Litigation in the Life Sciences: Key trends and issues for in-house counsel to keep in mind

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KEKER VAN NEST & PETERS

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Agenda

- **Milestone Litigation**
- **FCA Landscape**
- **Developments in Patent Law**
- **Drug Diversion Criminal Enforcement**

Milestone Litigation

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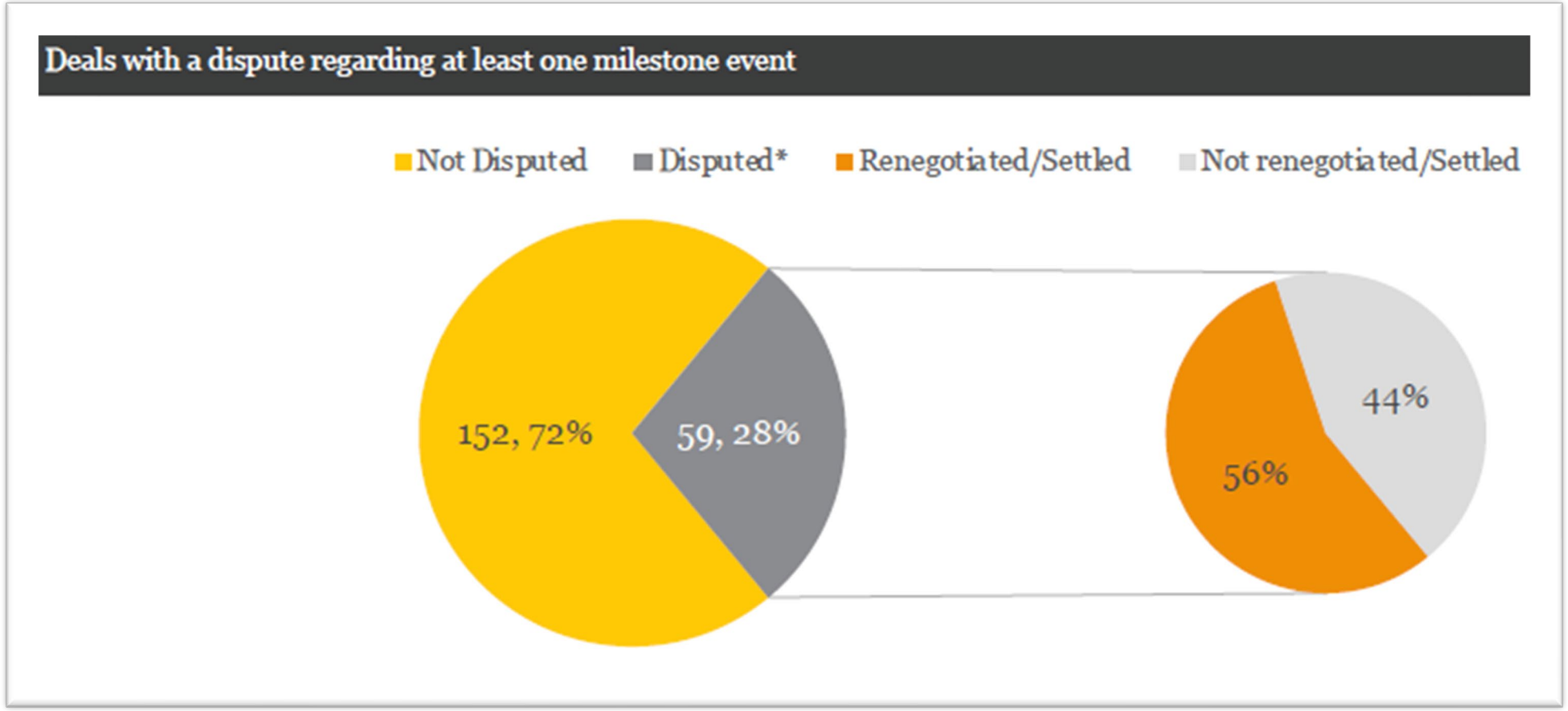
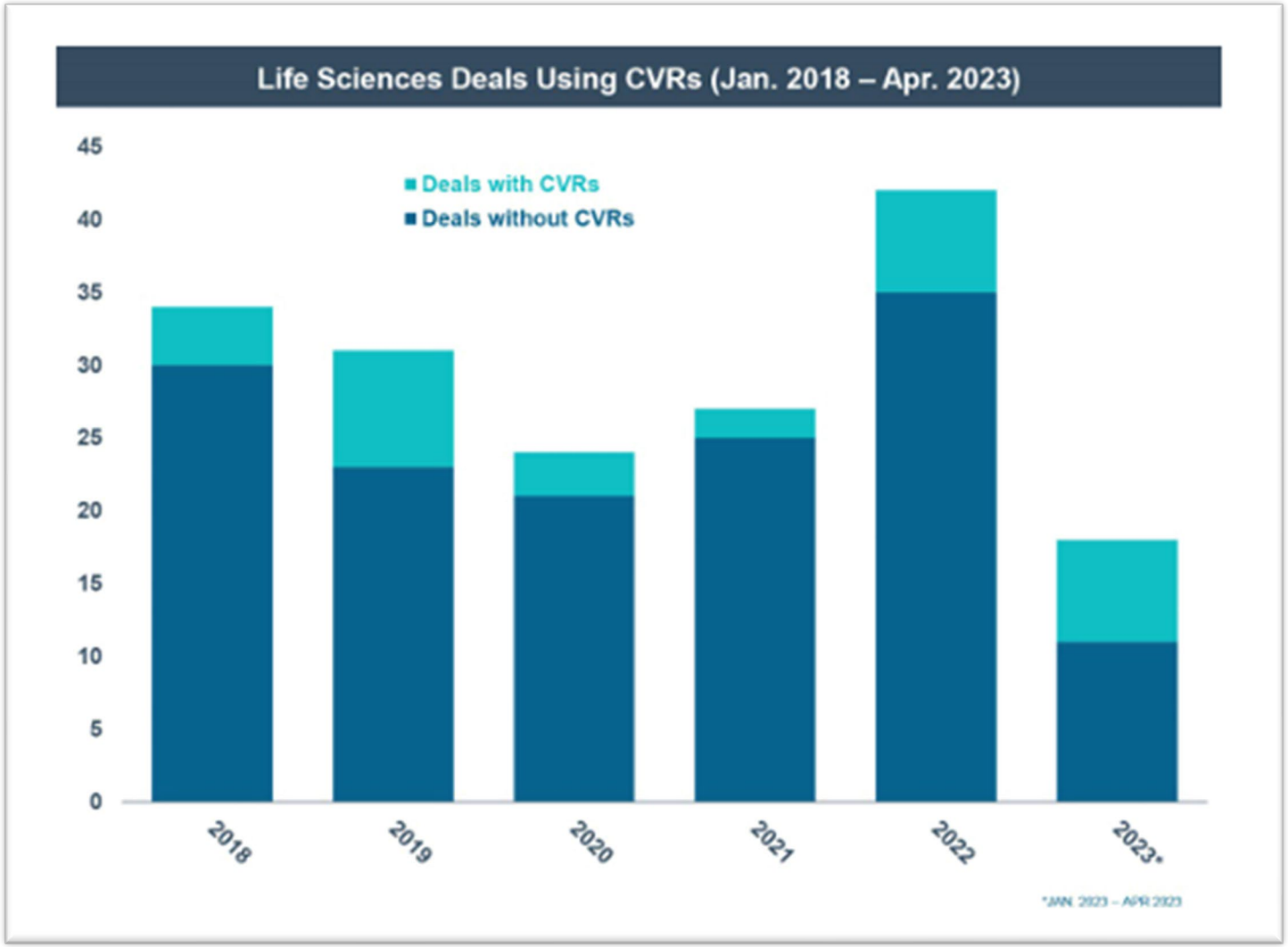
Earnout Disputes and Renegotiations



SRS Acquiom, 2023 Life Sciences M&A Study

Milestones Prevalent in Public-Company M&A Deals



Harvard Law School Forum on Corporate Governance, Key Components and Trends of CVRs in Life Sciences Public M&A Deals

Commercially Reasonable Efforts

General Background

» Efforts Clauses:

- **"Best Efforts"**
- **"Reasonable Best Efforts"**
- **"Every Effort"**
- Most common: **"Commercially Reasonable Efforts" or "CRE"**

» CRE: Subjective v. Objective

- Subjective: Inward-looking; efforts equivalent to company's own efforts on similar products
- Objective: Outward-looking; efforts typical in the industry for a similar product

Commercially Reasonable Efforts: Risks of Ambiguity

***Menn v. ConMed Corp.*, 2022 WL 2387802 (Del. Ch. June 30, 2022)**

Purchase agreement lacked "yardstick" by which "the court was to measure 'commercially reasonable' efforts":

> *"Buyer and the Company shall work in good faith and use* ***commercially best efforts*** *to maximize payouts for the benefit of the Shareholder Parties pursuant to Section 4.02 and Section 4.03* [FDA milestones] *hereto, including the maximization of net sales of Products."*

Chancery Court therefore interpret CRE as requiring the party to "do **essentially everything in its power** to fulfill its obligation"

Litigation Example: Subjective Definition

Fortis Advisors LLC vs. Johnson & Johnson, 2024 WL 4048060 (Del. Ch. Sept. 4, 2024)

Merger agreement defines "commercially reasonable efforts" as:

the expenditure of efforts and resources in connection with research and development and obtaining and furnishing of information to and communications with applicable Governmental Entities in connection with obtaining the applicable 510(k) premarket notification with respect to the applicable Robotics Products ***consistent with the usual practice of [J&J] and its Affiliates with respect to priority medical device products of similar commercial potential at a similar stage in product lifecycle to the applicable Robotics Products[.]***

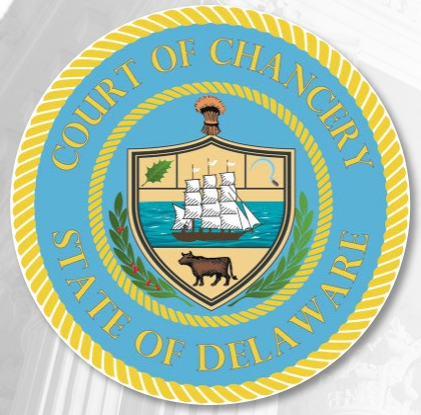
Litigation Example: Subjective Definition

Fortis Advisors LLC vs. Johnson & Johnson, 2024 WL 4048060 (Del. Ch. Sept. 4, 2024)

- Court interpreted this to mean the efforts were "at the high level J&J—a top company in the industry—set for itself, and for 'priority' devices within J&J."
- Ultimately the court found
  - *J&J could consider various factors in assessing the level of efforts to devote. But the end goal of those efforts was to achieve the iPlatform regulatory milestones – not to further J&J's robotics programs.* ***A 'priority' device would not have its system, technology, and team diluted to fix another device's problems.***

Court found breach after trial.

Commercially Reasonable Efforts: Objective Definition



Himawan v. Cephalon, Inc., 2018 WL 6822708 (Del. Ch. Dec. 28, 2018)

Merger agreement gave buyer full discretion with respect to seller's business, subject to CRE requirement to develop and commercialize drug:

> *the exercise of such efforts and commitment of such resources* ***by a company with substantially the same resources and expertise*** [as purchaser] . . . *with due regard to the nature of efforts and cost required for the undertaking at stake.*

Motion to dismiss denied.
Seller included allegations about what purportedly comparable companies were doing.

Commercially Reasonable Efforts: Objective Definition

Himawan v. Cephalon, Inc., 2024 WL 1885560 (Del. Ch. Apr. 30, 2024)

- Court found at trial that there were no valid real-world comparators ("no exemplar companies operate under the actual conditions of Defendants")
- Court applied CRE standard on buyer "as it found itself situated"
- "That is, if a reasonable actor with faced with the same restraints and risks would go forward in its own self-interest [to develop the drug], the buyer is contractually obligated to do the same."

Court found no breach after trial.

Commercially Reasonable Efforts: Objective Definition

S'holder Representative Servs. LLC v. Alexion Pharms., WL 4052343, (Del. Ch. Sept. 5, 2024)

Similar to *Himawan*, the merger agreement gave buyer full discretion with respect to seller's business, subject to CRE requirement to develop and commercialize drug:

> *[U]sing such efforts and resources* ***typically used by biopharmaceutical companies similar in size and scope to [Alexion]*** *for the development and commercialization of similar products at similar development stages taking into account. . .and other relevant scientific technical and commercial factors* ***typically considered by biopharmaceutical companies similar in size and scope to [Alexion] in connection with such similar products***.

Commercially Reasonable Efforts: Objective Definition

S'holder Representative Servs. LLC v. Alexion Pharms., WL 4052343, (Del. Ch. Sept. 5, 2024)

- Court found that while *Himawan* CRE provision allowed buyer to consider its own efforts and costs required, this provision does not. Alexion's CRE "is pegged to typical factors considered by typical companies–not Alexion's own self-interest."
- Court finds there are not adequate exemplar companies so they use a "hypothetical company approach," like in *Himawan*.
- This means there is a breach if the Court finds Alexion "fell short of the typical efforts a hypothetical company similarly situated to Alexion would have devoted to the program."

Court found breach after trial.

False Claims Act Litigation

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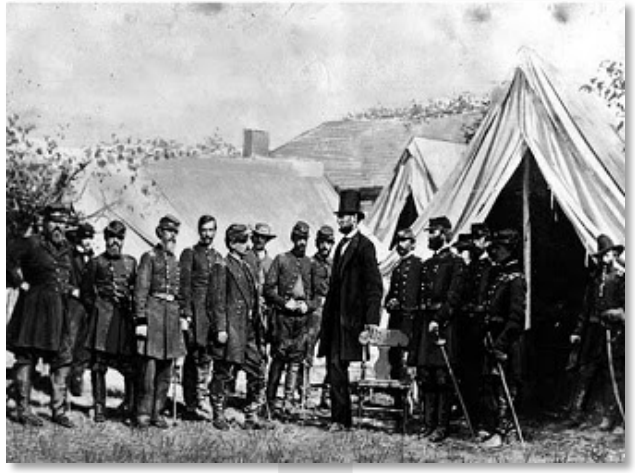
History of the False Claims Act



Enacted in 1863

To combat fraud by companies selling supplies to the Union Army

Revised in 1986

To encourage more whistleblowers to expose defense contractors during the Cold War

INCREASED DAMAGES:
From **2x** to **3x**

INCREASED PENALTIES PER FALSE CLAIM:
From **2k** to **5-10k**

Pharmaceutical Claims

Types:

- Price fixing
- Kickbacks
- Medicare
  - Drug pricing
  - Rebates
- Encouraging improper coding
- Off-label promotion
- Manufacturing practices / adulterated drug sales
- Drug safety misrepresentations / omissions

FCA Damages and Penalties Continue to Rise

False Claims Act Settlements and Judgments Exceed $2.9B in Fiscal Year 2024

https://www.justice.gov/archives/opa/pr/false-claims-act-settlements-and-judgments-exceed-29b-fiscal-year-2024

Number of FCA cases also on the rise

Year	New FCA cases
2021	810
2022	963
2023	1218
2024	1402

https://www.justice.gov/archives/opa/media/1384546/dl

FCA Enforcement Remains Priority for New Administration

Trump Officials Signal Continued Interest in FCA

February 20, 2025 Deputy AG Michael Granston: "The department wants to make clear — consistent with the new administration's stated focus on achieving governmental efficiency and rooting out waste, fraud and abuse — that the department plans to continue to aggressively enforce the False Claims Act."

Executive Order on "Ending Illegal Discrimination"*: "The head of each agency shall include in every contract or grant award … a term requiring the contractual counterparty or grant recipient to agree that its compliance in all respects with all applicable Federal anti-discrimination laws is material to the government's payment decisions."

*** Maryland District Court issued preliminary injunction on February 24 temporarily prohibiting enforcement of this provision, among others**

Qui tam provision

"Qui tam"

Qui tam pro domino rege quam pro se ipso in hac parte sequitur

=

"he who brings an action for the king as well as himself"

1

A **whistleblower**, or relator, files suit under seal in their private capacity on behalf of the government

2

The government has 60 days to decide whether to intervene or seek an extension

3

If the action is successful, the relator may receive 15-30% of proceeds

Recent Developments – Causation in Kickback Cases

Eighth, Sixth Circuits, and First Circuits

» "Resulting from" requires but-for causation–the defendant would not have included the item in their claim for reimbursement but for the kickbacks

Third Circuit

» A plaintiff need only prove "a link between the alleged kickbacks and the medical care received."

» Following *Regeneron*, Third Circuit is an outlier

United States v. Regeneron Pharma (Feb 18, 2025)

- Regeneron donates millions of dollars to a patient-assistance foundation to help patients cover the co-pays for Eylea
- Govt: Doctors prescribed Eylea because of the co-pay assistance they knew patients would receive from the foundation, and then submitted claims to Medicare, thereby submitting claims that "resulted from" an AKS violation
- Regeneron: If physician would have prescribed Eylea regardless of co-payment assistance, subsequent Medicare claim cannot have "result[ed] from" the illicit payments
- First Circuit: "The statutory history provides no reason to deviate from the ordinary course, in which we treat 'resulting from' as requiring but-for causation…And not even the government argues that it will rarely be able to prove but-for causation."

Polansky Concurrence and Dissent – FCA Constitutionality

- Justice Thomas's dissent: "substantial arguments that the qui tam device is inconsistent with Article II and that private relators may not represent the interests of the United States in litigation"
- Gaining some traction with lower courts in 2024

U.S. ex rel. Zafirov v. Fla. Medical Assoc. LLC (M.D. Fla. Sept. 30, 2024)

Court agrees with J. Thomas that qui tam provision may be unconstitutional

- FCA relators are "officer[s] of the United States," because they "exercise significant authority pursuant to the laws of the United States" and "occupy a 'continuing' position established by law"
- Therefore, Constitution requires that FCA relators be appointed consistent with the Appointments Clause, and a relator's "self-appointment, obviously, does not satisfy the Appointments Clause."

Litigating false claims in California

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California qui tam statutes

CA False Claims Act

- Enacted 1987
- Similar to federal FCA, but relators may receive **up to 50%** of the government's proceeds
- *Examples in healthcare:*

Prime Healthcare Services and Two Doctors Agree to Pay $37.5 Million to Settle Allegations of Kickbacks, Billing for a Suspended Doctor, and False Claims for Implantable Medical Hardware (2021)

Tenet Healthcare Corporation to Pay U.S. more than $900 Million to Resolve False Claims Act Allegations (2006)

California qui tam statutes

Insurance Frauds Prevention Act

- Enacted in 1993
- One of only two qui tam statutes in the country addressing fraud against private insurers
- IFPA provides for treble assessments and fines of $5-10k per violation

Sutter Secures Complete Win in Defeating IFPA claim

The *Duncan* decision (June 2024):

- Established that materiality is a requirement of an IFPA claim
- Resolved ambiguity in the law to hold that specific intent is required

Developments in Patent Law

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Enablement: 35 U.S.C. § 112(a)

» ***Amgen Inc. v. Sanofi,* 598 U.S. 594 (2023)**

- "For if our cases teach anything, it is that the more a party claims, the broader the monopoly it demands, the more it must enable."
  - Insufficient to provide a "roadmap" that "merely describes step-by-step Amgen's own trial-and-error method"
  - Insufficient to propose "conservative substitution," which would "require[] scientists to make substitutions to the amino acid sequences of antibodies known to work and then test the resulting antibodies to see if they do too."
- Identifying a "quality common" to every embodiment, but none identified in Amgen.

After Amgen: What is "undue experimentation"?

» **"We do not interpret Amgen to have disturbed our prior enablement case law, including Wands and its factors"**

- *Baxalta Inc. v. Genentech, Inc.*, 81 F.4th 1362, 1367 (Fed. Cir. 2023)

» ***In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)**

- States factors to determine whether "undue experimentation" would be necessary.

Claims That Are Not Enabled

- **The patent for an electric lamp claiming an "incandescing conductor" composed of "every fibrous and textile material," when the patent owner's lamp used only carbonized paper.** *Consol. Elec. Light Co v. McKeesport Light Co,* 159 U.S. 465, 468 (1895) (Edison lamp)

- **Claim for all antibodies that bind to Factor IX/IXa and increase the procoagulant activity of Factor IXa; 11 embodiments identified; "roadmap" involved performing random trial-and-error experimentation.** *Baxalta*.

- **Animal free Botox with a responder rate greater than 50%, when the trials accomplished only a 62% responder rate.** *Medytox, Inc. v. Galderma S.A.*, 71 F.4th 990, 993 (Fed. Cir. 2023).

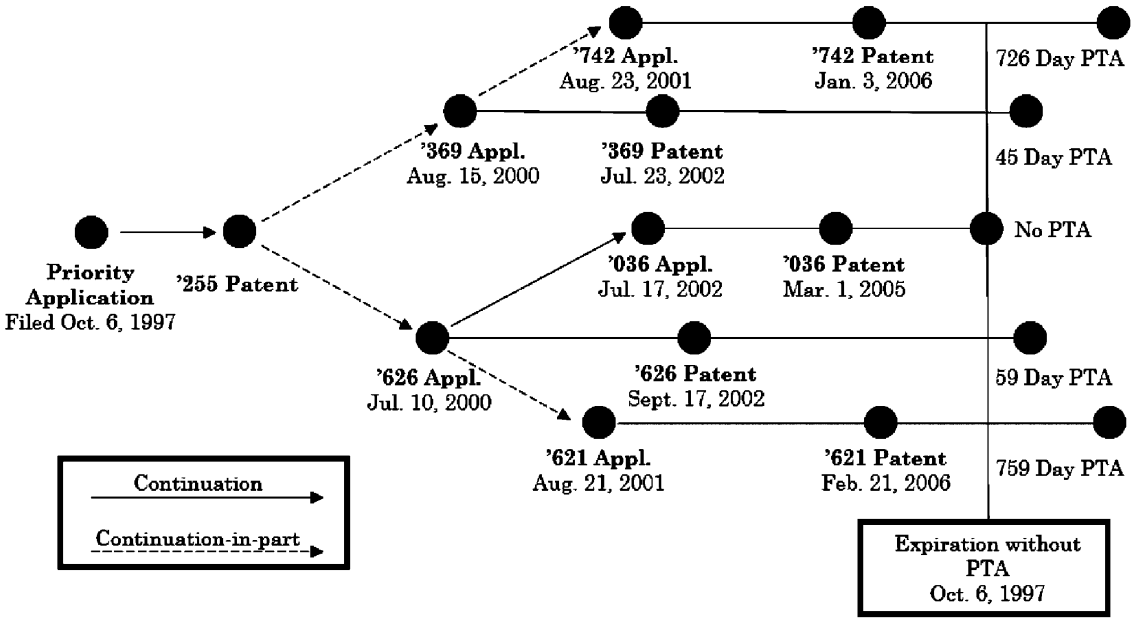
Doctrine of Double Patenting - Refresh

» **"The doctrine of double patenting seeks to prevent the unjustified extension of patent exclusivity beyond the term of a patent."**

- "Same Invention" under 35 U.S.C. § 101; or
- "Nonstatutory" – prohibits claims in later-expiring patent "not patentably distinct from claims in the first patent"

» **Avoid nonstatutory double patenting through a "terminal disclaimer" that limits patent period to original patent.**

Patent Term Adjustments: *In re Cellect*



- **Patent term adjustments granted to some variants during prosecution**
- ***Cellect* held that patent term adjustment made the patents "later-expiring" obvious variants**
- **"Terminal disclaimers were the solution" to this issue**

Guardrails on ODP Prior Art: *Allergan USA, Inc. v. MSN Lab'ys Priv. Ltd.,*

- **Can a "child" patent invalidate its own parent that received a patent term adjustment (and thus expires later)?**
- **Answer:**
- **A "first-filed, first-issued parent patent having duly received PTA" cannot be invalidated by a "later-filed, later-issued child patent with less, if any, PTA"**

Discretionary Institution and *Fintiv* Factors

» **Discretionary denial can occur if there is parallel litigation in district court**

» **PTAB evaluates six non-exhaustive factors and "takes a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review."**

- *Apple Inc. v. Fintiv, Inc.*, No. IPR2020-00019, 2020 WL 2126495, (P.T.A.B. Mar. 20, 2020) (precedential).

Vidal's 2022 *Fintiv* Guidance

UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

MEMORANDUM

DATE: June 21, 2022

TO: Members of the Patent Trial and Appeal Board

FROM: Katherine K. Vidal Katherine Kelly Vidal
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office (USPTO or the Office)

SUBJECT: INTERIM PROCEDURE FOR DISCRETIONARY DENIALS IN AIA POST-GRANT PROCEEDINGS WITH PARALLEL DISTRICT COURT LITIGATION

Introduction

Congress designed the America Invents Act (AIA) post-grant proceedings "to establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs." H.R. Rep. No. 112–98, pt. 1, at 40 (2011), 2011 U.S.C.C.A.N. 67, 69; *see* S. Rep. No. 110–259, at 20 (2008). Parallel district court and AIA proceedings involving the same parties and invalidity challenges can increase, rather than limit, litigation costs. Based on the USPTO's experience with administering the AIA, the agency has recognized the potential for inefficiency and gamesmanship in AIA proceedings, given the

Former USPTO Director Kathi Vidal

Vidal's 2022 *Fintiv* Guidance Rescinded

Patent Trial and Appeal Board

UNITED STATES PATENT AND TRADEMARK OFFICE
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USPTO rescinds memorandum addressing discretionary denial procedures

Today, the USPTO rescinded the June 21, 2022, memorandum entitled "Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation" (Memorandum).

Parties to post-grant proceedings should refer to Patent Trial and Appeal Board (PTAB) precedent for guidance, including Apple Inc. v. Fintiv, Inc., IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential) and Sotera Wireless, Inc. v. Masimo Corp., IPR2020-01019, Paper 12 (PTAB Dec. 1, 2020) (precedential as to § II.A).

To the extent any other PTAB or Director Review decisions rely on the Memorandum, the portions of those decisions relying on the Memorandum shall not be binding or persuasive on the PTAB.

USPTO Acting Director Coke Morgan Stewart

Prescription Drug Diversion and Counterfeiting: Lessons from Law Enforcement

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What is drug diversion?

- Drug diversion = the unlawful channeling of regulated pharmaceuticals from legal sources to the illicit marketplace
  - One example: Patient fills a prescription for a medication that is worth several thousand dollars but is paid for by Medicare, Medicaid or insurance. The patient then sells it for a fraction of the list price in cash. The buyer, known as an aggregator, removes the patient information, alters the bottle and sells it to the wholesale distributor, who sells it back to the pharmacy.

Common methods of prescription drug diversion

Diversion Method	Definition
Selling Prescription Drugs	Patients and other individuals selling prescription drugs that were obtained legally
Doctor Shopping	Soliciting multiple physicians using a variety of false pretenses to receive prescriptions for controlled substances
Illegal Internet Pharmacies	Rogue websites under the guise of legitimate pharmacies that may provide controlled substances to individuals without prescriptions and evade State licensing requirements and standards by operating across State and international borders
Drug Theft	Thefts may occur at any step of the prescription drug supply chain—from a manufacturer to a patient or stealing from relatives, friends, or health care professionals (for example: nurses, doctors, pharmacists, and other providers)
Prescription Pad Theft and Forgery	Printing or stealing prescription pads to write fraudulent prescriptions or altering a prescription to obtain an unauthorized quantity of prescribed drugs
Illicit Prescribing	Providing unnecessary prescriptions or prescribing larger quantities of tablets or capsules than what are medically necessary—commonly known as “pill mills”

https://www.cms.gov/files/document/prescriber-role-drugdiversion-033115pdf

Recent drug diversion cases

Redistribution scheme targeting HIV drugs

- **Civil suit:** Gilead files suit against Safe Chain, ProPharma, and others in 2021 accusing defendants of distributing counterfeit bottles of Biktarvy and Descovy**.** Gilead settles with defendants in 2023 and 2024; settlement with Safe Chain prohibits them from selling any Gilead products in US, relinquishing rights to $2.7m in frozen assets, and entering into consent judgment.

- **Criminal action**: Southern District of Florida indicts three owners of Safe Chain in June 2024 for "Conspiracy to Introduce Adulterated and Misbranded Drugs and to Defraud the United States" by allegedly buying large quantities of diverted HIV drugs, reselling them to pharmacy customers, and creating fake paperwork to cover up the trail.

- **FDA response:** FDA issues warning letter to Safe Chain in June 2023, raising concerns about Safe Chain's acquisition of HIV drugs from "unauthorized trading partners" and sales of illegitimate product, and threatening to pursue seizure and injunction.

Recent drug diversion cases

PRESS RELEASE

Ten Pharmaceutical Distributor Executives, Sales Representatives, and Brokers Charged in Connection with Unlawful Sales of Nearly 70M Opioid Pills

Thursday, October 3, 2024

For Immediate Release

Office of Public Affairs

- Indictment charges five pharma distributor execs and five sales reps and brokers in the Southern District of Texas, Southern District of Florida, Eastern District of Missouri, and Eastern District of North Carolina

- Case investigated by DEA, HHS-OIG, FBI, USPS-OIG, FDA-OCI, and MFCU, with assistance from Department of Homeland Security, Broward Sheriff's Office, Houston Police Department, and other federal and state law enforcement agencies

Working with Law Enforcement

- ***Very Few Specialists***
  - FDA has expertise, but not the manpower.
  - FBI has manpower, but not the expertise. Diversion typically not identified as an FBI priority.
  - In referrals, note money laundering, misleading documentation (fraud). FDA violations will likely be unfamiliar.
  - Referrals should "speak government" – industry assistance can be critical.
  - Consider law enforcement referrals beyond FDA.
- ***Geographically Limited***
  - Can be difficult to identify venue at the outset. Good case to be made for victim's home district.

Thank You

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