

No. 24-889

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

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

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

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ON WRIT OF CERTIORARI TO THE U.S. COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT

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**BRIEF OF ABBVIE INC. AND BRISTOL-  
MYERS SQUIBB COMPANY AS *AMICI CURIAE*  
IN SUPPORT OF RESPONDENTS**

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## QUESTIONS PRESENTED

1. When a generic drug label fully carves out a patented use, are allegations that the generic drugmaker calls its product a “generic version” and cites public information about the branded drug (e.g., sales) enough to plead induced infringement of the patented use?

2. Does a complaint state a claim for induced infringement of a patented method if it does not allege any instruction or other statement by the defendant that encourages, or even mentions, the patented use?

## TABLE OF CONTENTS

QUESTIONS PRESENTED .....	i
TABLE OF AUTHORITIES .....	iii
INTEREST OF AMICI CURIAE .....	1
SUMMARY OF ARGUMENT.....	1
ARGUMENT .....	7
I.    GENERIC DRUGMAKERS WITH SKINNY LABELS SHOULD NOT KNOWINGLY SUPPORT AND PROFIT FROM PERVASIVE END-USER INFRINGEMENT .....	7
II.   THIS IS A CLASSIC CASE OF INDUCED INFRINGEMENT.....	9
A.   Selling Goods With Knowledge Of Pervasive And Systemic Infringement By End Users, While Taking No Steps To Mitigate or Prevent It, Creates A Plausible Claim For Induced Infringement. ....	10
B.   The Comparison To Aiding And Abetting Liability Supports Inducement Liability.....	15
CONCLUSION.....	22

## TABLE OF AUTHORITIES

### CASES

<i>A&amp;M Records, Inc. v. Napster, Inc.</i> , 239 F.3d 1004 (9th Cir. 2001) .....	13, 14
<i>Armstrong v. McAlpin</i> , 699 F.2d 79 (2d Cir. 1983).....	20
<i>Aro Mfg. Co. v. Convertible Top Replacement Co.</i> , 377 U.S. 476 (1964) .....	17
<i>Bowker v. Dows</i> , 3 F. Cas. 1070 (C.C.D. Mass. 1878) (No. 1,734).....	18
<i>Camp v. Dema</i> , 948 F.2d 455 (8th Cir 1991) .....	20
<i>Capitol Records, Inc. v. MP3tunes</i> , 821 F. Supp.2d 627 (S.D.N.Y. 2011) .....	14
<i>Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S</i> , 566 U.S. 399 (2012) .....	8
<i>Casey v. U.S. Bank N.A.</i> , 127 Cal. App. 4th 1138 (2005).....	20
<i>Chas. H. Lilly Co. v. I.F. Laucks, Inc.</i> , 68 F.2d 175 (9th Cir. 1933) .....	18
<i>Costar Group, Inc. v. Loopnet, Inc.</i> , 164 F. Supp.2d 688 (D. Md. 2001), aff'd, 373 F.3d 544 (4th Cir. 2004).....	14

<i>Cox Communications, Inc. v. Sony Music Entertainment</i> , No. 24-171, 607 U.S. ___, slip op. (Mar. 25, 2026) .....	4, 15
<i>Dawson Chem. Co. v. Rohm &amp; Haas Co.</i> , 448 U.S. 176 (1980) .....	17
<i>Direct Sales Co. v. United States</i> , 319 U.S. 703 (1943) .....	21
<i>Disney Enters., Inc. v. Hotfile Corp.</i> , 798 F. Supp.2d 1303 (S.D. Fla. 2011) .....	14
<i>Fromberg, Inc. v. Thornhill</i> , 315 F.2d 407 (5th Cir. 1963) .....	15
<i>Global-Tech Appliances, Inc. v. SEB S.A.</i> , 563 U.S. 754 (2011) .....	2, 11, 12, 13, 14, 16, 17
<i>Greer v. Moon</i> , 83 F.4th 1283 (10th Cir. 2023).....	14
<i>Harper v. Shoppell</i> , 28 F. 613 (C.C.S.D.N.Y. 1886).....	19
<i>Henry v. A. B. Dick Co.</i> , 224 U.S. 1 (1912), overruled as superseded by statute, <i>Motion Picture Patents Co. v. Universal Film Mfg. Co.</i> , 243 U.S. 502 (1917) .....	19
<i>In re Terrorist Attacks on Sept. 11, 2001</i> , 714 F.3d 118 (2d Cir. 2013).....	20
<i>Keel v. Hainline</i> , 331 P.2d 397 (Okla. 1958) .....	20

<i>Louis Vuitton Malletier, S.A. v. Akanoc Sols., Inc.</i> , 591 F. Supp.2d 1098 (N.D. Cal. 2008) .....	14
<i>Mendelsohn v. Cap. Underwriters, Inc.</i> , 490 F. Supp. 1069 (N.D. Cal. 1979) .....	20
<i>Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.</i> , 545 U.S. 913 (2005) ...3, 5, 6, 11, 12, 13, 14, 16, 17	
<i>Monsen v. Consolidated Dressed Beef Co., Inc.</i> , 579 F.2d 793 (3d Cir. 1978).....	22
<i>Rosemond v. United States</i> , 572 U.S. 65 (2014) .....	20
<i>Smith &amp; Wesson Brands, Inc. v. Estados Unidos Mexicanos</i> , 605 U.S. 280 (2025) .....	22, 23
<i>Sony Corp. of America v. Universal City Studios, Inc.</i> , 464 U.S. 417 (1984) .....	15
<i>Tegal Corp. v. Tokyo Electron Co., Ltd.</i> , 248 F.3d 1376 (Fed. Cir. 2001).....	15
<i>Thomson-Houston Elec. Co. v. Ohio Brass Co.</i> , 80 F. 712 (6th Cir. 1897) .....	18
<i>Twitter v. Taamneh</i> , 598 U.S. 471 (2023) .....	21, 22, 23
<i>United States v. Thompson</i> , 539 F. App'x 778 (9th Cir. 2013).....	19

<i>Woodward v. Metro Bank of Dallas</i> , 522 F.2d 84 (5th Cir. 1975) .....	22
--	----

**STATUTES**

17 U.S.C. § 512(i)(1)(A) .....	5
35 U.S.C. § 271(b).....	2, 7, 17, 19

**FOREIGN JURISDICTION**

<i>Warner-Lambert Company LLC (Respondent) v Generics (UK) Ltd t/a Mylan and another (Appellants)</i> [2018] UKSC 56, on appeal from [2016] EWCA Civ 1006.....	10
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**OTHER AUTHORITIES**

4 Melville B. Nimmer & David Nimmer, NIMMER ON COPYRIGHT § 13E.03[B][2][b][iii] [Napster] (Oct. 2025).....	14
Lemley, <i>Inducing Patent Infringement</i> , 39 U.C. Davis L. Rev. 225 (2005).....	17
Restatement (Third) of Torts: Liab. for Econ. Harm § 28 .....	20
S. Rep. No. 82-1979 (1952), as reprinted in 1952 U.S.C.C.A.N. 2394 .....	17, 18

## **INTEREST OF AMICI CURIAE**

Amici curiae AbbVie Inc. and Bristol-Myers Squibb Company are innovator biopharmaceutical companies that spend billions of dollars researching and developing cutting-edge therapies for patients with unmet medical needs.<sup>1</sup> These therapies have led to treatments for myriad life-threatening conditions, including various types of cancer and autoimmune diseases. Amici rely on patents to protect their groundbreaking inventions, to ensure that they receive a reasonable return on their enormous investments in biopharmaceutical research and development, and to fund the next generation of research and development of innovative treatments.

## **SUMMARY OF ARGUMENT**

This case asks a narrow question: whether a manufacturer should be held liable for induced patent infringement when it continues to supply and profit from end users' pervasive and systematic infringing uses, while knowing that its profit is predominantly generated from such infringing uses, but taking no steps to try to mitigate or prevent such infringement. Specifically, Amarin alleges that Hikma continued selling and profiting from its generic product despite knowing that there are only two practical uses for its product and the overwhelming majority—75%—of uses have been and will be infringing. Hikma took no meaningful steps to mitigate or prevent the pervasive

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<sup>1</sup> No counsel for either party authored this brief in whole or in part, nor did any party or other person or entity other than amicus curiae or its counsel make a monetary contribution to the brief's preparation or submission.

and systemic infringement by end users, such as instructing major wholesalers or pharmacies that they should not sell or use the generic product for the patented indication, or telling major insurers not to reimburse for the generic product used for the patented indication. These allegations are sufficient to state a plausible claim for active inducement at the pleading stage under 35 U.S.C. § 271(b). Although not needed for a plausible pleading under the circumstances of this case, additional assertions regarding Hikma’s website, investor statements, or press releases further support a plausible desire by Hikma to induce the infringing uses, especially because it is at least plausible that downstream buyers such as wholesalers and pharmacies, as well as end users such as doctors and consumers, consider the terms “generic” or “AB rated” to mean that Hikma’s product can be used for all indications. This plausible interpretation by ordinary end users is supported by Hikma’s opening brief, which recognizes that “doctors and patients inevitably would use skinny-labeled generics for patented indications.” Pet. Br. 1.

The allegations here present an even stronger case for inducement than those this Court has previously found sufficient. In *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754 (2011), for example, this Court found induced infringement where the infringer (1) copied a product without investigating whether the product or its use was protected by any U.S. patent, (2) failed to disclose its copying effort to its patent counsel that might have helped counsel identify relevant patent(s) during clearance review, and (3) supplied the product to its U.S. customers. According to Amarin’s allegations,

Hikma did not merely close its eyes to infringement but had actual knowledge of pervasive and systematic infringement by end users but continued to supply its product while taking no steps to address the infringement. Additionally, it is plausible to infer, based on the circumstances of this case, that Hikma sought to make such infringement succeed, because Hikma marketed its product as “generic” or “AB rated”, but did not clarify to major wholesalers or pharmacies that its generic product should not be dispensed for the patented indication, or advise major insurers not to reimburse for the product when used for the patented indication.

Likewise, in *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913 (2005), this Court found contributory copyright infringement by a peer-to-peer filing sharing platform in which an alleged 90% of works available on the network were shown to be copyrighted. In support of its finding of contributory infringement, this Court cited (1) the defendants’ knowledge that many end users infringed copyrights, (2) their continuing marketing of their service, (3) their profiting from end users’ infringing uses, and (4) their failure to make any effort to mitigate or prevent infringing uses. Many of these facts emerged only after discovery. Here, at the pleading stage, Amarin alleges all of those elements already: (1) Hikma knew 75% of uses of its product infringe; (2) Hikma continued to market its product as a generic or AB-rated, statements that an end user could reasonably interpret to mean that the product is substitutable for all indications; (3) Hikma substantially profited from end users’ infringing uses—namely, 75% of its sales were attributable to such uses; and (4) Hikma took no steps to mitigate or prevent infringing uses.

The approach urged here is consistent with this Court’s recent decision in *Cox Communications, Inc. v. Sony Music Entertainment*, No. 24-171, 607 U.S. \_\_\_, slip op. (Mar. 25, 2026), which interpreted contributory copyright liability. The reasons given by this Court for not applying secondary liability in *Cox* are wholly absent here. For example, this Court emphasized that “Cox repeatedly discouraged copyright infringement by sending warnings, suspending services, and terminating accounts” and Cox “point[ed] out that its warning and suspension system ended 98% of identified infringement.” *Cox Communications*, Slip op. at 5, 9. By comparison, Hikma did not take any of the steps cited by this Court in *Cox*. In addition, “Cox also contractually prohibits its subscribers from” infringement. *Id.* at 4. Again, Hikma did nothing similar. Moreover, “Cox simply provided Internet access, which is used for many purposes other than copyright infringement.” *Id.* at 9. In contrast, Hikma’s product has only two practical uses, and Hikma knowingly sells 75% of its product for the infringing use. Moreover, the patent law does not contain any statutory defense akin to the safe harbor regime under the Digital Millennium Copyright Act (“DMCA”), 17 U.S.C. § 512(i)(1)(A), and even if the patent law had such defense, Hikma would not qualify because it has done nothing to meaningfully mitigate.

Hikma and its amici are wrong in arguing that this case threatens the “skinny label” or section viii carve-out. The section viii carve-out functioned exactly as intended here, and Hikma’s skinny labeled product was timely approved. The patentee does not seek to remove the skinny-labeled generic product from the market or stop its sale for the approved non-

infringing use. Instead, the patentee simply seeks to prevent the infringing uses of the patented indication. This case has little to do with skinny labels or the section viii carve-out. Rather, this case is simply about whether the alleged infringer should be permitted to continue profiting while knowingly supplying a product that it knows is used in pervasively and systemically infringing ways, while taking no steps to try to mitigate or stop those infringing uses.

By contrast, Hikma advances a categorical rule that would effectively expand the section viii carve-out to foreclose inducement claims whenever a skinny label is present, regardless of the defendant's knowledge of pervasive and systemic infringement and its decision not to try to mitigate or prevent it. This position runs directly afoul of *Grokster's* rejection of the suggestion that a producer can never be held liable so long as its product is capable of substantial lawful use. 545 U.S. at 934. Hikma's position is essentially a version of the argument that this Court rejected in *Grokster*: that "there is no liability when a defendant merely sells a commercial product suitable for some lawful use." Pet. Br. 25 (quoting *Grokster*).

Hikma seeks an unfair rule that would allow it to retain 75% of its profit through infringing uses without even attempting to mitigate or prevent them, and without sharing with the patent holder any of that 75% profit or otherwise compensating for the patent holder's losses. The precedents of this Court, as well as the patent statutes, have never allowed a manufacturer to circumvent patent rights by knowingly profiting from pervasive and systemic infringement while taking no steps to address it.

Other countries, confronting similar risks, have required generic manufacturers to take affirmative steps to ensure that their products are confined to approved, non-infringing indications. Hikma's unwillingness to take such steps here supports Amarin's claim of induced infringement.

Moreover, this case has important implications beyond pharmaceuticals and beyond patent law. It is one thing to decline to impose a duty on sellers to ferret out illegal uses of their products when they place undifferentiated goods into the stream of commerce without ongoing customer relationships or knowledge of misuse. It is quite another to immunize sellers that knowingly continue to supply and profit from end users' pervasive and systematic infringing uses, where the seller knows that its profits are predominantly generated from such infringing uses, yet takes no steps to mitigate or prevent that infringement. Imposing liability here would create a narrow and administrable rule that is consistent not just with well-established patent law, but also with well-established tort law, trademark law, and copyright law. In contrast, adopting Hikma's approach would trigger deleterious reverberations throughout all of these areas of law and frustrate the clear congressional purpose of Section 271(b) of the Patent Act.

## ARGUMENT

### I. **GENERIC DRUGMAKERS WITH SKINNY LABELS SHOULD NOT KNOWINGLY SUPPORT AND PROFIT FROM PERVASIVE END-USER INFRINGEMENT.**

Skinny labels, or section viii carve-outs, have been enormously successful in bringing generic products to the market more quickly, as demonstrated by this case, where Hikma’s product was timely approved under a skinny label and remains, and will continue to remain, available to patients for treating the off-patent indication. At the same time, this Court has instructed that “the FDA cannot authorize a generic drug that would infringe a patent” and that “FDA acceptance of the carve-out label allows the generic company to place its drug on the market . . . , but only for a subset of approved uses—i.e., those not covered by the brand’s patents.” *Caraco Pharm. Lab’ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405, 406 (2012) (emphasis added).

Yet in practice, many skinny-labeled products are also used for the carved-out infringing indications by end users such as doctors and patients, who are often unaware of the applicable patent protections. In fact, Hikma contends that doctors and patients will “inevitably infringe [a brand patent] by also practicing carved-out, patented indications,” in addition to unpatented indications. Pet. Br. 8. Hikma maintains that “market realities” mean that “even if a generic drug is formally approved only for unpatented uses, pharmacists and doctors will nonetheless substitute the generic for all indications

once it becomes available.” Pet. Br. 43 (internal quotation marks and citations omitted).

Hikma could easily have discouraged the infringement by clarifying to the purchasers or end users that its product as a generic is approved *only* for the non-patented indication, instructing major wholesalers or pharmacies that they should not sell or use the product for the patented indication, or instructing major insurers not to pay for the product used for the patented indication. These are readily available measures. With such steps, it is plausible that the pharmacists, doctors, or patients would stop or at least reduce infringing uses. But Hikma fully exploited end users’ confusion and misunderstanding and made the overwhelming majority of its profit from end users’ infringing uses.

Generic manufacturers typically have access to prescription data reflecting real-world usage patterns and are therefore aware of the extent of infringing uses of their skinny-labeled products, yet some may nevertheless continue supplying their products to unaware purchasers or end users for infringing uses without taking steps to mitigate those uses. Where a generic manufacturer knows that the overwhelming majority (e.g., 75%) of uses is for the patented indication, its continued distribution of the generic product, without taking any steps to prevent or mitigate that infringement, should plausibly support the inference that the manufacturer sought to bring about those infringing uses and therefore supports a plausible claim of induced infringement.

By way of illustration, other countries have taken steps to address induced infringement by requiring measures to ensure that generic products are limited

to approved non-infringing uses. In the United Kingdom’s *Lyrica* (pregabalin) litigation,<sup>2</sup> for example, the generic manufacturer (Actavis) wrote to over 7,500 pharmacists and English clinical commissioning groups (CCGs) informing them that authorization for its generic pregabalin was limited to the off-patent indications. Under court order, NHS England, a UK governmental agency, issued guidance to CCGs advising the use of *Lyrica* (the innovator’s product) for the on-patent indications. Software packages used by general practitioners were updated to provide warnings of the existence of patent rights when pregabalin is prescribed for pain. The UK Court of Appeal indicated that, absent such measures, infringement could be found against generic manufacturers with skinny label approval.

## **II. THIS IS A CLASSIC CASE OF INDUCED INFRINGEMENT.**

The allegations against Hikma readily satisfy the standard for a plausible claim of induced infringement. According to the pleadings, Hikma allegedly knows that approximately 75% of its skinny-labeled product is used for the patented cardiovascular indication, while only 25% is used for the approved, non-infringing indication. Yet it continues to sell—and profit from—the product without taking any steps to clarify its product or otherwise mitigate or prevent the infringing use, such as telling major wholesalers or pharmacies that they should not sell or use the product for the patented

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<sup>2</sup> *Warner-Lambert Company LLC (Respondent) v Generics (UK) Ltd t/a Mylan and another (Appellants)* [2018] UKSC 56, on appeal from [2016] EWCA Civ 1006.

indication, or telling major insurers not to pay for the product used for the patented indication. Those allegations alone, even without resorting to Hikma's website, investor statements, or press releases, are more than sufficient to establish a plausible claim of induced infringement at the pleading stage. But these additional public statements by Hikma further support a plausible inference that Hikma desires to continue to exploit unaware end users' confusion about the terms "generic" or "AB-rated," so that Hikma can continue to profit from end users' infringement.

**A. Selling Goods With Knowledge Of Pervasive And Systemic Infringement By End Users, While Taking No Steps To Mitigate or Prevent It, Creates A Plausible Claim For Induced Infringement.**

If the allegations pleaded here are insufficient, then there would have been no infringement liability in either *Global-Tech* or *Grokster*. In *Global-Tech*, the alleged infringer copied the product at issue, *did not* attempt to confirm whether any aspect of the product or its use was covered by any patent, *did not* know whether the end users would use its product in an infringing way, *did not* tell its patent attorney or end users about its copying, and did not explicitly promote or encourage the end users to infringe. This Court found induced infringement and made clear that willful blindness was the same as actual knowledge. Defendants who behave in this manner "are just as culpable as those who have actual knowledge," because those who "blind themselves to direct proof of critical facts in effect have actual knowledge of those facts." 563 U.S. at 766. Here, Hikma copied the

product at issue, *did* know that one of the only two practical uses of the product was covered by a patent, *did* know that 75% of the end users use the product in an infringing way, and *did* inform the public of its copying.

Amarin and Hikma debate whether Hikma promoted or encouraged the end users to infringe through its website, investor statements, press releases, and label. But *Global-Tech* makes clear such allegations are not necessary to state a claim for induced infringement. After all, the defendant in *Global-Tech* did not explicitly promote or encourage the end users to infringe, either.

Similarly, in *Grokster*, the defendants knew that many users (90% of all uses) infringed, marketed their product as a substitute for another product widely used to infringe, profited from that infringement, and took no meaningful steps to curb it. *Grokster* flatly rejected any suggestion that a manufacturer cannot be held liable so long as its product is capable of substantial lawful use. 545 U.S. at 934. Instead, the Court noted that each defendant company “showed itself to be aiming to satisfy a known source of demand” for the infringement; second, neither company developed software filtering tools to minimize their infringement; and third, the companies profited by the increased infringement of their users. *Id.* at 939-40.

The *Grokster* Court emphasized that the failure to implement measures to prevent known infringing uses “underscores [the defendants’] intentional facilitation” of infringement. *Id.* at 939. The same reasoning applies here: Hikma allegedly knew that roughly 75% of uses infringed and would continue to

infringe, sold its product as a “generic” or substitute for Amarin’s patented product, and made no effort to prevent end users’ pervasive and systemic infringing use. That is more than sufficient to state a claim for induced infringement at the pleading stage.

*Grokster* also makes clear that inducement liability does not require knowledge of specific acts of infringement—only general awareness that a device is being used to infringe. See 545 U.S. at 922 (Grokster “d[id] not ... know when particular files [were] copied”); see also *Global-Tech*, 563 U.S. at 768-69 (Grokster’s liability arose from its awareness that its file-sharing software was being used to infringe).

Likewise, in *A&M Records, Inc. v. Napster, Inc.*, 239 F.3d 1004, 1022 (9th Cir. 2001), the Ninth Circuit imposed liability where the peer-to-peer music sharing service failed to block access to known infringers or remove infringing material despite actual knowledge of specific infringing material. The Ninth Circuit rejected Napster’s argument that its service was merely a passive conduit, because “[t]he record supports the district court’s finding that Napster has *actual* knowledge that *specific* infringing material is available using its system, that it could block access to the system by suppliers of the infringing material, and that it failed to remove the material.” *Id.* The *Napster* court thus confirmed that knowledge of infringement combined with providing the means to infringe and refusing to remove known infringing material suffices for contributory copyright liability. A long line of precedent in the online

environment has firmly established that rule.<sup>3</sup> Here too, Hikma allegedly had actual knowledge that the overwhelming majority of end users were infringing, yet took no steps to mitigate or prevent it. These allegations more than suffice to plausibly state a claim of induced infringement, particularly given Hikma’s full exploitation, without any meaningful attempt at clarification, of potentially confusing terms such as “generic” or “AB-rated,” the interpretation of which may well depend on the audience.

Settled precedent also makes clear that there is no merit to Hikma’s position that inducement liability cannot attach to supposed “failures to take action” against infringers. The salient point of *Global-Tech* and *Grokster* (as well as *Napster*) is that continuing to supply goods or services after gaining knowledge of pervasive and systemic infringement, while taking no

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<sup>3</sup> See 4 Melville B. Nimmer & David Nimmer, NIMMER ON COPYRIGHT § 13E.03[B][2][b][iii] [Napster] (Oct. 2025) (citing as examples of online defendants deemed to provide material contribution to infringing activity; *Greer v. Moon*, 83 F.4th 1283, 1295 (10th Cir. 2023) (website that hosted infringing third-party submissions and failed to take them down after requests); *Louis Vuitton Malletier, S.A. v. Akanoc Sols., Inc.*, 591 F. Supp.2d 1098, 1102 (N.D. Cal. 2008) (website hosting service that provided service space and IP addresses to direct infringers and “fail[ed] to take simple measures to limit the known infringing activity taking place on their systems”); *Costar Group, Inc. v. Loopnet, Inc.*, 164 F. Supp.2d 688 (D. Md. 2001), aff’d, 373 F.3d 544 (4th Cir. 2004) (website that hosted and presented aggregated real estate listings); *Disney Enters., Inc. v. Hotfile Corp.*, 798 F. Supp.2d 1303, 1310 (S.D. Fla. 2011) (website allowing uploads and downloads of copyrighted films); *Capitol Records, Inc. v. MP3tunes*, 821 F. Supp.2d 627 (S.D.N.Y. 2011) (website giving users individual “lockers” into which they could download MP3 files from third-party websites)).

steps to mitigate or stop it, is itself *an act of assistance*, not an omission. The courts have recognized that the term “actively inducing” encompasses a wide range of conduct. The term “is as broad as the range of actions by which one in fact causes, or urges, or encourages, or aids another to infringe a patent.” *Tegal Corp. v. Tokyo Electron Co., Ltd.*, 248 F.3d 1376, 1379 (Fed. Cir. 2001) (quoting *Fromberg, Inc. v. Thornhill*, 315 F.2d 407, 411 (5th Cir. 1963)).

*Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417 (1984), is consistent with the approach urged here. Although this Court found no infringement in *Sony*, it was careful to note that the defendant did not “supply its products to identified individuals known by it to be engaging in continuing infringement of respondents’ copyrights.” *Id.* at 439 n.19. In addition, the Court observed that there were no obvious steps that Sony could have taken to prevent or reduce infringement by end users. *Id.* at 438. The allegations here are different on both points. Hikma knew that the vast majority of its drug would be used for an infringing indication. And Hikma had readily available means to mitigate or prevent that infringement yet took no steps to employ them.

This Court’s decision in *Cox Communications, Inc. v. Sony Music Entertainment*, No. 24-171, 607 U.S. \_\_\_, slip op. (Mar. 25, 2026), is also consistent with the approach urged here. While *Cox* held that an internet service provider could not be held liable for contributory copyright infringement for allowing customers to illegally download copyrighted music, the decision is inapposite here. In *Cox*, this Court stressed key facts that distinguish that case from the situation here. For example, this Court noted that

“Cox repeatedly discouraged copyright infringement by sending warnings, suspending services, and terminating accounts,” and Cox “point[ed] out that its warning and suspension system ended 98% of identified infringement.” Slip op. at 5, 9. Hikma did nothing similar. In addition, “Cox also contractually prohibits its subscribers from” infringement. *Id.* at 4. Again, Hikma did nothing similar. Moreover, “Cox simply provided Internet access, which is used for many purposes other than copyright infringement” and “merely providing a service to the general public with knowledge that it will be used by some to infringe copyright.” *Id.* at 1, 9. In contrast, Hikma’s product has only two practical uses, and Hikma knowingly sells 75% of its product for the infringing use. In short, the reasons given by this Court in *Cox* for not imposing secondary liability are wholly absent here.

**B. The Comparison To Aiding And Abetting Liability Supports Inducement Liability.**

Both *Grokster* and *Global-Tech* expressly acknowledged the aiding-and-abetting foundations of induced infringement. *Grokster* explained the “classic case of direct evidence of unlawful purpose occurs when one induces commission of infringement by another, or ‘entic[es] or persuad[es] another’ to infringe,” and it recognized “liability for inducement where one ‘actively and knowingly aid[s] and abet[s] another’s direct infringement.’” 545 U.S. at 935-36 (citation omitted) (brackets in original). *Global-Tech* was equally explicit, characterizing contributory infringement as “the aiding and abetting of direct infringement by another party.” 563 U.S. at 764

(quoting Lemley, *Inducing Patent Infringement*, 39 U.C. Davis L. Rev. 225, 227 (2005)).

Congress made clear that § 271(b) was intended to codify aiding-and-abetting liability for infringement. See S. Rep. No. 82-1979, at 8 (1952), as reprinted in 1952 U.S.C.C.A.N. 2394, 2402 (“Paragraph (b) recites in broad terms that one who aids and abets an infringement is likewise an infringer.”); cf. *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 485-86 n.6 (1964) (recognizing that Congress in the 1952 Patent Act intended to codify pre-1952 contributory infringement principles). In codifying contributory infringement, Congress explained that the doctrine exists to enjoin those who seek to cause infringement “by supplying someone else with the means and directions for infringing a patent,” and to prevent such actors from “appropriating the benefit of the patented invention.” *Id.*; see also *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 188 (1980) (contributory infringement “exist[ed] to protect patent rights from subversion by those who, without directly infringing the patent themselves, engage in acts designed to facilitate infringement by others”). Congress further made clear that liability does not turn on the provision of “specific” directions to infringe; “implied” directions may suffice where the defendant knowingly supplies the means for infringement and facilitates its commission. *Id.* Accordingly, Hikma is wrong in demanding that Amarin must plead specific directions to infringe.

Pre-1952 courts drew on aiding-and-abetting principles and applied them to what one court described as “trespass upon patent property.” *Thomson-Houston Elec. Co. v. Ohio Brass Co.*, 80 F.

712, 721 (6th Cir. 1897); *see also* *Chas. H. Lilly Co. v. I.F. Laucks, Inc.*, 68 F.2d 175, 181 (9th Cir. 1933). Recognizing that direct infringers were often difficult to reach, the Sixth Circuit (per then-Judge Taft) in *Thomson-Houston* held that “the only effective mode of preventing infringement” was to proceed against those who made infringement possible and “intentionally solicit[ed] and promote[d] such invasions of the patentee’s rights.” 80 F. at 721 . Even where the products were capable of non-infringing uses, contributory infringement could still be established by showing an intent to assist infringement through their distribution. *Id.* at 723. The court went so far as to impose on the defendant a duty to ensure that the combinations it was “intentionally inducing and promoting” were confined to lawful uses. *Id.*

Knowledge of downstream infringement has long been central in patent and other intellectual property cases. In *Bowker v. Dows*, 3 F. Cas. 1070 (C.C.D. Mass. 1878) (No. 1,734), the defendant was liable for selling a product to purchasers he knew intended to use it in an infringing combination. *Id.* at 1071. Likewise, in *Henry v. A. B. Dick Co.*, 224 U.S. 1 (1912), overruled as superseded by statute, *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 517–18 (1917), this Court held that when a seller knows purchasers will use a product to infringe, the sale may be treated as made with the intent that it be so used. *Id.* at 49. The Court added that, under those circumstances, “[i]t is not open to [defendants] to say that it might be used in a noninfringing way.” *Id.* Early copyright law applied the same principle: a defendant was held liable for selling a printing plate he knew would be used for infringement, even though

the plate was capable of lawful uses. *Harper v. Shoppell*, 28 F. 613, 615 (C.C.S.D.N.Y. 1886).

Measured against that framework, the pleading allegations here are more than adequate to state a claim of induced infringement. Hikma allegedly knew that the overwhelming majority of its product would be used for an infringing indication and nonetheless continued supplying it, while taking no steps to mitigate or prevent the infringement. This constitutes precisely the kind of affirmative facilitation that pre-1952 caselaw and well-established aiding-and-abetting precedent have long treated as sufficient to create secondary liability. Section 271(b), rooted in those same principles, does not demand explicit instructions to infringe; it reaches those who knowingly and purposefully make infringement succeed.

Supplying a person with a product or service with the knowledge they will misuse it creates clear aiding-and-abetting liability, even if the good or service is capable of proper use. For example, a person who gives a hammer to a friend known to be planning a burglary is aiding and abetting, even though lending tools to friends is usually perfectly innocent. See *United States v. Thompson*, 539 F. App'x 778, 779 (9th Cir. 2013). Someone who hands erasers to negligent students engaged in an eraser fight is aiding and abetting, even though the act of doing so in other contexts is innocent. See *Keel v. Hainline*, 331 P.2d 397, 400 (Okla. 1958). And a broker who processes trades from an investment advisor that the broker knows to be churning is aiding and abetting the churning, see *Armstrong v. McAlpin*, 699 F.2d 79, 91 (2d Cir. 1983); Restatement (Third) of Torts: Liab. for Econ. Harm § 28 cmt. d illus. 6, even though

providing routine financial services is typically free from liability to third persons. *See In re Terrorist Attacks on Sept. 11, 2001*, 714 F.3d 118, 126 (2d Cir. 2013); *Mendelsohn v. Cap. Underwriters, Inc.*, 490 F. Supp. 1069, 1083–84 (N.D. Cal. 1979).

“Routine” and “normal everyday business practices” might require “a higher degree of knowledge” to constitute aiding and abetting than shady or unusual business practices, but once that knowledge is achieved, liability will attach to any further aid. *Camp v. Dema*, 948 F.2d 455, 459 (8th Cir. 1991); *see also Casey v. U.S. Bank N.A.*, 127 Cal. App. 4th 1138, 1145 (2005) (“[C]ommon sense tells us that even ‘ordinary business transactions’ may be substantial assistance ‘if the bank actually knew those transactions were assisting the customer in committing a specific tort.’”).

As this Court explained in *Rosemond v. United States*, 572 U.S. 65, 73 (2014), even “minimal” assistance suffices to establish aiding and abetting liability, because “every little bit helps”; the “quantity of assistance [is] immaterial” so long as the accomplice does “something” to aid the crime. *Id.* (brackets altered). What matters is not the magnitude of the act but the combination of knowledge and purposeful facilitation.

In *Direct Sales Co. v. United States*, 319 U.S. 703 (1943), for example, a mail-order pharmacy was held liable for conspiracy because it “sold morphine sulphate to [one doctor] in such quantities, so frequently and over so long a period”—and after “the Bureau of Narcotics informed” the pharmacy “it was being used as a source of supply by convicted physicians”—that “it must have known” the doctor

was “distributing the drug illegally.” *Id.* at 705, 707. That decision shows that secondary liability can be created by continuing to sell to third parties knowing that they will use the product unlawfully. *Id.* at 712 & n.8. Indeed, the Court found relevant the supplier’s “stake in the venture”—which was “making the profits which it knew could come only from its encouragement of [the doctor’s] illicit operations.” *Id.* at 713.

This Court’s decision in *Twitter v. Taamneh*, 598 U.S. 471 (2023), supports the position advocated here. The *Twitter* Court recognized that there may be “situations where the provider of routine services does so in an unusual way or provides such dangerous wares that selling those goods to a terrorist group could constitute aiding and abetting a foreseeable terror attack.” *Id.* at 502. This Court also recognized that “there may be situations” where “a duty exists” that “would require ... communication-providing services to terminate customers after discovering that the customers were using the service for illicit ends.” *Id.* at 501. The Court further recognized the situation that a “failure to stop ISIS from using these platforms” could be “culpable” on a “strong showing of assistance and scienter.” *Id.* at 500. But it found that showing lacking on the allegations before it. *See, e.g., id.* at 505. Here, Amarin has plausibly alleged knowledge on Hikma’s part of pervasive and systemic infringement, which Hikma has taken no steps to prevent or mitigate. Hikma did not even try to clarify the confusing statements about “generic” or “AB-rated” by (for example) further explaining to the buyers or end users that its AB-rated product has not been authorized to be used for the patented

indication. Amarin’s allegations more than meet the standard.

The cases cited by this Court in *Twitter* provide additional support for the position urged here. As the Fifth Circuit explained in a case repeatedly cited by *Twitter*, even routine and everyday business practices can underpin an aiding and-abetting claim—provided the defendant consciously intended to assist the underlying wrong via those business practices. *Woodward v. Metro Bank of Dallas*, 522 F.2d 84, 97 (5th Cir. 1975) (cited in *Twitter*, 598 U.S. at 486, 492, 501). And even “inaction . . . may provide a predicate for liability where the plaintiff demonstrates that the aider-abettor Consciously intended to assist in the perpetration of a wrongful act.” *Monsen v. Consolidated Dressed Beef Co., Inc.*, 579 F.2d 793, 800 (3d Cir. 1978) (cited in *Twitter*, 598 U.S. at 491).

Nor does *Smith & Wesson Brands, Inc. v. Estados Unidos Mexicanos*, 605 U.S. 280 (2025), support Hikma. There, Mexico failed to allege any specific criminal acts facilitated by the gun manufacturer defendants resulting in harm to Mexico. *Id.* at 294. Mexico’s complaint alleged only that “some, though unidentified, dealers” in the defendant’s arms “often engage in illegal transactions with Mexican traffickers.” *Id.* at 296. The Court stated that, “[t]o survive, the charge must be backed by plausible allegations of ‘pervasive, systemic, and culpable assistance.’” *Id.* at 294.

Here, by contrast, Amarin alleges that Hikma has the knowledge of pervasive, systemic and culpable infringement that was lacking in *Twitter* and *Smith & Wesson*, thus establishing a clear nexus between the underlying infringement by end users and

Hikma's continuing provision of the means to carry it out, with no steps taken to prevent or mitigate it.

### CONCLUSION

Allowing the judgment below to stand preserves both the integrity of Section 271(b) and the continued viability of skinny-labeled generics. The Federal Circuit's judgment should be affirmed.

Respectfully submitted.

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