug application (ANDA) using paragraph IV to claim invalidity or noninfringement of the branded manufacturer's patents,

---

[10] S. Sean Tu & Charles Duan, *Pharmaceutical Patent Two-Step: The Adverse Advent of* Amarin v. Hikma *Type Litigation*, 12 N.Y.U. J. Intell. Prop. & Ent. L. 1, 26 (2022).

Congress has deemed the application itself to be an act of infringement that allows the patent dispute to be resolved *before* launching the generic drug. *See* 35 U.S.C. § 271(e)(2); *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1377 (Fed. Cir. 2012). But filing an ANDA to bring a generic drug to market using a skinny label is *not* an act of infringement; indeed, when generic manufacturers have tried to obtain patent certainty by seeking a declaratory judgments prior to a skinny-label launch, branded manufacturers have successfully defeated those claims by arguing that there is no statutory basis for them. *See, e.g.*, *Novartis Pharms. Corp. v. Alkem Lab'ys Ltd. (In re Entresto (Sacubitril/Valsartan) Patent Litig.)*, Nos. 20-cv-2930 etc., 2022 WL 4482717, at *5 (D. Del. Sept. 27, 2022) ("An ANDA applicant that submits a [s]ection viii statement does not create an 'actual controversy' because there is no cause of action.").

Thus, the generic manufacturer has no reliable way to obtain clarity prior to launch. Instead, it may have to launch the generic drug while the branded manufacturer lies in wait (running up the meter on potential damages all the while) before the issue can be resolved. Again, this is exactly contrary to Congress's intent in the Hatch-Waxman Act: to make the skinny-label process "a way for generics to *avoid* inducement liability—and thus litigation itself." *GSK III*, 25 F.4th at 955 (Prost, J., dissenting from the denial of the petition for rehearing en banc).

II. THE DECISION BELOW VIOLATES BLACK-LETTER PRINCIPLES OF INDUCEMENT LIABILITY.

The Federal Circuit's decision also flies in the face of this Court's inducement precedents. This Court has long

held that liability for inducing infringement of intellectual property attaches only when a defendant *actively* instructs or encourages others to infringe—not where, as here, a defendant is alleged to have done no more than provide information enabling infringement. Under these principles, Amarin's complaint should have been dismissed.

In setting out principles of inducement, this Court has recognized that broad theories of liability "compromise legitimate commerce" and "discourage innovation having a lawful promise." *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 937 (2005). Accordingly, the Court has made clear that inducement liability must be premised on "purposeful, culpable expression and conduct." *Id.* Inducement liability does not attach to "ordinary acts incident to product distribution, such as offering customers technical support or product updates." *Id.*

In the patent-infringement context, these principles are directly implicated by the Patent Act's requirement that there is liability only for "*actively* induc[ing] infringement of a patent." 35 U.S.C. § 271(b) (emphasis added). As this Court has explained, the sorts of "active" steps that create liability are "advertising an infringing use or instructing how to engage in an infringing use." *Grokster*, 545 U.S. at 936; *see also Glob.-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 768 n.8 (2011) (Section 271(b) imposes liability for "actively encourag[ing] others to violate patent rights").

The requirement that induced infringement must be active should apply with even more force in the context of generic drugs, given the Hatch-Waxman Act's careful scheme for enabling generics to reach the market.

Contrary to the Federal Circuit's conclusion, this Court's inducement precedents require dismissal of Amarin's complaint here.

As the court of appeals observed, it is undisputed that "Hikma's label does not provide an implied or express instruction to prescribe the drug for the [patented] indication." Pet. App. 16a. And the court further paid lip service to the requirement that, to state a claim for a Section 271(b) violation, the complaint must allege that Hikma actively induced physicians to infringe by "encourag[ing], recommend[ing], or promot[ing] infringement." *Id.* (quoting *Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015)). But in concluding that the label in conjunction with statements in press releases sufficed to state a claim for inducement, the court of appeals never even attempted to explained how the "active" element of an inducement claim was satisfied. *See id.* at 16a-19a. Instead, the court concluded that Amarin had stated a claim because its allegations "depend on what Hikma's label and public statements would communicate to physicians and the marketplace." *Id.* at 18a.[11]

---

[11] Even if the Federal Circuit were correct that Hikma's label must be "taken together" with Hikma's public statements in analyzing whether the complaint states a claim, Pet. App. 18a, it is difficult to see how Hikma's label supports liability. As the Solicitor General noted when supporting certiorari in *GSK*, "carved-out labeling is more naturally viewed as evidence of the generic manufacturer's 'inten[t] *not* to encourage infringement.'" U.S. *GSK* Br. 15 (alteration in original) (quoting *GSK II*, 7 F.4th at 1350 (Prost, J., dissenting)). Adding it to the mix of evidence should move the needle away from, not toward, induced-infringement liability.

If this is right—if a defendant can be liable for inducing patent infringement based on how *others* interpret innocent behavior—there is nothing left of the requirement that induced infringement be "active." Whenever a third party infringes a patent based on a defendant's behavior, the defendant will have taken *some* act. This Court (and, until recently, the Federal Circuit) has always recognized that culpable activity must go far beyond simply enabling the infringement or providing information that makes infringement more likely.

The Federal Circuit suggested that Hikma could have avoided liability by saying *more*—noting that a generic manufacturer may avoid facing meritless suits through "clarity and consistency in [its] communications regarding a drug marketed under a skinny label." Pet. App. 22a. This suggestion—that the onus was on Hikma to *prevent* physicians from prescribing infringing uses—is another major departure from inducement principles. Whether in the patent or copyright context, inducement liability *never* stems from the failure to take action to prevent infringement. *See Grokster*, 545 U.S. at 939 n.12 (no liability "based on a failure to take affirmative steps to prevent infringement"); *Takeda Pharms.*, 785 F.3d at 632 n.4 (plaintiff's burden is to show defendant "took affirmative steps to induce, not affirmative steps to make sure others avoid infringement"); *see also* Pet. 20-21.

In fact, this distortion of inducement law is especially problematic in the context of generic drug manufacturers, as generic labels are statutorily required to bear the "same . . . labeling approved" for the branded drug. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612-13 (2011)

(quoting 21 U.S.C. § 355(j)(2)(A)(v)). Accordingly, no "disclaimer" insert is legally possible.

Respondents' allegations cannot possibly state a claim for induced infringement under this Court's precedents. Put simply, Hikma cannot have "actively" induced infringement because it is not alleged to have even *mentioned the existence* of infringing uses. The entirety of the allegations against Hikma are that its skinny label did not disclaim patented uses (which would be prohibited); that it accurately stated that its generic drug was a therapeutic equivalent to Amarin's branded version (which Hikma was required to establish to gain FDA approval); and that Hikma accurately noted sales data of Amarin's drug without specifically differentiating between various uses (which is the sort of "ordinary act[] incident to product distribution," *Grokster*, 545 U.S. at 937, always considered permissible). Nowhere in that list is anything even *approaching* the sort of active encouragement, recommendation, or instruction that is supposed to be the prerequisite for liability under 35 U.S.C. § 271(b).

III. THE DECISION BELOW POSES A GRAVE THREAT TO GENERIC PHARMACEUTICALS, AND THUS TO AMERICAN PATIENTS.

By exploding the litigation risks and costs associated with bringing generic drugs to market, the Federal Circuit's recent decisions are not just crushing for generic manufacturers. They will also be devastating to the patients who rely on affordable, high-quality generic medications.

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.[12] Today, generics make up roughly 90% of all prescriptions dispensed,[13] while the median price of generics is a fraction of the price of branded drugs.[14] And across the United States, the robust market for generics has led to enormous financial and health benefits.[15]

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 patents. Generic versions of no-longer-patented drugs with patented uses launch with a skinny label nearly 50% of the time,[16] saving

---

[12] The 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.

[13] *Office of Generic Drugs 2021 Annual Report*, U.S. Food & Drug Admin., https://www.fda.gov/drugs/generic-drugs/office-generic-drugs-2021-annual-report (last updated Feb. 14, 2022).

[14] *See Generic Competition and Drug Prices*, U.S. Food & Drug Admin., https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices (last updated Oct. 17, 2024).

[15] *See AAM 2024 Savings Report*, *supra* note 2, at 7 (estimating $445 billion in savings in 2023 alone); Becky A. Briesacher et al., *Medication Adherence and the Use of Generic Drug Therapies*, 15 Am. J. Managed Care 450 (2009); Niteesh K. Choudhry et al., *Improving Adherence to Therapy and Clinical Outcomes While Containing Costs: Opportunities from the Greater Use of Generic Medications*, Annals Internal Med. (Nov. 24, 2015), https://doi.org/10.7326/M14-2427.

[16] Walsh, *supra* note 4, at 997.

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.[17] AstraZeneca's patent on the compound expired in 2016, but AstraZeneca had other method-of-use patents that would not expire until 2022.[18] 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.[19] 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.[20]

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

---

[17] Tracy Staton, *Top 10 Drug Patent Losses of 2014*, Fierce Pharma (Oct. 28, 2013, 9:55 AM), https://www.fiercepharma.com/special-report/top-10-drug-patent-losses-of-2014.

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

[19] *Id.* at 1.

[20] 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.

use, has reduced prices by more than 75%.[21] But without a clear skinny-label pathway, generic manufacturers will be disinclined to use section viii, allowing brands 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.

And it is not only patients that lose. The federal government's health-care expenditures are massive. In fiscal year 2024, the government spent nearly $2 trillion on health care—the largest category of federal spending and over a quarter of the federal budget.[22] Over $150 billion of this sum is spent on prescription drugs.[23] The unavailability of generic drugs will further inflate these figures, ultimately passing on a significant amount of the damage to the American taxpayers.

---

[21] U.S. *GSK* Br. 20 (citing Ryan Conrad et al., Ctr. for Drug Evaluation & Rsch., U.S. FDA, Estimating Cost Savings from New Generic Drug Approvals in 2018, 2019, and 2020, at 3-4 (Aug. 2022), https://www.fda.gov/media/161540/download).

[22] Juliette Cubanski et al., *What Does the Federal Government Spend on Health Care?*, KFF (Feb. 24, 2025), https://www.kff.org/medicaid/issue-brief/what-does-the-federal-government-spend-on-health-care.

[23] *See Drug Spending*, U.S. Dep't of Health & Hum. Servs. Off. of Inspector Gen. (updated Dec. 16, 2024), https://oig.hhs.gov/reports/featured/drug-spending.

CONCLUSION

For the foregoing reasons and those stated in the petition for a writ of certiorari, the petition should be granted.

Respectfully submitted.

KARIN HESSLER
ASSOCIATION FOR
ACCESSIBLE MEDICINES
601 New Jersey Avenue,
NW, Suite 850
Washington, DC 20001
(202) 249-7100

MATTHEW S. HELLMAN
Counsel of Record
JONATHAN J. MARSHALL
JENNER & BLOCK LLP
1099 New York Avenue,
NW, Suite 900
Washington, DC 20001
(202) 639-6000
mhellman@jenner.com

MARCH 2025