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Hikma v. Amarin Supreme Court Decision – Induced Infringement, FDA Approval, and Access to Affordable Medicine

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FDA DRUG APPROVAL PROCESS

New Drugs:

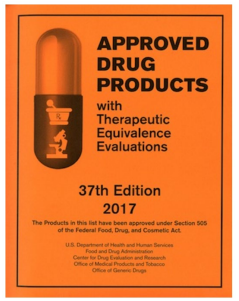
Investigational New Drug (IND): allows a drug manufacturer to **initiate clinical studies**

New Drug Application (NDA): an application to market a new drug in the US, requires preclinical & clinical data to **establish safety & effectiveness**

Brand Drugs or Reference Listed Drugs (RLDs): Approved NDA

THE ORANGE BOOK

The Orange Book: "*Approved Drug Products with Therapeutic Equivalence Evaluations*"



- Lists approved small molecule drugs (NDAs & ANDAs)
- Includes patents covering the **Drug Product**:
  - **Compound Patents**
  - **Formulation Patents**
  - **Medical Use Patents**
    - only those which claim 'approved' uses
- Lists FDA Exclusivities

FDA DRUG APPROVAL PROCESS

Generic Drugs: Equivalence Testing → ANDA

Comparable to an approved drug in dosage form, strength, route of administration, quality performance characteristics, & intended use.

- **Abbreviated New Drug Application (ANDA):** an application to market a drug product that is **bioequivalent** to an approved drug
- **State Substitution Laws:** All states have substitution laws that allow or require substitution of generic for brand

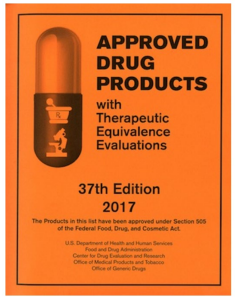
PATENT CERTIFICATIONS

Generic Applicant must make one of the following certifications as to each patent in the Orange Book:

- **Paragraph I:** no patent is listed in the Orange Book
- **Paragraph II:** listed patent(s) expired
- **Paragraph III**: approval not sought before listed patent will expire
- **Paragraph IV:** listed patent is invalid or will not be infringed by marketing the generic
- **Section viii Statement**: listed patent does not claim a use for which the applicant is seeking approval

SECTION VIII CARVE-OUT (SKINNY LABEL)

- The Orange Book Contains "Use Codes" for Method Patents



Product 001
ZOLEDRONIC ACID (RECLAST) INJECTABLE EQ 5MG BASE/100ML

Patent Data

Product No	Patent No	Patent Expiration	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	7932241	02/05/2028	DP			05/25/2011
001	7932241*PED	08/05/2028				
001	8052987	10/27/2023		U-1199	TREATMENT AND PREVENTION OF POSTMENOPAUSAL OR GLUCOCORTICOID-INDUCED OSTEOPOROSIS AND TREATMENT TO INCREASE BONE MASS IN MEN WITH OSTEOPOROSIS	

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration

There is no unexpired exclusivity for this product in the Orange Book database.

https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm

SECTION VIII CARVE-OUT (SKINNY LABEL)

- **Example: Reclast®**
  - **Use Code:** TREATMENT AND PREVENTION OF POSTMENOPAUSAL OR GLUCOCORTICOID-INDUCED OSTEOPOROSIS AND TREATMENT TO INCREASE BONE MASS IN MEN WITH OSTEOPOROSIS

RLD Label

Reclast® (zoledronic acid) Injection
Initial U.S. Approval: 2001

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

Reclast is a bisphosphonate indicated for:
- Treatment and prevention of postmenopausal osteoporosis (1.1, 1.2)
- Treatment to increase bone mass in men with osteoporosis (1.3)
- Treatment and prevention of glucocorticoid-induced osteoporosis (1.4)
- Treatment of Paget's disease of bone in men and women (1.5)

Limitations of Use
Optimal duration of use has not been determined. For patients at low-risk for fracture, consider drug discontinuation after 3 to 5 years of use (1.6)

Generic Label

Zoledronic Acid Injection
Initial U.S. Approval: 2005

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

Reclast is a bisphosphonate indicated for:
- ~~Treatment and prevention of postmenopausal osteoporosis (1.1, 1.2)~~
- ~~Treatment to increase bone mass in men with osteoporosis (1.3)~~
- ~~Treatment and prevention of glucocorticoid-induced osteoporosis (1.4)~~
- Treatment of Paget's disease of bone in men and women (1.5)

Limitations of Use
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PATENT INFRINGEMENT

- **Direct infringement**
  - Making, using, offering to sell, or selling any patented invention, in the United States, or
  - Importing into the United States

- **Indirect infringement**
  - **Inducement – actively causing another to infringe**
  - Contributory – selling an item that another uses to infringe a patent claim

35 U.S.C. § 271

INDUCED INFRINGEMENT

- Direct infringement by a third party
- Knowledge that induced acts constitute patent infringement
- **Active steps to encourage direct infringement**
  - Affirmative not passive steps
  - Ordinary acts related to product distribution not enough

Hikma v. Amarin, No. 24-889, slip op. at 4-5, 8 (U.S. June 4, 2026); 35 U.S.C. § 271(b)

HIKMA V. AMARIN – AMARIN LABEL

- Amarin drug – Vascepa (icosapent ethyl)
- 2012 – approved for severe hypertriglyceridemia (SH indication)
  - Limitation language - Effect on cardiovascular mortality and morbidity in patients with SH has not been determined
  - Hikma filed an ANDA and invalidated patents to SH indication
- 2019 – Before invalidation, second indication was added – reduce cardiovascular risk in hypertriglyceridemia patients who are also taking statins (CV Indication)
  - CV patents added to Orange Book
  - The limitation language was removed

Hikma v. Amarin, No. 24-889, slip op. at 5 (U.S. June 4, 2026)

HIKMA V. AMARIN – HIKMA LABEL

- Hikma filed a Section viii Statement to CV indication (skinny label)
  - Removed the limitation language

- ANDA approved with skinny label and AB rating (therapeutically equivalent to Vascepa)

- Hikma began marketing with skinny label

Hikma v. Amarin, No. 24-889, slip op. at 6 (U.S. June 4, 2026)

AMARIN – INDUCED INFRINGEMENT

- Amarin sues for induced infringement of CV method patents
  - Skinny label – omitted limitation and clinical study (some patients taking with statins)
  - Patient information leaflet – warned against side effects for patients with heart disease
  - Hikma website – AB rated and therapeutical category as "hypertriglyceridemia" – broader than SH indication
  - Press releases – "generic Vascepa" and Vascepa's sale figures from both indications

Hikma v. Amarin, No. 24-889, slip op. at 6-7 (U.S. June 4, 2026)

PATH TO SUPREME COURT

- District Court granted Hikma's motion to dismiss
  - Hikma's activities did not constitute induced infringement

- Federal Circuit reversed
  - Hikma's skinny label standing alone – no infringement
  - Physician could read label, website, and press releases as instruction or encouragement to prescribe for CV indication

Hikma v. Amarin, No. 24-889, slip op. at 7 (U.S. June 4, 2026)

AMARIN'S ARGUMENTS

- First Amendment case (*National Rifle Association of America v. Vullo*, 601 U.S. 175 (2024))
  - Amarin – induced infringement requires that conduct be "reasonably understood" to convey using for patented method
  - Court dismisses as not applicable because statute expressly requires "active inducement"
- *Grokster* case (*Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913 (2005))
  - "Advertisement or solicitation that broadcasts a message designed to stimulate others to commit violations"
  - Court - Designed is a subset of "could" and "could" is not sufficient

Hikma v. Amarin, No. 24-889, slip op. at 9-10 (U.S. June 4, 2026)

COURT'S INDUCED INFRINGEMENT STANDARD

- Vague language combined with how others may act is not sufficient
- Express language is not required – implicit encouragement is sufficient
- KEY – It must be "clear" and "affirmative"
- Federal Circuit trend – whether the label "could be read" as instructions to infringe – Court rejects this trend
  - Key Question – Did defendant actively encourage infringement through its statement?
  - Not how others may understand those statement

Hikma v. Amarin, No. 24-889, slip op. at 9-10 (U.S. June 4, 2026)

COURT'S HOLDING AND REASONING

- Hikma did not take any affirmative steps to encourage infringement
- Obvious alternative explanations – complying with law or standard industry practice should not be illegal conduct
  - Label – Hikma's label had to be identical to Amarin's except for carved-out indication – so limiting language had to be deleted
  - "Generic Vascepa" – normal industry practice and truthful that generic is equivalent
- Omissions are not sufficient
  - Limiting language
  - Press release failure to mention Hikma only approved for SH indication

Hikma v. Amarin, No. 24-889, slip op. at 11-12 (U.S. June 4, 2026)

COURT'S HOLDING AND REASONING (CONT'D)

- Patient information leaflet
  - Amarin – the leaflet encourages infringement because it identifies side effects for people with cardiovascular diseases
  - Court – this is passive not active and plausibly understood to infringe is not sufficient
  - If anything, this statement is warning patients against patented use
- Hikma's website – "AB" rated and "hypertriglyceridemia" therapeutic category
  - "Cancer drug" would not mean you induce a patented use for a specific type of cancer
  - "AB" means product is equivalent – consistent with label with carved-out CV indication
- Sales figures – vaguest of vague
  - Directed to investors not medical providers

Hikma v. Amarin, No. 24-889, slip op. at 13-14 (U.S. June 4, 2026)

IMPLICATIONS

- More clarity for generic providers
- Keeps skinny label strategy intact
- Prevents wrongful use of patents
- Earlier access to generic medication
- Broader non-pharma implications

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