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Hatch-Waxman 2024 Year in Review

January 22, 2025

Meet the Speakers

Megan Chacon
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Principal

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Overview

Topics

- Important Decisions
- Developments
- Practice Tips

Housekeeping

- CLE
- Questions
- Materials
- http://www.fr.com/webinars

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Agenda

2024 Trends for Hatch-Waxman Cases

Terminal Disclaimers & Obviousness-Type Double Patenting

Skinny Labeling

Challenging FDA Approval & Written Description: Entresto®

Other 2024 Developments

Looking Forward to 2025

2024 Trends for Hatch-Waxman Cases

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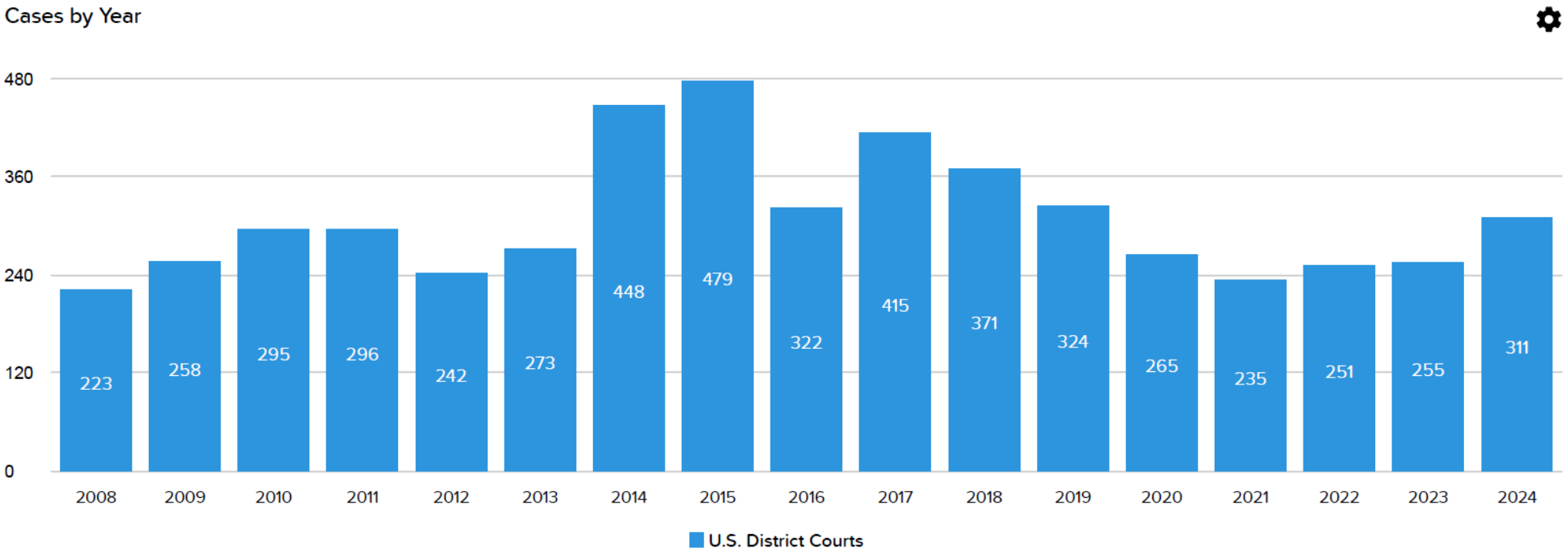
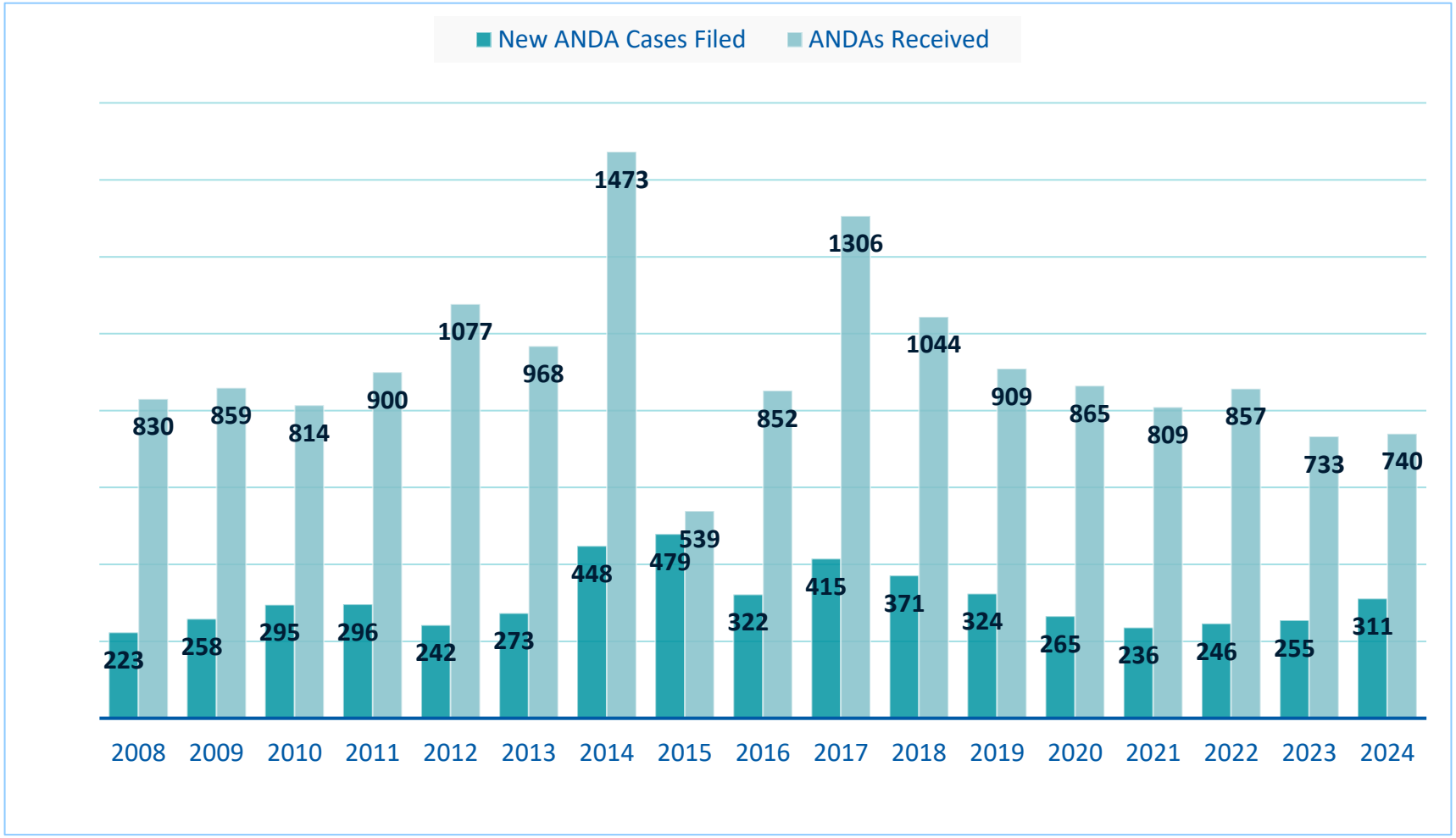
Number of ANDA Cases Filed



	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	YTD	2025 est
U.S. District Courts	223	258	295	296	242	273	448	479	322	415	371	324	265	235	251	255	311	12	220
Total	223	258	295	296	242	273	448	479	322	415	371	324	265	235	251	255	311	12	220

Source: docketnavigator.com (Case Type: Cases with ANDA Pleadings, through January 20, 2025)

ANDA Cases Filed v. ANDAs Submitted



Source: docketnavigator.com (Case Type: Cases with ANDA Pleadings); https://www.fda.gov/industry/generic-drug-user-fee-amendments/generic-drugs-program-monthly-and-quarterly-activities-report

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Busiest Venues for ANDA Cases in 2024

Courts		
D.Del.	374	56%
D.N.J.	253	38%
N.D.W.Va.	11	2%
N.D.Ill.	8	1%
D.Mass.	6	1%
Other Courts	19	3%

Open ANDA Cases
(Between January 1 and December 31, 2024)

Courts		
D.N.J.	172	55%
D.Del.	121	39%
N.D.Ill.	5	2%
E.D.N.C.	3	1%
N.D.W.Va.	3	1%
Other Courts	9	3%

New 2024 ANDA Cases
(through December 31, 2024)

Source: lexmachina.com (tag Patent: ANDA; data through December 31, 2024)

Busiest Judges for ANDA Cases

District Judges		
Richard Gibson Andrews (D.Del.)	100	15%
Colm Felix Connolly (D.Del.)	98	15%
Gregory Brian Williams (D.Del.)	81	12%
Jennifer Lynne Hall (D.Del.)	65	10%
Maryellen Noreika (D.Del.)	61	9%
65 Other Judges		

Open ANDA Cases
(Between January 1 and December 31, 2024)

District Judges		
Brian R. Martinotti (D.N.J.)	39	12%
Jennifer Lynne Hall (D.Del.)	27	9%
Colm Felix Connolly (D.Del.)	27	9%
Michael Andre Shipp (D.N.J.)	26	8%
Maryellen Noreika (D.Del.)	23	7%
42 Other Judges		

New 2024 ANDA Cases
(through December 31, 2024)

Source: lexmachina.com (tag Patent: ANDA; data through December 31, 2024)

Terminal Disclaimers & Obviousness-Type Double Patenting

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Statutory Additions to Patent Term

Patent Term Adjustment (PTA)

- Extension of patent term for delays at the PTO
- Based on delay in examination of the specific patent
- Governed by 35 U.S.C § 154

Patent Term Extension (PTE)

- Extension of patent term for delays in regulatory review by FDA or USDA
- Added to one patent of patentee's choice covering a specific product whose marketing approval was delay
- Governed by 35 U.S.C. § 156

In re Cellect: ODP From Expiration Date After PTA

United States Court of Appeals
for the Federal Circuit

IN RE: CELLECT, LLC,
Appellant

2022-1293, 2022-1294, 2022-1295, 2022-1296

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. 90/014,453, 90/014,454, 90/014,455, 90/014,457.

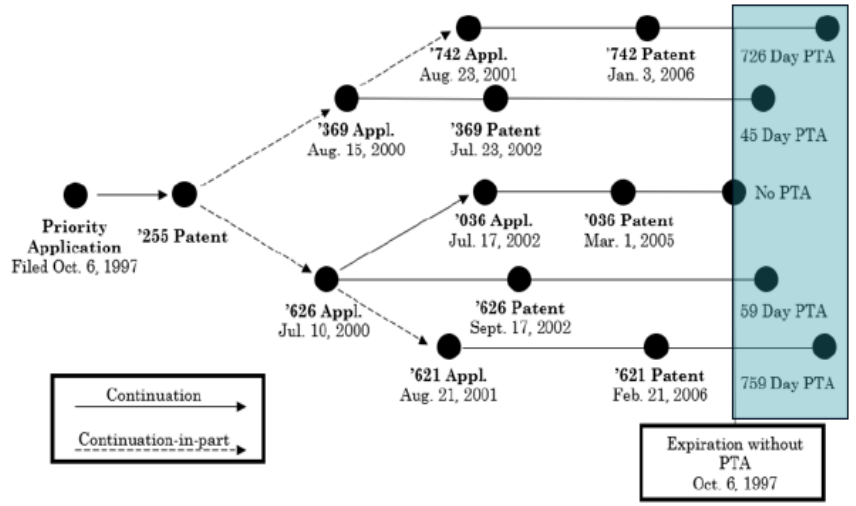
Decided: August 28, 2023

PAUL J. ANDRE, Kramer Levin Naftalis & Frankel LLP, Redwood Shores, CA, argued for appellant. Also represented by JAMES R. HANNAH, LISA KOBIALKA; JONATHAN CAPLAN, JEFFREY PRICE, New York, NY.

KAKOLI CAPRIHAN, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, argued for appellee Katherine K. Vidal. Also represented by THOMAS W. KRAUSE, AMY J. NELSON, BRIAN RACILLA, FARHEENA YASMEEN RASHEED.

JEREMY LOWE, Leydig, Voit & Mayer, Ltd., Chicago, IL, for amicus curiae Alvogen PB Research & Development LLC. Also represented by KEELIN BIELSKI, STEVEN H. SKLAR.

KURT A. MATHAS, Winston & Strawn LLP, Chicago, IL,

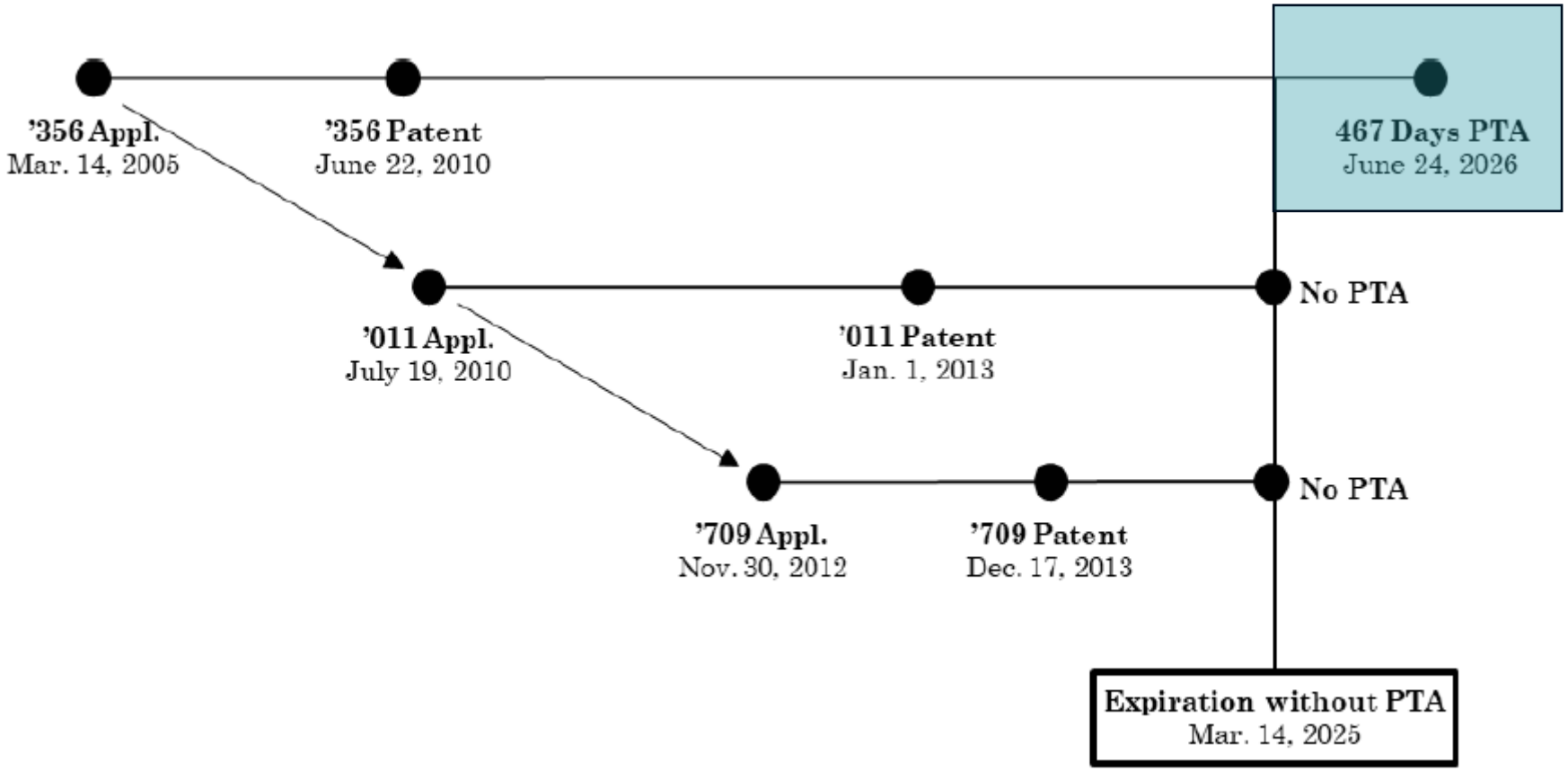


We thus conclude that ODP for a patent that has received PTA, regardless whether or not a terminal disclaimer is required or has been filed, must be based on the expiration date of the patent after PTA has been added. We therefore further conclude that the Board did not err in finding the asserted claims unpatentable under ODP.

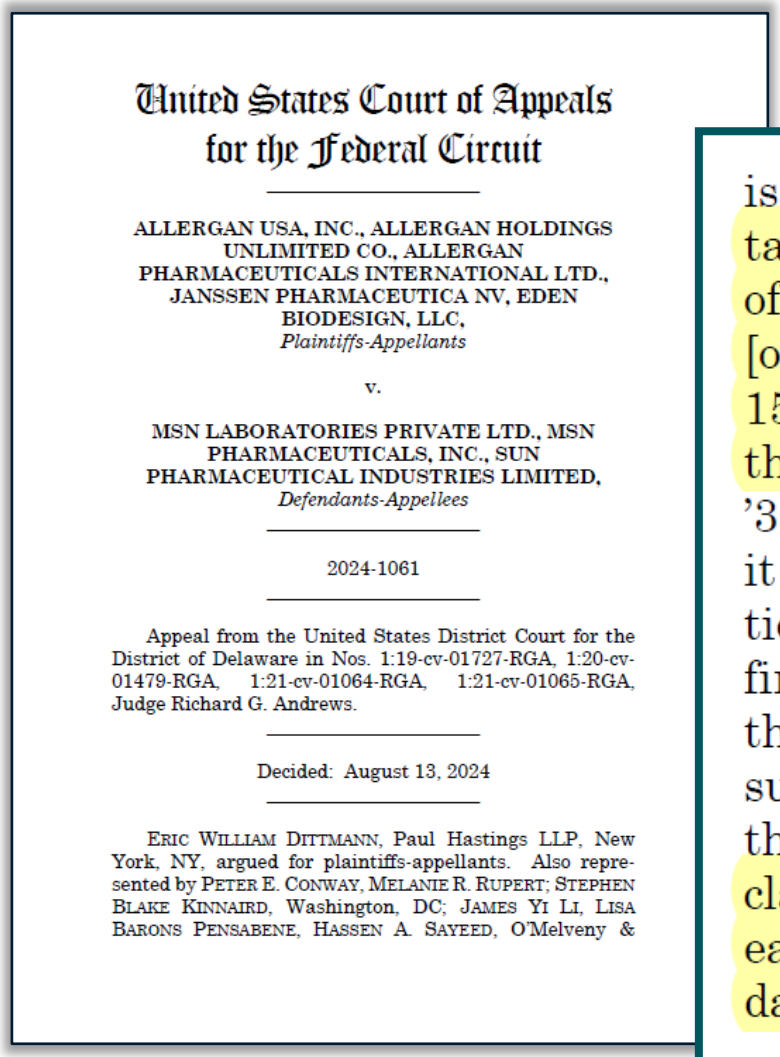
81 F.4th 1216, 1229 (Fed. Cir. 2023)

Obviousness-type Double Patenting (ODP) v. PTA

Allergan USA LLC v. MSN Labs., 111 F.4th 1358 (Fed. Cir. 2024)



Federal Circuit: No ODP on 1st Filed, 1st Issued Claim



United States Court of Appeals
for the Federal Circuit

ALLERGAN USA, INC., ALLERGAN HOLDINGS UNLIMITED CO., ALLERGAN PHARMACEUTICALS INTERNATIONAL LTD., JANSSEN PHARMACEUTICA NV, EDEN BIODESIGN, LLC,
Plaintiffs-Appellants

v.

MSN LABORATORIES PRIVATE LTD., MSN PHARMACEUTICALS, INC., SUN PHARMACEUTICAL INDUSTRIES LIMITED,
Defendants-Appellees

2024-1061

Appeal from the United States District Court for the District of Delaware in Nos. 1:19-cv-01727-RGA, 1:20-cv-01479-RGA, 1:21-cv-01064-RGA, 1:21-cv-01065-RGA, Judge Richard G. Andrews.

Decided: August 13, 2024

ERIC WILLIAM DITTMANN, Paul Hastings LLP, New York, NY, argued for plaintiffs-appellants. Also represented by PETER E. CONWAY, MELANIE R. RUPERT; STEPHEN BLAKE KINNAIRD, Washington, DC; JAMES YI LI, LISA BARONS PENSABENE, HASSEN A. SAYEED, O'Melveny &

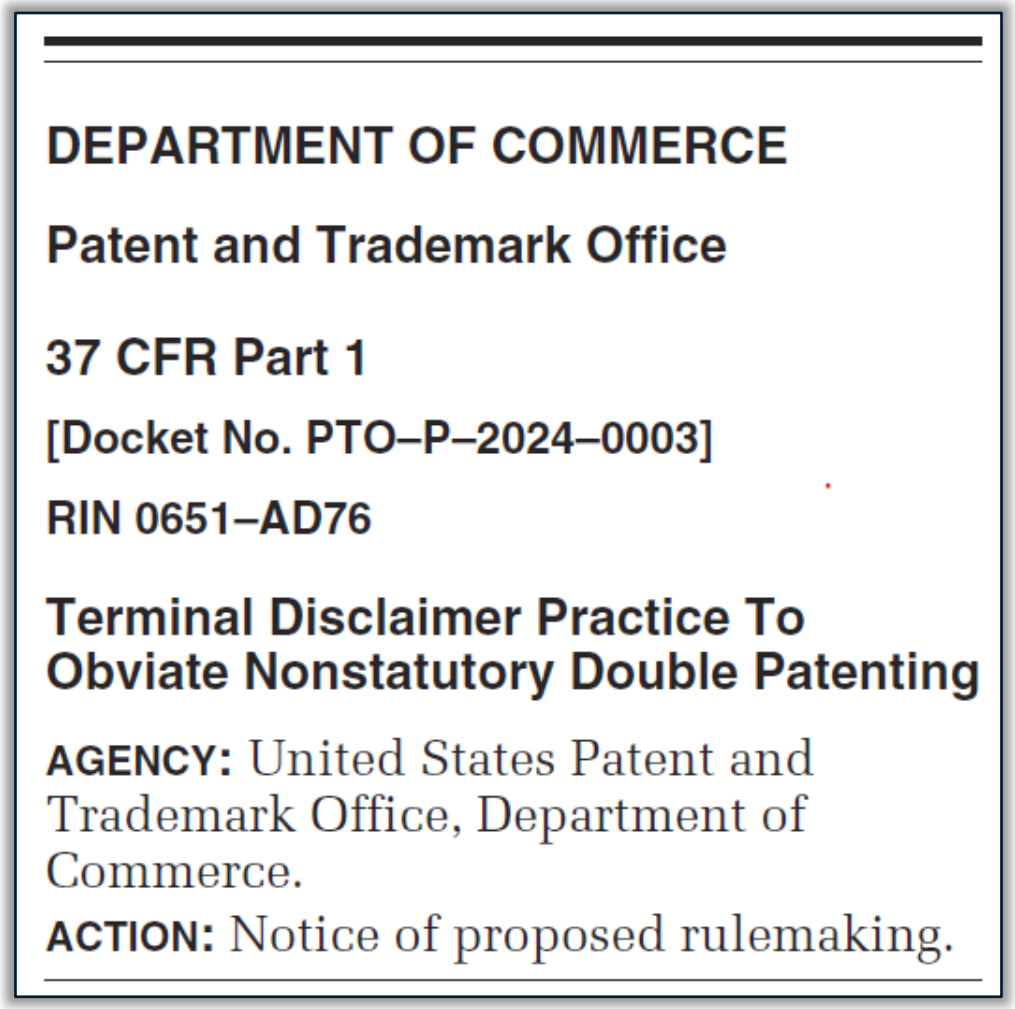
issue, with claims to eluxadoline. Applying the fundamental purposes of ODP to these undisputed facts, the claims of the '356 patent do not "extend or prolong the monopoly [on eluxadoline] beyond the period allowed by law," *Miller*, 151 U.S. at 198, and therefore are not subject to ODP over the '011 and '709 patents. Put otherwise, the fact that the '356 patent expires later is of no consequence here because it is not a "*second*, later expiring patent for the same invention." *Abbvie*, 764 F.3d at 1373 (emphasis added). As the first-filed, first-issued patent in its family, it is the patent that sets the maximum period of exclusivity for the claimed subject matter and any patentably indistinct variants. We therefore hold that a first-filed, first-issued, later-expiring claim cannot be invalidated by a later-filed, later-issued, earlier-expiring reference claim having a common priority date.

111 F.4th at 1369

Post-Allergan v. MSN Takeaways

- **Creation of ODP "Safe Harbor" for Parent Patent**
- **Selection of Parent Patent Is Critical**
- **Monitor further developments**

USPTO Proposes & Withdraws TD Rule



DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No. PTO–P–2024–0003]

RIN 0651–AD76

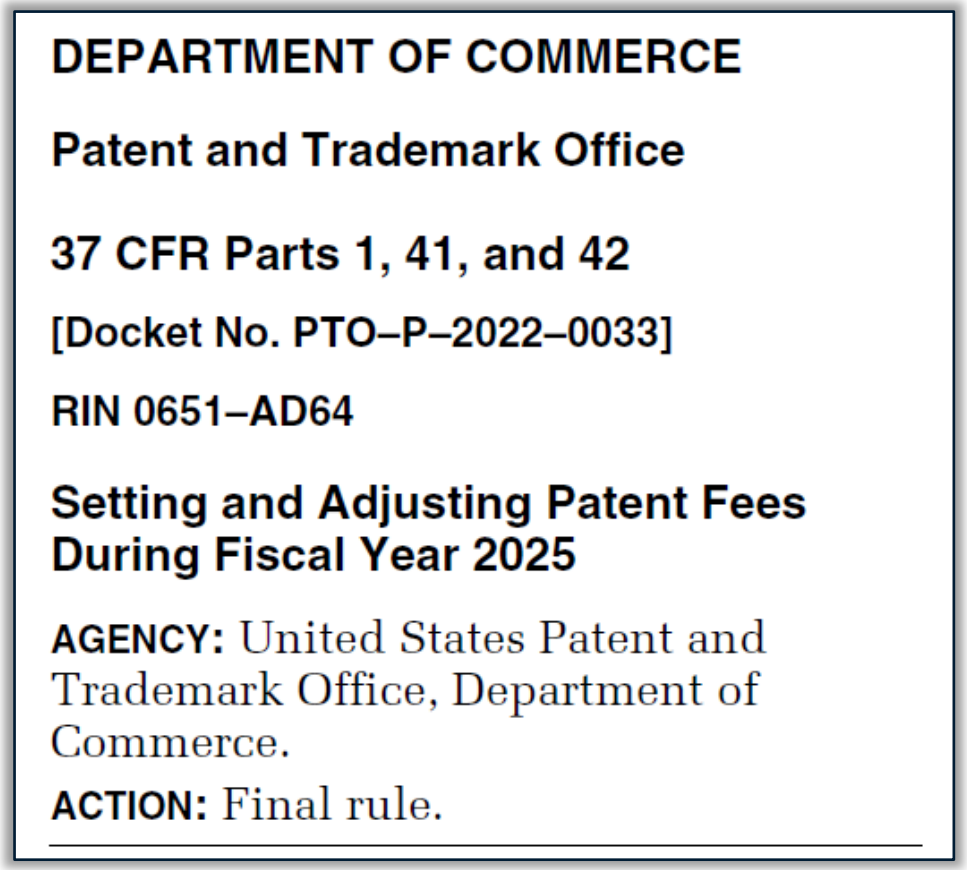
Terminal Disclaimer Practice To Obviate Nonstatutory Double Patenting

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of proposed rulemaking.

- **TDs to overcome ODP would be enforceable only if patent is not tied by TD to another patent in which:**
  - Any claim has been finally held unpatentable or invalid as anticipated or obvious; or
  - A statutory disclaimer of a claim is filed after any challenge based on anticipation or obviousness to that claim has been made.

USPTO Opts Instead for Fee-Based Approach



DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Parts 1, 41, and 42

[Docket No. PTO–P–2022–0033]

RIN 0651–AD64

Setting and Adjusting Patent Fees During Fiscal Year 2025

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Final rule.

- USPTO setting or adjusting 433 patent fees (including 52 new fees) as well as Patent Trial and Appeal Board (PTAB) fees
- Fees not covered by targeted adjustments subject to an across-the-board increase of approximately 7.5%
- Front-end fees (i.e., filing, search, and examination fees) subject to an additional 2.5% increase on top of the 7.5% across-the-board increase (10% in total)
- USPTO declined to implement proposed tiered pricing for TDs

Skinny Labeling

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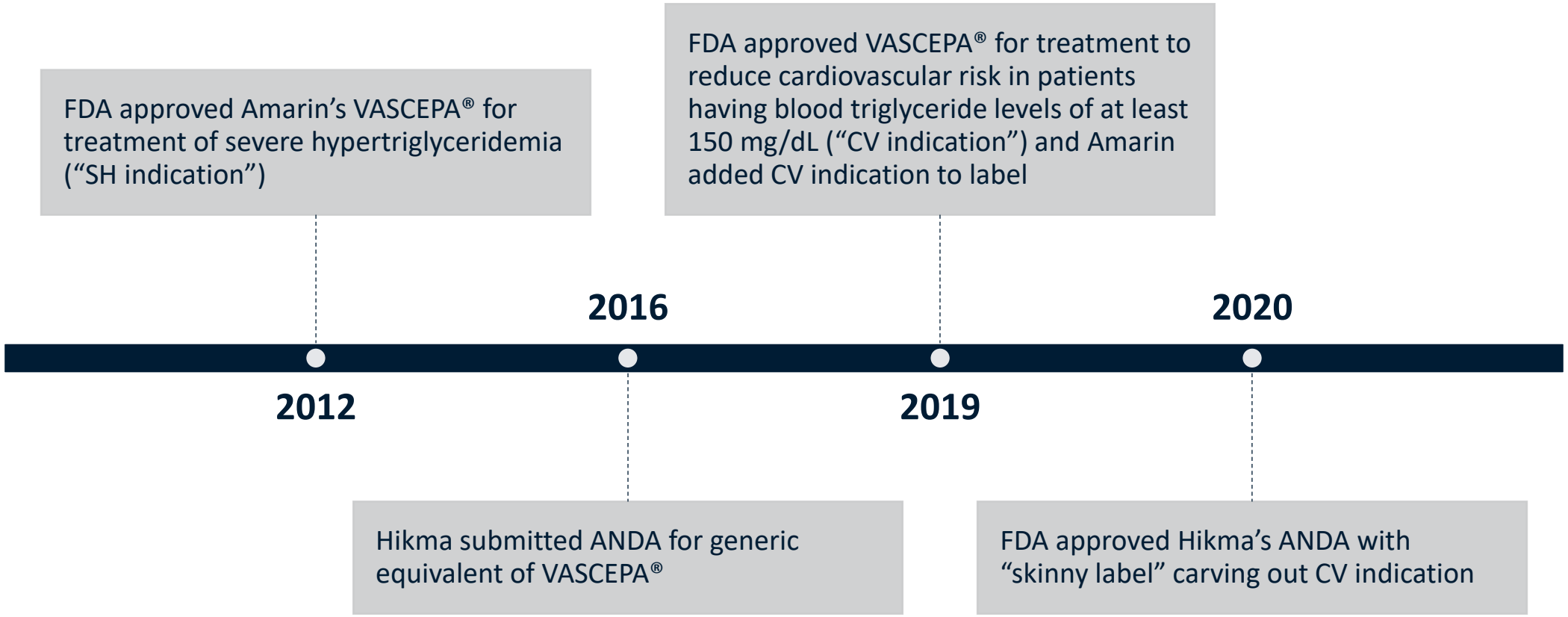
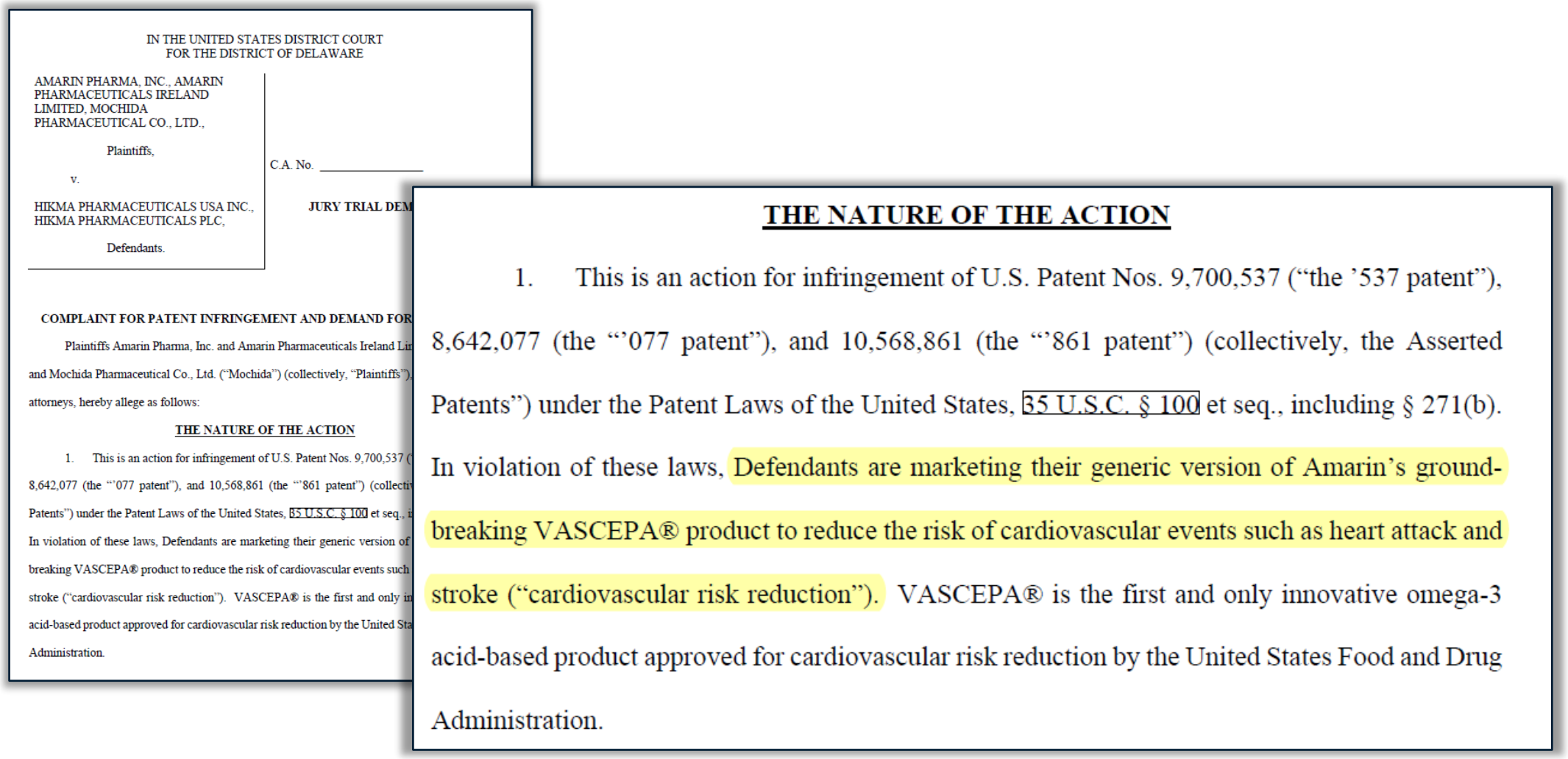
Amarin's VASCEPA® and Hikma's ANDA



VASCEPA® Related Litigation



IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS IRELAND LIMITED, MOCHIDA PHARMACEUTICAL CO., LTD.,

Plaintiffs,

v.

HIKMA PHARMACEUTICALS USA INC., HIKMA PHARMACEUTICALS PLC,

Defendants.

C.A. No. _____

JURY TRIAL DEM

COMPLAINT FOR PATENT INFRINGEMENT AND DEMAND FOR

Plaintiffs Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Lir
and Mochida Pharmaceutical Co., Ltd. ("Mochida") (collectively, "Plaintiffs"),
attorneys, hereby allege as follows:

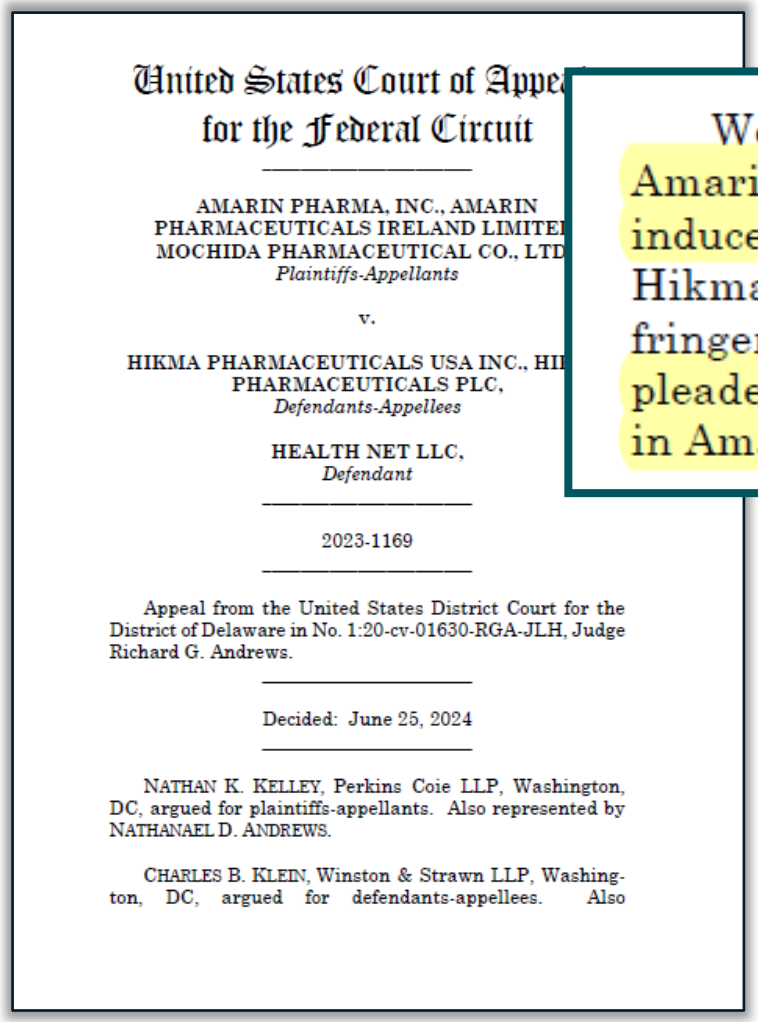
THE NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent Nos. 9,700,537 (
8,642,077 (the "'077 patent"), and 10,568,861 (the "'861 patent") (collectiv
Patents") under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., i
In violation of these laws, Defendants are marketing their generic version of
breaking VASCEPA® product to reduce the risk of cardiovascular events such
stroke ("cardiovascular risk reduction"). VASCEPA® is the first and only in
acid-based product approved for cardiovascular risk reduction by the United Sta
Administration.

THE NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent Nos. 9,700,537 ("the '537 patent"), 8,642,077 (the "'077 patent"), and 10,568,861 (the "'861 patent") (collectively, the Asserted Patents") under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., including § 271(b). In violation of these laws, Defendants are marketing their generic version of Amarin's ground-breaking VASCEPA® product to reduce the risk of cardiovascular events such as heart attack and stroke ("cardiovascular risk reduction"). VASCEPA® is the first and only innovative omega-3 acid-based product approved for cardiovascular risk reduction by the United States Food and Drug Administration.

Amarin Pharma. v. Hikma Pharma. (Fed. Cir. 2024)



United States Court of Appe
for the Federal Circuit

AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS IRELAND LIMITE
MOCHIDA PHARMACEUTICAL CO., LTD
Plaintiffs-Appellants

v.

HIKMA PHARMACEUTICALS USA INC., HI
PHARMACEUTICALS PLC,
Defendants-Appellees

HEALTH NET LLC,
Defendant

2023-1169

Appeal from the United States District Court for the District of Delaware in No. 1:20-cv-01630-RGA-JLH, Judge Richard G. Andrews.

Decided: June 25, 2024

NATHAN K. KELLEY, Perkins Coie LLP, Washington, DC, argued for plaintiffs-appellants. Also represented by NATHANAEL D. ANDREWS.

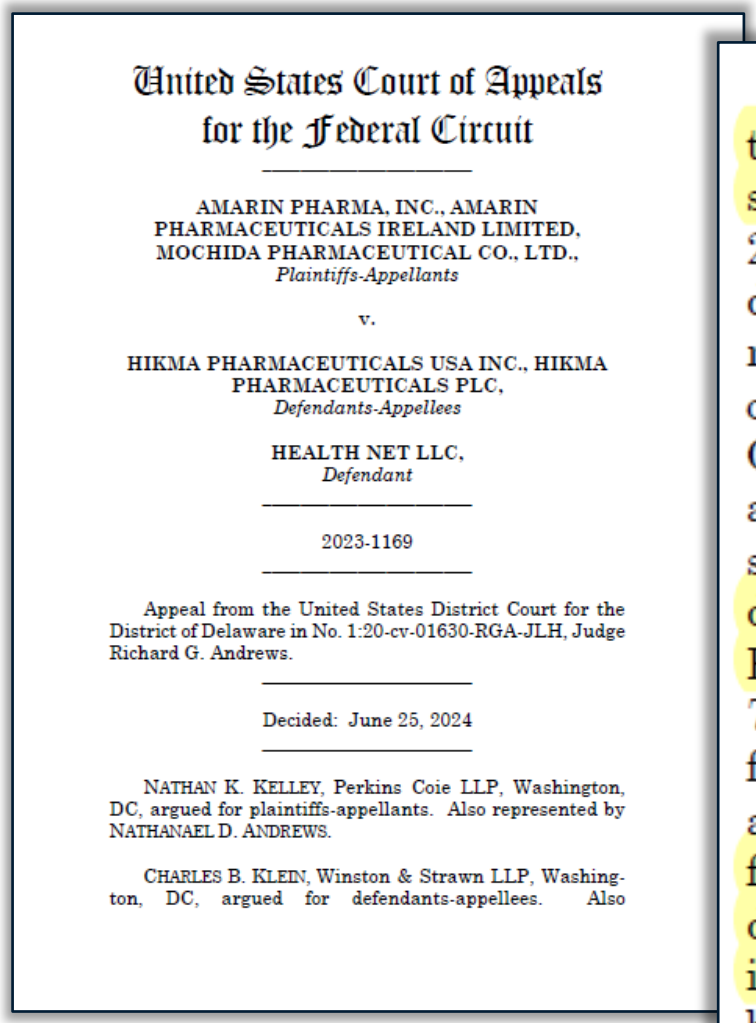
CHARLES B. KLEIN, Winston & Strawn LLP, Washington, DC, argued for defendants-appellees. Also

We therefore focus narrowly on the question whether Amarin's complaint plausibly pleads that Hikma "actively" induced healthcare providers' direct infringement, *i.e.*, that Hikma "encourage[d], recommend[ed], or promote[d] infringement." *Takeda*, 785 F.3d at 631. Accepting all well-pleaded facts as true and drawing all reasonable inferences in Amarin's favor, we conclude that it does.

Those allegations, taken together with those relating to Hikma's label, at least plausibly state a claim for induced infringement. As Amarin notes, and the magistrate judge observed, many of the allegations depend on what Hikma's label and public statements would communicate to physicians and the marketplace. *See* Amarin Br. at 39–41. As we observed in *GSK*, that is a question of fact—not law—and is therefore not proper for resolution on a motion to dismiss. *See* 7 F.4th at 1330 ("Critically, the

104 F.4th at 1377, 1379

Federal Circuit: No Death Knell for Skinny Labels



United States Court of Appeals
for the Federal Circuit

AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS IRELAND LIMITED, MOCHIDA PHARMACEUTICAL CO., LTD.,
Plaintiffs-Appellants

v.

HIKMA PHARMACEUTICALS USA INC., HIKMA PHARMACEUTICALS PLC,
Defendants-Appellees

HEALTH NET LLC,
Defendant

2023-1169

Appeal from the United States District Court for the District of Delaware in No. 1:20-cv-01630-RGA-JLH, Judge Richard G. Andrews.

Decided: June 25, 2024

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CHARLES B. KLEIN, Winston & Strawn LLP, Washington, DC, argued for defendants-appellees. Also

Finally, we reject Hikma's inflated characterizations that a reversal in this case would "effectively eviscerate section viii carve-outs." Hikma Br. at 48; Oral Arg. at 20:10–26 (counsel for Hikma asserting that "the entire industry is watching this case. It's a test case . . . . And if merely calling a generic product a 'generic version' is sufficient to get past the pleading stage, section viii is dead."). Our holding today is limited to the allegations before us and guided by the standard of review appropriate for this stage of proceedings. We continue to acknowledge, as we did in *GSK*, that there is a "careful balance struck by the Hatch-Waxman Act regarding section viii carve-outs." 7 F.4th at 1326. That balance benefits both brand manufacturers and generic manufacturers alike. What we can also say is that clarity and consistency in a generic manufacturer's communications regarding a drug marketed under a skinny label may be essential in avoiding liability for induced infringement. Here, because Amarin has plausibly pleaded that, despite its section viii carve-out, Hikma

104 F.4th at 1381

Challenging FDA ANDA Approval: Entresto®

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Novartis's Entresto® and MSN's ANDA

- **2015:** FDA approved Novartis's chronic heart failure medication Entresto® (Sacubitril (ARB) / Valsartan (NEPi))
- **2019**: MSN submits ANDA; Novartis submitted a citizen petition (the "Active Ingredient Petition") requesting FDA not approve any Entresto-related ANDA for drugs not comprised of "one complex with coordinated ionic bonds between anionic sacubitril, anionic valsartan, and cationic sodium."
- **2022**: Novartis submitted another citizen petition (the "Labeling Petition") requesting that FDA refrain from approving ANDAs proposing the labeling carveouts challenged in this action.
- **2024**: FDA denied the Active Ingredient Petition and the Labeling Petition; FDA approved MSN's ANDA for generic sacubitril and valsartan tablets; Novartis files suit to challenge denial of citizen petitions and files TRO/PI to set aside MSN's approval

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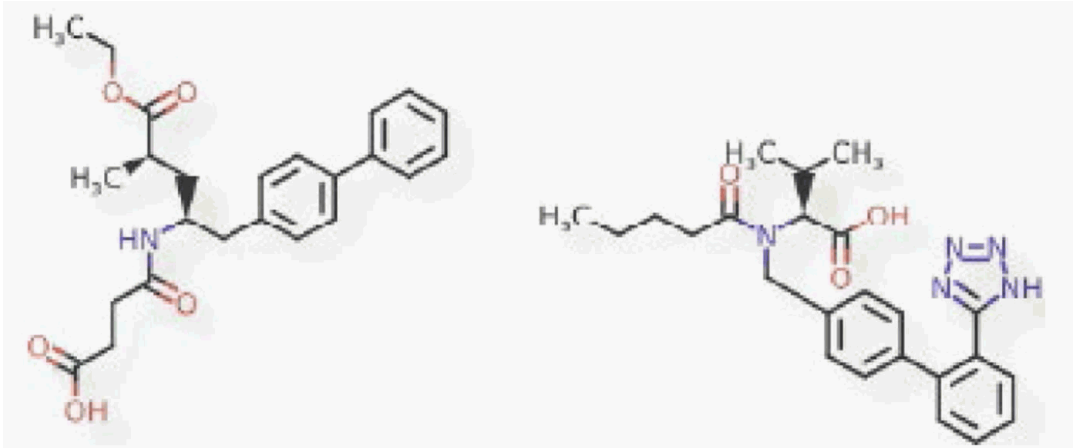
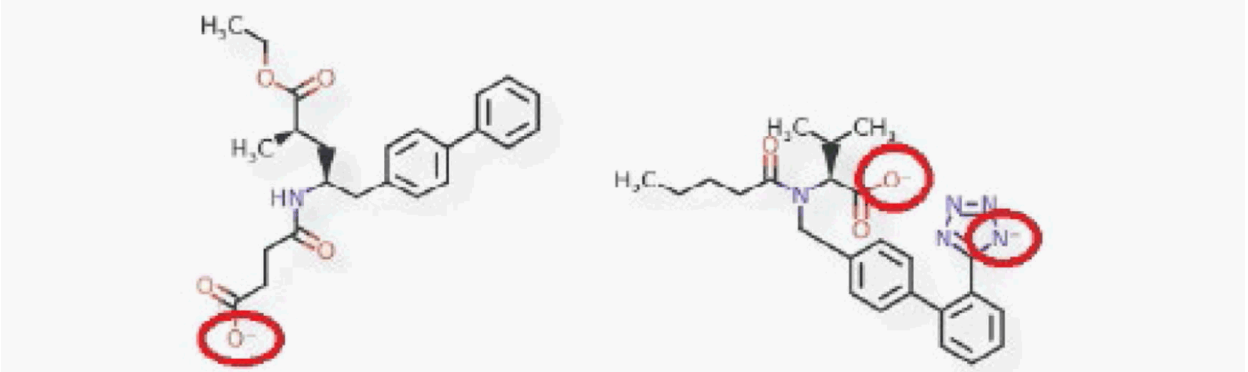
Novartis's Entresto® Active Ingredient



Sacubitril **Valsartan**



Sacubitril Anion (–1 charge) **Valsartan Anion** (–2 charge)

Novartis's Entresto® and MSN's ANDA Label

Entresto Label § 1.1	*Generic Label* § 1.1, Dkt. 13-1 (modifications emphasized)
ENTRESTO is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal. LVEF is a variable measure, so use clinical judgment in deciding whom to treat.	Sacubitril and valsartan tablets are indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure *and reduced ejection fraction*. ~~Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal.~~ *Left ventricular ejection fraction (LVEF)* is a variable measure, so use clinical judgment in deciding whom to treat.

Entresto Label § 2.6	*Generic Label* §§ 2.4–2.7
2.6 Dose Adjustment for Patients Not Taking an ACE inhibitor or ARB or Previously Taking Low Doses of These Agents In patients not currently taking an ACE inhibitor or an angiotensin II receptor blocker (ARB) and for patients previously taking low doses of these agents, start ENTRESTO at half the usually recommended starting dose. After initiation, increase the dose every 2 to 4 weeks in adults ... to follow the recommended dose escalation thereafter.	*N/A*

Novartis Pharms. Corp. v. Becerra, No. 24-CV-02234 (D.D.C. Oct. 15, 2024)

Labeling Sameness

Labeling for the generic drug must be the same as the labeling for the reference drug ***EXCEPT***:

- Manufacturing information
- Can omit an indication or other labelling aspects protected by patent or exclusivity
  - ***BUT***: changes must not render the proposed generic drug product less safe or effective than the reference drug for all remaining, non-protected conditions of use

Court found MSN's generic drug consistent with FDA statutory and regulatory requirements that mandate same label and active ingredients; FDA did not act arbitrarily in approving removal of dosing regimen from MSN's label

- Law allows changes to generic's label to account for patent-protected indications
- FDA did not contravene statutory requirement that a generic label not be compared to a previous version of Novartis's label
  - FDA record showed FDA compared the generic to "most recently approved" Entresto
- Indication carveout complies with FDA regulations permitting the "omission of an indication or other aspect of labeling protected by patent."
  - An "omission" under the regulation must turn on the "substance of the information that is omitted—not whether that substantive omission is accomplished by adding words or deleting them.

Novartis Pharms. Corp. v. Becerra, No. 24-CV-02234 (D.D.C. Oct. 15, 2024)

FDA's approval of the dosage regimen carveout was not arbitrary and capricious

Court cannot substitute its judgment for that of FDA on drug safety issues

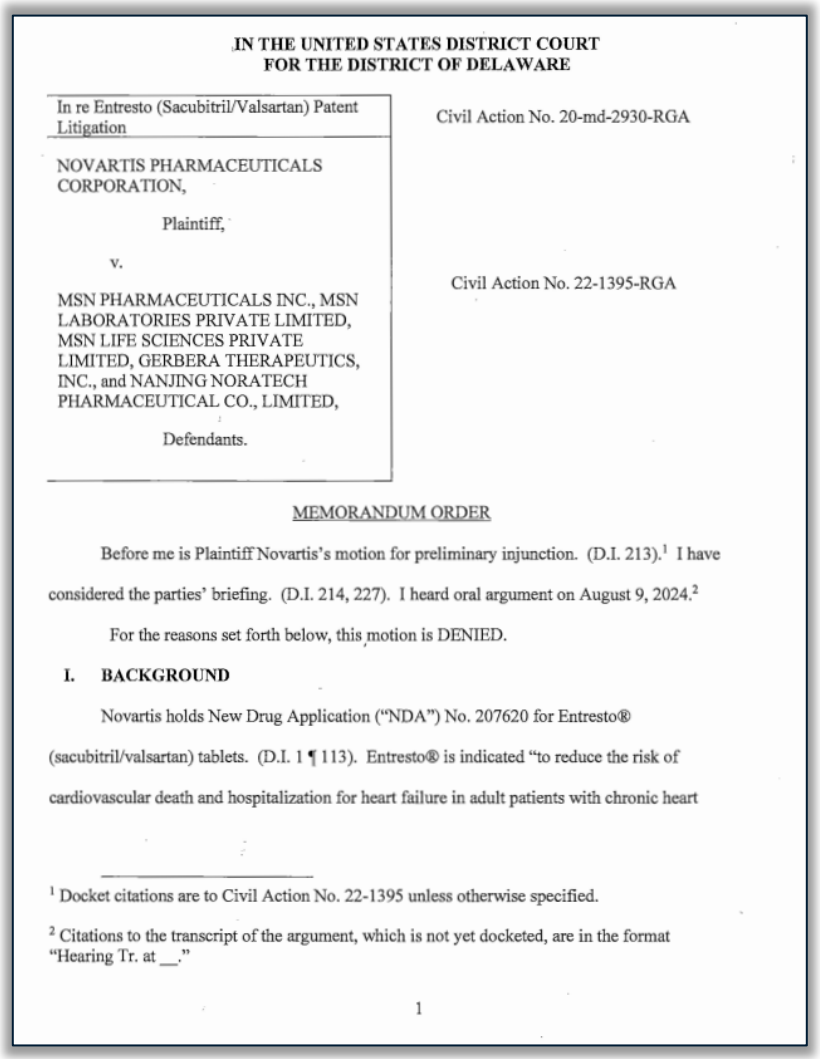
- FDA provided a reasoned scientific basis for allowing MSN to carve out Section 2.6
- While Section 2.6 was "reasonable" for FDA to approve because it "may" reduce the risks of adverse reactions, the agency has never taken the position that the clinical study's conclusions were definitive or "necessary" for the approval of Entresto

FDA's determination on chemical identity sameness reflects its reasoned "scientific analysis," which deserves "a high level of deference"

FDA rejected Novartis argument that generic Entresto required co-crystal complex

- Distinction between co-crystal or physical mixture of two independent salt was irrelevant to the sameness inquiry
  - a "a co-crystal composed of two active ingredients" is merely a different solid-state form of the ingredients, "not a new active ingredient"

FDA Gives Final Approval to MSN's Generic Entresto



IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Entresto (Sacubitril/Valsartan) Patent Litigation	Civil Action No. 20-md-2930-RGA
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, MSN LIFE SCIENCES PRIVATE LIMITED, GERBERA THERAPEUTICS, INC., and NANJING NORATECH PHARMACEUTICAL CO., LIMITED, Defendants.	Civil Action No. 22-1395-RGA

MEMORANDUM ORDER

Before me is Plaintiff Novartis's motion for preliminary injunction. (D.I. 213).[1] I have considered the parties' briefing. (D.I. 214, 227). I heard oral argument on August 9, 2024.[2]

For the reasons set forth below, this motion is DENIED.

I. BACKGROUND

Novartis holds New Drug Application ("NDA") No. 207620 for Entresto® (sacubitril/valsartan) tablets. (D.I. 1 ¶ 113). Entresto® is indicated "to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart

[1] Docket citations are to Civil Action No. 22-1395 unless otherwise specified.

[2] Citations to the transcript of the argument, which is not yet docketed, are in the format "Hearing Tr. at __."

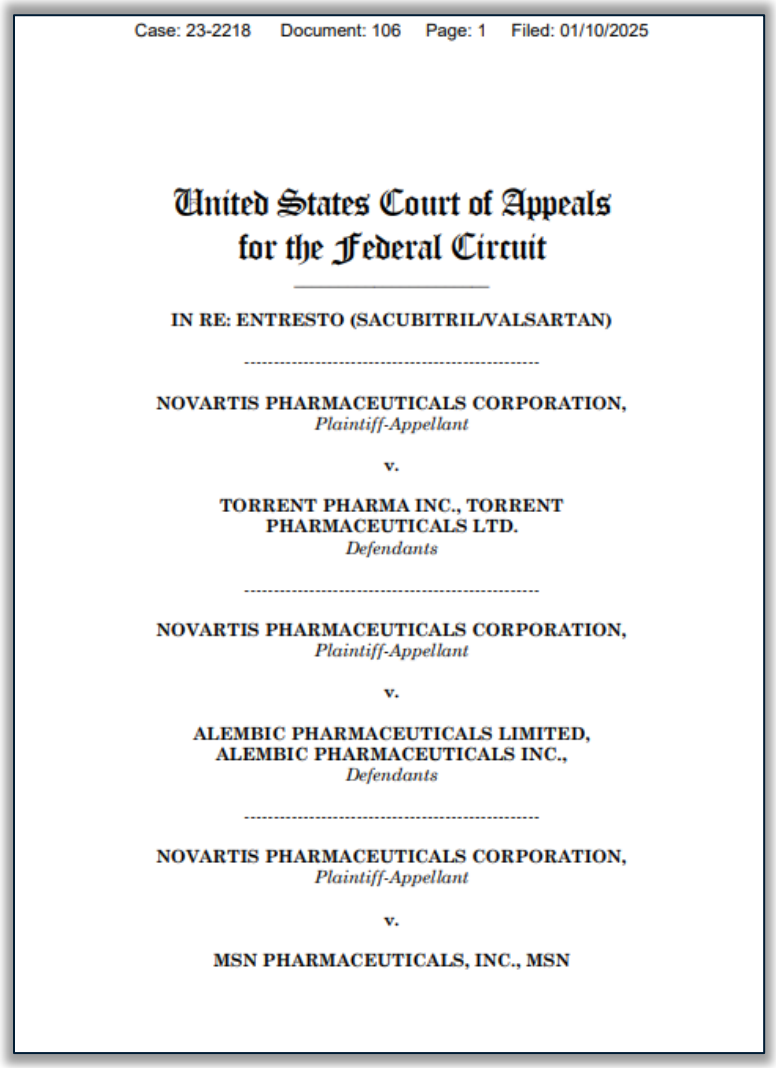
1

On July 24, 2024, MSN received final FDA approval for its ANDA product. (D.I. 210 at 1; D.I. 211 at 1). Novartis moves for a preliminary injunction to prevent the prospective at-risk launch of MSN's generic sacubitril/valsartan product. (D.I. 213). Should its motion be denied, Novartis moves for a short stay to allow Novartis to seek injunctive relief from the Federal Circuit. (*Id.*). MSN also moves to strike (D.I. 237) portions of Dr. Matzer's declaration (D.I. 221), which was submitted by Novartis in support of its motion for preliminary injunction.[6]

Hatch-Waxman Suit: Entresto®

FISH.

In re Entresto, No. 2023-2218, (Fed. Cir. Jan. 10, 2025)



Case: 23-2218 Document: 106 Page: 1 Filed: 01/10/2025

United States Court of Appeals
for the Federal Circuit

IN RE: ENTRESTO (SACUBITRIL/VALSARTAN)

NOVARTIS PHARMACEUTICALS CORPORATION,
Plaintiff-Appellant

v.

TORRENT PHARMA INC., TORRENT PHARMACEUTICALS LTD.
Defendants

NOVARTIS PHARMACEUTICALS CORPORATION,
Plaintiff-Appellant

v.

ALEMBIC PHARMACEUTICALS LIMITED, ALEMBIC PHARMACEUTICALS INC.,
Defendants

NOVARTIS PHARMACEUTICALS CORPORATION,
Plaintiff-Appellant

v.

MSN PHARMACEUTICALS, INC., MSN

- **2015:** FDA approved Novartis's chronic heart failure medication Entresto®
  - '659 patent claiming pharmaceutical composition of valsartan and sacubitril where both are administered in combination in a 1:1 ratio, expired January 15, 2025
- **2019**: ANDAs filed, suits consolidated in MDL in Delaware (Torrent, Alembic, MSN, Hetero)
- **2023:** Judge Andrews found patents not invalid for obviousness or enablement, but shown to be **invalid for lack of written description**
- **2024:** Denial of Novartis motion for preliminary injunction
- **2025**: Fed. Circ. **reversed written description** and affirmed on lack of enablement and obviousness

In re Entresto, No. 2023-2218, (Fed. Cir. Jan. 10, 2025)

Claim Construction

*"wherein said [valsartan and sacubitril] are administered **in combination**"*

- MSN argued term should be limited to administration of the active ingredients as two separate components (i.e., in a non-complexed form, such as a physical mixture)
- District court agreed with Novartis and gave term plain and ordinary meaning
  - Court relied on intrinsic record, including statements Novartis made to the Patent Office for PTE application: Entresto includes non-separate, complexed valsartan and sacubitril
- MSN stipulated to infringement

In re Entresto, No. 2023-2218, (Fed. Cir. Jan. 10, 2025)

Written Description

*"Because the '659 patent does not **claim valsartan-sacubitril complexes**, those complexes need not have been described."*

- '659 patent adequately described two drugs administered "in combination" and disclosures "plainly show that the inventors had possession of a pharmaceutical composition comprising valsartan and sacubitril administered 'in combination'."

- The "complex—not discovered until four years after the priority date of the '659 patent [2002]—is not what is claimed."

  - District court erroneously conflated the distinct issues of patentability and infringement by stating that the claims were "***construed to cover*** complexes of valsartan and sacubitril."

  - Only need to answer whether that which is claimed (administering "in combination") is adequately described.

In re Entresto, No. 2023-2218, (Fed. Cir. Jan. 10, 2025)

Enablement

- The later-discovered valsartan-sacubitril complexes, which arguably may have improved upon the "basic" or "underlying" invention claimed in the '659 patent, cannot be used to "reach back" and invalidate the asserted claims.

Obviousness

- Even if a person of ordinary skill in the art had been motivated to provide an ARB-NEP inhibitor combination therapy, there was ***no motivation in the relied-upon prior art to combine valsartan and sacubitril***, let alone with any reasonable expectation of success.

The Race to January 15, 2025 ('659 Patent Expires)

Case 1:20-md-02930-RGA Document 1713 Filed 01/13/25 Page 1 of 2 PageID #: 63906

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Entresto (Sacubitril/Valsartan) Patent Litigation	C.A. No. 20-2930-RGA
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, MSN LIFE SCIENCES PRIVATE LIMITED, Defendants.	C.A. No. 19-2053-RGA

NOVARTIS'S MOTION FOR INJUNCTIVE RELIEF AGAINST MSN ON U.S. PATENT NO. 8,101,659

Plaintiff Novartis Pharmaceuticals Corporation ("Novartis") has prevailed in its Hatch-Waxman patent suit against Defendants MSN Pharmaceuticals Inc., MSN Laboratories Private Limited and MSN Life Sciences Private Limited (collectively "MSN") on Novartis's U.S. Patent

ORDER

For the reasons stated in open court, the motion for injunctive relief (D.I. 1713), the motion for post-judgment modification (D.I. 1722) and the motion for leave to amend answer (D.I. 1728) are all DISMISSED without prejudice for lack of jurisdiction.

United States District Court
1/15/25

1

Case 1:25-cv-00090-DLF Document 3-1 Filed 01/13/25 Page 1 of 35

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff,* v. XAVIER BECERRA, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, and ROBERT M. CALIFF, M.D., in his official capacity as COMMISSIONER OF FOOD AND DRUGS, FOOD AND DRUG ADMINISTRATION, *Defendants.*	Civil Action No. 25-90

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF NOVARTIS'S MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

Susan M. Cook (D.C. Bar No. 462978)
Marlan Golden (D.C. Bar No. 1673073)
Jacob T. Young (D.C. Bar No. 90014334)

Corporation

Filed: 2025-01-15

Order

MINUTE ORDER. For the reasons given in today's hearing, the plaintiff's 3 Motion for TRO is DENIED. On or before January 17, 2025, the parties shall file a joint status report proposing a briefing schedule for further proceedings. So Ordered by Judge Dabney L. Friedrich on January 15, 2025. (lcdlf1) (Entered: 01/15/2025)

USCA Case #24-5235 Document #2094402 Filed: 01/15/2025 Page 1 of 1

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 24-5235 **September Term, 2024**

1:24-cv-02234-DLF

Filed On: January 15, 2025

Novartis Pharmaceuticals Corporation,

Appellant

v.

Xavier Becerra, in his official capacity as Secretary of Health and Human Services, et al.,

Appellees

BEFORE: Millett, Wilkins, and Rao, Circuit Judges

ORDER

Upon consideration of the emergency motion for administrative stay and stay pending appeal; the Food and Drug Administration's ("FDA") responses; MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited's (collectively, "MSN") response, which includes a request for bond; and the reply, it is

ORDERED that the Food and Drug Administration's approval of intervenor-appellees' abbreviated new drug application for a generic version of Entresto be administratively stayed pending further order of the court. The purpose of this administrative stay is to give the court sufficient opportunity to consider the emergency motion for stay pending appeal and should not be construed in any way as a ruling on the merits of that motion. See D.C. Circuit Handbook of Practice and Internal Procedures 33 (2024).

Per Curiam

FOR THE COURT:
Clifton B. Cislak, Clerk

BY: /s/
Michael C. McGrail
Deputy Clerk

Additional 2024 Developments

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Safe Harbors and Orange Book Listings

- **Safe Harbor (*Edwards Lifesciences v. Meril Life Sciences*, Fed. Cir. Mar. 25, 2024)**
  - Addressed whether the importation of two demonstration-only transcatheter heart valves for a conference during the process of pre-market approval was protected by the safe harbor, and ultimately affirmed grant of summary judgment of no infringement
  - **Takeaway**: What role, if any, intent plays in a safe harbor analysis regarding, *inter alia*, presentations at industry conferences may be an ongoing discussion for the courts
- **Orange Book Listings (*Teva v. Amneal Pharm*., Fed. Cir. Dec. 20, 2024)**
  - Teva asserted five Orange Book-listed patents covering its ProAir® HFA (albuterol sulfate) inhaler against Amneal. District Court held that while Teva's inhaler product falls under the broad definition of "drug" as defined in 21 U.S.C. § 321(g)(1), the inhaler is not the drug for which Teva submitted its NDA. CAFC affirmed
  - **Takeaway**: Patent holders will likely want to review the claims for listed and soon-to-be-listed Orange Book patents to consider whether their claims cover the active ingredient that is part of the drug substance or drug product for which applicants submitted their NDA

Patent Eligbility and Polymorphs

- **Patent Eligibility (*Astellas Pharma v. Sandoz*, Fed. Cir. Sept. 18, 2024)**
  - CAFC vacated district court's *sua sponte* decision finding Astellas Orange Book listed-patent for Myrbetriq® ineligible under Section 101. CAFC applied the party presentation principle as neither party advanced any claim or defense of invalidity based on patent eligibility. CAFC also noted flaws in the district court's substantive application of Section 101 to the asserted patent.
  - **Takeaway**: District courts and parties should treat eligibility of issued patents under Section 101 in the same manner they treat other invalidity defenses.
- **Obviousness of Polymorphs (*Salix Pharm. v. Norwich Pharm.*, Fed. Cir. Apr. 11, 2024)**
  - Generic argued prior art contained examples that disclosed in detail the process that would produce the claimed polymorph, evidencing a reasonable expectation of success in doing so. District Court found claims obvious under Section 103 and CAFC affirmed
  - **Takeaway**: The nonobviousness of polymorph patents is not a guaranteed, despite the unique, unpredictable nature of the science and cases finding as such

Impact of Trump Administration – New USPTO Director

- Appointment of USPTO Director and impact on Office
  - Director has impact on patent policy, including patent examination and post-grant proceedings
    - Operational efficiency, reducing regulations, strengthening patents, relaxing § 101 requirements
    - Appropriate for PTAB to exercise more discretion when considering whether to institute
  - Trump Names **Coke Morgan Stewart** new Deputy Undersecretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office
- Trump Appointee Agenda
  - Could be more relaxed on § 101 issues
  - Would look to strengthen patents and break down barriers in litigation and at the patent office
  - Likely to be more pro-business and pro-inventor
  - Policies likely will make invalidating patents at PTAB harder

Impact of Trump Administration – Changes at FTC

- Former FTC chair Lina Khan took enforcement actions related to pharmaceutical IP
  - Challenged Orange Book listings in 2023 and 2024
  - Issued rule banning non-competes in 2024, which could have implications for trade secret protection.
  - Supported Biden admin's proposed march-in rights framework, which allows agencies to include drug price as a factor to consider when exercising march-in rights under Bayh-Dole Act
- New FTC Chair could affect pharmaceutical IP
  - Trump named Andrew Ferguson as FTC chair. Nominated Mark Meador to replace Lina Khan
  - Ferguson likely to role back Khan initiatives
  - More focus on Big Tech than biopharma industry

Impact of Trump Administration – Pharmaceutical Patents

- **Inflation Reduction Act (IRA)**
  - Impact on pharma patents because IRA allows CMS to negotiate drug prices
  - We have limited data; only two rounds of products have been selected under IRA to date.
  - Trump would push for rollbacks of the IRA's climate-related policies, including redirecting unspent climate-related funds to road, bridge, and dam projects.
  - Unclear how a Trump admin would handle drug price negotiations.
  - Probably not going anywhere, but Trump admin would not seek to expand or expedite it
- **March-in rights (Bayh-Dole)**
  - Dec. 2023, Biden Administration announced a policy to permit agencies to exercise "March-In" rights under the Bayh-Dole Act for patents arising from federal research, including based upon drug prices. FTC supported the rule.
  - Trump has a history of opposing march-in-rights based on price; unlikely to pursue
  - March-in rights have been around for a long time. Immediate likelihood of march-in rights affecting companies is low
- **Pending legislation**
  - Affordable Prescriptions for Patients Act (passed Senate unanimously)
    - Bans product hopping
  - Medication Affordability and Patent Integrity Act (introduced in Senate)
    - Requires sponsors of applications under FDCA to certify to FDA and USPTO that information submitted to each is consistent with information submitted to the other
    - Requires sponsor to submit to USPTO any information "material to patentability" or "applicable patents" that it submitted to FDA
    - Adds new defense to patent infringement based on patentee's failure to comply

Looking Forward to 2025

FISH.

What to Watch for in 2025

- **Further Shift from ANDA cases in DE to DNJ**
- **Any additional shake ups in ODP law?**
- **The Skinny Label Sagas Continue (*Amarin v. Hikma*; *GSK v. Teva*)**
- **Renewed hope for fending off written description? (*In re Entresto*)**
- **New USPTO Director and FTC Chair**
- **Trump administration impact on pharmaceutical patents and FDA**

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