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Modern Induced Infringement: Evolving Standard Based on Recent Supreme Court Decisions

May 12, 2026



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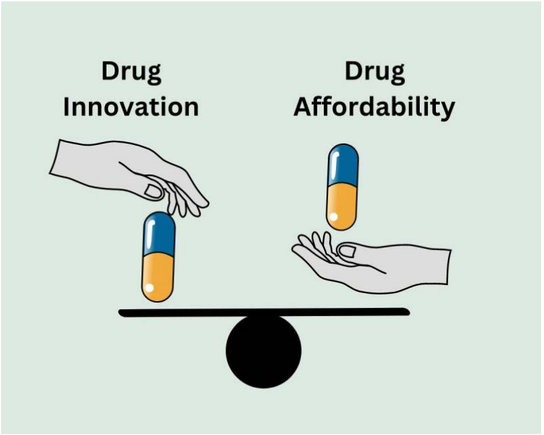
Overview of Induced Infringement

- Induced Infringement Under 35 U.S.C. § 271(b): "Whoever actively induces infringement of a patent shall be liable as an infringer." Inducement requires proof that the defendant knew of the patent, knew the induced acts constitute infringement, and took affirmative steps to encourage those acts. The Supreme Court has emphasized that inducement requires "active steps" and "culpable expression and conduct," not merely awareness that third parties might infringe
- Supreme Court has held that mere knowledge that some customers might infringe is insufficient; there must be “clear expression or other affirmative steps taken to foster infringement.” Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd., 545 U.S. 913, 936-37 (2005)
- Supreme court has interpreted the statute to require “affirmative steps to bring about” infringement. Glob.-Tech Appliances, Inc. v. SEB S.A., 563 U.S. 754, 760 (2011)

Induced Infringement: Requirements

- Inducement plaintiff must establish five elements:
  1. The defendant must know of the patent or be willfully blind to its existence
  2. The defendant must have specific intent to encourage the infringing acts
     - The Supreme Court reinforced this distinction in *Commil USA, LLC v. Cisco Systems, Inc.*, clarifying that induced infringement requires proof that the defendant knew the acts were infringing and intended to encourage them
  3. The defendant must take affirmative acts of encouragement (not merely sell a product knowing it might be used in an infringing way)
  4. An actor must actually perform the patented method (requires direct infringement)
  5. There must exist a causal connection between the defendant's inducing acts and the direct infringement
     - The Federal Circuit has held that inducement requires proof that the defendant's actions actually led to infringement, rejecting jury instructions suggesting liability regardless of whether encouragement was received. (Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc., 843 F.3d 1315, 1332--33 (Fed. Cir. 2016))

Hatch-Waxman (Background)



- Generic drugs must have package inserts identical to their branded counterparts. If the branded drug is protected by a patent on the drug product itself, a generic company may not lawfully sell that drug unless it proves that the patent is invalid or that its generic product won't infringe. Similarly, if a brand company's patents cover all of its drug's FDA-approved uses, a generic's package insert must, by law, recite the same, patented uses.

- The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (the "Hatch-Waxman Act") provides an exception to generics' package insert identity requirement. If at least one FDA-approved use of the branded drug is unpatented, a generic can avoid patent infringement and obtain FDA approval by "carving out" the patented uses from its package insert, leaving only the unpatented use.
    - Goal was to balance facilitating a) generic drug entry and b) ensuring that the Patent Act continues to incentivize the innovation of new medicines

Hatch-Waxman Act: Section viii

- Hatch-Waxman's section viii provisions, 21 U.S.C. § 355(j)(2)(A)(viii):
  - A generic manufacturer may certify that its proposed labeling does not include any indication covered by a listed method-of-use patent. The FDA approves the abbreviated new drug application (ANDA) with labeling that "carves out" the patented uses. Unlike paragraph IV certifications that challenge patent validity, section viii statements do not trigger the 30-month litigation stay, allowing faster generic entry for non-patented indications

- Context: Doctors routinely prescribe drugs for off-label uses and generally do not see the generic manufacturer's FDA-approved labeling when writing prescriptions. In certain jurisdictions, pharmacists *must* dispense the generic unless the prescriber explicitly requires the brand
  - Pharmacists cannot readily determine whether a particular prescription corresponds to the generic's carved-out label or the brand's broader indications
  - A majority of new FDA approvals directed to new uses for already approved drugs

Hatch-Waxman Act & Patent Law

- Will a skinny-label generic be used to infringe a patent of a brand-name drug?
  - Generics are required by FDA to mimic the brand's label; is a defendant *intentionally* inducing patent infringement by saying something a government agency has required them to. Generic companies be even be expressly trying to avoid encouraging infringement convincing the FDA to allow them to remove from their label language referencing the patented method

  - Generic manufacturers would like the "skinny label" to provide full immunity from patent infringement, including the right to collect profits on sales that end up being used for the patented indication
  - The branded manufacturer would ideally like to use its patent to effectively block the generic from the market entirely, even for unpatented uses
  - <u>The Dilema</u>:
    - If ruling in favor of the generic, implies certain method-of-use patents are effectively unenforceable for branded manufacturers once the compound goes off-patent (undermines incentive to invest in new indications for existing drugs)
    - If ruling in favor of the brand, provide patent holders a way to extend their monopoly over the entire molecule beyond what Congress intended (patients lose access to cheaper alternatives for unpatented uses)

Recent Relevant Rulings



- **GlaxoSmithKline v. Teva (2021) (Fed. Cir)**
  - Involved carvedilol, a heart medication, sold by GlaxoSmithKline (GSK) under the brand name “Coreg”.
  - FDA had approved carvedilol for three uses: treatment of hypertension, treatment of congestive heart failure (CHF), and “to reduce cardiovascular mortality in patients suffering from left ventricular dysfunction following a myocardial infraction”; GSK owned a patent on a method of using carvedilol to treat CHF.
  - Teva filed a Section viii statement that its label would not include the CHF indication; its FDA-approved drug label initially included only two indications: hypertension and post-MI LVD.
  - Four years after Teva launched its generic, the FDA instructed Teva to revise its drug label to be identical to GSK’s label for Coreg, and Teva changed its drug label to include the previously carved-out CHF indication.
  - The Federal Circuit upheld a jury verdict in favor of the patentee (GSK) even though the generic had carved out of its label the only indication covered by the patent.
    - Federal Circuit reasoned, Teva’s partial label (CHF indication carved out) encouraged an infringing use “via the post-MI LVD indication” that remained on the label and through Teva’s marketing materials
  - This ruling seemingly complicated generics’ path to market

Recent Relevant Rulings

- **GlaxoSmithKline v. Teva (2021) (Fed. Cir) (Cont.)**
  - Teva filed for a writ of certiorari with the Supreme Court, to which the government (Solicitor General) recommended granting review; Supreme Court declined review
  - GlaxoSmithKline established a new theory of induced infringement based not on a label's express instructions to engage in activity that necessarily infringes, but on the mere existence of package insert language that was interpreted by an expert witness to simply mention a patented use, despite a generic carving such a patented use out of the label

Recent Relevant Rulings

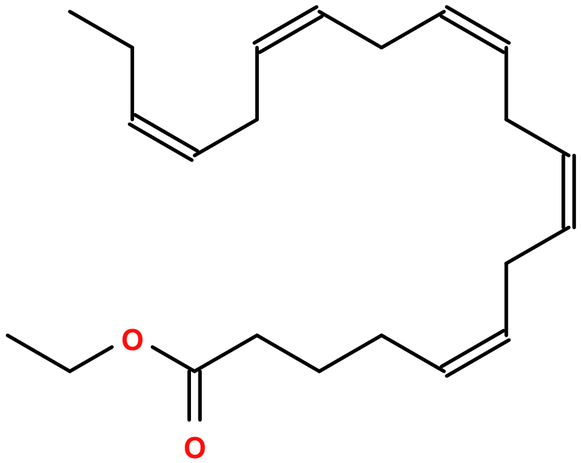
- **Cox Communications, Inc. v. Sony Music Entertainment (2026) (S. Ct.)**
  - Copyright case regarding whether an ISP can be held liable for contributory copyright infringement for continuing to provide internet access to subscribers it knows are repeat infringers, without proof of specific affirmative conduct to promote infringement
    - The Copyright Act of 1976 contains no express provision defining secondary liability
    - The Supreme Court has adopted elements from patent law's contributory infringement and inducement statutes into copyright law (*Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417 (1984)); (*Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913 (2005))
    - The Supreme Court reversed the verdict against Cox Communications, holding that an internet service provider (ISP) cannot be held contributorily liable for its users' copyright infringement simply because it knows about the infringement and continues providing service. (*Cox Communications, Inc. v. Sony Music Entertainment*, No. 24-171 (U.S. Mar. 25, 2026))
      - Indicates present Supreme Court's skepticism toward expansive secondary liability

Amarin v. Hikma
(Currently Pending Supreme Court Review)



Vascepa (icosapent ethyl)

- Form of the omega-3 fatty acid EPA derived from fish oil
- FDA approval in 2012 for treating severe hypertriglyceridemia, a condition marked by dangerously elevated blood fat levels
- In 2019, Amarin secured a label expansion for cardiovascular risk reduction based a study showing that Vascepa reduced heart attacks and strokes even in high-risk patients already taking statins
- Also in 2019, Hikma obtained FDA approval in 2019 for a generic version of Vascepa using a section viii carve-out





Vascepa (icosapent ethyl) (cont.)

- Amarin sued Hikma for actively inducing patent infringement based upon the skinny label and sales coupled with Hikma's press releases referring to its product as an "AB rated" "generic version" of Vascepa
  - The asserted patents, U.S. Patent Nos. 9,700,537 and 10,568,861, are directed to methods of using icosapent ethyl to reduce the risk of cardiovascular events.
- Amarin had originally held method-of-use patents covering both severe hypertriglyceridemia (SH) and cardiovascular risk reduction (CV), but the SH patents were invalidated leaving only the CV patents (CV indication drives the overwhelming majority of Vascepa prescriptions)
- While Hikma carved out the CV indication and labeled its product only for the unpatented SH use, the generic is regularly prescribed and used for the infringing CV indication
- Can a generic drug manufacturer be liable for induced infringement when using a "skinny label" that carves out patented uses?

Hikma Pharmaceuticals USA Inc. v. Amarin Pharma, Inc.: Timeline

Feb 2022

The District of Delaware dismissed Amarin's complaint for failure to state a claim, reasoning that Hikma had complied with the section viii framework and that no specific statement encouraged the patented use

June 2024

The Federal Circuit reversed - acknowledged that Hikma's label did not instruct infringement but found that the allegations, "taken together," plausibly stated a claim for induced infringement. Amarin Pharma, Inc. v. Hikma Pharms. USA Inc., 104 F.4th 1370 (Fed. Cir. 2024)

Dec 2025

The government argues in Solicitor General's brief that the Federal Circuit conflated plausible pleading with plausible inducement, treating routine commercial speech as affirmative steps toward encouraging patent infringement

Jan 2026

Supreme Court grants certiorari to address whether a generic drug manufacturer can face induced infringement liability when it markets a product using a "skinny label" that fully carves out patented uses

April 2026

Supreme Court holds oral hearings

Questions (from Petition for Writ of Certiorari)

The questions presented are:

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?

Oral Argument (April 29, 2026)

- Justice Sotomayor expressed that no new doctrine is needed to decide the case
  - In response, several justices (e.g., Barrett) expressed doubt over whether the Court should hear the case, if indeed it focused on factual error review rather than legal doctrine
- Solicitor General argued that a “strong case of active inducement” would arise in the case of two hypotheticals:
  - (1) if Hikma had paired its “generic Vascepa” identification with the statement that “Vascepa is approved to treat cardiovascular risks,” said “in the same breath.”
  - (2) if a generic asserting that “studies have shown that icosapent ethyl . . . reduces cardiovascular risks”
- Evidence shows Hikma repeatedly identified itself as “the generic version of Vascepa”, during a similar time from as when Vascepa and cardiovascular risk reduction was first identified

Predicted Outcome

- Unlikely that the Supreme Court creates a specific inducement doctrine for skinny labels
- The outcome will likely impact all patent doctrine, not only life sciences
- Supreme Court may clarify Federal Circuit's "totality" approach
- Will Supreme Court reinforce requirement of causation?
  - The United States Government supported the accused infringers in both Cox and Hikmam, both instances advocating for narrower secondary liability

Opinion: Sherkow and Gugliuzza

In pharmaceutical patent cases, the Federal Circuit has effectively equated drug labels to patent claims for the purpose of demonstrating induced infringement. This theory of infringement—infringement *by* label—is both doctrinally and factually wrong. It ignores the realities that should be at the heart of the inducement analysis, such as what actual doctors would or would not take away from a drug's label. It threatens to upend large swaths of the Hatch-Waxman Act, especially Section viii carve-outs. It is unfaithful to longstanding principles of patent law doctrine. And it is plagued by procedural quirks that obscure what the law regarding inducement really demands. The Federal Circuit could address many of these ills by simply recognizing nuances of drug labeling that its recent decisions ignore.

Opinion: Dennis Crouch

> The Supreme Court's choice need not be binary. Neither rubber-stamp the Federal Circuit's approach nor adopt the amici's categorical rule. Recognize that inducement analysis is contextual—the same promotional conduct carries different significance in different markets. In markets where skinny labels can channel prescriptions, generics should be free to compete. In markets where they cannot, generics must take responsibility for the foreseeable consequences of their promotional choices.
>
> If the result is that skinny-label entry is unviable in certain markets, the remedy is legislative, not judicial. Proposals for a statutory safe harbor have been introduced.[86] The current Hatch-Waxman framework does not provide blanket immunity for generics that knowingly prime markets for infringement; if Congress wants that result, it should say so explicitly.
>
> The skinny label alone does not induce. But neither does it immunize.

Opinion: AIPLA

> There is no basis for this Court to read special protections into inducement law for section viii entrants as Hikma proposes. Section 271(b) is not only industry-agnostic, but also flexible. Adopting a categorical rule that excludes certain public statements made on a generic drug company's website, such as in press releases, from qualifying as evidence of inducement would fracture the uniformity of inducement law, create a technology-specific safe harbor that Congress has not authorized, and invite other industries to seek similar exemptions from liability under § 271(b).

Further Resources

- Crouch, Dennis D., The Tinderbox: Market Structure, Skinny Labels, and Induced Patent Infringement (March 16, 2026). University of Missouri School of Law Legal Studies Research Paper No. 2026-30, 73 UCLA L. Rev. Discourse ___ (Forthcoming 2026), SSRN: https://ssrn.com/abstract=6427020; http://dx.doi.org/10.2139/ssrn.6427020
- Sherkow, Jacob S. and Gugliuzza, Paul R., Infringement by Drug Label (March 28, 2025). 78 Stanford Law Review 131 (2026), University of Illinois College of Law Legal Studies Research Paper No. 25-10, SSRN: https://ssrn.com/abstract=5145419; http://dx.doi.org/10.2139/ssrn.5145419
- Brief of Amicus Curiae American Intellectual Property Law Association in Support of Affirmance, HIKMA PHARMACEUTICALS USA INC., et al., Petitioners, v. AMARIN PHARMA, INC., et al., Respondents., 2026 WL 917112

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Thank you

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