Life Sciences Webinar Series

Hatch-Waxman 2021 Year in Review

December 9, 2021

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Meet The Speakers

Megan Chacon
Principal

Geoff Biegler
Principal

Overview

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

Agenda

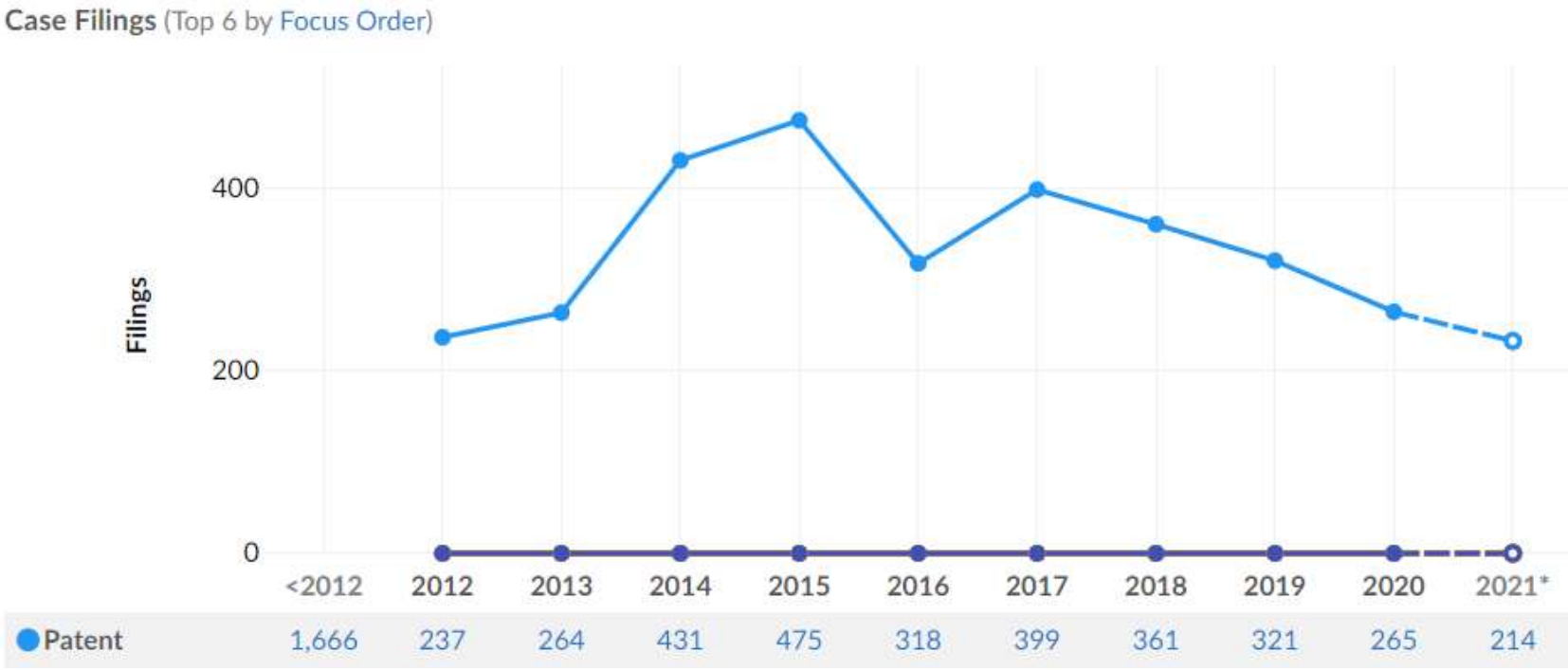
1. 2021 Trends in Hatch Waxman Filings
2. Venue
3. Inducement and Skinny Labels
4. Safe Harbor
5. Written Description and Enablement
6. Orange Book Patent Validity Challenges at the PTAB
7. Settlement and Antitrust
8. Looking forward to 2022

The Hatch-Waxman Act (1984)

- **Safe Harbor**
  - 35 U.S.C. § 271(e)(1)
- **Abbreviated Approval Pathway**
  - 505(b)(2) “paper” NDA
  - 505(j) ANDA
- **Patent Listing/Challenge Procedures**
  - Orange Book
  - 30-Month Stay
- **Technical Act of Patent Infringement**
  - 35 U.S.C. § 271(e)(2)
- **Patent Term Restoration**
- **Exclusivities**

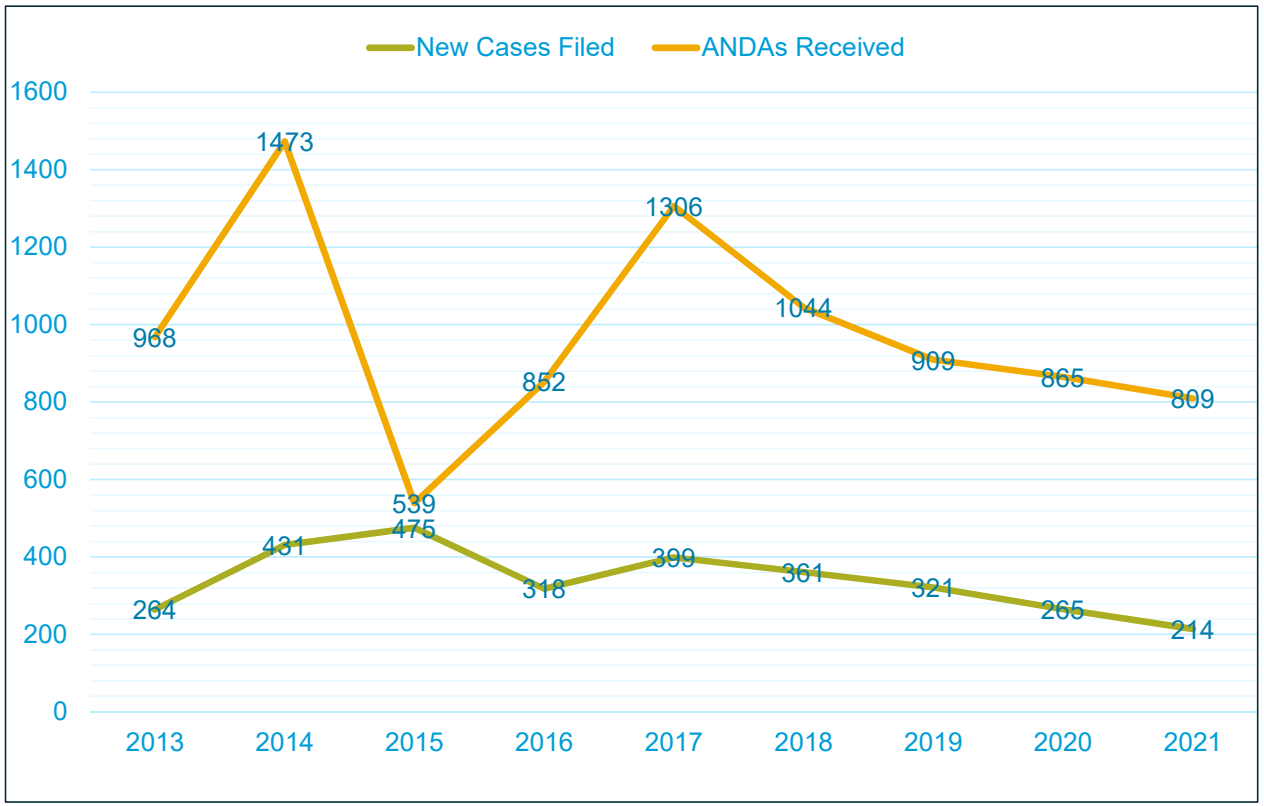
2021 Trends in Hatch Waxman Litigation

Number of Cases Filed



Source: lexmachina.com (tag Patent: ANDA; data through December 8, 2021)

Number of Cases Filed v. Number of ANDAs Submitted



Source: lexmachina.com (tag Patent: ANDA; data through December 8, 2021); https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/generic-drugs-program-activities-report-monthly-performance

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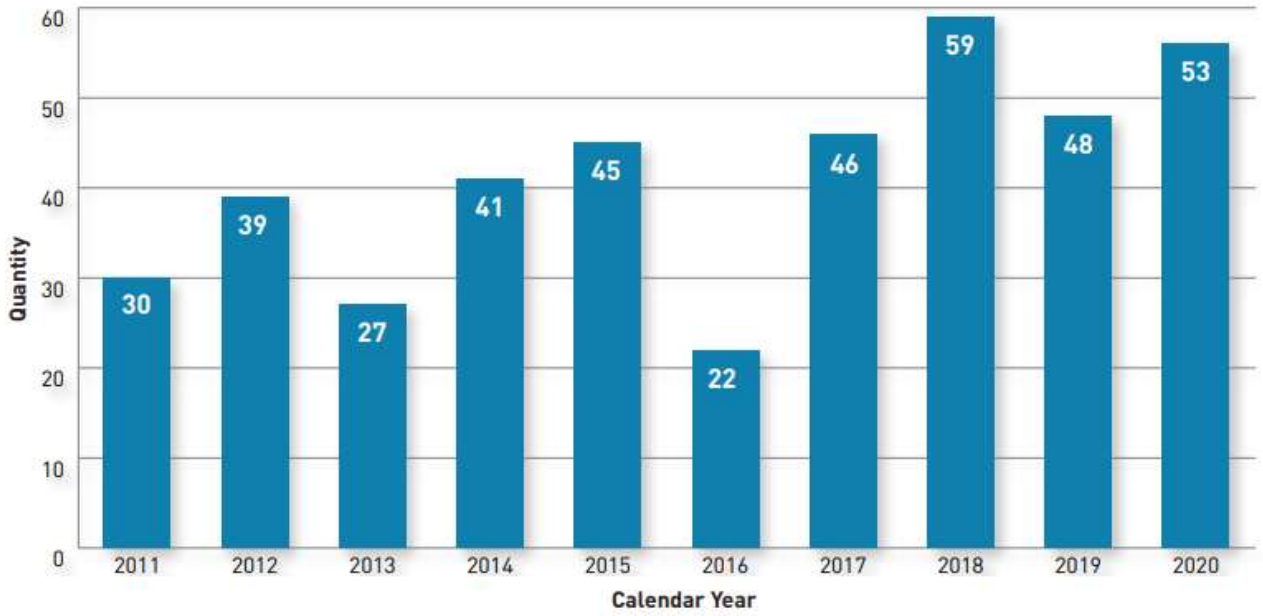
New Drug Approvals – 2011-2020

CDER's Annual Novel Drug Approvals: 2011 - 2020

In 2020, CDER approved 53 novel drugs. The 10-year graph below shows that from 2011 through 2019, CDER has averaged about 40 novel drug approvals per year



https: www.fda.gov/media/144982/download

Busiest Venues for ANDA Cases in 2021

Source: lexmachina.com (tag Patent: ANDA; data through December 8, 2021)

Busiest Judges for ANDA Cases

Open ANDA Cases

New 2021 ANDA Cases

Source: lexmachina.com (tag Patent: ANDA; data through December 8, 2021)

Judge Stark Appointed to Federal Circuit

Venue Update

The Patent Venue Statute – 28 U.S.C. § 1400(b)

- **Any civil action for patent infringement may be brought in the judicial district**

  (1) Where the defendant resides, or

  (2) Where the defendant has committed acts of infringement and has a regular and established place of business.

Venue Options after *TC Heartland*

- **Venue is proper in defendant's state of incorporation**

- **Venue is proper where acts of infringement have occurred *and* defendant has a <u>regular and established place of business</u>**
  - There must be a physical place in the district;
  - It must be a regular and established place of business;
  - It must be the place of the defendant.

  In re Cray Inc., 871 F.3d 1355 (Fed. Cir. 2017)

Evolution of Venue in Hatch-Waxman Cases

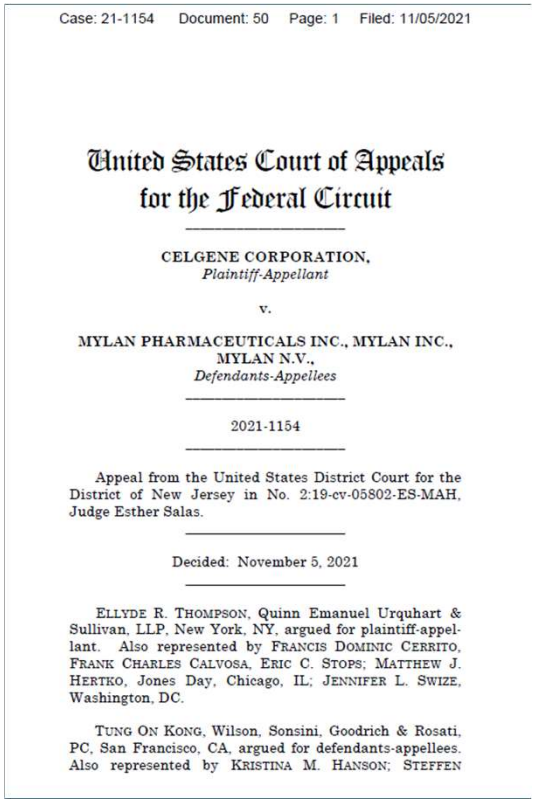
- **Historical issue of defining the "act of infringement"**
  - Some courts said potential future infringing acts where the generic company intended to sell its ANDA products. *See Bristol-Myers Squibb v. Mylan Pharm. Inc.*, 2017 WL 3980155, at *6–*8 (D. Del. Sept. 11, 2017); *Celgene Corp. v. Hetero Labs Ltd.*, No. 17-cv-3387-ES-MAH, 2018 WL 1135334 (D.N.J. Mar. 2, 2018)
  - Other courts said only where the act of submitting the ANDA itself is occurring. *See, e.g.*, *Galderma Labs., L.P. v. Teva Pharms. USA, Inc.*, 290 F. Supp. 3d 599 (N.D. Tex. 2017).

Evolution of Venue in Hatch-Waxman Cases

"[I]n cases brought under 35 U.S.C. § 271(e)(2)(A), infringement occurs for venue purposes only in districts where actions related to the submission of an Abbreviated New Drug Application ("ANDA") occur, not in all locations where future distribution of the generic products specified in the ANDA is contemplated."

– *Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc., 978 F.3d 1374 (Fed. Cir. 2020)*

Celgene Corp. v. Mylan Pharms, Inc., 2021 WL 5143311 (Nov. 5, 2021 Fed. Cir.)



Case: 21-1154 Document: 50 Page: 1 Filed: 11/05/2021

United States Court of Appeals
for the Federal Circuit

CELGENE CORPORATION,
Plaintiff-Appellant

v.

MYLAN PHARMACEUTICALS INC., MYLAN INC.,
MYLAN N.V.,
Defendants-Appellees

2021-1154

Appeal from the United States District Court for the District of New Jersey in No. 2:19-cv-05802-ES-MAH, Judge Esther Salas.

Decided: November 5, 2021

ELLYDE R. THOMPSON, Quinn Emanuel Urquhart & Sullivan, LLP, New York, NY, argued for plaintiff-appellant. Also represented by FRANCIS DOMINIC CERRITO, FRANK CHARLES CALVOSA, ERIC C. STOPS; MATTHEW J. HERTKO, Jones Day, Chicago, IL; JENNIFER L. SWIZE, Washington, DC.

TUNG ON KONG, Wilson, Sonsini, Goodrich & Rosati, PC, San Francisco, CA, argued for defendants-appellees. Also represented by KRISTINA M. HANSON; STEFFEN

United States Court of Appeals
for the Federal Circuit

CELGENE CORPORATION,
Plaintiff-Appellant

v.

MYLAN PHARMACEUTICALS INC., MYLAN INC.,
MYLAN N.V.,
Defendants-Appellees

A

First, we address whether MPI and Mylan Inc. "committed acts of infringement" in New Jersey. We conclude that they did not.

B

Next we address whether MPI and Mylan Inc. had a "regular and established place of business" in New Jersey. We conclude that they did not.

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Celgene Corp. v. Mylan Pharms (Fed. Cir. 2021)

Celgene

Mylan®

Celgene Corp. v. Mylan Pharms (Fed. Cir. 2021)

- **Court concluded that venue in New Jersey for the Mylan domestic companies was improper under Section 1400(b)**

- **No act of infringement in New Jersey**
  - Key question is where the ANDA submission occurred and what acts it included
  - For Hatch-Waxman cases, this means venue is proper "where an ANDA-filer submits its ANDA to the FDA," not "wherever future distribution of the generic is contemplated." (Citing *Valeant*)
  - Receipt of the notice letter in New Jersey was not enough; not part of the “submission”

- **No “regular and established place of business” in New Jersey**
  - Homes in New Jersey belonging to Mylan employees was not enough to establish “place of the defendant” under *In re Cray*
  - Now-defunct Mylan entity in New Jersey was not enough to impute venue based on alter-ego theory

Key Takeaways from *Celgene*

- A Paragraph IV Letter is not considered "part of" an ANDA submission, so venue cannot be predicated upon where the letter is received.
- Demonstrating that an in-district physical place is "of the defendant" requires a strong and particularized showing of the defendant's "ratification" of that place.
- Venue maybe imputed to a parent based on a subsidiary's place of business under an alter ego theory, only when corporate formalities are disregarded and corporate separateness is not maintained.
- Bare allegations of cooperation and control are insufficient to state a claim against a would-be Hatch-Waxman defendant who did not sign or submit the ANDA.

Inducement – *GSK v. Teva*

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).

"Section vii" Carve Out – 505(j)(2)(A)(viii)

- **Permits a generic to "carve out" from the generic label indications included on the brand label**
- **Generic not seeking approval for carved out indications**
  - Generic product must still be safe and effective for remaining approved uses
- **ANDA with carved out label can be approved absent an unresolved PIV certification on another patent (e.g., a compound patent)**

Early Federal Circuit Decisions on Section viii Carve Outs

- **Two leading cases from 2003**
  - *Warner-Lambert v. Apotex* (2003)
  - *Allergan v Alcon* (2003)
- **Both cases were:**
  - Brought under 35 U.S.C. § 271(e) pre-launch
  - Both cases are for claims of induced infringement for off-label uses
- **Holdings**
  - 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® (carvedilol)

- **Three approved uses**
  - (#1) Heart Failure
  - (#2) Left ventricular dysfunction in patients post infarction (MI/LVD)
  - (#3) Hypertension
- **Hypertension patent expired with compound 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's Carvedilol

- **Originally, pursued full-label, but launched as skinny label**
  - Sought indications for left ventricular dysfunction and hypertension
  - Attempted a section viii carve out for 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 finds infringement for both skinny and full label periods**
  - Presented with evidence of full label, catalogs, websites and press releases as evidence of inducement
  - Found that Teva induced infringement
  - Awarded damages of $235 million

- **District Court grants Judgement as a Matter of Law (JMOL) centered on causation**
  - 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 for heart failure

2020 Federal Circuit Decision

- **Majority:**
  - Jury verdict of infringement (and damages) re-instated
  - Labels, press releases, catalogs and other conduct indicated inducement
  - Attempt to shift blame to GSK not supported under the law of inducement

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

- **Strong dissent from Chief Judge Prost**

2021 Federal Circuit Decision

- **August 2021 decision focuses on Teva's failure to successfully carve out congestive heart failure**
  - "As this record reflects, in both time periods, substantial evidence supports that Teva actively induced by marketing a drug with a label encouraging a patented therapeutic use. They did not 'omit[] all patented indications' or 'merely note[] (without mentioning any infringing uses) that FDA had rated a product as therapeutically equivalent to a brand-name drug.'"
  - "This is a case in which substantial evidence supports a jury finding that the patented use was on the generic label at all relevant times and that, therefore, Teva failed to carve out all patented indications."
  - Causation can be inferred: "It was fair for the jury to infer that when Teva distributed and marketed a product with labels encouraging an infringing use, it actually induced doctors to infringe."

- **Another strong dissent from Chief Judge Prost**

Safe Harbor

Safe Harbor – 35 U.S.C. § 271(e)(1)

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a **patented invention** (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

Safe Harbor Scope

- In *Merck KGaA v. Integra Life Sciences,* 545 U.S.193, 206 (2005), the Supreme Court stated:
  - "[T]he statutory text [of § 271(e)(1)] makes clear that it provides a **wide berth** for the use of patented drugs in activities related to [FDA] approval." *Id*. at 202 (emphasis added)
  - ""[W]e think it apparent from the statutory text that § 271(e)(1)'s exemption from infringement extends to **all** uses of patented inventions that are **reasonably related** to the development and submission of any information to the [FDA]. This necessarily includes preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process." *Id*. (emphasis added)
  - "[The exemption] necessarily includes **preclinical** studies of patented compounds that are appropriate for submission to the FDA in the regulatory process." *Id.* (emphasis added).
  - "[T]he FDA requires that applicants include in an IND summaries of the **pharmacological, toxicological, pharmacokinetic, and biological qualities of the drug in animals**. . .The primary (and, in some cases, only) way in which a drug maker may obtain such information is through preclinical *in vitro* and *in vivo* studies." *Id.* at 203 (emphasis added).

What is Covered by The Safe Harbor

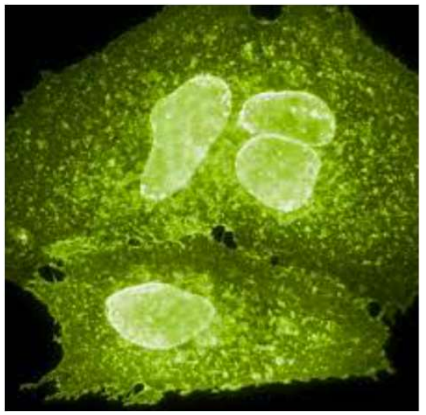
- **Applies To . . .**
  - ITC actions
  - Medical devices
  - Manufacture of patented items, most of which were used to generate data for the FDA
  - Submission of data to foreign regulatory agencies, where data are also submitted to the FDA
  - Use of patented product to develop alternative FDA approved manufacturing process
  - Use of FDA generated data to prepare patent applications
- **Does Not Apply To…**
  - Stockpiling — even for launch after patent expiry
  - Manufacturing patented products in the U.S. for shipment to foreign regulatory authorities
  - Use of product for foreign clinical trials where no indication that results would be submitted to the FDA
  - "Basic research"
  - Activity must in some way relate to potential FDA approval of drug (device), supplemental approval, or label modifications
  - Activities to support non U.S. approval are not protected

What about Research Tools?

- The Supreme Court in *Merck* stated: "We therefore need not –and do not –express a view about whether, or to what extent, §271(e)(1) exempts from infringement the use of 'research tools' in the development of information for the regulatory process." 545 U.S. at 205 n.7.
- The Federal Circuit later addressed the issue in *Proveris Sci. Corp. v. Innovasystems, Inc.,* 536 F.3d 1256 (Fed. Cir. 2008)
  - Innovasystems asserted Safe Harbor protection for its sales of optical spray machines used in analyzing the final product subject to FDA approval.
  - The Federal Circuit held that, although the devices were only used in developing data for FDA submissions, they were "not itself subject to FDA premarket approval process." *Id.* at 1265.
  - Thus, section 271(e)(1) did not apply.
- District courts have applied *Merck* and *ProverisSci* to research tools differently
  - Compare *Isis Pharms. Inc. v. Santaris Pharma A/S Corp.,* No. 3:11-CV-2214-GPC-KSC, 2014 WL 2212114 (S.D. Cal. May 28, 2014) (Safe harbor does not encompass research tools), *with Teva Pharms. USA, Inc. v. Sandoz Inc.,* No. 09-CV-10112 KBF, 2013 WL 3732867 (S.D.N.Y. July 16, 2013) (Safe harbor encompasses research tools).

Allele Biotechnology & Pharms., Inc. v. Pfizer, Inc., 2021 WL 1749903 (S.D. Cal. May 4, 2021)

- Allele sued Pfizer for infringement of its U.S. Patent No. 10,221,221 ("the '221 patent")
- Allele alleged Pfizer's use of Allele's mNeon Green product, in its research, development and testing of its SARS-COV-2 vaccine candidates, infringed the '221 patent
- Pfizer moved to dismiss complaint under Fed. R. Civ. P. 12(b)(6) arguing that it's use was covered by The Safe Harbor
- Allele argued that mNeon Green – a research tool – was not a "patented invention" under section 271(e)(1).
- Pfizer responded that the Safe Harbor applied because the use was for developing information for FDA approval of its COVID-19 vaccine



Allele Court – NO Safe Harbor for Research Tool

- **Court denied Pfizer's Motion to Dismiss, relying on *ProverisSci.***
  - **Reason 1**: Allele's mNeon Green product was not subject to FDA premarket approval and thus was "not within the category of entities for whom the safe harbor provision was designed to provide relief." *See* 2021 WL 1749903, *4.
  - **Reason 2:** Because Allele's mNeon Green product was not subject to FDA premarket approval, it could not be extended under 35 U.S.C § 156(a), meaning it was not a "**patented invention**" within Section 271(e)(1). *See* 2021 WL 1749903, *4.

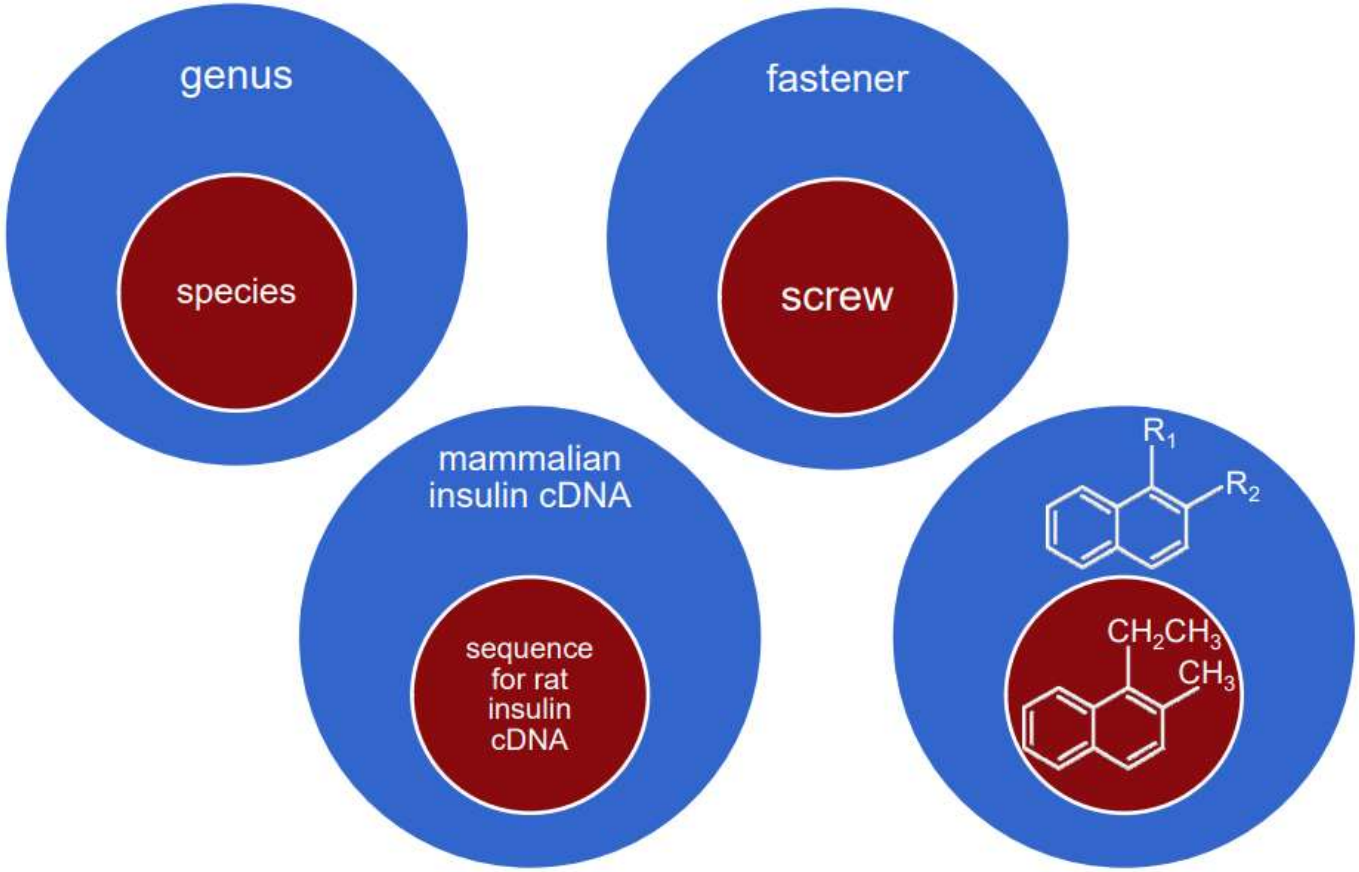
Written Description and Enablement

35 U.S.C. § 112(a)

§ 112. Specification

(a)IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

Genus Claims



Genus Claims and Section 112

- How can a patentee adequately describe and enable a genus?
- 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." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*).
- Generally, a genus can be sufficiently disclosed by "either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Id.* at 1350.
- Genus sufficiently enabled if a skilled artisan would be able to practice the full scope of the claimed invention without 'undue experimentation.'" *In re Wands*, 858 F.2d 731, 736–37 (Fed. Cir. 1988).

Genus Claims and Section 112

- ***Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1349 (Fed. Cir. 2010) (en banc)**
  - Held genus claims encompassing the use of all substances that achieve the desired result of reducing the binding to certain recognition sites invalid for lack of written description.
  - The written description "problem is especially acute with genus claims that use functional language to define the boundaries of a claimed genus."

- ***Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380 (Fed. Cir. 2013)**
  - Held claims to method for treating restenosis using genus of rapamycin analogues invalid for lack of enablement where only one such analogue disclosed in patent.
  - "Even putting the challenges of synthesis aside, one of ordinary skill would need to assay each of at least tens of thousands of candidates. Wyeth's expert conceded that it would take technicians weeks to complete each of these assays. The specification offers no guidance or predictions about particular substitutions that might preserve the immunosuppressive and antirestenotic effects observed in sirolimus. The resulting need to engage in a systematic screening process for each of the many rapamycin candidate compounds is excessive experimentation."

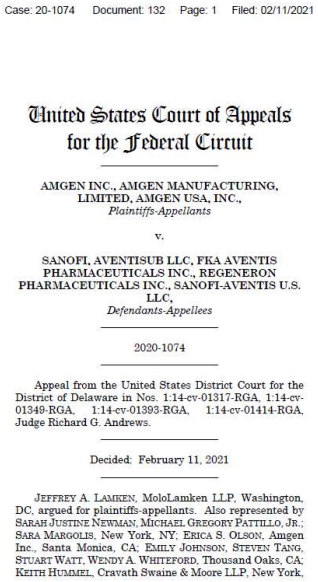
- ***AbbVie Deutschland GmbH v. Janssen Biotech, Inc.*, 759 F.3d 1300 (Fed. Cir. 2014)**
  - Held genus claims to a human antibody "that binds human IL-12" invalid for lack of written description where specification disclosed only a small subset of the antibodies that might perform the claimed binding function.
  - "[A]nalogizing the genus to a plot of land, if the disclosed species only abide in a corner of the genus, one has not described the genus sufficiently to show that the inventor invented, or had possession of, the genus."

- ***Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1164 (Fed. Cir. 2019)**
  - Held invalid for lack of written description and lack of enablement claims that required nucleosides effective against hepatitis C virus because specification only provided certain examples of supposedly effective nucleosides, but did not explain what makes them effective, or why, so that a person of skill the art would recognize the effective nucleosides.

Amgen v. Sanofi (Fed. Cir. 2021)

- Amgen patents describe antibodies that purportedly bind to the PCSK9 protein and lower LDL levels.
- Claim 1: "An isolated monoclonal antibody that binds to PCSK9, wherein the isolated monoclonal antibody binds an epitope on PCSK9 comprising at least one of residues 237 or 238 of SEQ ID NO: 3, and wherein the monoclonal antibody blocks binding of PCSK9 to LDLR."
- Sanofi contended that there are millions of antibody candidates within the scope of the claims, antibody generation is unpredictable, and practicing the full scope of the claims requires substantial trial and error.
- Specification includes three dimensional structures of two antibodies (including Amgen's Repatha) and amino acid sequences of 22 other antibodies that compete with them.

Amgen v. Sanofi (Fed. Cir. 2021)



Case: 20-1074 Document: 132 Page: 1 Filed: 02/11/2021

United States Court of Appeals
for the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING, LIMITED, AMGEN USA, INC.,
Plaintiffs-Appellants

v.

SANOFI, AVENTISUB LLC, FKA AVENTIS PHARMACEUTICALS INC., REGENERON PHARMACEUTICALS INC., SANOFI-AVENTIS U.S. LLC,
Defendants-Appellees

2020-1074

Appeal from the United States District Court for the District of Delaware in Nos. 1:14-cv-01317-RGA, 1:14-cv-01349-RGA, 1:14-cv-01393-RGA, 1:14-cv-01414-RGA, Judge Richard G. Andrews.

Decided: February 11, 2021

JEFFREY A. LAMKEN, MoloLamken LLP, Washington, DC, argued for plaintiffs-appellants. Also represented by SARAH JUSTINE NEWMAN, MICHAEL GREGORY PATTILLO, JR.; SARA MARGOLIS, New York, NY; ERICA S. OLSON, Amgen Inc., Santa Monica, CA; EMILY JOHNSON, STEVEN TANG, STUART WATT, WENDY A. WHITEFORD, Thousand Oaks, CA; KEITH HUMMEL, Cravath Swaine & Moore LLP, New York,

- **Held: claim invalid for lack of enablement**
  - Claims broad both in number and in functional diversity
  - Unpredictable field of science with respect to satisfying functional limitations
  - Evidence only that a small subset of examples of antibodies can be predictably generated
- **"As the district court noted, the only ways for a person of ordinary skill to discover undisclosed claimed embodiments would be through either 'trial and error, by making changes to the disclosed antibodies and then screening those antibodies for the desired binding and blocking properties,' or else 'by discovering the antibodies De novo' according to a randomization-and-screening 'roadmap.' Either way, we agree with the district court that the required experimentation 'would take a substantial amount of time and effort.'"**
- **Enablement can be a high hurdle for broad, functionally defined genus claims**
  - "What emerges from our case law is that the enablement inquiry for claims that include functional requirements can be particularly focused on the breadth of those requirements, especially where predictability and guidance fall short."
  - "While functional claim limitations are not necessarily precluded in claims that meet the enablement requirement, such limitations pose high hurdles in fulfilling the enablement requirement for claims with broad functional language."

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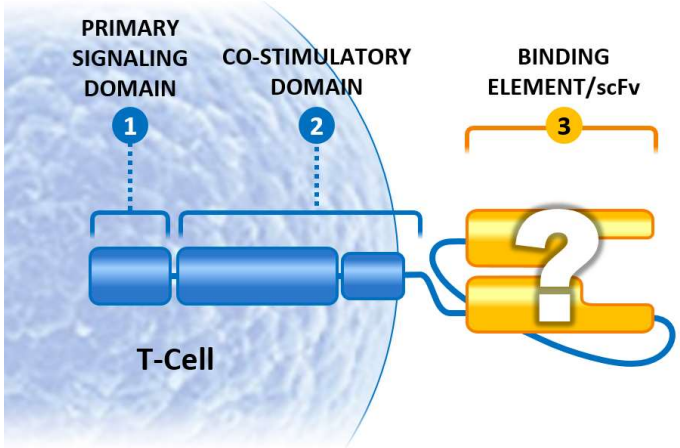
Juno Therapeutics v. Kite Pharma (Fed. Cir. 2021)

YESCARTA



- Involved Kite's CAR-T therapy Yescarta®, indicated for treatment of certain types of blood cancer
- Juno inventors claimed to have invented a CAR with three explicit portions: (1) a primary signaling domain, (2) a costimulatory signaling domain, and (3) a binding element
- Claims specified the amino acid sequence for the two signaling portions
- But identified the binding element generically by its function: binding to a particular antigen, called CD19
- Specification had only one, vaguely disclosed example of a CAR that binds to CD19 and no amino acid sequence provided for that example

Juno Therapeutics v. Kite Pharma (Fed. Cir. 2021)

- **Kite arguments on appeal**
  - Claims cover an enormous number (millions of billions) of scFv candidates
  - Only a fraction of which satisfy the functional binding limitation for any given target
  - Field is unpredictable since an scFv's binding ability depends on a variety of factors
  - The '190 patent discloses neither (1) representative species or (2) common structural features of the claimed scFv genus to identify which scFvs would function as claimed

- **Juno arguments on appeal**
  - scFvs were well-known (as was how to make them)
  - The '190 patent describes two working scFv embodiments that are representative of all scFvs
  - scFvs had been incorporated in CARs well before the '190 patent's priority date
  - scFvs are interchangeable and have common structural features
  - *Ariad* was irrelevant because the real invention was the combination of the signaling domains, not the scFv portion

Juno Therapeutics v. Kite Pharma (Fed. Cir. 2021)

United States Court of Appeals
for the Federal Circuit

JUNO THERAPEUTICS, INC., SLOAN KETTERING INSTITUTE FOR CANCER RESEARCH,
Plaintiffs-Appellees

v.

KITE PHARMA, INC.,
Defendant-Appellant

2020-1758

Appeal from the United States District Court for the Central District of California in No. 2:17-cv-07639-PSG-KS, Judge Philip S. Gutierrez.

Decided: August 26, 2021

MORGAN CHU, Irell & Manella LLP, Los Angeles, CA, argued for plaintiffs-appellees. Also represented by ALAN J. HEINRICH, ELIZABETH C. TUAN; GREGORY A. CASTANIAS, JENNIFER L. SWIZE, Jones Day, Washington, DC; LISA LYNN FURBY, Chicago, IL; ANDREA WEISS JEFFRIES, Los Angeles, CA; MATTHEW J. RUBENSTEIN, Minneapolis, MN.

E. JOSHUA ROSENKRANZ, Orrick, Herrington & Sutcliffe LLP, New York, NY, argued for defendant-appellant. Also represented by MELANIE L. BOSTWICK, ROBBIE MANHAS, JEREMY PETERMAN, Washington, DC; GEOFFREY DONOVAN

While it is true that scFvs in general were known, and even known to bind, the record demonstrates that, for even the narrowest claims at issue, the realm of possible CD19-specific scFvs was vast and the number of known CD19-specific scFvs was small (five at most). The '190 patent, however, provides no details about which scFvs bind to CD19 in a way that distinguishes them from scFvs that do not bind to CD19. Without this guidance, under our controlling *Ariad* decision, no reasonable jury could find the '190 patent satisfies the written description requirement.

CONCLUSION

Substantial evidence does not support the jury's verdict in Juno's favor on the issue of written description. For the claimed functional scFv genus, the '190 patent does not disclose representative species or common structural features to allow a person of ordinary skill in the art to distinguish between scFvs that achieve the claimed function and those that do not. Accordingly, we reverse.

REVERSED

Takeaways on Functional Genus Claims

1. Federal Circuit isn't afraid to use § 112 to limit claim scope

2. Functionally defined genus claims can be inherently vulnerable to § 112

3. Describing a genus requires (1) representative species or (2) common structural features sufficient to differentiate what is claimed from what is not

4. The test is the same whether the claim element is essential or auxiliary to the invention

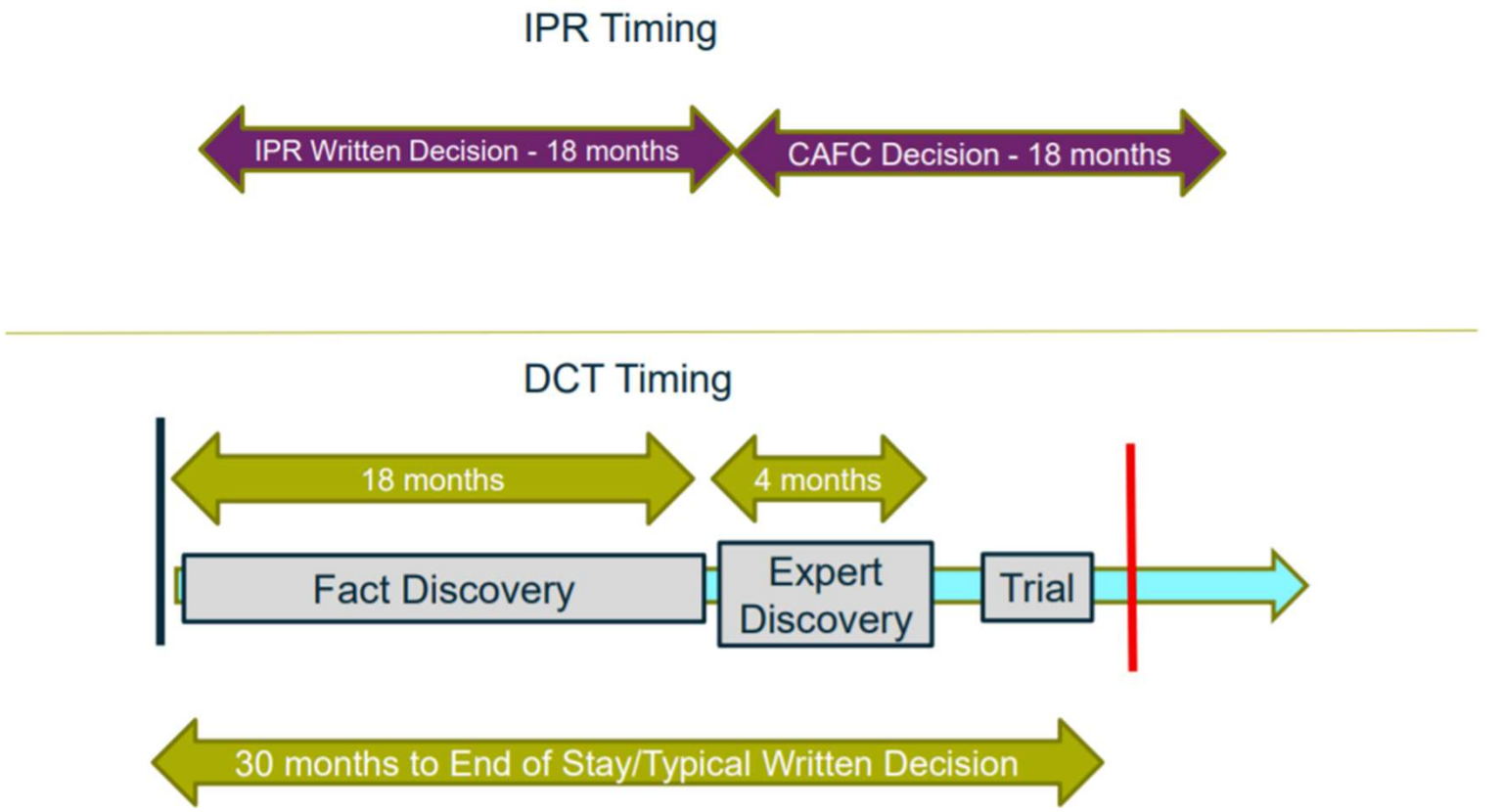
5. Predictability is key

BIOGEN V. MYLAN (Fed. Cir. 2021)

- **Biogen sued Mylan for infringement of a patent directed to a method of treating multiple sclerosis (MS) with dimethyl fumarate (DMF).**
- **Claim 1 recites inter alia "wherein the therapeutically effective amount of [DMF]… is about 480 [milligrams] per day [DMF480]."**
- **The only reference in the patent specification to an effective dose of DMF stated: "an effective dose of DMF… can be… from about 240 mg to about 720 mg per day; or from about 480 mg to about 720 mg per day; or about 720 mg per day."**
- **The Federal Circuit affirmed invalidity based on a lack of written description.**
  - First, the specification's reference to DMF480 was part of a wide dosage range. Specifically, DMF480 appeared in only a single range among multiple ranges and appeared at the end of that range.
  - The Federal Circuit contrasted this with the specification's reference to DMF720 independently as a therapeutically efficacious dose.
- **The Federal Circuit further noted that one of the inventors stated that his research was not focused on informing the clinical dosing of DMF and "denied that his research could be extrapolated to a clinical dose of DMF."**

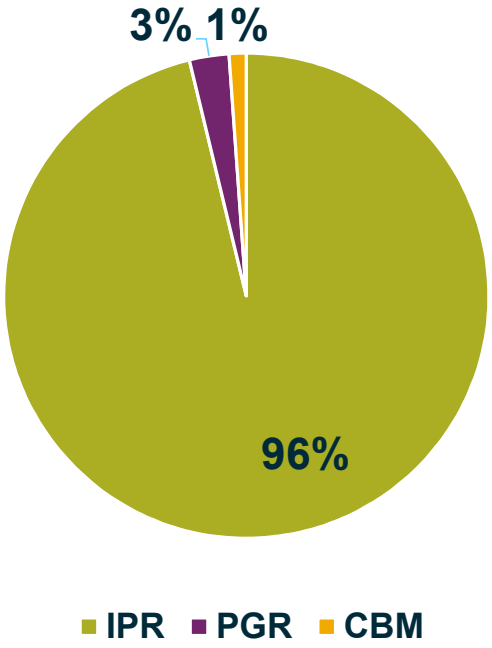
Orange Book Patent Validity Challenges at the PTAB

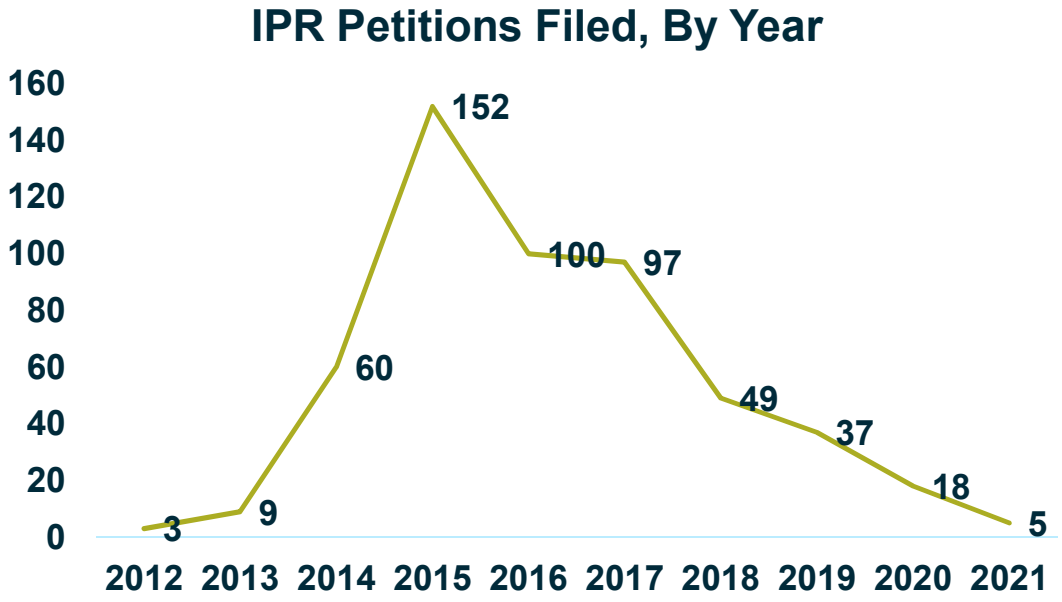
IPR vs. District Court



Orange Book Patents - PTAB

Since inception, 530 petitions (IPR, PGR, CBM) have been filed at the PTAB related to Orange Book listed patents (3.82% of all petitions filed)





Source: lexmachina.com (tag Patent: FDA Orange Book; data through December 3, 2021

Discretionary Denial of Institution

35 U.S.C. § 314(d):

(d)NO APPEAL.—The determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable.

Co-Pending H-W District Court Litigation and IPR

***Janssen Pharmaceuticals, Inc. et al v. Mylan Laboratories Ltd. et al.*, 2-19-cv-16484 (DNJ)**

***Janssen Pharmaceuticals, Inc. et al v. Teva Pharmaceuticals USA, Inc. et al.*, 2-18-cv-00734 (DNJ)**

***Mylan Labs. Ltd. v. Janssen Pharmaceutica, N.V.*, No. IPR2020-00440**

FISH & RICHARDSON

Substantial Overlap under *Fintiv*?

Trials@uspto.gov
571-272-7822

Paper 17
Date: September 16, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN LABORATORIES LTD.
Petitioner,

v.

JANSSEN PHARMACEUTICA NV,
Patent Owner.

IPR2020-00440
Patent 9,439,906 B2

Before JOHN G. NEW, KRISTINA M. KALAN, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

NEW, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

In *Fintiv*, the Board set forth six factors relating to whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding:

1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
2. proximity of the court's trial date to the Board's projected statutory deadline for a final written decision;
3. investment in the parallel proceeding by the court and the parties;
4. overlap between issues raised in the petition and in the parallel proceeding;
5. whether the petitioner and the defendant in the parallel proceeding are the same party; and
6. other circumstances that impact the Board's exercise of discretion, including the merits.

IV. CONCLUSION

For the reasons we have explained, we conclude that, pursuant to an analysis of the factors set forth in our precedential opinion in *Fintiv* with respect to the specific facts of this case, we find that the balance of the factors favor the exercise of our discretion to deny the Petition for institution of *inter partes* review in this case.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED, pursuant to 35 U.S.C. § 314(a), that the Petition for *inter partes* review of claim 1–21 of the '428 patent is DENIED with respect to all grounds in the Petition; and

FURTHER ORDERED that no *inter partes* review is instituted.

First instance of a discretionary denial based on parallel Hatch-Waxman litigation

Mylan Labs, Ltd. v. Janssen Pharmaceutica, N.V., 989 F.3d 1375 (Fed. Cir. 2021)

United States Court of Appeals
for the Federal Circuit

MYLAN LABORATORIES LTD.,
Appellant

v.

JANSSEN PHARMACEUTICA, N.V.,
Appellee

ANDREW HIRSHFELD, PERFORMING THE FUNCTIONS AND DUTIES OF THE UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Intervenor

2021-1071

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2020-00440.

ON MOTION

DEEPRO MUKERJEE, Katten Muchin Rosenman LLP, New York, NY, argued for appellant. Also represented by LANCE SODERSTROM; JOHNJERICA HODGE, ERIC THOMAS WERLINGER, Washington, DC; JITENDRA MALIK, Charlotte,

United States Court of Appeals
for the Federal Circuit

MYLAN LABORATORIES LTD.,
Appellant

v.

JANSSEN PHARMACEUTICA, N.V.,
Appellee

ANDREW HIRSHFELD, PERFORMING THE FUNCTIONS AND DUTIES OF THE UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Intervenor

For the foregoing reasons, we lack jurisdiction over Mylan's direct appeal. Though we have jurisdiction over its request for mandamus, Mylan has failed to show a clear right to relief. Accordingly,

IT IS ORDERED THAT:

(1) Janssen's motion is granted;

(2) Mylan's petition for a writ of mandamus is denied; and

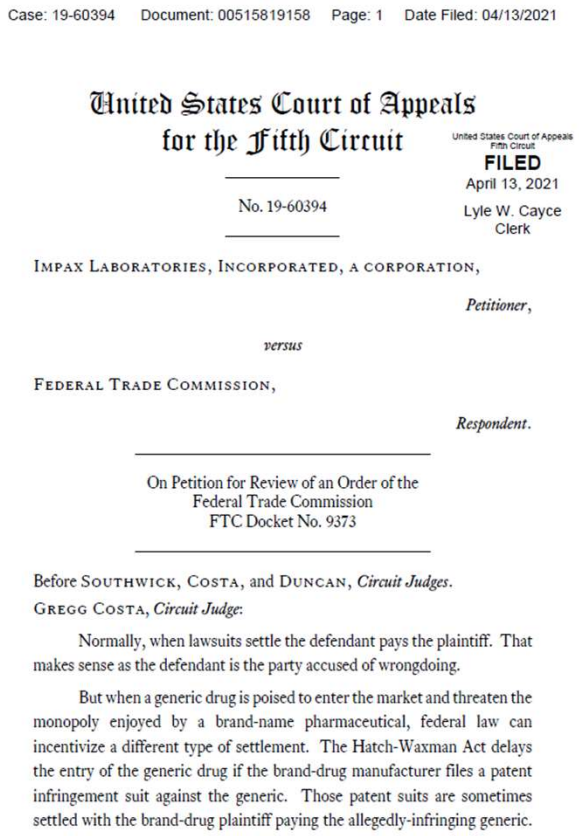
(3) Costs are awarded to Janssen.

Key Takeaways from *Mylan Labs*

- **For now, discretionary denial of institution currently not appealable. *See* 35 U.S.C. § 314(d).**
  - Supreme Court to review
- **Decision important to Hatch-Waxman litigants:**
  - Hatch-Waxman cases often involve many patents and many generics
  - Frequently, invalidity arguments in IPR petitions overlap with those asserted in district court litigations/PIV notice letters
  - Particularly important in cases where there are multiple waves of suits over the same patent against different generics
  - Trial readiness, including of related cases, important
- **Discretionary denial under *Fintiv* may reduce threat to branded drug maker of:**
  - Expedited patent review (and potential invalidity finding)
  - Lower burden of proof
  - Expedited approval, launch, and entry of generics

Settlement/Antitrust Update

Impax Labs v. FTC (5th Cir. 2021)



Case: 19-60394 Document: 00515819158 Page: 1 Date Filed: 04/13/2021

United States Court of Appeals
for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
April 13, 2021
Lyle W. Cayce
Clerk

No. 19-60394

IMPAX LABORATORIES, INCORPORATED, A CORPORATION,

Petitioner,

versus

FEDERAL TRADE COMMISSION,

Respondent.

On Petition for Review of an Order of the
Federal Trade Commission
FTC Docket No. 9373

Before SOUTHWICK, COSTA, and DUNCAN, *Circuit Judges*.

GREGG COSTA, *Circuit Judge*:

Normally, when lawsuits settle the defendant pays the plaintiff. That makes sense as the defendant is the party accused of wrongdoing.

But when a generic drug is poised to enter the market and threaten the monopoly enjoyed by a brand-name pharmaceutical, federal law can incentivize a different type of settlement. The Hatch-Waxman Act delays the entry of the generic drug if the brand-drug manufacturer files a patent infringement suit against the generic. Those patent suits are sometimes settled with the brand-drug plaintiff paying the allegedly-infringing generic.

- **Impax and Endo entered into a settlement agreement whereby Impax agreed to stay off the generic market for more than two years**
- **In exchange, Endo agreed to (1) not to launch an authorized generic during Impax's generic exclusivity period, and (2) to payments that ended up being worth over $100 million.**
- **However, the settlement gave consumers access to generic Opana ER starting nine months before expiration of the initial patents and sixteen years before the expiration of other Endo patents.**
- **FTC alleged the settlement was an illegal "reverse payment" agreement**

FISH
FISH & RICHARDSON

Key Takeaways from *Impax Labs*

- **The Fifth Circuit decision was the FTC's first fully litigated challenge to a so-called "pay for delay" deal between a branded-drug maker and a would-be generic rival since the Supreme Court's decision in *Actavis***

- **Holding: agreement anticompetitive**
  - "The size of these payments is comparable to other cases where courts have inferred anticompetitive effect."
  - The Court found it did not need to assess whether there were procompetitive benefits because any of the purported procompetitive benefits from Endo granting licenses to Impax could have been achieved with a less restrictive alternative.

- **Going forward**
  - Any reverse payment will likely be viewed as delaying entry, unless limited to litigation costs.
  - Any exchange of value regardless of the form might be actionable as a reverse payment. May include "no-AG" agreements, payments for collaboration agreements, favorable supply agreements, agreements to settle damages claims at substantially less than they are worth, etc.
  - The argument that reverse payment settlements are procompetitive because they provide a date for generics to enter and provide the patent licenses to the generic is unlikely to succeed.

Looking Forward to 2022

What to Expect in 2022 for Hatch-Waxman Litigants

- **Rebound in the number of ANDA litigations and ANDAs approved by FDA post-COVID?**
- **Shift in where Hatch-Waxman cases are litigated in light of *Celgene v. Mylan*?**
- **Continued trend on pharma genus claims in Section 112 cases?**
- **Supreme Court action on *Impax v. FTC*, *Mylan Labs v. Janssen*?**

Thank You!

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Please send your NY CLE forms to mcleteam@fr.com

Any questions about the webinar, contact Makayla Mainini at mainini@fr.com

A replay of the webinar will be available for viewing at http://www.fr.com/webinars

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