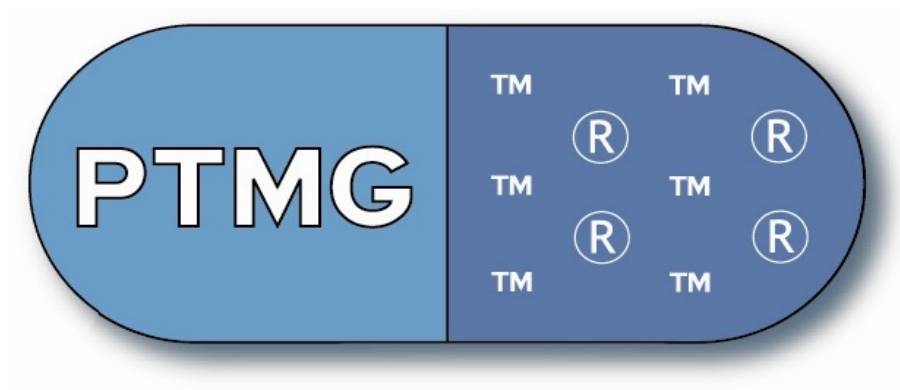




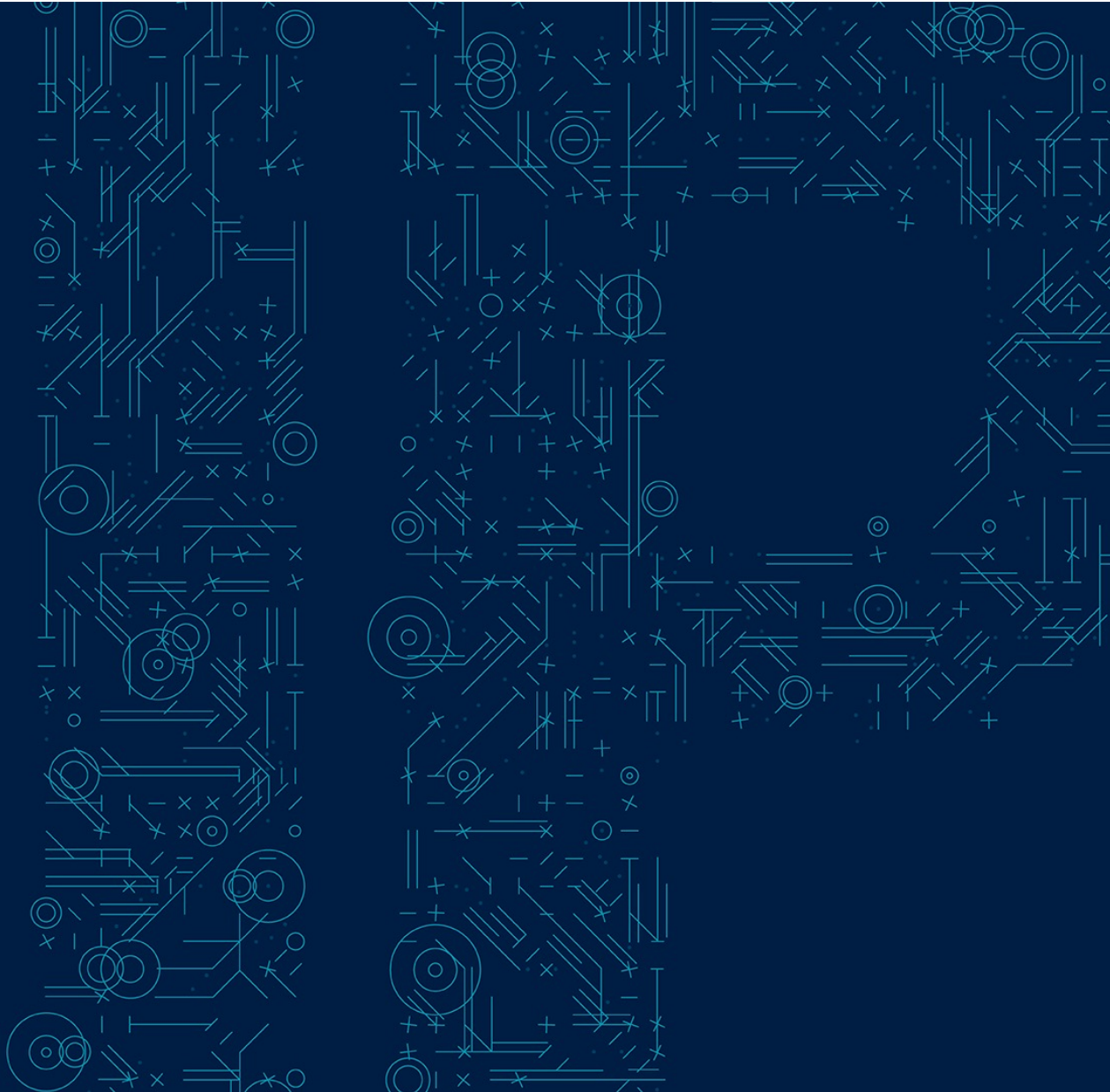
Cynthia Walden

Fish & Richardson

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

Cynthia Walden

FISH.



Agenda

- Background
- The Parties
- Procedural History
- Issues Presented
- The U.S. Supreme Court Decision
- Import of the Decision Outstanding Issues
- Take-Aways



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 **Poll Everywhere**

Join our poll - Scan the QR Code and get ready!



 Edit



Respond at
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 **Poll Everywhere**

What is a 'Skinny Label'?



A/ A tall, narrow label running down the side of a pill bottle

B/ A bare-bones label, showing only the drug name and strength

C/ A generic drug name that carves out patented uses

D/ The approved label for a 'weight loss' medication

A



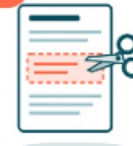
A tall, narrow label running down the side of a pill bottle

B



A bare-bones label showing only the drug name and strength

C



A generic drug label that carves out patented uses

D



The approved label for a weight-loss medication



Edit



Choices



Results



Lock



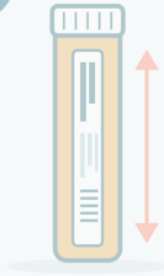
Correctness

Hikma v. Amarin

And the answer is... C

It's about patents — not the label's shape, size, or the drug's purpose

A



A tall, narrow label running down the side of a pill bottle

It's not about shape

B



A bare-bones label showing only the drug name and strength

Not just less info — specific uses removed

C



A generic drug label that carves out patented uses

✓ **Correct!**

D

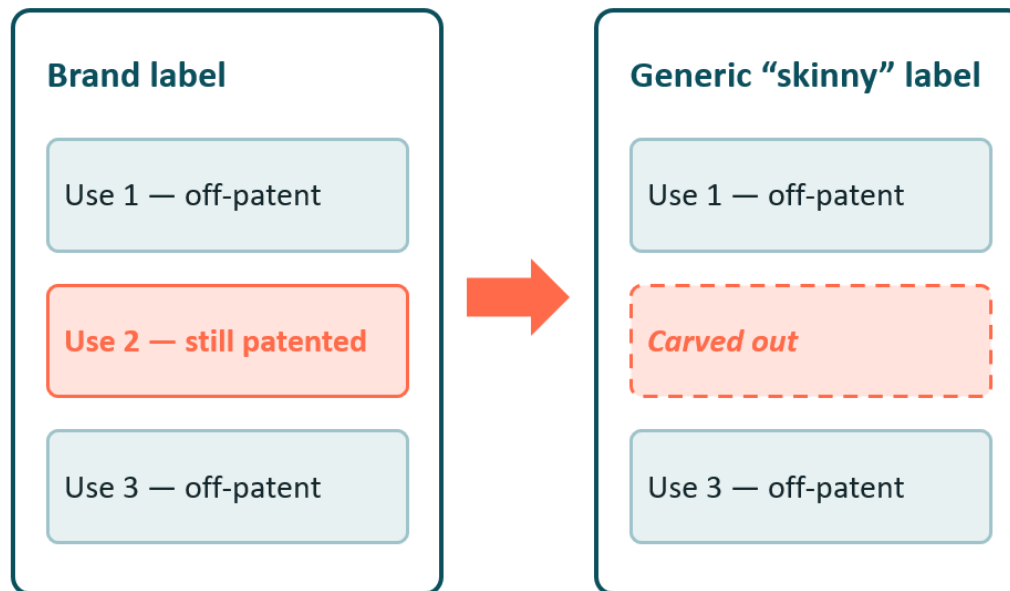


The approved label for a weight-loss medication

Patents, not pounds

Hikma v. Amarin

How a skinny label works



- A generic copies the brand's label, minus the uses still covered by method-of-use patents.
- The generic files a “section viii statement” (21 U.S.C. § 355(j)(2)(A)(viii)) instead of challenging those patents.
- It can launch now for the unpatented uses, bringing lower prices sooner.

Hikma v. Amarin

Generics in the US - Background and Marketplace Realities

- The Hatch-Waxman Act
- Abbreviated New Drug Application (ANDA)
- Use of Skinny Label
- AB rated generics are therapeutically equivalent to brand name when used for labeled indications
- State laws re substitution of AB rated generic alternatives to the brand name product
- Substitution typically happens at the pharmacy level / Direct Infringers are the pharmacists and doctors

Hikma v. Amarin

The Parties

- Amarin Pharma, Inc.

Innovator that developed VASCEPA (icosapent ethyl) which has two indications

2012 – FDA approved VASCEPA, which was the first FDA approved drug to treat severe hypertriglyceridemia and that does not raise LDL-C (the “**SH indication**”); patent later invalidated – **unpatented**

2019 – FDA approved VASCEPA for a second indication to reduce risk of cardiovascular events for patients who are already taking statins (compared to statins alone, 25% reduction in major cardiovascular events)(the “**CV indication**”); **patented**

\$1.1B in sales as of September 2020 / the **CV indication** accounted for roughly 90% of VASCEPA sales

Vascepa[®]
(icosapent ethyl)

Hikma v. Amarin

Amarin Labels

2017 FDA-Approved Label

(sole indication with FDA approval until 12/12/19 was Severe Hypertriglyceridemia)

HIGHLIGHTS OF PRESCRIBING INFORMATION

VASCEPA® (icosapent ethyl) Capsules, for oral use
Initial U.S. Approval: 2012

These highlights do not include all the information needed to use VASCEPA® safely and effectively. See full prescribing information for VASCEPA.

-----INDICATIONS AND USAGE-----

VASCEPA is an ethyl ester of eicosapentaenoic acid (EPA) indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. (1)

Limitations of Use:

- The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined. (1)

- The effect of VASCEPA on cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined. (1)

2019 FDA-Approved Label

(No CV Limitation of Use)

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use VASCEPA® safely and effectively. See full prescribing information for VASCEPA.

VASCEPA® (icosapent ethyl) capsules, for oral use
Initial U.S. Approval: 2012

-----RECENT MAJOR CHANGES-----

Indications and Usage (1)	12/2019
Warnings and Precautions, Atrial Fibrillation/Flutter (5.1)	12/2019
Warnings and Precautions, Bleeding (5.3)	12/2019

-----INDICATIONS AND USAGE-----

VASCEPA is an ethyl ester of eicosapentaenoic acid (EPA) indicated:

- as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and
 - established cardiovascular disease or
 - diabetes mellitus and 2 or more additional risk factors for cardiovascular disease. (1)
- as an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. (1)

Limitations of Use:

- The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined. (1)

Hikma v. Amarin

The Parties

- Hikma Pharmaceuticals USA Inc.
Manufacturer of generic Icosapent Ethyl Capsules

2016 - Hikma submitted an ADNA No. 209457 for generic icosapent ethyl

2020 (bet. January and May) - Hikma supplemented its ANDA with a Section viii statement indicating they would market their drug for one or more methods of use not covered by the Amarin patents, and sought approval for a skinny label that only included the SH indication

2020 (May 21, 2020) - FDA approved the skinny label in 2020 with an AB rating



Hikma v. Amarin

Hikma Label – No CV Limitation of Use

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ICOSAPENT ETHYL CAPSULES safely and effectively. See full prescribing information for ICOSAPENT ETHYL CAPSULES.

ICOSAPENT ETHYL capsules, for oral use

Initial U.S. Approval: 2012

----- RECENT MAJOR CHANGES -----

Warnings and Precautions, Atrial Fibrillation/Flutter (5.1)	12/2019
Warnings and Precautions, Bleeding (5.3)	12/2019

----- INDICATIONS AND USAGE -----

Icosapent ethyl capsules are an ethyl ester of eicosapentaenoic acid (EPA) indicated:

- as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. (1)

Limitations of Use:

- The effect of icosapent ethyl on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined. (1)

Hikma v. Amarin

Hikma Website

Touts AB Rating in the Therapeutic Category “Hypertriglyceridemia” which is broader than the Indications and Usage sections of Hikma’s label which only includes “Severe Hypertriglyceridemia”

Browse our products

Icosapent Ethyl Capsules

Search

Icosapent Ethyl Capsules



Generic Name:

Therapeutic Category:

Rating:

Storage - Safety:

Icosapent Ethyl Capsules

Hypertriglyceridemia

AB

Store at 20° to 25°C (68° to 77°F). See USP Controlled Room Temperature.



BAR CODE

All other trademarks listed herein are the property of their respective owners and are used for illustrative purposes only. These trademark owners are not associated or affiliated with Hikma Pharmaceuticals USA Inc.

Hikma's generic version is indicated for fewer than all approved indications of the Reference Listed Drug.

Product Image	NDC Number	Strength	Unit Size	Package Quantity	Downloads
 ✓	0054-0508-23	1 gram	120 Capsules Per Bottle	PI MS DS	

PI

Package Insert

MS DS

Material Safety Data Sheet

FISH.

fr.com | 13

Hikma v. Amarin

Hikma Press Releases

March 2020 Press Release:

hikma.

Press Release

Hikma confirms favourable ruling in generic Vascepa® patent suit

London, March 31, 2020 – Hikma Pharmaceuticals PLC (Hikma, Group), the multinational generic pharmaceutical company, today confirms that the United States District Court for the District of Nevada has ruled that Hikma's generic version of Amarin Corporation's Vascepa® (icosapent ethyl) 1 gm capsules does not infringe six United States Patents, as asserted by Amarin, because the asserted claims of these patents were held to be invalid.

Hikma is working closely with the U.S. Food and Drug Administration (FDA) to gain approval for its Abbreviated New Drug Application (ANDA) for its generic version of Vascepa®. The company is evaluating its options for launching the product following FDA approval, including an at-risk launch in the event the District Court's decision is appealed.

"We are very pleased with the District Court's decision, which demonstrates our continued ability to successfully litigate to bring greater value to our customers and patients in the US," said Brian Hoffmann, President of Generics, Hikma. "We look forward to providing patients and health care providers in the US with a generic version of this important medicine."

Vascepa® is a prescription medicine that is indicated, in part, as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

According to IQVIA, US sales of Vascepa® were approximately \$919 million in the 12 months ending February 2020.

September 2020 Press Release:

hikma.

Press Release

Hikma receives favourable court ruling for its generic Vascepa®

London, September 3, 2020 – Hikma Pharmaceuticals PLC (Hikma), the multinational pharmaceutical company, announces that the US Court of Appeals for the Federal Circuit today upheld a ruling by the US District Court for the District of Nevada finding that Hikma's generic version of Vascepa®^{®1} (icosapent ethyl) 1gm does not infringe any valid claim of six key Amarin-owned patents. Hikma received FDA approval for the product in May 2020 and is working towards a launch.

Vascepa® is a prescription medicine that is indicated, in part, as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. According to IQVIA, US sales of Vascepa® were approximately \$1.1 billion in the 12 months ending July 2020.

"We are very pleased with the Federal Circuit's swift decision and to be one step closer to launching a generic version of this important medicine for US patients and healthcare providers, helping us to continue putting better health, within reach, every day," said

Brian Hoffmann, President of Hikma Generics. "Today's decision demonstrates Hikma's ability to successfully challenge patents on important medicines and to provide value to our customers and millions of patients across the United States."

Hikma v. Amarin

Timeline and Procedural History

- 2016: Hikma files ANDA and Paragraph IV certification
- 2019: FDA approves VASCEPA's CV indication
- 2020: Hikma pursues a Section viii carve-out and FDA approves Hikma's skinny-label generic
- 2021 - Amarin files suit in District of Delaware; dismissed under Rule 12(b)(6)
- 2024 – Federal Circuit reverses dismissal under an “at least plausible” reading
- June 4, 2026: U.S. Supreme Court unanimously reverses and remands
- On remand. Return to District of Delaware

Hikma v. Amarin

Standard for Evaluating Motion to Dismiss for Failure to State a Claim:

The Twombly/Iqbal “Plausibility” Pleading Standard:

The “plausibility” standard requires a complaint to contain enough factual matter, accepted as true, to state a claim to relief that is plausible on its face. The plausibility standard also requires “more than a sheer possibility” that a defendant acted unlawfully.

Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007)

Ashcroft v. Iqbal, 556 U.S. 662 (2009)

Hikma v. Amarin

Induced Infringement: The Three Requirements

- Direct infringement by another person
- Knowledge that the induced acts constitute infringement
- **Active steps** to encourage the direct infringement*

*The Court incorporated the standard applied in copyright cases in holding that “mere knowledge of infringing potential or of actual infringing uses [is] not ...enough”, and there must be active steps to encourage direct infringement.

Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd., 545 U.S. 913 (2005)

Cox Communications, Inc. v. Sony Music Entertainment, 607 U.S. ___, No. 24-171, slip op. at ____ (U.S. Mar. 25, 2026)

Hikma v. Amarin

Issues Presented:

The central question is whether Amarin plausibly alleged that Hikma actively encouraged infringing uses, not merely whether doctors could plausibly read the alleged statements as instructions to infringe.

- What constitutes active steps and affirmative conduct to induce infringement?
- Did Hikma's various statements, when considered in totality, boost Amarin's lawsuit over the 12(b)(6) hurdle?

Hikma v. Amarin

What Amarin Said Crossed the Line

- The skinny label and patient information leaflet
- Website references to a broad “Hypertriglyceridemia” category
- Press releases calling the product a “generic version of VASCEPA” or “generic VASCEPA”
- References to total VASCEPA sales without separating SH and CV uses
- Alleged knowledge that much of the market related to the patented CV use

What was argued in the Amicus Briefs

Hikma v. Amarin

Amici test the line with hypotheticals

SUPPORTS HIKMA The “in part” catch-22

The Federal Circuit faulted Hikma for saying Vascepa was approved only “in part” for the unpatented use. Had Hikma dropped that qualifier, the government argued:

“it could equally have been faulted for failing to provide sufficient notice”

— United States (Solicitor General), Feb. 2026

SUPPORTS HIKMA The batter at the plate

Telling a batter to make contact isn’t urging a foul ball; likewise, listing a drug under “Hypertriglyceridemia” isn’t urging the patented use.

“Some batted balls go fair, others go foul”

— Association for Accessible Medicines, Feb. 25, 2026

NEITHER PARTY Same words, different setup

Calling the drug a “generic version” of Vascepa may be harmless alone, but placed after a statement that Vascepa is approved for both the CV and SH uses, it may encourage both.

“The crucial point here is that context matters.”

— Intellectual Property Owners Ass’n, Mar. 9, 2026

SUPPORTS AMARIN Targeted outreach

For a drug labeled only for adults, a generic could use neutral materials yet aim its outreach at pediatricians, implicitly encouraging the unapproved use.

“generic manufacturers may still target pediatricians to discuss the drug”

— Sanofi, Mar. 2026

Hikma v. Amarin

Hikma September 2020 Press Release

- Does not state Hikma's generic version should not be used for the CV Indication or that the effect of the of icosapent ethyl on cardiovascular mortality and morbidity had not been determined
- Includes reference to total revenue for VASCEPA (but the majority of which is associated with the CV Indication)
- “Hikma's generic version of Vascepa®” is misleading

hikma.

Press Release

Hikma receives favourable court ruling for its generic Vascepa®

London, September 3, 2020 – Hikma Pharmaceuticals PLC (Hikma), the multinational pharmaceutical company, announces that the US Court of Appeals for the Federal Circuit today upheld a ruling by the US District Court for the District of Nevada finding that Hikma's generic version of Vascepa®¹ (icosapent ethyl) 1gm does not infringe any valid claim of six key Amarin-owned patents. Hikma received FDA approval for the product in May 2020 and is working towards a launch.

Vascepa® is a prescription medicine that is indicated, in part, as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. According to IQVIA, US sales of Vascepa® were approximately \$1.1 billion in the 12 months ending July 2020.

“We are very pleased with the Federal Circuit's swift decision and to be one step closer to launching a generic version of this important medicine for US patients and healthcare providers, helping us to continue putting better health, within reach, every day,” said

Brian Hoffmann, President of Hikma Generics. “Today's decision demonstrates Hikma's ability to successfully challenge patents on important medicines and to provide value to our customers and millions of patients across the United States.”

Hikma v. Amarin

Labels

2019 VASCEPA Label

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use VASCEPA® safely and effectively. See full prescribing information for VASCEPA.

VASCEPA® (icosapent ethyl) capsules, for oral use
Initial U.S. Approval: 2012

RECENT MAJOR CHANGES	
Indications and Usage (1)	12/2019
Warnings and Precautions, Atrial Fibrillation/Flutter (5.1)	12/2019
Warnings and Precautions, Bleeding (5.3)	12/2019

INDICATIONS AND USAGE

- VASCEPA is an ethyl ester of eicosapentaenoic acid (EPA) indicated:
- as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and
 - established cardiovascular disease or
 - diabetes mellitus and 2 or more additional risk factors for cardiovascular disease. (1)
 - as an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. (1)

Limitations of Use:

- The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined. (1)

2020 Hikma Label

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ICOSAPENT ETHYL CAPSULES safely and effectively. See full prescribing information for ICOSAPENT ETHYL CAPSULES.

ICOSAPENT ETHYL capsules, for oral use
Initial U.S. Approval: 2012

RECENT MAJOR CHANGES	
Warnings and Precautions, Atrial Fibrillation/Flutter (5.1)	12/2019
Warnings and Precautions, Bleeding (5.3)	12/2019

INDICATIONS AND USAGE

Icosapent ethyl capsules are an ethyl ester of eicosapentaenoic acid (EPA) indicated:

- as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. (1)

Limitations of Use:

- The effect of icosapent ethyl on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined. (1)

Hikma v. Amarin

Allegation of intent to induce infringement

128. As described above, the totality of Hikma's March 2020 Press Release and September 2020 Press Release, the Hikma Label, and the Hikma Website, instruct, promote, and encourage healthcare providers and patients to administer Hikma's icosapent ethyl capsules just like VASCEPA® including to reduce the risk of CV events per the CV Indication awarded to VASCEPA®.

129. On information and belief, Hikma knew that when an AB-rated generic drug is available, many pharmacies and/or third party payers of prescription drugs (e.g., health insurance plans, Medicare and Medicaid programs) have adopted policies that encourage or require the substitution of the AB-rated generic drugs for the branded drugs, regardless of whether the generic drug label includes all the indications in the branded drug labeling. Some (but not all) states have similar policies. As a result, on information and belief, Hikma knew and intended that its generic product would be substituted for all VASCEPA® prescriptions, not just the prescriptions directed to the Severe Hypertriglyceridemia Indication.

Hikma v. Amarin

The Supreme Court's Holding

- Amarin alleged no more than a “sheer possibility” of active inducement
- The question is what Hikma actively communicated—not merely whether a doctors could plausibly read the alleged statements as instructions to infringe
- Active steps to encourage infringement require “purposeful, culpable expression and conduct”
- Encouragement must be **affirmative** and **clear to the relevant audience**
- FDA-compliant labeling and ordinary generic-identification language did not supply the missing affirmative step
- Judgment reversed; case remanded

Hikma v. Amarin

The Supreme Court's Holding – Affirmative Steps Required

This case requires us to apply these familiar pleading standards to the third element of an induced-infringement claim: that the inducer took “active steps . . . to encourage direct infringement.” *Grokster*, 545 U. S., at 936 (internal quotation marks omitted).² Our case law defining “active steps” thus governs the boundaries of a plausible induced-infringement claim. Most fundamentally, “inducement must involve the taking of affirmative,” as opposed to passive, “steps to bring about the desired result” of patent infringement. *Global-Tech.*, 563 U. S., at 760; see also *Grokster*, 545 U. S., at 935 (requiring “statements or actions directed to promoting infringement”); *Cox Communications*, 607 U. S., at ___ (slip op., at 9) (citing lack of “evidence of express promotion [or] marketing” as a reason for no liability (internal quotation marks omitted)). To avoid “trenching on regular commerce,” “ordinary acts incident to product distribution” are insufficient to support liability. *Grokster*, 545 U. S., at 937.

Given these standards, Amarin misses the mark in arguing that it need not do more than “allege . . . a plausible chain of events through which statements made by [Hikma] could lead a healthcare provider . . . to prescribe or dispense Hikma’s drug to reduce a patient’s cardiovascular risk.”

Hikma v. Amarin

The Supreme Court's Holding – Failure to Allege “more than a sheer possibility”

All in all, inducement cannot be based only on “vague” language “combined with speculation about how [others] may act.” *Takeda Pharmaceuticals U. S. A., Inc. v. West-Ward Pharmaceutical Corp.*, 785 F. 3d 625, 632 (CA Fed. 2015); see also *Grokster*, 545 U. S., at 937 (requiring “purposeful, culpable expression and conduct”). That said, Hikma overshoots by urging that active inducement must be “express.” See Reply Brief 22–23. A defendant can achieve active inducement through implicit encouragement, as StreamCast did through the “suggestiv[e]” name of its “OpenNap program.” *Grokster*, 545 U. S., at 937, 938. But implicit or explicit, the necessary inducement must be “clear” to the relevant audience and “affirmative.” See *id.*, at 937.

III

Applying these standards to the complaint here, Amarin fails to allege “more than a sheer possibility” that Hikma actively induced infringement of Amarin’s CV-indication patents. *Iqbal*, 556 U. S., at 678. Amarin’s allegations, whether viewed together or separately, fail to establish that Hikma took any affirmative steps to encourage infringement.

Hikma v. Amarin

Why the Alleged Statements Were Insufficient

- **“Generic version”**: ordinary, truthful identification of the reference drug
 - **AB rating**: equivalence only when used according to labeling
 - **Sales figures**: commercial context, but no instruction to practice the CV method
 - **Label and leaflet**: omissions or required language were not affirmative encouragement
 - **Totality**: combining non-inducing acts did not create a plausible inducement claim
-
- The court rejected the Federal Circuit’s audience-perception trend and distinguished *GlaxoSmithKline v. Teva*, 7 F.4th 1320 (Fed. Cir. 2021)

Hikma v. Amarin

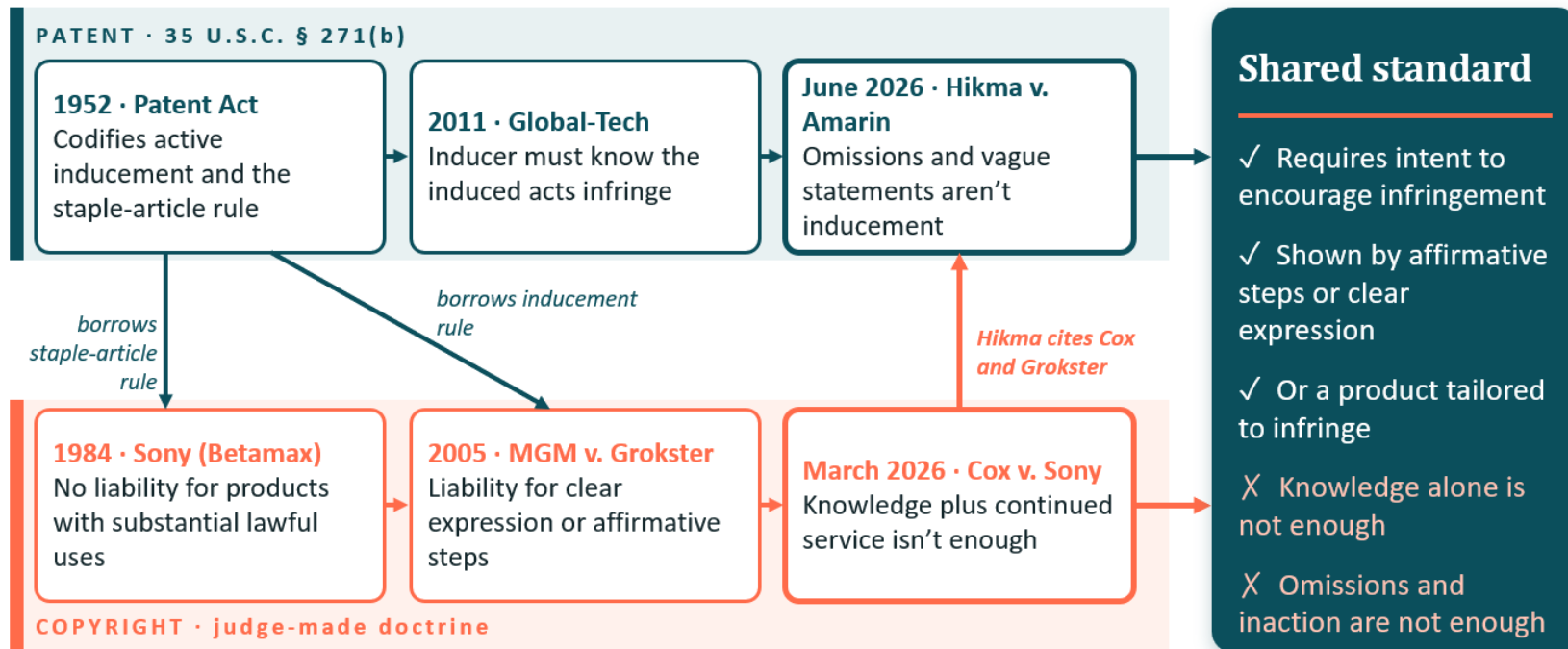
Import of the Decision

- **Active, affirmative steps are required to prove induced patent infringement**
Affirmative conduct does not have to be express, implicit encouragement can suffice if it is clear to the relevant audience and affirmative in nature.
- **Omissions, neutral statements, or ambiguous language are insufficient**
- **Ordinary commercial behavior, such as truthful “generic equivalent” statements, the use of AB ratings, and broad therapeutic classification language is, without more, unlikely to support liability.**
- **Inducement claims will likely be harder to plead and face more scrutiny following this decision.**

Hikma v. Amarin

Import of the Decision

Patent and copyright liability converge



Hikma v. Amarin

How do Lanham Action claims fit in?

The Lanham Act Asks Different Questions

- § 43(a)(1)(A): likely confusion about affiliation, sponsorship, or approval
- § 43(a)(1)(B): false or misleading commercial advertising about goods

How does this align with the defense of Nominative Fair Use?

Hikma v. Amarin

The Guardrails: POM Wonderful, Nominative Use, and Dastar

- *POM Wonderful*: FDA regulation does not automatically displace competitor Lanham Act claims
- But the Lanham Act cannot become a private vehicle to enforce the FDCA
- Using VASCEPA to identify the reference drug may be legitimate nominative use
- Risk increases when brand use is unnecessarily prominent or implies endorsement or full-use approval
- *Dastar*: trademark law cannot recreate patent-like exclusivity over an unprotected product or idea

POM Wonderful LLC v. Coca-Cola Co., 537 U.S. 102 (2014)

Dastar Corp. v. Twentieth Century Fox Film Corp., 539 U.S. 23 (2003)

Hikma v. Amarin

Potential Repercussions of Dicta

- Amarin also finds fault in Hikma's statements describing its product as 'generic Vascepa' or the 'generic equivalent' of Vascepa in the prelaunch press releases. But as we have explained, **it is 'normal industry practice' to 'truthfully describe' a generic drug as 'equivalent' to the brand-name comparator.** See *Inwood Laboratories*, 456 U. S., at 847–848; §353d(a)(3) (defining the term 'generic version' as 'a drug approved under [§355] whose reference listed drug is a covered drug')."
- We decline to put generic manufacturers between a rock and a hard place by turning adherence to the law and industry standards into building blocks for illegal conduct.

Hikma v. Amarin

Questions the Decision Leaves Open

- How explicit must encouragement be—and can context make an implicit message clear?
- Can post-launch field conduct cure pleading deficiencies based on public statements?
- When does an omission become part of an affirmative misleading communication?
- How should courts treat algorithmic targeting, formulary messaging, and indication-blind substitution?
- Where is the line between high-volume lawful sales and purposeful cultivation of patented use?
- What role remains for state unfair-competition or Lanham Act claims?

Core tension: Conduct insufficient to encourage infringement may still create a misleading marketplace impression.

Hikma v. Amarin

What is next in this case?

- **Remand**
- **Possibility to replead with more specific reference to affirmative steps**
- **Possibility to include Lanham Act claim**



Respond at
pe.app/**ptmgprague**

 **Poll Everywhere**

Which statement crosses the line...?

After Hikma, which generic statement is most likely to support an inducement claim?

A/ Press release: "The AB-rated generic equivalent of [Brand]"

B/ Label identical to the brand's except, the carved out use

C/ Website says nothing about the patented use and has no disclaimer

D/ Sales sheet to cardiologists: 'Cuts heart-attack risk, just like [Brand]'



Edit

☒ Choices

☒ Results

☐ Lock

☐ Correctness

Hikma v. Amarin

Poll 2 answer: D

After Hikma, which generic statement is most likely to support an inducement claim?



Press release: “the AB-rated generic equivalent of [Brand]”

Truthful equivalence claim: too vague



Label identical to the brand’s, except the carved-out use

Required by FDA’s sameness rule



Website says nothing about the patented use and has no disclaimer

Silence and omissions don’t induce



Sales sheet to cardiologists: “cuts heart-attack risk, just like [Brand]”

✓ Clear, affirmative push toward the patented use



Respond at
pe.app/**ptmgprague**

 **Poll Everywhere**

How implicit is too implicit?

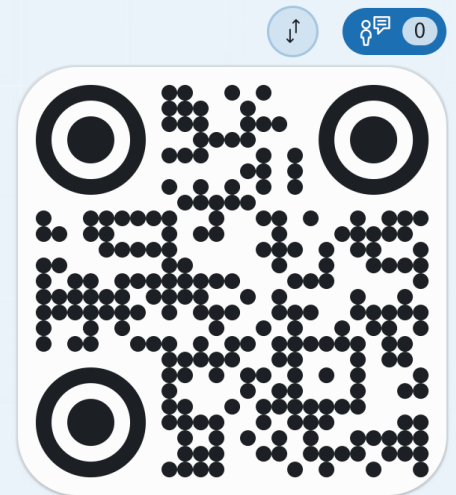
The Court said encouragement can be implicit if it is clear. Which conduct comes closest?

A/ Press release cites the brand's total sales, including the patented use

B/ Mailer to cardiologists summarizing the brand's patented-use trial, with the generic's logo

C/ Pricing well below the brand to win substitution at pharmacies

D/ Selling to the same wholesalers and pharmacies the brand uses



Edit

☒ Choices

☒ Results

☐ Lock

☐ Correctness

Hikma v. Amarin

Poll 3 answer: B

The Court said encouragement can be implicit if it is clear. Which conduct comes closest?



Press release cites the brand's total sales, including the patented use

Like Hikma's facts: not enough



Mailer to cardiologists summarizing the brand's patented-use trial, with the generic's logo

✓ **No words of instruction, but the message is clear**



Pricing well below the brand to win substitution at pharmacies

Ordinary price competition



Selling to the same wholesalers and pharmacies the brand uses

Regular commerce, not inducement



Respond at
pe.app/**ptmgprague**

Poll Everywhere

Does this ad induce?

Would this statement plausibly allege inducement under Hikma v. Amarin?



A/ Yes: clear, affirmative promotion of the carved-out patented use

B/ No, it's just a truthful generic-equivalence statement

C/ No: vague marketing that needs speculation about doctors

D/ No: only statements to the FDA-Approved label can induce



Edit

HYPOTHETICAL GENERIC AD



**“Delivers VASCEPA’s
proven cardiovascular-
risk reduction”**

*Generic icosapent ethyl capsules · label carves out
the CV indication*

☒ Choices

☒ Results

☐ Lock

☐ Correctness

Hikma v. Amarin

Poll 4 answer: A

Would this statement plausibly allege inducement under *Hikma v. Amarin*?

HYPOTHETICAL GENERIC AD



**“Delivers VASCEPA’s
proven cardiovascular-
risk reduction”**

*Generic icosapent ethyl capsules · label carves out
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A

Yes: clear, affirmative promotion of the carved-out patented use

✓ **Names the patented use and invites it**

B

No: it’s just a truthful generic-equivalence statement

It goes beyond equivalence to the CV use itself

C

No: vague marketing that needs speculation about doctors

Nothing vague: it targets the carved-out use

D

No: only statements on the FDA-approved label can induce

Ads and sales materials count too

Hikma v. Amarin

Would the following claims form the basis for a Lanham Action claim?

VASCEPA displayed as the dominant headline, with Amarin-like colors and packaging cues

Amarin's logo appears beside "preferred partner" or "authorized CV alternative"

A payor deck uses VASCEPA trade dress and says "same brand outcomes, lower cost"

Hikma v. Amarin

What a Plausible Winning Complaint Would Plead

- The exact commercial statement, image, placement, and dissemination channel
- The relevant audience and the specific false or misleading takeaway
- Why the message concerns the carved-out indication—not merely product identity
- Materiality to prescribing, dispensing, formulary, or purchasing decisions
- Evidence of deception: surveys, customer reactions
- Proximate injury: reputational harm, price erosion

Hikma v. Amarin

Action Items for Brand-Side Counsel

- Expect increased skinny label entry and higher pleading bar for enforcement
- Conduct thorough pre-suit investigation to minimize chances of dismissal
- Monitor marketing, websites, press releases, payer materials, sales aids, etc.
- Catalog every channel where an equivalence claim appears without an indication of scope disclaimer

Hikma v. Amarin

Takeaways

- *Hikma* requires clear, affirmative encouragement to infringe —not foreseeability, ambiguity, or omission alone
- The question is not whether the generic's statements could mislead, but whether you can document the generic actively encouraging infringing use
- Lanham Act analysis turns on the message conveyed, materiality, confusion, and commercial injury
- Strong claims target separate promotion that falsely expands approval, efficacy, substitutability, or affiliation

Thank You!



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