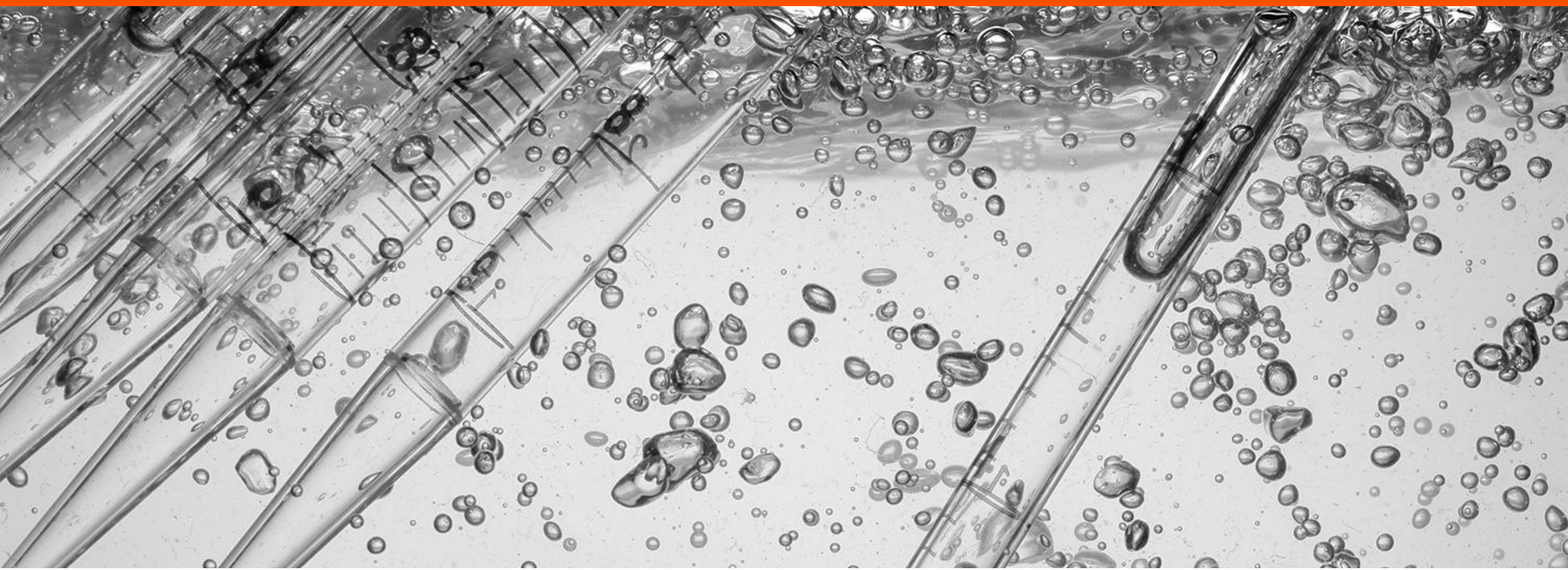




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Observations and Impact of US Pharma Patent Litigation

Zhibin Li, Ph.D., Shareholder; Ling Zhong Ph.D., Shareholder

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Hatch-Waxman Litigation (ANDA Litigation)

- **Notice Letter and Pleadings (3-5 months)**
- **Fact Discovery (8-12 month)**
 - Documents collection, production, and review
 - Contentions – noninfringement and/or invalidity bases
 - Depositions – examination of witnesses
 - **Markman proceeding**
- **Expert Discovery (4-7 month)**
 - Facts gathered during discovery
 - Experience in the field
- **Pretrial and Trial (1-3 months)**
 - Most of the ANDA cases are litigated in the District of New Jersey or the District of Delaware
- **Appeal**

District Court Litigation normally last 24 months – due to 30-month stay

Ben Venue Labs., Inc. v. Novartis Pharm. Corp., 146 F. Supp. 2d 572, 579 (D.N.J. 2001) (“[T]he purpose of the 30-month stay is...to create an adequate window of time during which to litigate the question of whether a generic will infringe the patented product, without actually having to introduce the generic product to the market.”)

Entresto (sacubitril/valsartan) (沙库巴曲缬沙坦)

In 2024, Entresto generated \$7.82 billion (U.S. Sales: \$4.05 billion) in global revenue for Novartis, achieving a 31% year-over-year growth

In 2025, Entresto generated \$7.75 billion (U.S. Sales: \$3.29 billion) in global revenue for Novartis, a slight 1% decline compared to 2024

In July/August 2025, generic sacubitril/valsartan products entered the U.S. market

- Q3 2025, Novartis's U.S. sales \$798 million, a 12.5% decrease year-over-year
- Q4 2025, Novartis's U.S. sales \$95 million, a 92.4% decrease year-over-year

Novartis's Patent and Citizen Petition Strategies

In 2022, eight Orange-Book listed patents (4 patent families)

- **Combination patents:** 8,101,659 (expiry 7/15/2025); 8,796,331 (expiry 7/14/2023)
- **Cocrystal patents:** 8,877,938 (expiry 11/27/2027); 9,388,134 (expiry 5/8/2027)
- Method of treating patents: 9,517,226; 9,937,143; 11,135,192 (all expiry 8/22/2033)
- Dosing regimen patent: 11,058,667 (expiry 5/9/2036)

One non-Orange-Book listed patent

- Amorphous patent: 11,096,918 (expiry 11/8/2026)

Citizen Petition

- 2019/2021 Petitions – requested that the FDA reject any generic version that did not present the active ingredients in the exact singular salt/co-crystal complex structure as Entresto
- September 2022 Petition – requested that the FDA reject any generic version that utilized "label carve-outs"

Entresto ANDA Filers

18 ANDA Applicants (first filers; date of submission July 8, 2019)

- Each ANDA filers may have different noninfringement strategies
 - Impact claim construction
 - Impact expert opinions
- All ANDA filers do share common invalidity position
 - Based on their unique noninfringement positions, each ANDA filer may want to focus on different invalidity position

Strategic collaboration within a joint defense group

- Forming a joint defense group (joint defense agreement)
- Joint defense meeting and divide the action items
- What would be the best for your client?

Entresto Litigation Landscape

District of Delaware Litigations (ANDA litigations)

- *In re: Entresto (Sacubitril/Valsartan) Patent Litigation*, 1:20-md-02930 (D. Del. Mar 27, 2020)
- *Novartis v. Torrent Pharma Inc.*, 23-02218 (Fed. Cir. Jul 31, 2023) (Combination - '659 patent)
 - *MSN Pharms., Inc. v. Novartis Pharms. Corp.*, 146 S. Ct. 983, 223 L. Ed. 2d 425 (2025) (Petition for *writ of certiorari* denied)
- *Novartis v. MSN Pharmaceuticals, Inc.*, Docket No. 25-01927 (Fed. Cir. Jul 14, 2025) (amorphous - '918 patent)
- *Novartis v. MSN Laboratories Private Limited*, Docket No. 25-81 (D. Del. Jan 17, 2025) (Damage case for MSN's manufacturing/importation of ANDA products during the term of the '659 patent)

District of New Jersey Litigation (Trademark/Trade dress litigation – MSN only)

- *Novartis AG et al v. Novadoz Pharmaceuticals LLC et al*, 2:25-cv-00849 (D.N.J. Jan 30, 2025)

District of Columbia Litigation (FDA/Regulatory litigation – section viii carve-out) (Dosing regimen)

- *Novartis v. Becerra et al*, 1:24-cv-02234 (D.D.C. Jul 30, 2024)
- *Novartis v. Robert F. Kennedy Jr., et al*, Docket No. 24-05235 (D.C. Cir. Oct 15, 2024)

'659 patent *Markman* (claim term)

■ '659 patent claim 1

1. A pharmaceutical composition comprising:

- (i) the AT 1-antagonist valsartan or a pharmaceutically acceptable salt thereof;
- (ii) the NEP inhibitor [sacubitril²] or [sacubitrilat³] or a pharmaceutically acceptable salt thereof; and
- (iii) a pharmaceutically acceptable carrier;

wherein said (i) AT 1-antagonist valsartan or a pharmaceutically acceptable salt thereof *and said (ii)* NEP inhibitor [sacubitril] or [sacubitrilat] or a pharmaceutically acceptable salt thereof, *are administered in combination* in about a 1:1 ratio.



'659 patent *Markman* (constructions)

- Parties' proposed construction

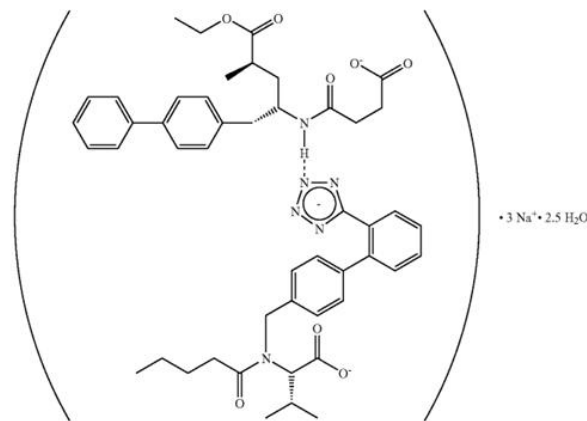
“wherein said (i) ... and said (ii) ... are administered in combination”
(’659 Patent, claim 1)

Novartis’s Proposal	Defendants’ Proposal
wherein said (i) ... and said (ii) ..., are administered in combination	wherein said (i) . . . and said (ii) . . . are administered in concert as two separate components

- Not all defendants actively participated in construction of this term

’938 Patent:

1. *Trisodium [3-((1*S*,3*R*)-1-biphenyl-4-ylmethyl-3-ethoxycarbonyl-1-butylcarbamoyl)propionate-(*S*)-3'-methyl-2'-(pentanoyl{2''-(tetrazol-5-ylate)biphenyl-4'-ylmethyl}amino)butyrate] hemipentahydrate in crystalline form.*



'659 patent *Markman* (Parties' brief)

Novartis's position

- . . .
- The '659 patent need not describe trisodium [sacubitril-valsartan] hemipentahydrate to cover that compound
- The '659 patent need not enable trisodium [sacubitril-valsartan] hemipentahydrate

Defendants' position

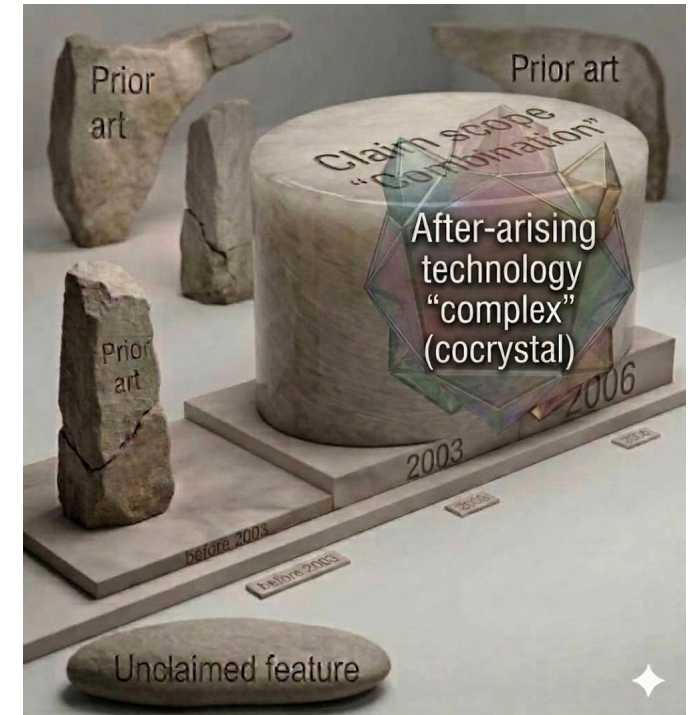
- . . .
- Novartis's statements confirm the "combination" of the '659 patent requires separate components, and that a complex is not sufficiently disclosed or enabled
- *MagSil Corp. v. Hitachi Glob. Storage Techs., Inc.*, 687 F.3d 1377, 1381 (Fed. Cir. 2012) (holding that the enablement "doctrine prevents both inadequate disclosure of an invention and overbroad claiming that might otherwise attempt to cover more than was actually invented. Thus, a patentee chooses broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage.").

'659 patent *Markman* (Judge Stark's Opinion and Order)

- Court adopted Novartis's construction

Defendants further contend that Plaintiff's construction will render the claims invalid.

(See D.I. 253 at 20-21, 39-40) Novartis admits that its two patents “do not disclose or suggest” a one-unit-dose-form embodiment. (See *id.* at 39) This seems to be an admission by Novartis that, at the very least, there will be a non-frivolous issue of written description and/or lack of enablement as this case proceeds on Novartis's preferred construction. See generally *Ruckus Wireless, Inc. v. Innovative Wireless Sols., LLC*, 824 F.3d 999, 1004 (Fed. Cir. 2016). At this point, the Court has no basis to believe that the construction it is adopting is necessarily consigning the asserted claims to a judgment of invalidity. Since this construction is otherwise supported, the Court will adopt it. See, e.g., *Phillips*, 415 F.3d at 1327 (“While we have acknowledged the maxim that claims should be construed to preserve their validity, we have not applied that principle broadly, and we have certainly not endorsed a regime in which validity analysis is a regular component of claim construction.”).



'659 patent Validity (Judge Andrew's Opinion on Written Description)

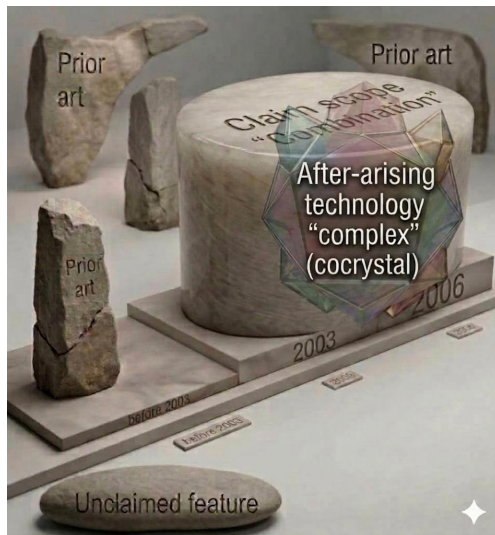
- “The touchstone of written description is possession as of the priority date. See *Chiron*, 363 F.3d at 1255 (explaining that ‘[t]he function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him.’) (quoting *In re Wertheim*, 541 F.2d 257, 262 (CCPA 1976)).” *In re Entresto (Sacubitril/Valsartan) Pat. Litig.*, 2023 WL 4405464, at *21 (D. Del. July 7, 2023).
- “Plaintiff's trouble is that written description also requires that common structural features be described ‘with enough precision that a relevant artisan can visualize or recognize the members of the genus.’ *Regents of the University of Minnesota v. Gilead Sciences, Inc.*, 61 F.4th 1350, 1356 (Fed. Cir. 2023) (citing *Ariad*, 598 F.3d at 1350–52). ‘A broad outline of a genus's perimeter is insufficient.’” *Id.* at 22.
- **“The common features that Plaintiff identifies—sacubitril and valsartan—draw a fence around a genus that includes both complexes and physical mixtures of valsartan and sacubitril. But the '659 Patent specification describes physical mixtures only.** The specification did not, and could not, have allowed a POSA to visualize the members of the entire genus sufficient to show possession of complexes, which, to a POSA's knowledge, had not yet been discovered. See *Chiron*, 363 F.3d at 1255.” *Id.* at 22.

Fed. Cir. Reversed – Written Description

- “The issue is not whether the ’659 patent describes valsartan-sacubitril complexes. Because the ’659 patent does not claim valsartan-sacubitril complexes, those complexes need not have been described.” *In re Entresto*, 125 F.4th 1090, 1097 (Fed. Cir. 2025).
- **“A specification adequately describes an invention when it ‘reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.’** The fact that the ’659 patent does not describe a complexed form of valsartan and sacubitril does not affect the validity of the patent. That complex—not discovered until four years after the priority date of the ’659 patent—is not what is claimed.” *Id.* at 1097-1098.

Did the Fed. Cir. address the claim scope?

- “after claim construction, MSN stipulated to infringement of the as-construed claims.⁵ In light of that stipulation and the fact that the ’659 patent does not claim valsartan-sacubitril complexes, any further issue regarding such complexes is not before us.” *Id.* at 1099.
 - fn. 5: **To the extent MSN maintains that the claims were construed to claim valsartan-sacubitril complexes** (i.e., to the extent MSN alleges that its stipulation of infringement was made on that basis), **that construction would have been error**. “Claim interpretation requires the court to ascertain the meaning of the claim to one of ordinary skill in the art at the time of invention.” *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1338 (Fed. Cir. 2005) (emphasis added); see *Phillips*, 415 F.3d at 1313. Because valsartan-sacubitril complexes were undisputedly unknown at the time of the invention, see Decision, at *20, the ’659 patent could not have been construed as claiming those complexes as a matter of law.



VS.



(*In re Entresto*, 125 F.4th 1090, 1099, fn. 5 (Fed. Cir. 2025).)

The Supreme Court denied the *writ of certiorari*

MSN's petition: "The question presented is: Whether, in a patent-infringement suit, a court may consider after arising technology to hold that the patent is invalid under § 112(a) of the Patent Act."

- The Idenix Line: Decisions holding that after-arising technology is relevant to validity, and that ensnaring after-arising technology for infringement risks invalidity. *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149 (Fed. Cir. 2019).
- The Hogan-Entresto Line: Decisions holding that after-arising technology is irrelevant to validity, and that **ensnaring after-arising technology** for infringement does not risk invalidity. *In re Hogan*, 559 F.2d 595 (C.C.P.A. 1977).
- The Schering Line: Decisions narrowly construing patents to exclude after-arising technology and finding no infringement. *Schering Corp. v. Amgen Inc.*, 222 F.3d 1347, 1353 (Fed. Cir. 2000).
- The SuperGuide Line: Decisions broadly construing patents to cover after-arising technology and finding infringement. *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 876 (Fed. Cir. 2004)

Seven *amicus curiae* briefs in support of MSN's Petition

Novartis waived right to respond; the Supreme Court requested Novartis to respond; Novartis filed a brief arguing the fact patterns are different from the lines of cases cited by MSN

- *Yancey v. Enright*, 230 F. 641, 647 (5th Cir. 1916) ("[A]ddition of an improving feature does not excuse the appropriation of the appellant's invention.")

On December 15, 2025, the Supreme Court denied MSN's petition for a *writ of certiorari*

Novartis's April 18, 2019 Citizen Petition

- **For a drug product to be approved under an ANDA, it must include active ingredients (active pharmaceutical ingredients, APis) that are "the same as" the RLD.** . . . FDA cannot permit an ANDA based on a physical mixture of individual sodium salts (or other salts) of sacubitril and valsartan. FDA must require that for a generic version of ENTRESTO to be approved under an ANDA, sponsors of generic versions of ENTRESTO must present the active ingredients in the same chemical structure as in the RLD.
- **ENTRESTO neither contains a physical mixture of the free acids of sacubitril and valsartan nor does it contain a physical mixture of the individual sodium salts of sacubitril and valsartan (or other salts of sacubitril or valsartan).** Instead, **ENTRESTO contains a complex of sacubitril and valsartan in which the chemical structure of each active ingredient is distinct from a mixture of free acids or alternate salts of sacubitril and valsartan.** The distinct chemical structure of the active ingredients in ENTRESTO is reflected in physico-chemical properties that are distinctly different from those that would exist in a physical mixture of sacubitril and valsartan, or a mixture of sacubitril and valsartan salts, such as sodium, potassium or other salts.

Hikma v. Amarin

The boundaries of skinny-label induced infringement

Abbreviated New Drug Application (ANDA)

Hatch-Waxman Act of 1984

- Generic drugs with demonstrated equivalence in safety, efficacy, and quality to a previously approved reference-listed drug (RLD)

ANDA Preparation

- Proposed label

ANDA Submission

- Orange Book patents
- Paragraph IV certification & ANDA litigation
- Section viii statement - skinny label

FDA Decision

Induced Infringement

- “Whoever actively induces infringement of a patent shall be liable as an infringer.” (35 U.S.C. 271(b))
- Requirements:
 1. There must be direct infringement by a third party.
 2. The inducer must know that the induced acts constitute patent infringement.
 3. The inducer must take active steps to encourage direct infringement.

“

**Supreme Court of the United States
No. 24-889**

***HIKMA PHARMACEUTICALS USA INC. ET AL. v.
AMARIN PHARMA, INC., ET AL.***

Cited as 608 U.S. ____ (2026)

”

Background

- Amarin developed Vascepa with icosapent ethyl (二十碳五烯酸的乙酯) as the active ingredient.
- 2012: FDA approval of Vascepa for treating severe hypertriglyceridemia (the “SH indication”) (高甘油三酯血症).
- 2019: FDA approval of Vascepa for reducing cardiovascular risk in hypertriglyceridemia patients who already take statins (the “CV indication”) (心血管风险适应症).
- The CV indication is a more common use and covered by Amarin’s two method-of-use patents.

Background

- 2016: Hikma filed an ANDA for generic icosapent ethyl.
 - Paragraph IV certification: Amarin's SH-indication patents were invalid.
 - District court invalidated Amarin's SH-indication patents.
 - Hikma supplemented its ANDA with a section viii statement seeking approval of a skinny label that included only the SH indication and carved out Vascepa's still-patented CV-indication.
- 2020: FDA approved Hikma's ANDA with the skinny label with an "AB" rating indicating therapeutic equivalence to Vascepa when used according to its label.

Litigation History

- Amarin sued Hikma for actively inducing others to infringe Amarin's CV-indication patents based on the totality of Hikma's statements across the skinny label, the patient information leaflet, Hikma's website, and its press releases.
- The district court granted Hikma's motion to dismiss for failure to state a claim, explaining that none of the statements constituted active steps to encourage infringement.
- The Federal Circuit reversed, finding it at least plausible that a physician could read the relevant statements as an instruction or encouragement to infringe.

SCOTUS

... 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. We therefore reverse the judgment of the Federal Circuit and remand the case for further proceedings.

Take Away

Skinny label and off-label use

Induced infringement based on a generic competitor's active encouragement of infringing uses, not plausible scenario of active inducement

Encouragement vs omissions, industry-standard descriptions or vague statements

Brand's label drafting and Orange Book patents

BPCIA Biosimilar Litigation and Challenges

A Strategic Guide for Biosimilar Companies Entering the U.S. Market

The U.S. Biosimilar Opportunity

\$90B+ projected U.S. biosimilar market by 2024

55+ blockbuster biologics losing exclusivity by 2032

5% of U.S. prescriptions are biologics, but 51% of drug spending

Challenges

- The U.S. requires biosimilar applicants to navigate a complex patent litigation process before market entry
- The BPCIA (Biologics Price Competition and Innovation Act of 2009) created the abbreviated approval pathway for biosimilars — including a structured patent dispute resolution process
- The “patent dance” determines which patents will be litigated and when — directly impacting your timeline to market
- Strategic decisions during the patent dance can accelerate or delay launch by years and affect litigation costs by millions of dollars
- Chinese companies must understand this process BEFORE committing to U.S. biosimilar development

Total Patent Dance Timeline: ~ 250 days

BA discloses BLA to RPS: 20 days

RPS provides patent list: 60 days

BA provides contentions + patent list: 60 days

RPS provides contentions: 60 days

Negotiate patent list: 15 days

Exchange lists / resolve disputes: ~ 35 days

RPS files compliant: 30 days

Notice of Commercial Marketing & Phase II Litigation

BA must provide 180-day Notice of Commercial Marketing (NCM) before launch. This can be filed at any time — even before FDA approval.

Upon receiving NCM, RPS may seek preliminary injunction on remaining patents not litigated in Phase I (patent dance). This triggers Phase II litigation.

Patent Dance is Optional

Pros

- Preserves right to file declaratory judgment
- Narrows patents for litigation (reduce costs)
- Early insight into RPS's positions
- May facilitate earlier settlement

Cons

- Protects confidential manufacturing information
- RPS controls timing and patent selection
- BA loses declaratory judgment rights
- May face broader litigation immediately

Strategic Considerations for Chinese Companies

Start IP Analysis Early

- Map the reference product's patent landscape well before filing your BLA. Understand the full portfolio — composition, formulation, method of treatment, and manufacturing process patents.

Budget for U.S. Litigation

- BPCIA litigation typically costs \$5–20M+ through trial. Factor this into your development budget from Day 1. Consider partnering with a U.S. firm experienced in biosimilar litigation.

Consider the NCM Timing

- Filing your 180-day Notice of Commercial Marketing early can “collapse” Phase I and Phase II, reducing overall timeline. But it also accelerates the RPS's ability to seek a preliminary injunction.

Settlement is the Norm

- Most BPCIA cases settle. Your litigation strategy should maximize your settlement leverage — strong invalidity/non-infringement positions are key.

Patent Prosecution Matters for Biosimilars

Defensive positioning: Your own patents on manufacturing processes, formulations, or purification methods create leverage during BPCIA negotiations and settlement discussions

Competitive moats: Process patents protect your investment against other biosimilar competitors entering the same market

Settlement leverage: A strong patent portfolio gives you cross-licensing currency during negotiations with the RPS

Valuation & partnerships: U.S. patent assets enhance company valuation and attract U.S. commercialization partners

Freedom-to-operate: Filing your own patents forces you to deeply understand the IP landscape — which improves your FTO analysis

5

How Buchanan Can Help

Patent landscape
analysis

Patent
prosecution

ANDA litigation
BPCIA litigation

Competitive
intelligence

Regulatory
strategy

Settlement
Negotiations

Buchanan at a Glance

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**ATTORNEYS AND GOVERNMENT
RELATIONS PROFESSIONALS**

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- Corporate Finance
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- Labor & Employment
- Federal & State Government Relations
- Commercial Litigation
- Government Investigations
- Antitrust & Trade Regulation
- Class Action & Complex Litigation Defense
- Products Liability

- **AmLaw 200 Firm** recognized as a “powerhouse national law firm” by the **National Law Journal** and a “go-to law firm” by **Corporate Counsel Magazine**.
- **Recognized in Chambers & Partners for Commercial Litigation, Intellectual Property, Employment and Antitrust** capabilities along with 15 other categories.
- **Ranked as a National Tier 1 Firm for Commercial and IP Litigation** through *U.S. News & World Report’s* Best Law Firms as well as 29 National honors and 84 metro rankings.
- **Collaborative Life Sciences Industry Team**, bringing together institutional and niche practices for a comprehensive approach to our clients’ business strategies.

Patent and Hatch-Waxman Litigation

- Our Hatch-Waxman litigation experience on behalf of generic pharmaceutical companies covers a range of issues, including formulating pre-litigation strategies, notice letters, litigation, and settlement negotiations.
- Our lawyers have litigated complex cases with multiple defendants and jurisdictions for blockbuster drugs as well as niche drugs with smaller markets, and we understand that each requires its own approach. Our lawyers are skilled courtroom advocates with experience litigating Paragraph IV cases in key venues such as Delaware and New Jersey and are recognized among the leading Hatch-Waxman litigation groups in the U.S.
- Our lawyers have represented U.S. and international clients, including Zydus, Lupin, Baxter, Novugen, HEC Pharma, Alembic, etc.
- Our lawyers have litigated patents claiming compound, formulation, polymorph/salt/cocrystal, method of use, purity, dissolution, pharmacokinetics, side effects, dosage regimen, sustained release, method of making, REMS (Risk Evaluation and Mitigation Strategies), device/package, among others

Buchanan Life Sciences

Helping Protect, Defend and Extend the Product Lifecycle at Every Step

- Recognized IP litigators experienced with **Patent and Hatch-Waxman Litigation**.
 - A **full range of FDA services** covering the entire product lifecycle
 - Highly regarded **patent procurement** and prosecution with a focus on biotechnology and pharmaceuticals
 - Knowledgeable **M&A attorneys** crafting highly focused and customized approaches to **life sciences transactions**
 - **Specialized Antitrust lawyers** well versed in **price-fixing, reverse payment, merger clearance** and other issues
 - Seasoned **commercial litigators** experienced in pharmaceutical **products liability, class actions, trade secrets** and **government investigations**
- Lawyers across 10+ firm practice areas
 - Rare mix of strong Food & Drug (FDA), Intellectual Property, Corporate, Antitrust and Litigation services delivered through one team
 - Offer a complete package of services to support each stage of development from idea conception to commercialization

Buchanan | IP Overview

Buchanan IP - Strength in Numbers

400+ IP district court litigations in the last 10 years,
with IP litigation experience across the U.S.

8 Named to Top ANDA Litigator, Patexia ANDA Litigation Intelligence Report
5 Illinois Super Lawyers®, Intellectual Property Litigation

Ranked as a *Chambers & Partners* Leading Law Firm

Ranked as a Top 50 Best Performing law firms overall by Patexia,
and a Top 5 firm representing patent owners

Recognized in Best Lawyers as a top Intellectual Property Litigation firm

12 Best Lawyers in America, 3 Ones to Watch
Best Lawyers in America 2025

- Our IP team is recognized globally with rankings in **World IP Review 2025, Managing Intellectual Property's IP Stars, and Chambers USA.**
- **Ranked as a National Tier 1 Firm for Patent Law** through *U.S. News & World Report's* Best Law Firms as well as 29 National honors and 84 metro rankings.
- **AmLaw 200 Firm** recognized as a **"powerhouse national law firm"** by the **National Law Journal** and a "go-to law firm" by Corporate Counsel Magazine.

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