Life Sciences Webinar Series

2020 Year in Review

January 27, 2021

FISH.

FISH & RICHARDSON

Meet The Speakers

Chad Shear
Principal

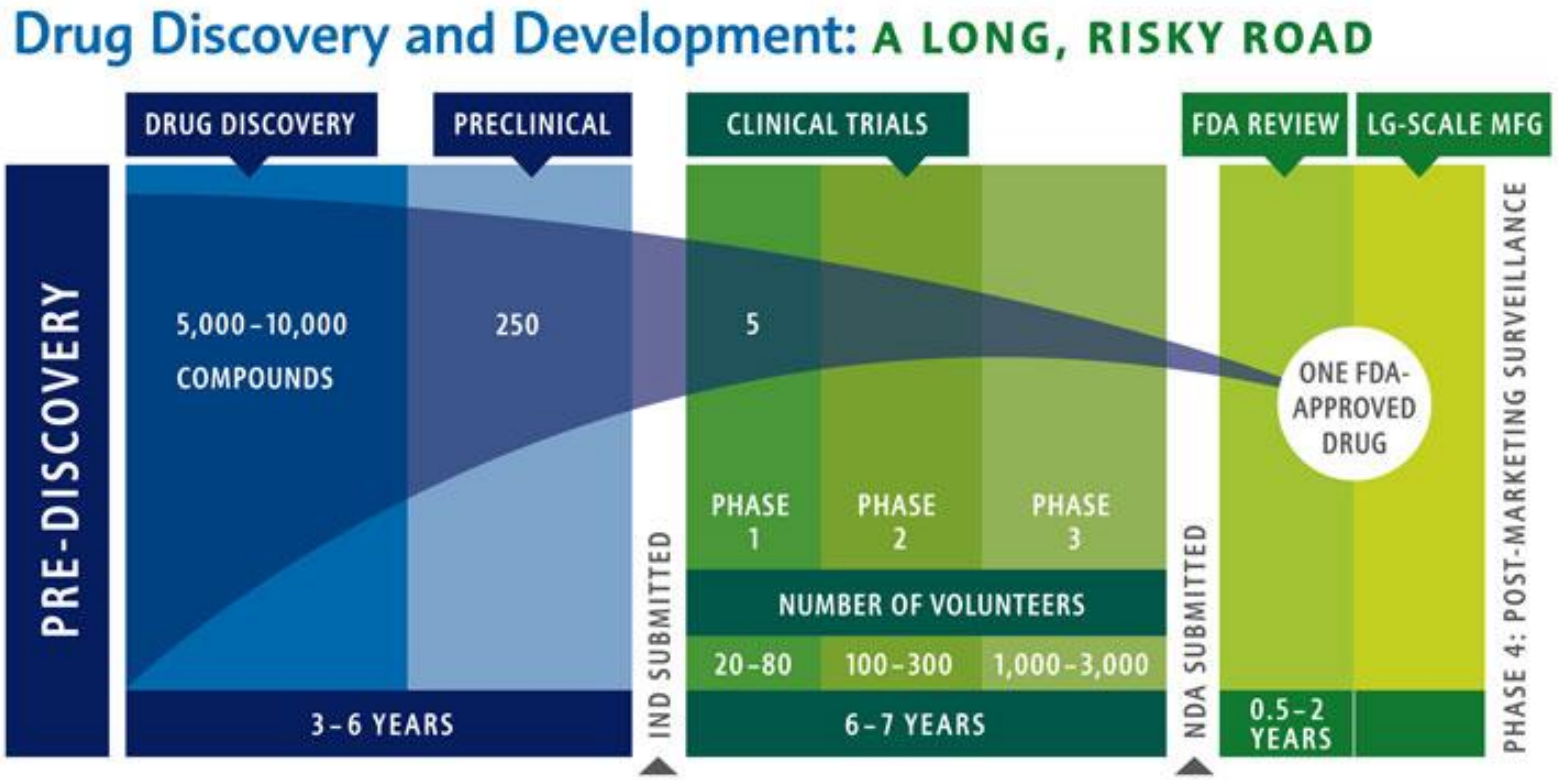
Teresa Lavoie
Principal

Agenda

- Inducement
- §101
- Venue
- Doctrine of Equivalence

GSK v Teva

Drug Development is a Long Road



Source: Pharmaceutical Research and Manufacturers of America

Orange Book – Patent Listing

- **Typical types of patents generated from R&D**
  - Compound, method of treatment, formulation, form, manufacture, metabolite, intermediates, packaging
- **Eligibility**
  - Patent must claim a drug or method of using a drug for which a claim of patent infringement could reasonably be asserted
  - 2003 Orange Book Reforms – no packaging patents, metabolites or intermediates

Patent Certification

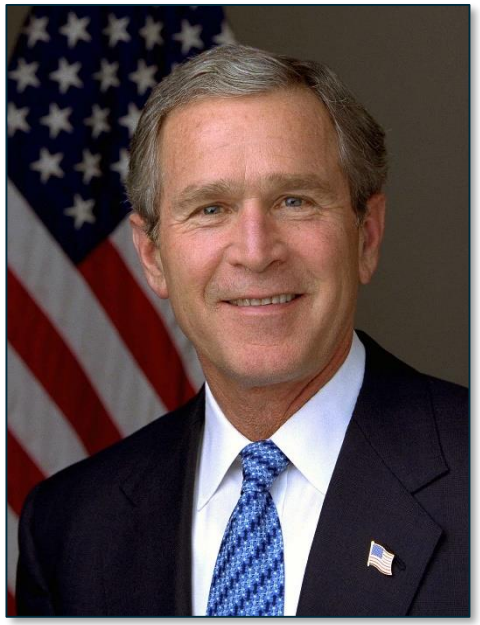
For each patent listed in the Orange Book, Generics must certify one of the following:

- **Paragraph I** – patent information has not been filed
- **Paragraph II** – patent has expired
- **Paragraph III** – date patent will expire
- **Paragraph IV** – such patent is invalid or will not be infringed by the manufacture use or sale of the drug for which the application is submitted

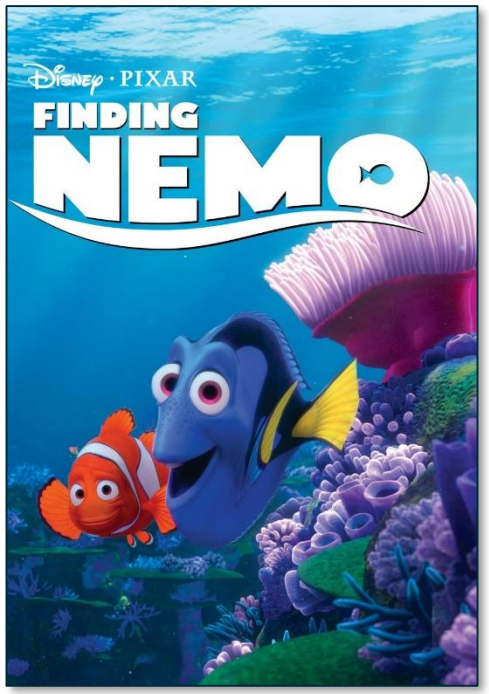
“Section viii” Carve Out – 505(j)(2)(A)(viii)

- **Permits a generic to “carve out” of label approved uses that it is not seeking approval for**
  - Generic product must still be safe and effective for remaining approved uses
  - Impact: ANDA with carved out label can be approved absent another PIV (i.e. no First to File blocking approval)

2003



iTunes



YAHOO!

msn

A Little Context . . .

2003

Gabapentin

- **Approved for the treatment of epilepsy**
- **Orange Book listed patent was to the treatment of neurodegenerative disorders**
  - Epilepsy is not a neurodegenerative disorder
- **78% of actual use by doctors was *not* for epilepsy, it was for neurodegenerative disorders**
- **Neurodegenerative disorders are not on the label**

Alphagan

- **Approved for the treatment of glaucoma**
- **Substantial off-label use for neuro protection**
- **Asserted patent was for neuro protection**
- **Neuro protection is not on the label**

2003

- Both cases are brought under 35 U.S.C. § 271(e) pre-launch
- Both cases are for claims of induced infringement for off-label uses
- Both cases are dismissed by the respective District Courts for failing to state a cause of action under § 271 (e)
- Both cases arrive that the Federal Circuit at the same time
- Both cases present the same issue of first impression
- Both cases are argued the same week to *different* panels

Law for Induced Infringement

“Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). "[I]nducement requires that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another’s infringement.” *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc in relevant part) (citation omitted) (internal quotation marks omitted).

35 U.S.C. § 271(b); *Astrazeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010).

Warner-Lambert v. Apotex (2003)

- **Neurontin (gabapentin)**
  - Approved Use: treatment of epilepsy
  - Compound and Original Method Patent Expired
  - Asserted patent: method of treating neurodegenerative disorders (did not include epilepsy)
  - No FDA approval for any of conditions covered by asserted patent
- **Apotex Generic**
  - Labeled for Epilepsy
  - Paragraph IV certification of non-infrignement to Neurodegenerative patent based on limitation of intended FDA approval

Warner-Lambert v. Apotex (2003)

- **Held:**
  - Apotex entitled to judgment as a matter of law
  - Despite:
    - **75% of the use of the drug was not for epilepsy**
    - **Acknowledgement that doctors would use the drug for infringing uses, just as Gabapentin was**
  - Hatch-Waxman Act only allows for patent listing, and infringement of on-label, approved uses
- **So, Warner-Lambert should not have listed the patent in the Orange Book**
- **Conversely, Apotex should have provided a section viii (though, at the time, FDA would not have allowed it)**
  - Eventually, in 2003, statute amended to clarify how this all works
- **Case did not foreclose Warner-Lambert from suing later for infringement if they chose**

Allergan v Alcon (2003)

- Issues shortly after *Warner-Lambert*
- *Per curiam* opinion concluding that *Warner-Lambert* controls and therefore it must affirm the District Court's decision
- Acknowledges that mandatory substitution laws require a pharmacist to substitute the generic product for both on and off label uses regardless of what the approved use is
- *FIREY* "dissents" from each of the three judges attacking the *Warner-Lambert* decision

End Result

- **Under § 271(e)**
  - Recognizes § 271(e) involves a hypothetical act of infringement
    - **Forced to analyze what will likely happen based on ANDA as opposed to analyzing direct evidence**
  - Concludes cannot bring a claim for inducement for an off-label use
  - Leaves open whether a claim for inducement can be brought *post-launch*

Coreg®

- **Coreg (carvedilol)**
  - Three approved uses
    - **(#1) Heart Failure**
    - **(#2) Left ventricular dysfunction in patients post infarction (MI/LVD) [ultimately litigated as a species of heart failure]**
    - **(#3) Hypertension**
  - Hypertension patent expired with molecule patent
  - GSK only ever marketed for heart failure
  - GSK obtained the ‘000 re-issue patent, which covered heart failure, but only after generics had launched

Teva

- **Carvedilol**
  - Originally, pursued full-label, but launched as skinny label,
    - **Sought indications for left ventricular dysfunction and hypertension**
    - **Submitted a section viii to heart failure**
  - After a few years, Teva put heart failure back on label
  - Advertised that it was A-B rated for all uses

GSK v Teva – District Court

- **Jury charged to decide infringement**
  - Presented with evidence of full label, catalogs, websites and press releases as evidence of inducement
- **Jury Teva induced infringement**
- **Jury awards damages of $235 million**
- **District Court grants Judgement as a Matter of Law (JMOL) centered on causation**
  - Teva argued that GSK was required to prove that "Teva's alleged inducement, as opposed to other factors, actually caused the physicians to directly infringe."
  - GSK argued that Federal Circuit precedent accepted circumstantial evidence such as instructions/ labels, catalogs and other materials as evidence of inducement
  - District Court held that:
    - **GSK had not shown "that any doctor was ever induced to infringe the patent by Teva's label (either skinny or full)**
    - **Teva, on the other hand, had shown that other factors caused physicians to prescribe its generic**

Federal Circuit

“Precedent makes clear that when the provider of an identical product knows of an markets the same product for intended direct infringing activity, the criteria of induced infringement are met.”

Federal Circuit - Reverses

- **Held:**
  - Jury verdict of infringement (and damages) re-instated
  - Press releases, catalogs and other conduct indicated inducement
  - Attempt to shift blame to GSK not supported under the law of inducement
- **Strong Dissent from Chief Judge Prost**

Illumina v. Ariosa

Are Process of Preparation Claims Patent Eligible?

- **Yes.**
  - This is not a diagnostic case. And it is not a method of treatment case. This is a process of preparation case.
  - Claims directed to process of enriching for cff DNA relative to cf maternal DNA and analyzing a genetic locus of the same.
    - **Distinguish prior Ariosa case to detecting cf DNA itself.**

Are Process of Preparation Claims Patent Eligible?

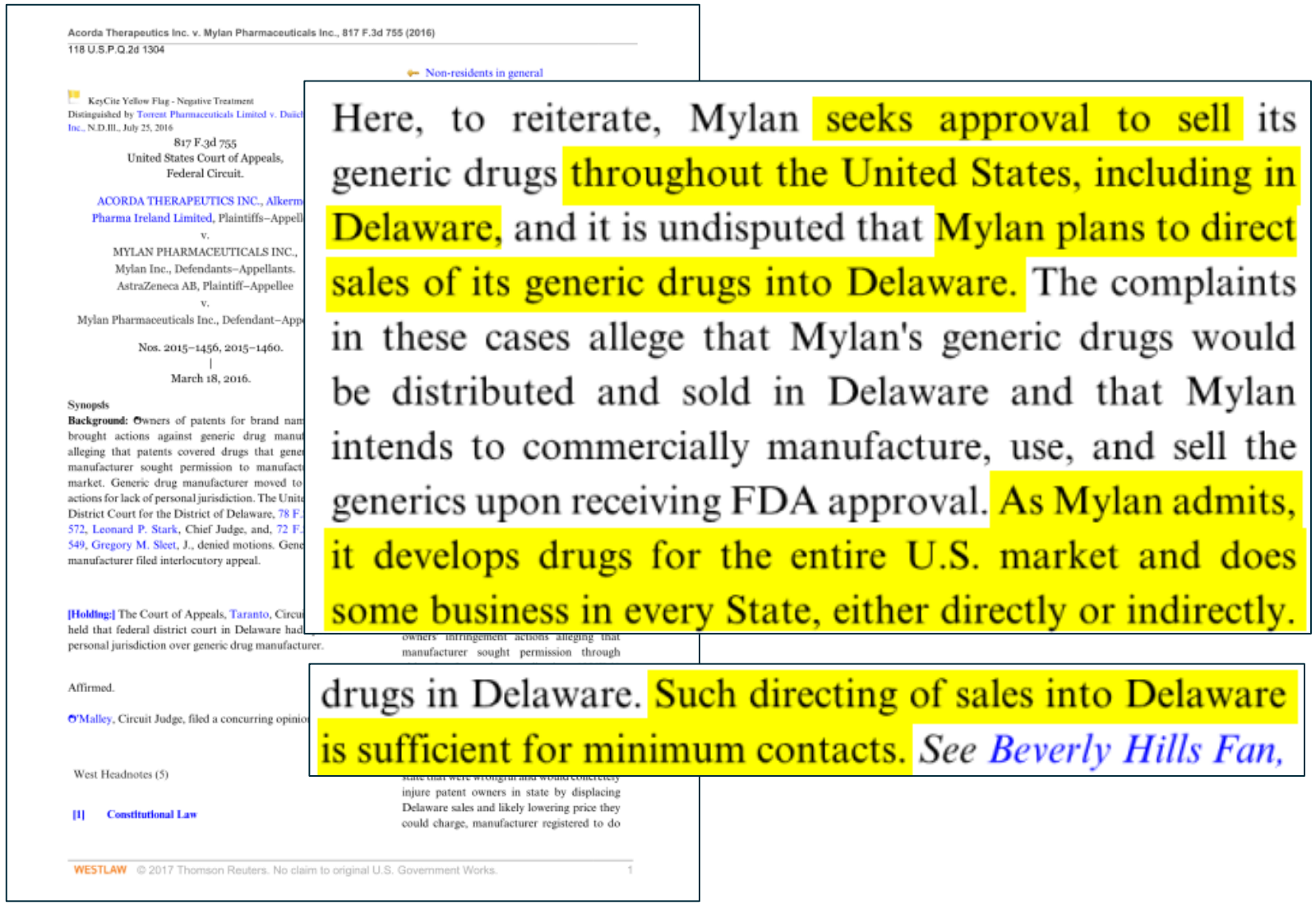
- Under *Mayo*, claims are not "directed to" a natural phenomenon.
  - **Not directed to cff DNA itself.**
  - **While common techniques to enrich used (e.g., size exclusion chromatography), not relevant to eligibility, because no need to go to the second step of Mayo analysis.**
- Distinguish discovery from practical application of discovery.
- Cellz direct analogy (process of preparing frozen hepatocytes).

Valeant v Mylan

Typically Two Limitations on Where Cases Are Filed

- **Personal Jurisdiction**
  - Individual State's Long Arm Statute
  - Typically commensurate in scope with Constitutional limits
    - **Minimum Contacts**
    - **Exercise of jurisdiction does not violate traditional notions of fair play and substantial justice**
- **Venue**

Personal Jurisdiction in Hatch Waxman Cases



Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc., 817 F.3d 755 (2016)
118 U.S.P.Q.2d 1304

Non-residents in general

KeyCite Yellow Flag - Negative Treatment
Distinguished by Torrent Pharmaceuticals Limited v. Dudch Inc., N.D.Ill., July 25, 2016

817 F.3d 755
United States Court of Appeals,
Federal Circuit.

ACORDA THERAPEUTICS INC., Alkerm
Pharma Ireland Limited, Plaintiffs–Appell
v.
MYLAN PHARMACEUTICALS INC.,
Mylan Inc., Defendants–Appellants.
AstraZeneca AB, Plaintiff–Appellee
v.
Mylan Pharmaceuticals Inc., Defendant–App

Nos. 2015–1456, 2015–1460.
|
March 18, 2016.

Synopsis
Background: Owners of patents for brand nam brought actions against generic drug manu alleging that patents covered drugs that gene manufacturer sought permission to manufact market. Generic drug manufacturer moved to actions for lack of personal jurisdiction. The Unite District Court for the District of Delaware, 78 F. 572, Leonard P. Stark, Chief Judge, and, 72 F. 549, Gregory M. Sleet, J., denied motions. Gene manufacturer filed interlocutory appeal.

[Holding:] The Court of Appeals, Taranto, Circu held that federal district court in Delaware had personal jurisdiction over generic drug manufacturer.

Affirmed.

O'Malley, Circuit Judge, filed a concurring opinio

West Headnotes (5)

[1] Constitutional Law

owners infringement actions alleging that manufacturer sought permission through

injure patent owners in state by displacing Delaware sales and likely lowering price they could charge, manufacturer registered to do

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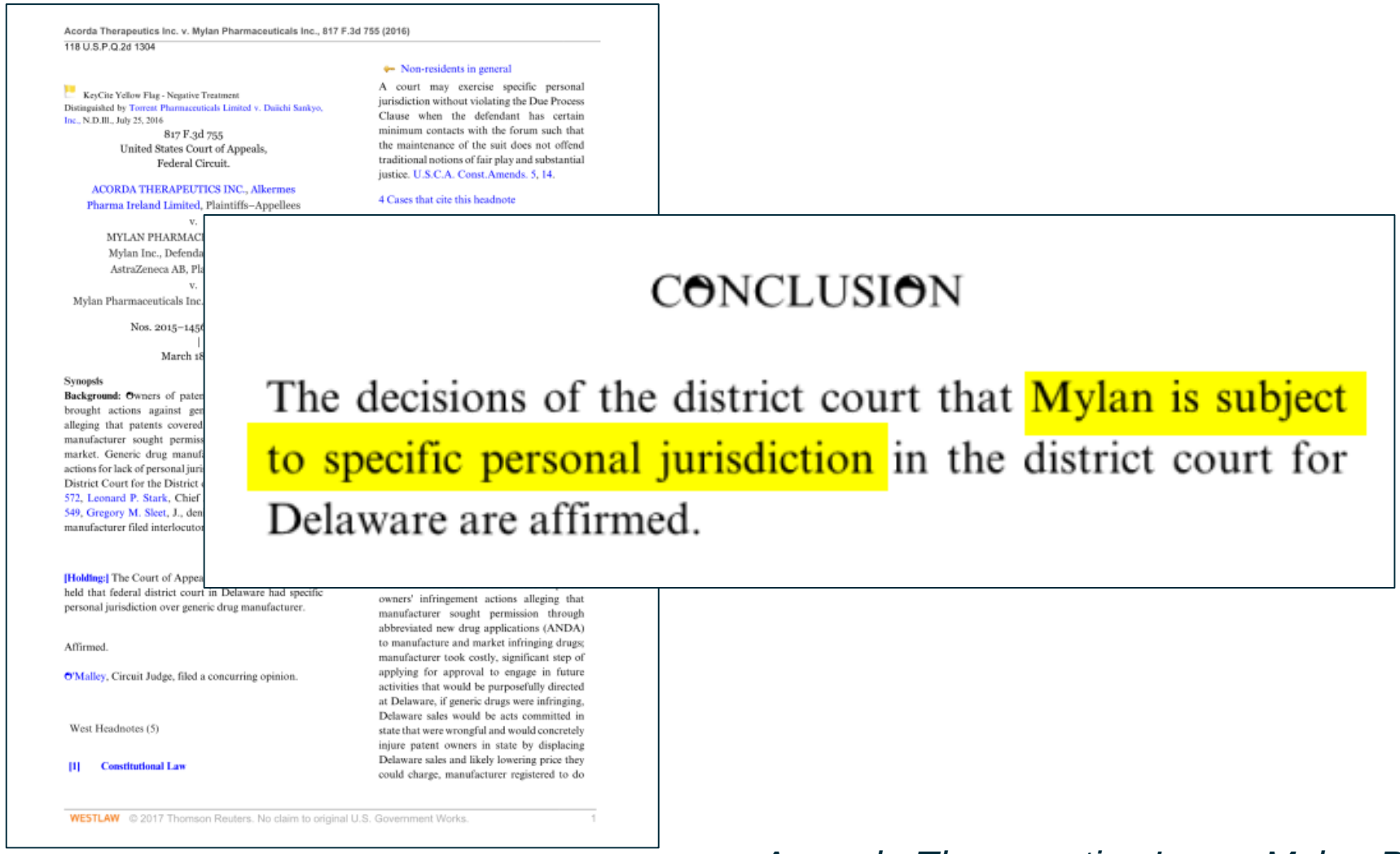
Here, to reiterate, Mylan seeks approval to sell its generic drugs throughout the United States, including in Delaware, and it is undisputed that Mylan plans to direct sales of its generic drugs into Delaware. The complaints in these cases allege that Mylan's generic drugs would be distributed and sold in Delaware and that Mylan intends to commercially manufacture, use, and sell the generics upon receiving FDA approval. As Mylan admits, it develops drugs for the entire U.S. market and does some business in every State, either directly or indirectly.

drugs in Delaware. Such directing of sales into Delaware is sufficient for minimum contacts. *See Beverly Hills Fan,*

Accorda Therapeutics Inc. v. Mylan Pharmaceuticals, Inc.

Personal Jurisdiction



Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc., 817 F.3d 755 (2016)
118 U.S.P.Q.2d 1304

KeyCite Yellow Flag - Negative Treatment
Distinguished by Torrent Pharmaceuticals Limited v. Daiichi Sankyo, Inc., N.D.Ill., July 25, 2016

817 F.3d 755
United States Court of Appeals,
Federal Circuit.

ACORDA THERAPEUTICS INC., Alkermes Pharma Ireland Limited, Plaintiffs–Appellees
v.
MYLAN PHARMACI
Mylan Inc., Defenda
AstraZeneca AB, Pl
v.
Mylan Pharmaceuticals Inc.

Nos. 2015–145
|
March 18

Synopsis
Background: Owners of paten
brought actions against ge
alleging that patents covered
manufacturer sought permiss
market. Generic drug manuf
actions for lack of personal juri
District Court for the District
572, Leonard P. Stark, Chief
549, Gregory M. Sleet, J., den
manufacturer filed interlocuto

[Holding:] The Court of Appea
held that federal district court in Delaware had specific personal jurisdiction over generic drug manufacturer.

Affirmed.

O'Malley, Circuit Judge, filed a concurring opinion.

West Headnotes (5)

[1] **Constitutional Law**

Non-residents in general

A court may exercise specific personal jurisdiction without violating the Due Process Clause when the defendant has certain minimum contacts with the forum such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice. U.S.C.A. Const.Amends. 5, 14.

4 Cases that cite this headnote

owners' infringement actions alleging that manufacturer sought permission through abbreviated new drug applications (ANDA) to manufacture and market infringing drugs; manufacturer took costly, significant step of applying for approval to engage in future activities that would be purposefully directed at Delaware, if generic drugs were infringing, Delaware sales would be acts committed in state that were wrongful and would concretely injure patent owners in state by displacing Delaware sales and likely lowering price they could charge, manufacturer registered to do

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CONCLUSION

The decisions of the district court that Mylan is subject to specific personal jurisdiction in the district court for Delaware are affirmed.

Accorda Therapeutics Inc. v. Mylan Pharmaceuticals, Inc.

Venue – Patents and Copyrights – 28 U.S.C. § 1400

"Any civil action for patent infringement may be brought in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business."

28 U.S.C. §1400(b)

Venue Generally – 28 U.S.C. § 1391

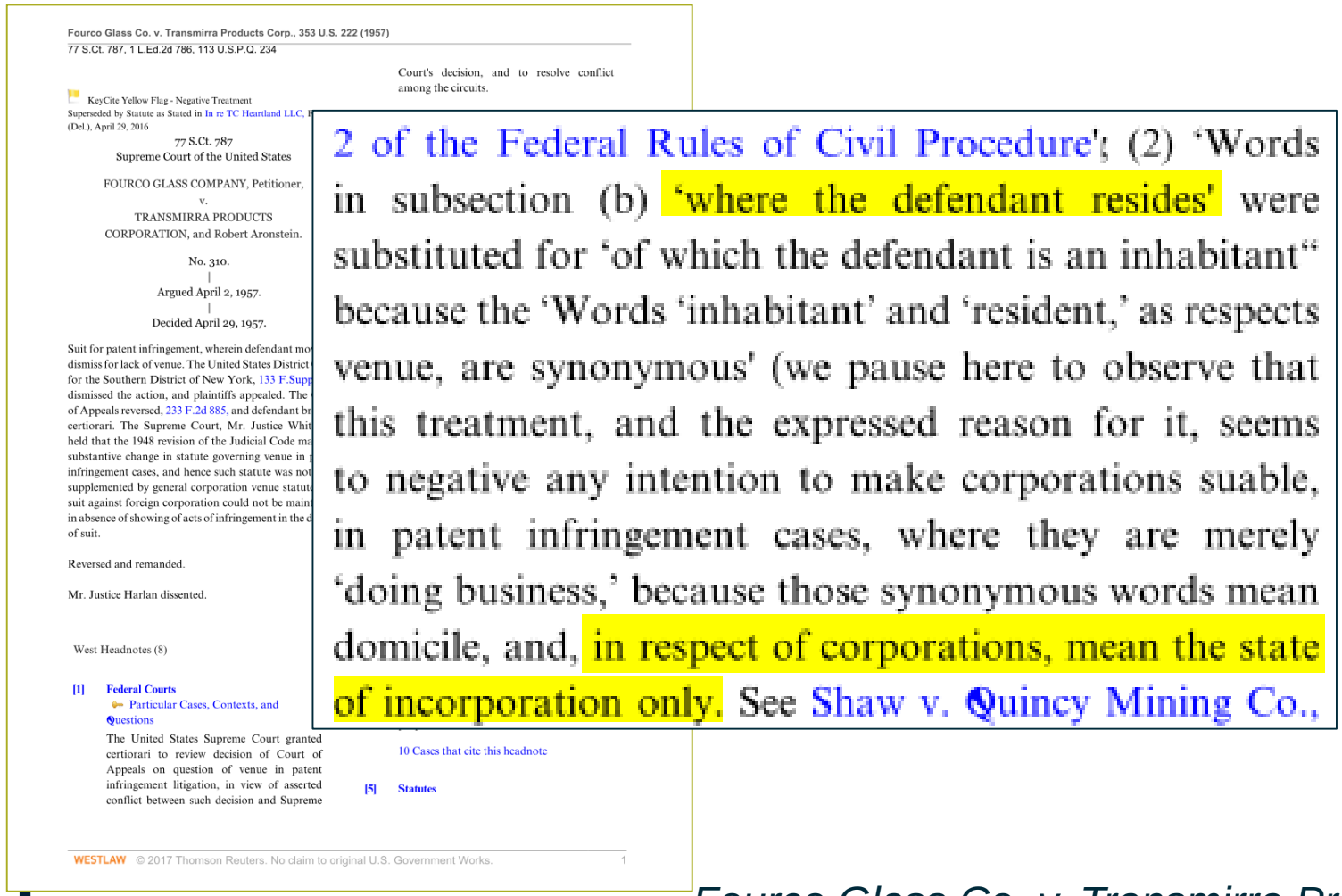
(c) Residency.—For all venue purposes—

(1) a natural person, including an alien lawfully admitted for permanent residence in the United States, shall be deemed to reside in the judicial district in which that person is domiciled;

(2) an entity with the capacity to sue and be sued in its common name under applicable law, whether or not incorporated, shall be deemed to reside, if a defendant, in any judicial district in which such defendant is subject to the court's personal jurisdiction with respect to the civil action in question and, if a plaintiff, only in the judicial district in which it maintains its principal place of business; and

(3) a defendant not resident in the United States may be sued in any judicial district, and the joinder of such a defendant shall be disregarded in determining where the action may be brought with respect to other defendants.

“Resides” per § 1400(b)



Fourco Glass Co. v. Transmirra Products Corp., 353 U.S. 222 (1957)
77 S.Ct. 787, 1 L.Ed.2d 786, 113 U.S.P.Q. 234

Court's decision, and to resolve conflict among the circuits.

KeyCite Yellow Flag - Negative Treatment
Superseded by Statute as Stated in In re TC Heartland LLC, (Del.), April 29, 2016

77 S.Ct. 787
Supreme Court of the United States

FOURCO GLASS COMPANY, Petitioner,
v.
TRANSMIRRA PRODUCTS CORPORATION, and Robert Aronstein.

No. 310.
Argued April 2, 1957.
Decided April 29, 1957.

Suit for patent infringement, wherein defendant mo dismiss for lack of venue. The United States District for the Southern District of New York, 133 F.Supp dismissed the action, and plaintiffs appealed. The of Appeals reversed, 233 F.2d 885, and defendant br certiorari. The Supreme Court, Mr. Justice Whit held that the 1948 revision of the Judicial Code ma substantive change in statute governing venue in p infringement cases, and hence such statute was not supplemented by general corporation venue statute suit against foreign corporation could not be maint in absence of showing of acts of infringement in the d of suit.

Reversed and remanded.

Mr. Justice Harlan dissented.

West Headnotes (8)

[1] Federal Courts
Particular Cases, Contexts, and Questions

The United States Supreme Court granted certiorari to review decision of Court of Appeals on question of venue in patent infringement litigation, in view of asserted conflict between such decision and Supreme

10 Cases that cite this headnote

[5] Statutes

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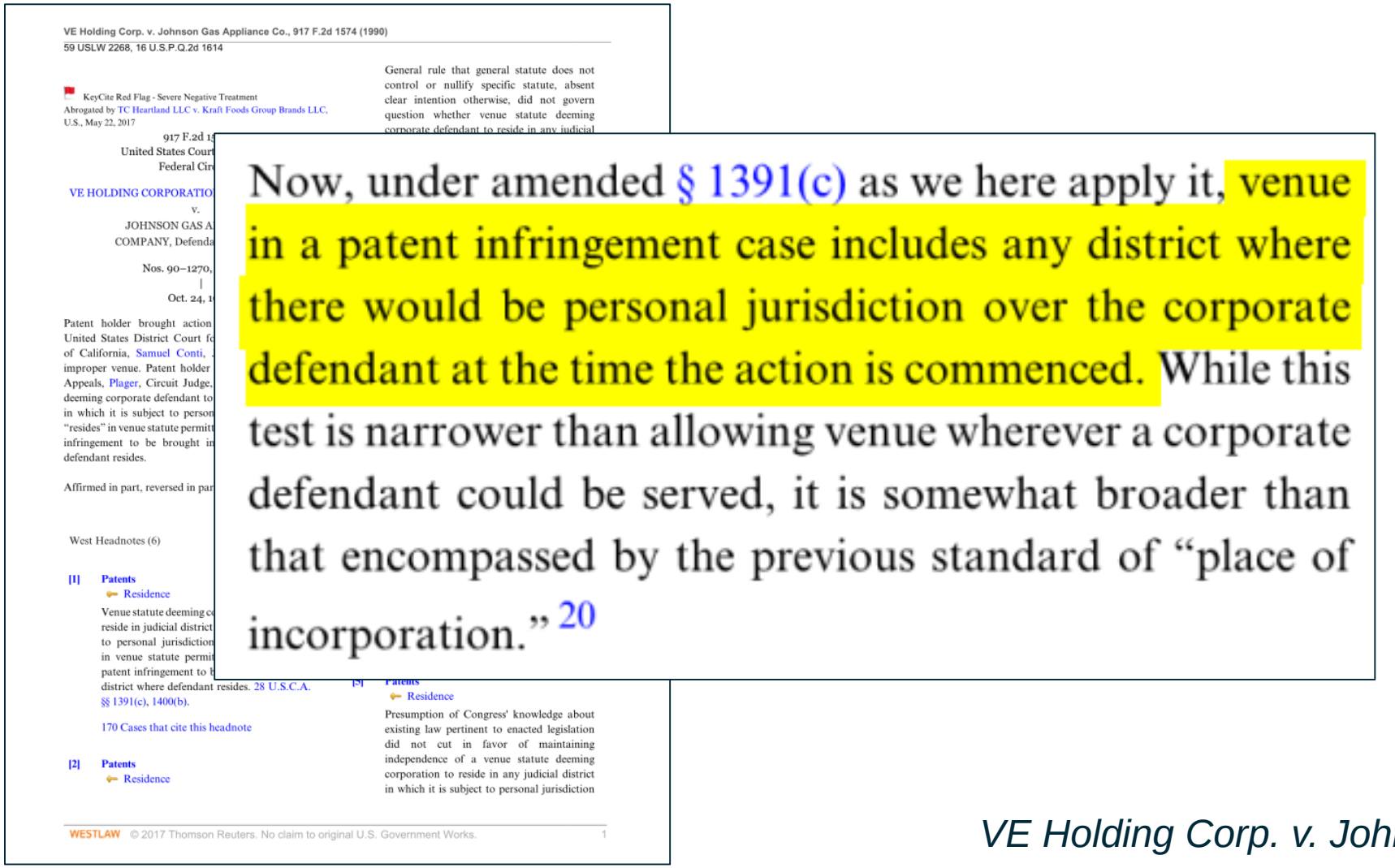
2 of the Federal Rules of Civil Procedure'; (2) 'Words in subsection (b) 'where the defendant resides' were substituted for 'of which the defendant is an inhabitant" because the 'Words 'inhabitant' and 'resident,' as respects venue, are synonymous' (we pause here to observe that this treatment, and the expressed reason for it, seems to negative any intention to make corporations suable, in patent infringement cases, where they are merely 'doing business,' because those synonymous words mean domicile, and, in respect of corporations, mean the state of incorporation only. See Shaw v. Quincy Mining Co.,

Fourco Glass Co. v. Transmirra Products, Corp. 353 US 222(1957)

The Expansion of the Doctrine



VE Holding Corp. v. Johnson Gas Appliance Co., 917 F.2d 1574 (1990)
59 USLW 2268, 16 U.S.P.Q.2d 1614

KeyCite Red Flag - Severe Negative Treatment
Abrogated by TC Heartland LLC v. Kraft Foods Group Brands LLC, U.S., May 22, 2017

917 F.2d 1

United States Court
Federal Cir

VE HOLDING CORPORATIO

v.

JOHNSON GAS A
COMPANY, Defenda

Nos. 90–1270,

Oct. 24, 1

Patent holder brought action
United States District Court fo
of California, Samuel Conti,
improper venue. Patent holder
Appeals, Plager, Circuit Judge,
deeming corporate defendant to
in which it is subject to person
"resides" in venue statute permitt
infringement to be brought in
defendant resides.

Affirmed in part, reversed in par

West Headnotes (6)

[1] Patents
Residence

Venue statute deeming c
reside in judicial district
to personal jurisdiction
in venue statute permit
patent infringement to b
district where defendant resides. 28 U.S.C.A. §§ 1391(c), 1400(b).

170 Cases that cite this headnote

[2] Patents
Residence

General rule that general statute does not control or nullify specific statute, absent clear intention otherwise, did not govern question whether venue statute deeming corporate defendant to reside in any judicial

[5] Patents
Residence

Presumption of Congress' knowledge about existing law pertinent to enacted legislation did not cut in favor of maintaining independence of a venue statute deeming corporation to reside in any judicial district in which it is subject to personal jurisdiction

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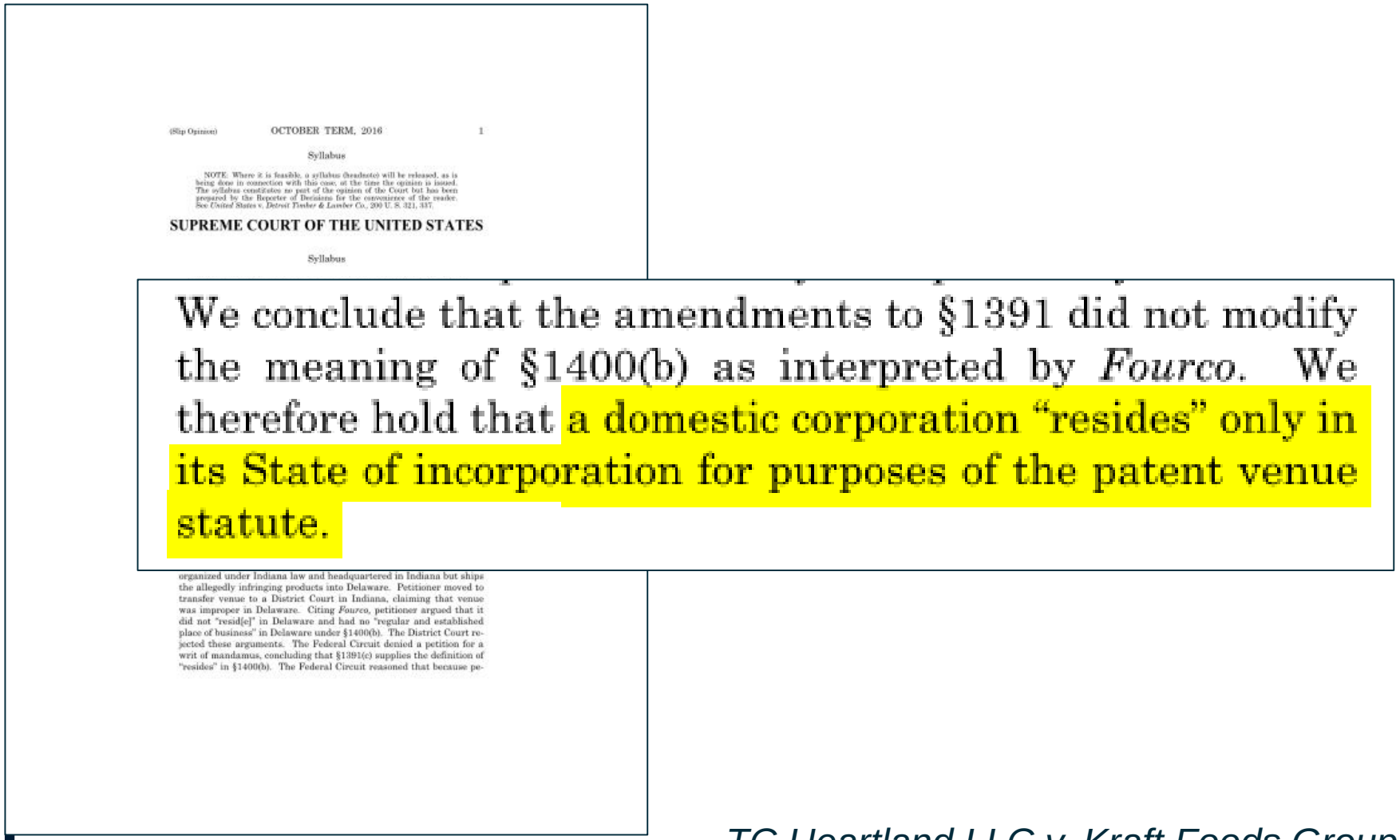
Now, under amended § 1391(c) as we here apply it, venue in a patent infringement case includes any district where there would be personal jurisdiction over the corporate defendant at the time the action is commenced. While this test is narrower than allowing venue wherever a corporate defendant could be served, it is somewhat broader than that encompassed by the previous standard of "place of incorporation." 20

VE Holding Corp. v. Johnson Gas Appliance Co.

The Retraction of the Doctrine



(Slip Opinion) OCTOBER TERM, 2016 1

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

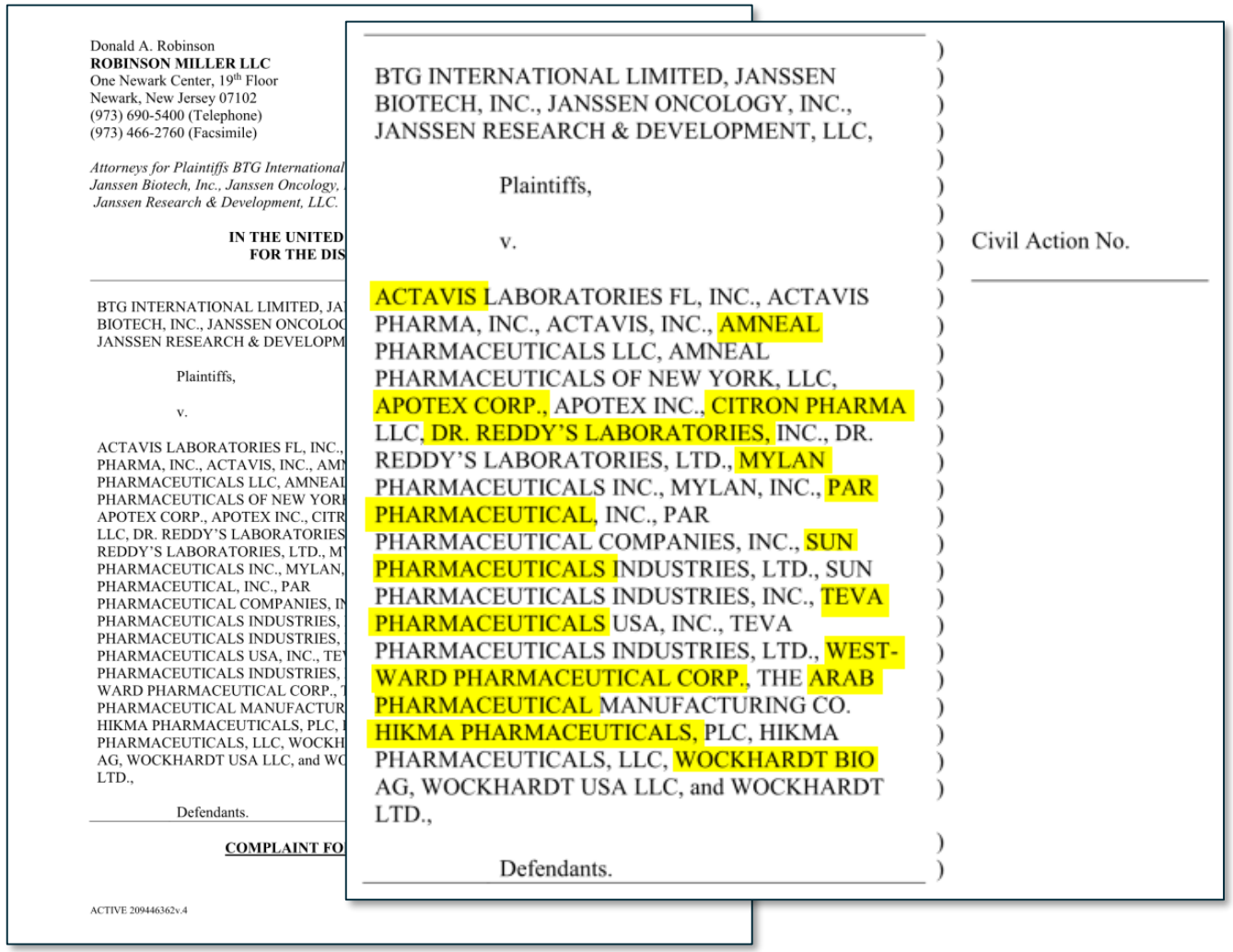
Syllabus

We conclude that the amendments to §1391 did not modify the meaning of §1400(b) as interpreted by *Fourco*. We therefore hold that a domestic corporation "resides" only in its State of incorporation for purposes of the patent venue statute.

organized under Indiana law and headquartered in Indiana but ships the allegedly infringing products into Delaware. Petitioner moved to transfer venue to a District Court in Indiana, claiming that venue was improper in Delaware. Citing *Fourco*, petitioner argued that it did not "resid[e]" in Delaware and had no "regular and established place of business" in Delaware under §1400(b). The District Court rejected these arguments. The Federal Circuit denied a petition for a writ of mandamus, concluding that §1391(c) supplies the definition of "resides" in §1400(b). The Federal Circuit reasoned that because pe-

TC Heartland LLC v. Kraft Foods Group, 137 S. Ct. 1514 (2017)

The Dilemma . . .



Donald A. Robinson
ROBINSON MILLER LLC
One Newark Center, 19th Floor
Newark, New Jersey 07102
(973) 690-5400 (Telephone)
(973) 466-2760 (Facsimile)

Attorneys for Plaintiffs BTG International Janssen Biotech, Inc., Janssen Oncology, Janssen Research & Development, LLC.

IN THE UNITED
FOR THE DIS

BTG INTERNATIONAL LIMITED, JA
BIOTECH, INC., JANSSEN ONCOLOG
JANSSEN RESEARCH & DEVELOPM

Plaintiffs,

v.

ACTAVIS LABORATORIES FL, INC.,
PHARMA, INC., ACTAVIS, INC., AM
PHARMACEUTICALS LLC, AMNEAL
PHARMACEUTICALS OF NEW YORK
APOTEX CORP., APOTEX INC., CITR
LLC, DR. REDDY'S LABORATORIES
REDDY'S LABORATORIES, LTD., M
PHARMACEUTICALS INC., MYLAN,
PHARMACEUTICAL, INC., PAR
PHARMACEUTICAL COMPANIES, IN
PHARMACEUTICALS INDUSTRIES,
PHARMACEUTICALS INDUSTRIES,
PHARMACEUTICALS USA, INC., TE
PHARMACEUTICALS INDUSTRIES,
WARD PHARMACEUTICAL CORP.,
PHARMACEUTICAL MANUFACTUR
HIKMA PHARMACEUTICALS, PLC,
PHARMACEUTICALS, LLC, WOCKH
AG, WOCKHARDT USA LLC, and WO
LTD.,

Defendants.

COMPLAINT FO

ACTIVE 209446362v.4

BTG INTERNATIONAL LIMITED, JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC,

Plaintiffs,

v.

Civil Action No.

ACTAVIS LABORATORIES FL, INC., ACTAVIS PHARMA, INC., ACTAVIS, INC., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, APOTEX CORP., APOTEX INC., CITRON PHARMA LLC, DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., MYLAN PHARMACEUTICALS INC., MYLAN, INC., PAR PHARMACEUTICAL, INC., PAR PHARMACEUTICAL COMPANIES, INC., SUN PHARMACEUTICALS INDUSTRIES, LTD., SUN PHARMACEUTICALS INDUSTRIES, INC., TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICALS INDUSTRIES, LTD., WEST-WARD PHARMACEUTICAL CORP., THE ARAB PHARMACEUTICAL MANUFACTURING CO. HIKMA PHARMACEUTICALS, PLC, HIKMA PHARMACEUTICALS, LLC, WOCKHARDT BIO AG, WOCKHARDT USA LLC, and WOCKHARDT LTD.,

Defendants.

States/Countries of Incorporation

- Delaware – 9
- Florida – 1
- Michigan – 1
- Nevada – 1
- New Jersey - 2
- Pennsylvania – 1
- West Virginia – 1
- Canada – 1
- India – 1
- Israel – 1
- Jordan – 1
- Switzerland – 1
- UK – 1

Valeant v. Mylan

- **Valeant brought suit under the Hatch Waxman Act against three Mylan entities in New Jersey**
  - Those Mylan entities are incorporated in West Virginia, Pennsylvania and India
- **Mylan moved to dismiss for improper venue**
- **Valeant alleged that Mylan had a regularly established place of business in New Jersey and planned future acts, i.e. selling their product, in New Jersey**
- **Valeant conceded that Mylan's actions related to its ANDA submission did not occur in New Jersey**
- **The District Court granted Mylan's motion concluding that the future sales were not "acts of infringement" under § 1400(b)**

Valeant Pharm. N. Am. LLC v. Zydus Pharm. (USA) Inc., No. 18CV13635PGSLHG, 2019 WL 4179832 (D.N.J. Aug. 14, 2019), *aff'd in part, rev'd in part and remanded sub nom. Valeant Pharm. N. Am. LLC v. Mylan Pharm. Inc.*, No. 2019-2402, 2020 WL 6495091 (Fed. Cir. Nov. 5, 2020).

Valeant v. Mylan

- On appeal, the Federal Circuit panel affirmed the District Court
- The Court held: "acts of infringement" in Hatch-Waxman cases under § 1400(b) occur "where actions related to the ANDA submission occur," not merely where "a generic product specified in an ANDA is likely to be distributed."
- The Court also noted: "[a] plain language reading of [§ 1400(b)] directs us to the conclusion that it is the submission of the ANDA, and only the submission, that constitutes an act of infringement in this context."

Valeant v. Mylan

However, the Federal Circuit also acknowledged "strong policy reasons" for a broader reading of § 1400(b), including "lost judicial efficiencies" and potential gamesmanship:

> **"For example, a generic company may game the system to avoid venue in certain jurisdictions. And brand name drug companies may be required to file and maintain largely identical suits in multiple districts causing an increase in time and expense to resolve the cases and resulting in inconsistent judgments."**

So Where Does That Leave Us . . .

- **More cases brought solely against foreign counterparts**
- **More use of the MDL**
- **More effort to get parties to consent to venue**
  - Most cases will be filed in Delaware or New Jersey

Doctrine of Equivalence

Maybe it isn't totally dead yet . . .

- ***Eli Lilly & Co. v. Apotex, Inc*. (Fed. Cir. 2020)**
  - Affirms finding of infringement under doctrine of equivalents
- ***Eagle Pharmaceuticals Inc. v. Slayback Pharma LLC* (Fed. Cir. 2020)**
  - Affirms finding of no doctrine of equivalents under dedication-disclosure doctrine to affirm dismissal
- ***Galderma Laboratories, L.P. v. Amneal Pharmaceuticals LLC* (Fed. Cir. 2020)**
  - Affirms finding of infringement under doctrine of equivalents

Thank You!

Teresa Lavoie
Principal
lavoie@fr.com

Chad Shear
Principal
shear@fr.com

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