No. 24-889

IN THE
Supreme Court of the United States

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

v.

AMARIN PHARMA, INC., ET AL.,
Respondents.

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

BRIEF OF FORMER FEDERAL CIRCUIT CHIEF JUDGE PAUL R. MICHEL AND SCHOLARS OF LAW AND ECONOMICS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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[1] No counsel for any party authored any portion of this brief or made any monetary contribution intended to fund its preparation or submission. Counsel for both parties have granted consent for the filing of this brief.

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INTRODUCTION AND SUMMARY OF ARGUMENT

As the Court of Appeals recognized, this case "is nothing more than a run-of-the-mill induced infringement case arising under 35 U.S.C. § 271(b)." Pet. App. 13a. And, because the procedural posture of the case places it at the "nascent stage" of litigation (a motion to dismiss under Fed. R. Civ. P. 12(b)(6)), Pet. App. 14a, the ultimate question here is whether the totality of the plaintiffs' allegations, taken as true, plausibly plead a case of induced infringement—that is, actively inducing another to commit acts of direct infringement. *Id.*

This framing is critical, because Petitioners seek to portray this as a case about so-called "Section viii

carve-outs," known colloquially as "skinny labels." *See* 21 U.S.C. § 355(j)(2)(A)(viii). A "skinny label" allows an applicant seeking approval to market a generic drug under the Hatch-Waxman Act to "carve out" a patented use of a drug by making, on the proposed label, "a statement that the method of use patent does not claim such a use." *Id.*

But this case is about substantially more than skinny labels. It is about the totality of the allegations necessary to state a plausible claim for induced patent infringement—including, but not limited to, allegations about the content of the skinny label itself—necessary to state a plausible claim for induced patent infringement. The presence of a skinny label alone is just part of the evidence of inducement; it does not provide a bright-line safe harbor against claims of induced infringement where, as here, the evidence of intentional, actual inducement comprises more than just the label.

Unlike direct infringement, which is a strict-liability tort, induced infringement is an intent-based liability standard. *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 930 (2005). Indeed, this Court has held that the patent statute's "actively induces" standard necessarily requires intentional, affirmative steps by the inducer. *Global-Tech Appliances, Inc. v. SEB SA*, 563 U.S. 754, 760 (2011); *Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632, 642 (2015); *see Grokster*, 545 U.S. at 936 ("a showing that infringement was encouraged overcomes the law's reluctance to find liability when a defendant merely sells a commercial product suitable for some lawful use"); *Cox Commc'ns, Inc. v. Sony Music Entertainment*, 607 U.S. ___, 2026 WL 815283, at *6

(U.S. Mar. 25, 2026) ("A provider induces infringement if it actively encourages infringement through specific acts.").

And, it is well settled in all areas of law, not just patent law, that matters of intent must be proven inferentially, based on the totality of the circumstances. *E.g.*, *St. Mary's Honor Center v. Hicks*, 509 U.S. 502, 511 (1993); *Washington v. Davis*, 426 U.S. 229, 239-40 (1976). Recourse to inferential, totality-of-the-circumstances evidence is necessary when intent is at stake, for, as Justice Frankfurter wrote, quoting "an early English judge," "The devil himself knoweth not the mind of man." *NLRB v. Donnelly Garment Co.*, 330 U.S. 219, 229 (1947) (referring to Chief Justice Brian's dictum in Y.B. 7 Ed IV, f.2, pl.2 (1468)).

Courts therefore must take into account the totality of the circumstances when pharmaceutical method-of-treatment patents such as Amarin's are at stake. Commonplace off-label prescription practices, as well as the FDA's therapeutic equivalence ratings and the state substitution laws that rely on them, readily allow direct infringement by healthcare providers in prescribing generic equivalents of drugs for use in patented methods of treatment. Intermediaries such as insurance companies and pharmaceutical benefits managers (PBMs) also effectively condone such infringement by requiring generic substitution for a drug, regardless of the indication for which it was prescribed. Everyone, including generic drug manufacturers, is well aware that such direct infringement inevitably is enabled by generic drug entry into the marketplace. *See generally* Erika Lietzan, *Paper Promises for Drug Innovation*,

26 GEORGE MASON L. REV. 168, 193-95 (2018). And the economic incentives for doing so are ample and obvious. In this context, then, a generic manufacturer need not do much to actively encourage further, and more entrenched, infringement of method-of-treatment patents. Dennis Crouch, *The Tinderbox: Market Structure, Skinny Labels, and Induced Patent Infringement*, 73 UCLA L. REV. DISCOURSE ___ (forthcoming 2026) (urging that, because generics launch skinny-labeled products into markets "primed for infringement," even "routine commercial activities that would be innocuous in other contexts" can constitute inducement).

It follows, then, that a complaint such as Amarin's need not plead much in terms of a generic manufacturer's actions—including, but scarcely limited to, its skinny label—to establish a plausible claim that the accused infringer has expressed an affirmative intent that the generic drug be used to induce infringement of a method-of-treatment patent.

Thus, the Court of Appeals in this case correctly held that Amarin's pleadings, which included the label itself, as well as the contents of Hikma's public pronouncements (including Hikma's press releases as well as a demonstrative exhibit created by Hikma in prior litigation), answered the question of whether Amarin plausibly pleaded induced infringement with a resounding "yes." *Cox Commc'ns*, 2026 WL 815283, at *7 ("'evidence of express promotion, marketing, and intent to promote' infringement" supports inducement liability); *see Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 556 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw

the reasonable inference that the defendant is liable for the misconduct alleged.").

But, were this Court to embrace Petitioners' arguments and hold, in words or substance, that the Section viii skinny-label carve-out insulates a defendant from liability for induced infringement, the consequences for our Nation's innovation economy would be profoundly negative. Continued innovation, including the discovery of new therapeutic indications for existing products, plays a vital role in advancing patient care and delivering significant benefits to society. The system of incentives reflected in the patent bargain would be seriously undercut if a defendant were immunized from liability simply by claiming a narrow indication in its label, while at the same time engaging in other conduct demonstrating an intent to encourage healthcare practitioners to administer the drug for infringing, off-label uses. The result—yet further devaluation of method-of-use pharmaceutical patents—would shrink the innovation incentive yet more. Congress did not intend such a result.

ARGUMENT

I. Innovation in Identification and Clinical Trials Testing of New Indications Yields Great Public Benefits but Requires the Incentive of Patent Protection

Pharmaceutical innovation is wholly dependent on strong patent protection. "[The] widespread consensus in the patent community" is "that strong patents are important to encourage pharmaceutical innovation." S. Sean Tu & Mark A. Lemley, *What Litigators Can Teach the Patent Office About*

Pharmaceutical Patents, 99 WASH. U. L. REV. 1673, 1675 (2022). This dependence stems from the need for companies to have an opportunity to recoup the long and expensive research and development investments necessary for discovering and—more to the point—testing new drug products. COMM'N ON INTELL. PROP. RTS., INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 29 (2002), http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf.

In the case of pharmaceuticals, the limited exclusionary rights conferred by a patent may cover the drug itself, or particular methods of use, or both. When the drug itself is the subject of a patent, anyone who "makes, uses, offers to sell, sells," or imports into the United States" that substance, without permission, directly infringes the patent. 35 U.S.C. § 271(a). Thus, in that circumstance, any of a manufacturer, user, merchant, or importer can directly infringe the patent.

Where the patent claims a particular method of use, however, the class of direct infringers is typically narrow. Merely making and selling a drug that *might* be used to infringe the patented method of use does not give rise to direct-infringement liability, so the value of a method-of-use claim lies in the patent owner's ability to enforce its exclusionary rights against indirect infringers (those who "actively induce[]" infringement under § 271(b) or are "contributory infringer[s]" under § 271(c)).

Patents on new methods of using a known drug product to treat new disease states are particularly vulnerable to both direct and indirect infringement.

Despite the great need for new ways of treating various medical conditions, developing and obtaining FDA approval for new indications is expensive, difficult, and time-consuming. The Court should not make patents on new methods of treatment even more defenseless to induced infringement. To do so would scuttle the pharmaceutical industry's incentives to invest in such R&D.

A. Identifying New Indications for Existing Drugs Is Important but Difficult. Taking an existing drug and inventing a new and useful method of use for it is exceedingly beneficial to the public. It allows medical conditions to be addressed for a greater number of patients, at lower costs—and on more rapid timelines—than the invention of an entirely new substance. *See, e.g.*, M.S. Hussain *et al.*, *From Lab to Clinic: Success Stories of Repurposed Drugs in Treating Major Diseases*, ADV. PHARMACOL. PHARM. SCI. (2025). When an inventor discovers that an existing drug can serve in new, and different, and beneficial ways for patients, that is itself an inventive act worthy of the encouragement of patent protection. Such inventive work is "gaining attention as a way to introduce pharmaceutical agents with established safety profiles to new patient populations," including in the field of biologics, viewed as having even wider application than in the area of small molecule drugs. *See* J. Israr, *Chapter 12—Repurposing of biologics and biopharmaceuticals*, in *Progress in Molecular Biology and Translational Science* 277-302 (Vol. 205, 2024). That is what Amarin did here—it started with the Vascepa® that was "originally approved … to treat severe hypertriglyceridemia," and thereafter "invested several years, and hundreds of millions of

dollars, into extensive clinical trials to discover and demonstrate that Vascepa is also a revolutionary medicine for a different condition affecting far more patients: cardiovascular risks arising from hypertriglyceridemia." Br. for Respondents 3.

Despite the potential benefits of repurposing or repositioning existing drugs, identifying these new and useful methods of use is neither inexpensive nor easy, as Amarin's own experience with Vascepa® demonstrates. Medical research is inherently unpredictable, and the inventive task of discovering which indications might share the same or similar biological pathways with another indication is rarely obvious. For example, colchicine, which has been used for centuries to treat gout, has more recently been approved for the treatment of Familial Mediterranean Fever (FMF), a rare genetic disorder that affects about 100,000 patients worldwide. Aaron Kesselheim & Daniel Solomon, *Incentives for Drug Development—The Curious Case of Colchicine*, 362 N. ENG. J. MED. 2045, 2046 (2010).

Similarly, thalidomide—a drug long used for the treatment of leprosy, but also long avoided because of its associated risk of birth defects—has found new purchase as a method of treatment for multiple myeloma, *see* Tahir Latif, *Thalidomide and its analogues in the treatment of Multiple Myeloma*, 11 EXP. & HEMATOL. ONCOL. 1:27 (2012), as well as for persons with a high genetic risk of cardiovascular disease, due to thalidomide's anti-inflammatory and anti-angiogenic properties, as well as its inhibition of blood-vessel formation. *Thalidomide is an effective treatment for abnormal blood vessel formations*, European Society of Human Genetics, News Release

(June 10, 2022), *available at* bit.ly/3NRiuEQ. These new, nonobvious, and useful treatments have proven invaluable to the patients who receive them.

Other drugs which have been later discovered to have new and useful approved indications are discussed in Lietzan, *supra*, at 168 (expressing concern that while "[i]nnovation does not stop when new medicines are launched," "the incentives federal law provides for new-use research … are little more than paper promises").

Likewise, there is no guarantee that a drug indicated for one stage of a disease will have any efficacy at a later stage of the same disease. In fact, confirming that even one stage of the same disease will respond in the same way to a drug administered at a different stage is more often nonobvious than many outside the field of medical research may appreciate. Simply because two disease states overlap with one another and have some characteristics in common does not mean that a therapeutic for treating the first disease state necessarily will be effective treating the second. David Cavalla & Gamal Crichton, *Drug Repurposing: Known Knowns to Unknown Unknowns—Network Analysis of the Repurposome*, 28 DRUG DISCOVERY TODAY 1, 5 (2023).

And in many cases, the later identified additional indications for drugs fall well outside the therapeutic category of the originally identified indication. Lietzan, *supra*, at 173-74. Discovery of these more distant indications often rely on the serendipity associated with research investments and are far from obvious. *Id*. at 175; Jigar Katwala, *Drug Repurposing*, in 4 INTRODUCTION TO BASICS OF PHARMACOLOGY &

TOXICOLOGY 491, 493-94 (ed. Avinash Arivazhahan *et al.* 2025) (listing dozens of examples).

The pharmaceutical industry has thus relied on method-of-use patents to protect its investments in new indications. *See generally* 35 U.S.C. § 100(b) (a patentable "process"—a term that specifically embraces "methods"—"includes a new use of a known … composition of matter"). This is as it should be: Pharmaceutical researchers are the best suited to understand, appreciate, and develop the potential applications of these new indications.

Further, with the advent of biologics, this kind of research and development is taking on increased importance. The U.S. patent law's innovation economy needs to recognize and protect this critical work, for without the incentive of intellectual-property protection, few if any will be motivated to make the vast investments needed to do that essential work.

B. Incentivizing Companies to Make Significant Investments in Clinical Trials Is Important. Patent protection is also essential to ensure that clinical trials for new methods of treatment occur. The clinical trials needed for FDA approval of these new methods, and to confirm their safety and efficacy, require significant investments of money and personnel. Lietzan, *supra*, at 171. Phase III trials—the final trials necessary prior to marketing—are "usually the most expensive," averaging in the several hundreds of millions of dollars. *Id.* at 171 & n.11 (citing Joseph A. DiMasi *et al.*, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 24

(2016)); 21 C.F.R. § 312.21(c) (Phase III studies "gather … additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug"); Nicola Nosengo, *Can You Teach Old Drugs New Tricks?*, 534 NATURE 314, 315 (2016).

To be sure, doctors and other prescribers may prescribe a drug approved for one purpose for other, non-approved purposes. This is known as "off-label" prescribing. But it does not make the off-label use an approved use under the Food, Drug and Cosmetic Act. In 1962, Congress amended the definition of a "new drug," 21 U.S.C. § 321(p), to require that drugs be demonstrated safe and effective for "use under the conditions prescribed," meaning that all uses for a drug must obtain FDA approval. *See also* 108 Cong. Rec. S17366 (daily ed. Aug. 23, 1962) (statement of Senator Eastland).

FDA approval of all indications after rigorous clinical trials serves valuable ends. First, it incentivizes private companies to generate this important information at their own expense. Second, through its independent, expert, and consistently applied review of this data, the FDA safeguards the integrity of the pharmaceutical system. *See* Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. TECH. L. REV. 345, 347-48 (2007); Ryan Abbott & Ian Ayres, *Evidence and Extrapolation: Mechanisms for Regulating Off-Label Uses of Drugs and Devices*, 64 DUKE L.J. 377, 388 (2014) ("The central problem with off-label use is that there is an information deficit."); David L. Simon, *Off-Label Innovations*, 56 GA. L. REV. 701, 708-11 (2022). Third, FDA approval may also be necessary for

insurance coverage. *See* Joshua Cohen *et al.*, *Off-Label Use Reimbursement*, 64 FOOD & DRUG L.J. 391, 396-97 (2009) (in a study of 179 payers, one-quarter excluded off-label use reimbursement altogether, and half of the remaining payers imposed restrictions on this reimbursement).

The value of these studies—for generating important information, for establishing safety and efficacy, and for ensuring patient reimbursement from their insurers—is further confirmed by the FDA's now-standard practice of requiring "Phase IV," post-marketing studies "to delineate additional information about the drug's risks, benefits, and optimal use." 21 C.F.R. § 312.85; *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach*, 445 F.3d 470, 489 (D.C. Cir. 2006); Osman Moneer *et al.*, *New Drug Postmarketing Requirements and Commitments in the US: A Systematic Review of the Evidence*, 43 DRUG SAFETY 305, 306 (2022).

Grants of Orphan Drug Exclusivity for "orphan indications" of existing drugs—seven years of market exclusivity granted where FDA finds that a drug or biologic is intended to treat, diagnose, or prevent rare diseases affecting fewer than 200,000 people in the United States—further underscores the importance of generating and promulgating this data. *See* 21 U.S.C. §§ 360aa-ee (Orphan Drug Act); *Sigma-Tau Pharms., Inc. v. Schwetz*, 288 F. 3d 141, 143-44 (4th Cir. 2002).

Finally, the most marked example of the value of clinical trials data may well be pediatric exclusivity. Because of the difficulties of doing large-scale clinical trials in children, pediatric patients are by far the

most common object of off-label prescription practices. Congress therefore established pediatric exclusivity, which extends patent or regulatory exclusivities by six months to incentivize pediatric testing on drugs conducted at the FDA's behest. Allan M. Joseph, *Kid Tested, FDA Approved: Examining Pediatric Drug Testing*, 72 FOOD & DRUG L.J. 543, 547-48 (2017).

C. Incentives to Invest in Approval of New Indications Are Already Extremely Limited. If the Section viii carve-out is viewed as enough to foreclose inducement-of-infringement claims at the pleading stage, companies now will have practically no incentive to engage in this important research and clinical work.

First, because off-label prescribing practices are routine, physicians can prescribe generic drugs for indications for which they are not approved (but the branded drug at issue is), even if that use is otherwise protected by method-of-use patent claims. Eisenberg, *supra*, at 369-71.

Second, the FDA typically provides generic drugs with "AB ratings." Receiving an AB rating means that the generic is not only bioequivalent, but pharmaceutically equivalent to the brand drug—meaning it has the same active ingredient, dosage form, strength, and route of administration as the brand drug. U.S. Dep't of Health & Human Servs., FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* xxi-xxiii (46th ed. 2026) (the "Orange Book"). Although this rating is based entirely on the qualities of the generic pharmaceutical, not on how it is used, it serves as a basis for freely substituting a generic for a brand-name drug,

regardless of the indication for which it was prescribed. As a result, "partial labeling ['skinny labeling'] to respect protected uses is functionally irrelevant when FDA deems a generic drug AB-rated to the innovator's drug in the Orange Book, without regard for the scope of its approval." Lietzan, *supra*, at 191.

And third, all states have now enacted substitution laws allowing—in some cases mandating—automatic substitution of generics to fill prescriptions off-label, as doctors typically do not provide the indications for which they are prescribing the drug in writing their prescriptions. Insurers, too, cover and frequently demand such use of generics regardless of their approved indications. *Id.* ("if the physician prescribes the innovator's product for the new use, state law and payer policies will generally lead to dispensing of the generic product anyway"). Generics thus benefit from the fact that the public now knows what was once an untested use now has official FDA approval.

Consequently, direct infringement of method-of-treatment patents has become unchecked. Pharmaceutical innovators cannot realistically enforce their method of use patents against patients or physicians. Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y L. & ETHICS 717, 724-25 (2005). *Cf. Cox Commc'ns*, 2026 WL 815283, at *4 ("pursuing each individual infringer does little to stem the tide").

Various regulatory exclusivities the FDA is empowered to grant offer no protection to holders of pharmaceutical patents against off-label uses. Neither the three-year exclusivity granted for New

Clinical Indications, *Bristol-Myers-Squibb Co. v. Shalala*, 91 F.3d 1493, 1500 (D.C. Cir. 1996), nor seven-year Orphan Drug Exclusivity, *Sigma-Tau Pharms.*, 288 F.3d at 145, protects against the prescribing of generics for off-label uses. *See, e.g.*, Lietzan, *supra*, at 180-81; Maxwell R. Morgan, *Regulation of Innovation Under Follow-on Biologics Legislation: FDA Exclusivity as an Efficient Incentive Mechanism*, 11 COLUM. SCI. & TECH. L. REV. 93, 98 (2010).

And at least one recent study shows that the resulting loss in investment in testing for new indications is significant when patents become paper tigers against carved-out methods of treatment. Eric Budish *et al.*, *Missing Markets for Innovation: Evidence from New Uses of Existing Drugs*, NBER Working Paper 34222, at 3 (2025) ("When intellectual property rights become unenforceable, research and development essentially cease."); *id.* at 37 ("we estimate that the social cost of this particular missing market is on the order of $2.5 to $10 trillion in present value terms").

Even the United States' brief in this case recognizes this problem. It acknowledges that prohibiting or limiting off-label prescriptions would "encourage valuable innovation by creating a financial incentive for brand-name manufacturers to identify new therapeutic benefits of their existing products," yet concludes, inconsistently, that Section viii carve-outs reflect congressional approval of off-label prescription practices, at least "so long as they do not actively encourage infringement." U.S. Br. 19.

II. Section viii Was Never Intended to Be a Safe Harbor for Infringement of Method of Use Patents

When Congress passed the Hatch-Waxman Act in 1984, Section viii merely allowed for generics equivalents to enter the market for unpatented uses. Section viii could never have been intended as implicitly condoning off-label use of generics for patented methods of treatment because this practice did not exist in any meaningful sense at that time. Thus, contrary to the Solicitor General's brief, U.S. Br. 12, Congress could not have seen any "measure of direct patent infringement" of method-of-treatment patents as an "acceptable price" for facilitating generic market entry.

Prior to Hatch-Waxman, generics comprised only nineteen percent of prescription drugs sold in the U.S. In fact, generic drugs were scarce at the time—only thirty-five percent of the top-selling drugs no longer under patent protection had generic equivalents—and generic versions of other drugs were even less likely to exist. CONG. BUDGET OFF., HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 1 (1998).

Congress thus could not have countenanced any level of direct infringement of method-of-treatment patents through generic substitution because this phenomenon did not even develop until years later. Indeed, dispensing of generic drugs continued to be minimal for at least another twenty years after enactment of the Hatch-Waxman Act. Murray Aitken *et al.*, *Prescription Drug Spending Trends in the United*

States: Looking Beyond the Turning Point, 27 HEALTH AFF. 151 (2008).

Had Congress intended the Hatch-Waxman Act to protect generic manufacturers from all claims of induced infringement, or intended, via Section viii, to allow generic manufacturers to market their skinny-label-approved products without any fear of an inducement claim, "Congress could have said" exactly that, "[b]ut it didn't." *Harrington v. Purdue Pharma, LP*, 603 U.S. 204, 218 (2024). Expediting market entry for a limited use of a drug is a far cry from ensuring that it can then be marketed and sold for any use whatsoever, even patented uses.

III. Allowing This Case to Proceed Past the Rule 12 Stage Will Not Deter Section viii Carve-Outs

Section viii is not part of the Patent Act. It is instead part of the Hatch-Waxman Act, a regulatory scheme that, among other things, creates an exception allowing generic drugs to enter the marketplace limited to unpatented uses. Even if, as the Court of Appeals in this case suggested, Petitioners' carved-out label in this case did not—on its own—induce others to infringe Amarin's patent, *see* Pet. App. 17a, that label, *in combination with other factors*, certainly could be enough to state a claim for induced infringement, as it was in the context of this case. Even the various *amicus* briefs filed in support of the Petitioner here focus on its statements of equivalence and investor statements, not the "skinny label" by itself. That alone points to the conclusion that the mere fact that Petitioners use a Section viii "skinny

label" should not immunize them from the totality of their inducing conduct, in sum or in substance.

The Court need not look past the very drug involved in this case, icosapent ethyl, to understand this. The FDA's Orange Book shows numerous separate approvals of this active ingredient, only two of which are Hikma's. *See also* Br. for Respondents 4 ("There are seven other manufacturers in the same market selling the same generic drug using materially identical 'skinny labels' as petitioners."). These other manufacturers have labels all but identical to that of Hikma's product, yet Amarin has not sued them for merely possessing the same carved-out label because they have not engaged in the same inducing conduct beyond the label itself. Thus, contrary to the concerns expressed by Petitioner and their *amici*, a ruling in favor of Amarin here will not encourage innovator companies to engage in perpetual patenting by sequential method-of-treatment patents, nor will it deter generics from entering the market with Section viii carveouts.

All of this leads to the conclusion that this Court should not adopt anything resembling a bright-line rule that gives a Section viii carve-out any special power to immunize generic manufacturers from inducement-of-infringement lawsuits. Infringement is a classic question of fact, *Markman v. Westview Instrs., Inc.*, 517 U.S. 370, 384 (1996), and the elements of induced infringement (of which the factual question of direct infringement is itself an element) likewise present fact questions. *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1129 (Fed. Cir. 2018).

As with most factual inquiries, there is no restriction on the type of evidence that is required to prove induced infringement. Even "[c]ircumstantial evidence can support a finding of specific intent to induce infringement." *Id.*; *see also AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010) (citing *Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1988)). That said, Amarin's burden at the pleading stage was mere plausibility of its complaint's claim of inducement; it was not required to fully prove its claim there. *See* pp. 4-5, above.

Amarin's pleading plainly cleared that modest bar. It alleged that Hikma's skinny label provided instructions on dosage, routes of administration, potential interactions with other drugs, and other information necessary to practice the administration of the drug regardless of indication. The label alone gave every relevant instruction except "take it for this unapproved, infringing indication."

And here, Hikma's other statements took the allegation of induced infringement past the line of plausibility. Its statement of generic equivalence—made without any caveat that its product was *not* in fact approved for all of the same uses as Amarin's Vascepa®—by itself accomplished that: Unlike in any other technological area, that statement can lead directly to qualifying the drug for off-label prescriptions and automatic substitutions under state law and insurers' demands. *See* pp. 12-13, above. Its investor statements and other facts brought out in the pleadings added further, context-specific allegations that Hikma not only expected, but intended and encouraged prescribers to administer its newly approved but label-limited drug for indications going

far beyond the ones permitted by the "skinny label." *See Kalem Co. v. Harper Brothers*, 222 U. S. 55, 62–63 (1911) (Holmes, J.) ("The defendant not only expected but invoked by advertisement the use of its films for dramatic reproduction of the story. … It is liable on principles recognized in every part of the law.") (cited in *Cox Commc'ns*, 2026 WL 815283, at *6).

A court could certainly draw a reasonable inference from all of these pleaded facts that Hikma saw the vast financial gains available from marketing its generic for the un-carved-out applications, and, through the *combination* of its acts and statements as pled, actively and intentionally induced prescribers to administer its generic drug for those infringing uses. The Court of Appeals held nothing more or less than that, Pet. App. 17a-19a; it did not, contrary to the claim of some of our academic colleagues who have filed a brief in this case, premise the possibility of liability on "infringement by label." Br. *Amici Curiae* of Patent Law Professors Gugliuzza & Sherkow 2. In fact, the Court of Appeals explicitly distinguished this case from a prior, "label-only case," Pet. App. 19a-20a (discussing and distinguishing *HZNP Meds. LLC v. Actavis Lab'ys UT, Inc.*, 940 F.3d 680, 702 (Fed. Cir. 2019)).

This holding was consistent with longstanding Federal Circuit precedent, which holds that so long as the generic's label itself does not induce infringement, and if an induced infringement claim is not "based on communications outside the ANDA label," no such infringement claims can stand. *H. Lundbeck A/S v. Lupin Ltd.*, 87 F.4th 1361, 1370 (Fed. Cir. 2023) (distinguishing *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1333 (Fed. Cir. 2021)

(per curiam) on this basis). As the Federal Circuit said of the label alone in *H. Lundbeck*: "Accordingly, we do not see how, in the normal course, a label required to market the drug for a use covered by expired patents could demonstrate the required specific intent to encourage infringement of new patents covering different uses." *Id.*

In short, determining inducement infringement in this case is a "fact-specific" inquiry; it is far from the "simple, clear, easily determined matter" suggested by others of our academic colleagues, particularly at this nascent pleading stage. Br. *Amici Curiae* of 76 Scholars of Law, Business, Economics and Medicine 2. The Court should decline these invitations to upset the law of patent infringement by injecting the kind of bright-line approach, based on what is at best a patent-adjacent regulatory scheme, that these *amici* and Petitioners themselves urge upon the Court. Instead, the Court should hold that the Federal Circuit correctly concluded that "the label *in combination* with Hikma's public statements and marketing materials," Pet. App. 17a-18a, yielded "the reasonable inference that [Hikma] is liable for the misconduct alleged," inducement of others to infringe Amarin's patent claims. *Iqbal*, 556 U.S. at 678.

CONCLUSION

For these reasons, the Court should affirm the Federal Circuit's decision.

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Respectfully submitted,

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