Claims 2024: What's happening? What you need to know.

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Agenda

01

What you need to know about doing business across borders

- Foreign clinical trials
- Theft of intellectual property
- Tariffs
- Practical advice and solutions

02

Loper Bright

- What is *Loper Bright*?
- What does it mean for the life science industry?
- What is on the horizon?

03

Important 2024 Verdicts and Decisions

- Acetaminophen ADHD/Autism lawsuits
- Zantac decisions
- Duty to innovate
- Apex doctrine

04

Crystal ball

- What is on the horizon in 2025?

Supply chain management

- Manufacturing and distribution of drugs and devices is global
- FDA reviews drugs and devices entering the US
- Historical issues:
  - Quality control
  - Contamination
- Continued challenges:
  - Chinese manufacturing problems are increasing
    - Recalls for broad range of syringes and inhalers
    - Financial instability among Chinese factories
    - Distrust of foreign companies, particularly the US

New considerations

- Rise of geo-political tensions between the US and China
- Theft of intellectual property:
  - Chinese government's monitoring of private clinical trials and manufacturing facilities
  - Forced technology transfer as a condition of doing business in China
  - Bad faith trademark registrations
  - Counterfeiting

Issues with international clinical trials

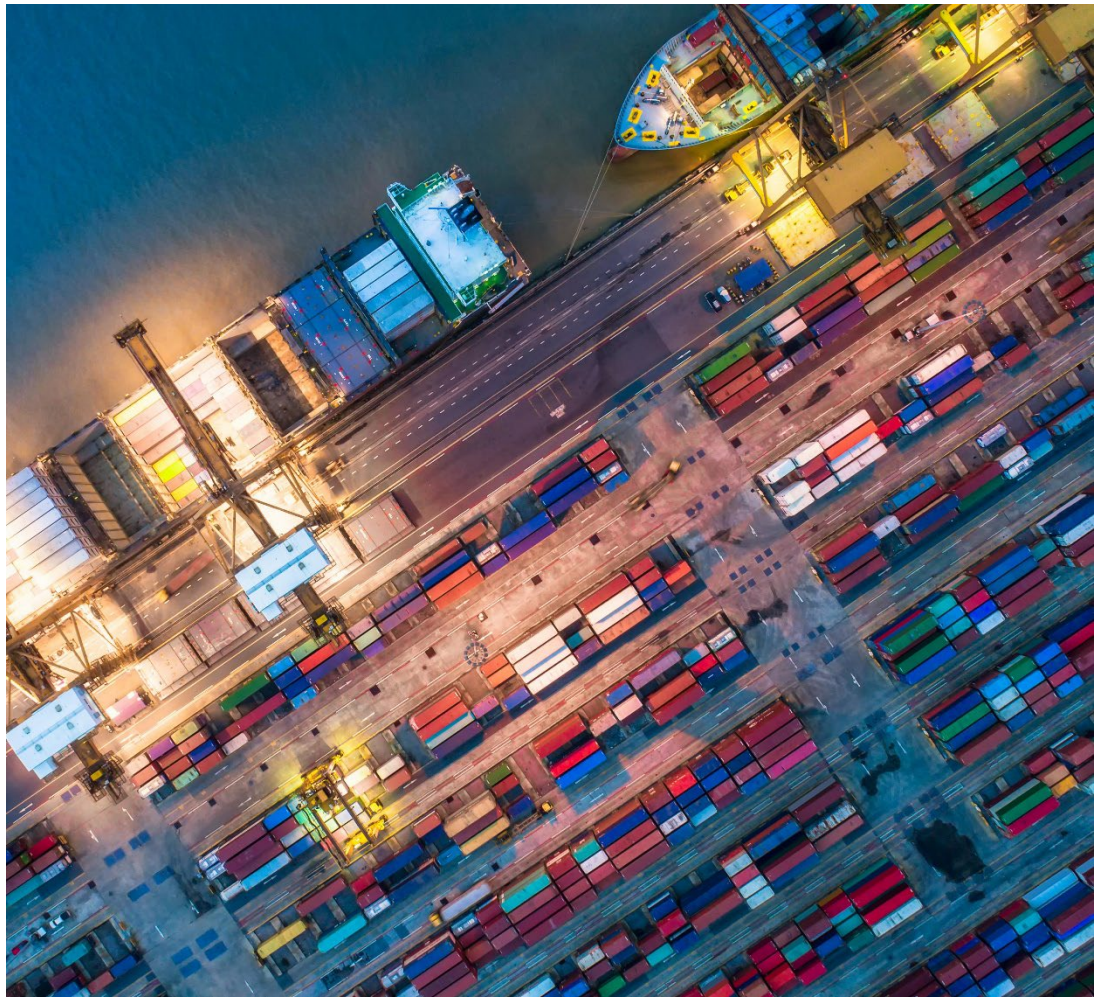
- Two frequent countries utilized for clinical trials: India and China
- Somewhat different issues with each country:
- India:
  - Patient recruitment
  - Informed consent
  - Trial oversight:
    - Undertrained care managers and monitors
    - Undermanned personnel to conduct oversight

Issues with clinical trials in China

- Enormous growth in clinical trials in China:
- Similar challenges to trials in India:
  - Research misconduct and data integrity issues
  - Ethical concerns with informed consent
  - Cultural concerns impacting recruitment and retention
- Chinese Communist Party- military involvement:
  - State oversight of private clinical trials
  - House Select Committee on Strategic Competition
  - BIOSECURE Act

Other issues affecting supply chains

- **US restriction of semiconductors to China;**
- **Response:**
  - Export ban/restriction (gallium, germanium, antimony)
- **New administration – potential tariffs:**
  - 25% increase on goods from Canada & Mexico
  - 10% increase on goods from China:
    - Semi-Conductors & EVs'
    - 2018 tariff on steel & aluminum
- **Alternate sourcing likely results in increased prices**



https://www.reuters.com/markets/commodities/china-bans-exports-gallium-germanium-antimony-us-2024-12-03/#:~:text=China%20accounted%20last%20year%20for,in%20batteries%20and%20photovoltaic%20equipment. (Last visited 12/8/2024)

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Supply Chain Management – What Can We Do?

- Constant review/audit of the supply chain:
  - Do they have similar missions?
  - Functions:
    - Who are their vendors?
  - Structure/Workloads
  - Is there a written contract?
    - Is it current?
- Online Research Tools:
  - Https://www.transparency.org/en
  - Fsi.taxjustice.net

Loper Bright Enters. v. Raimondo, 144 S. Ct. 2244 (2024)

- **Background:**
  - **Administrative Procedures Act (1946)**
    - Section 706 – "To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action."
  - ***Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984):**
    - Required courts to defer to federal agency legal interpretations of ambiguous or silent statutes if the interpretation is based on a permissible construction;
    - Inevitable outcomes: Binding deference to agency interpretations even if the agency interpreted the statute inconsistently over time, and continuous clarification attempts by SCOTUS and inconsistent applications by lower courts
  - **RESULT: *Chevron* overruled (6-3 / 6-2):**
    - APA requires courts to independently judge statutory language and courts may not defer to agency interpretations of ambiguous laws
    - Courts have Article III authority to decide and say what the law is, per *Marbury v. Madison*

Photo courtesy of: National Sea Grant Law Center

Loper Bright—the rest of the story

- Who pays for observers required on commercial fishing boats by federal law?
  - Commerce Department says the fishing vessels pay for the observers. Fishermen disagree
  - Statute is silent on this issue
- Pre-*Loper Bright*, lower courts deferred to Commerce Department's view
- Lower court is trying to decide the issue again under *Loper Bright*:
  - Two-hour argument
  - Court is trying compare this program to other programs to find analog that would allow it to determine intent
  - Trying to decipher congressional intent from statute's language (or lack thereof)

Taylor Mills, *Loper Bright Oral Arguments Get Mixed Reception at D.C. Circuit*, November 4, 2024, Bloomberg Law; Taylor Mills, *Loper Bright Remand Is Early Test for Agency Rules Post-Chevron*, November 1, 2024, Bloomberg Law.

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Any limits to *Loper Bright*???

- **"Agency policymaking" or "agency factfinding:"**
  - Deferential standard of review remains for these actions
  - Agencies retain their "discretionary functions:"
    - e.g., FTCA decisions on marketing of prescription medical products or product labeling within scope of FDA
- **Other forms of deference remain:**
  - *Skidmore* deference: Allows courts to consider and give weight to agency's interpretation of statutes or regulations "based on . . . specialized experience."
  - *Auer* defense: Courts defer to agency's interpretation of its regulations unless the interpretation is "plainly erroneous or inconsistent with the regulation."
    - *Kisor v. Wilkie*, 588 U.S. 558 (2019) – adopted two-part *Chevron-style* analysis for *Auer* deference questions; cited favorably in *Loper Bright*
  - Agency scientific determinations:
    - *Kleppe v. Sierra Club*, 427 U.S. 390, 412 (1976): Issues "requiring a high level of technical expertise . . . [are] properly left to the informed discretion of responsible federal agencies."

See Bexis, *Limits to Loper Bright*, Drug & Device Law (Nov. 18, 2024), https://www.druganddevicelawblog.com/2024/11/limits-to-loper-bright.html (last visited Dec. 7, 2024); Colter Paulson, *The limits of Loper Bright and the long decline of Chevron*, Sixth Circuit Appellate Blog (Jul. 17, 2024), https://www.sixthcircuitappellateblog.com/news-and-analysis/the-limits-of-loper-bright-and-the-long-decline-of-chevron/ (last visited Dec. 7, 2024); Ellen M. Moskal, *Loper Bright: What is Not Impacted by the Supreme Court's Recent Ruling Overturning the Chevron Doctrine*, Somach Simmons & Dunn, https://somachlaw.com/policy-alert/loper-bright-what-is-not-impacted-by-the-supreme-courts-recent-ruling-overturning-the-chevron-doctrine/ (last visited Dec. 7, 2024).

What will *Loper Bright* mean to life science companies?

- **Chaos!**
  - What new legal standards come from *Loper Bright?*
    - Further SC cases will likely materialize regarding how lower courts should interpret and apply *Loper Bright*?
  - How will *Loper Bright* substantively impact life science/FDA case law?
    - Will the FDA's ban on off label promotion be overturned?
    - Will FDA interpretations that limit the scope of preemption be overturned?

Bexis, *Could Loper Bright Finally Do in FEDA's Ricekty Off-Label Speech Ban?*, August 5, 2024, available at https://www.druganddevicelawblog.com/2024/08/could-loper-bright-finally-do-in-fdas-rickety-off-label-speech-ban ; Bexis, *Loper Bright Likely Lays Lohr Low,* September 9, 2024, available at https://www.druganddevicelawblog.com/2024/09/loper-bright-likely-lays-lohr-low.html (last visited 12/3/2024).

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What will *Loper Bright* mean to life science companies? *Cont'd*

- **Judges aren't scientists:**
  - Justice Kagan: "When does an alpha amino acid polymer qualify as a protein . . . I don't know many judges who would feel confident resolving that issue."
- **Politics/advocacy groups:**
  - Advocacy groups have become adept at forum shopping to find specific courts and judges that they will believe will run in their favor
  - This risk will be greater for products that touch on political issues (i.e., Mifepristone)

Kevin Dunleavy, *SCOTUS overturn of Chevron doctrine opens a Pandora's box for biopharma industry ,expert says*, Augst 27, 2024, https://www.fiercepharma.com/pharma/scotus-overturn-chevron-doctrine-opens-pandoras-box-biopharma-industry (last visited 9/3/2024); Robert Iafolla, *GOP-Picked Judges Take Hard Line on Rules After Chevron's Demise, Bloomberg Law News*, September 4, 2024 .

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What will *Loper Bright* mean to life science companies? *Cont'd*

- **Can you rely on FDA's decisions?**
  - Agency decisions (good or bad) were unlikely to be overturned through litigation. Now . . .
    - 26 decisions since *Loper Bright*: 4 decisions striking down rules; 15 halting their enforcement; 3 rejecting government requests to stay earlier injunctions
  - Uncertainty isn't all bad:
    - Life science companies can challenge unfavorable agency decisions that were previously unlikely to be overturned by the courts
  - Congress will likely need greater technical assistance drafting laws creating opportunities for industry involvement

Kevin Dunleavy, *SCOTUS overturn of Chevron doctrine opens a Pandora's box for biopharma industry ,expert says*, Augst 27, 2024, https://www.fiercepharma.com/pharma/scotus-overturn-chevron-doctrine-opens-pandoras-box-biopharma-industry (last visited 9/3/2024); Robert Iafolla, *GOP-Picked Judges Take Hard Line on Rules After Chevron's Demise, Bloomberg Law News*, September 4, 2024; Christopher White, *What Chevron's Demise Could Mean for Medtech*, June 3, 2024, available at https://www.advamed.org/2024/06/03/what-chevrons-demise-could-mean-for-medtech/ (last visited 12/3/2024) .

FCC v. Consumer's Research—the next Loper Bright?

- E-Rate program:
  - Federal Communications Commission program that allows a nonprofit to collect fees from telecom companies
  - Fees are to subsidize phone and internet in rural areas
- Consumer group challenged the program:
  - It violates non-delegation doctrine, which says Congress can't delegate power to legislate to other government branches
  - It makes a similar argument that the program violates the private non-delegation doctrine, which forbids the government from delegating power to private entities
  - Both doctrines were last used in response to New Deal legislation;
- Federal circuit courts have reached differing decisions on this issue. U.S. Supreme Court took up the appeal
- If consumer group prevails, it could further limit how federal government is allowed to operate
- FDA user fees could face a similar attack

Kalvis Golde, *FCC asks court to uphold constitutionality of nationwide rural phone and internet subsidies*, available at https://www.scotusblog.com/2024/11/fcc-asks-court-to-uphold-constitutionality-of-nationwide-rural-phone-and-internet-subsidies/ (last visited 12/3/2024).

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Acetaminophen MDL

- Background
- Litigation:
  - MDL
  - Rule 702
  - Expert testimony and rulings

Rule 702 Amendment (The Really Good)

- **Best development in 2023-24!**
- **Rule 702 Amendment Cases:**
  - *In Re Acetaminophen* (S.D.N.Y.)(MDL)
  - Onglyza Products Cases (Cal App 2023)
  - *Sprafka v. Medical Device Business Services (DePuy)* (U.S. Dist Court of Minnesota)
  - Diabetes Drug MDL (E.D. Ky)

Zantac (ranitidine) litigation

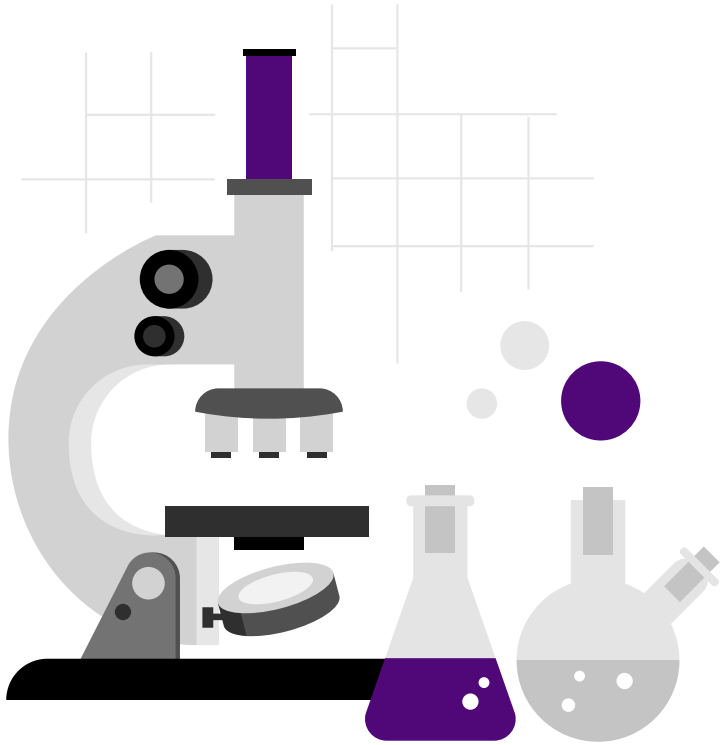
- **Background:**
  - Lawsuits claim Zantac / ranitidine were contaminated with or degraded into NDMA, a carcinogen linked to increased cancer risks
  - FDA pulled Zantac from the market in April 2020
- **Allegations:**
  - Manufacturers knew / should have known of NDMA contamination risk but failed to warn patients and/or healthcare professionals
  - Delay in recalling Zantac/ranitidine and downplaying of adverse effects
- **Lawsuits**:
  - Nationwide lawsuits against Zantac makers, including GlaxoSmithKline, Pfizer, Patheon, Boehringer Ingelheim, and Sanofi
  - MDL in Southern District of Florida formed in February 2020 (*In Re: Zantac (Ranitidine) Products Liab. Litig.*, 20-MD-2924):
    - Covered consumer class action claims, third-party claims, bodily injury cases, third-party payer claims, and medical monitoring claims

Zantac (ranitidine) litigation, cont'd

- **Verdicts/Results:**
  - Florida MDL dismissed numerous claims for lack of correlating scientific evidence in 2022
  - Hung jury / mistrial in California trial against Boehringer Ingelheim (jury deadlocked on causation but found Zantac was dangerous and failure to warn) (Nov. 2024)
  - Mistrials in Illinois cases against Boehringer Ingelheim (Sept. 2024)
  - Plaintiffs' experts excluded in Florida state court (Aug. 2024)
  - GSK defense verdict in Illinois state court (Aug. 2024)
  - Delaware state court denied *Daubert* challenge to plaintiffs' experts; Delaware Supreme Court took matter on interlocutory review (Aug. 2024)
- **Settlements:**
  - October 2024: GSK settled approx. 80,000 lawsuits for $2.2B
  - September 2024: GSK entered two confidential settlements over lawsuits in California (Russell and Hughes cases)
  - April 2024: Sanofi agreed to pay $100M to approx. 4,000 plaintiffs

Duty to innovate – How did we get here?

- Gilead Life Sciences
- Products used to treat HIV and Hepatitis B:
  - TDF – Approved by the FDA in 2001
  - TAF – Human trials started 2001; stopped in 2004
- 2018 – Litigation ensued:
  - Approximately 24,000 plaintiffs who took TDF to treat HIV
  - Known side effects of TDF include bone, kidney, &/or tooth injuries
- Theory of liability:
  - Negligence
  - Breach of duty of care
  - No allegations of strict liability
- 2022 – trial court denied Gilead's summary judgment motion. Court of Appeals affirmed.



https://www.gilead.com/company (Last accessed 12/8/2024)

Gilead Life Science v. Superior Court

(*Gilead Tenofovir Cases, No. CJC-19-005043, JCCP No. 5043*)

What happened?

- Created an affirmative duty to innovate in California, requiring all manufacturers to develop an alternate product that it knows to be safer for some subset of consumers, and to do so without delay
- CA Supreme Court granted Gilead's petition for review in May 2024
- 26 separate amicus briefs filed since
- No timeframe set for CA Sup. Court

Potential Implications

- Wide-spread effects
- Disincentivize innovation
- Discourage manufacturers from investigating and developing ways to improve products
- Expand litigation targeting earlier, non-defective products

https://www.gilead.com/company (Last accessed 12/8/2024)

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What is the apex doctrine?

- Origin of the doctrine is a products liability case where deposition of Chrysler CEO Lee Iacocca was sought:
  - "The fact remains [Iacocca] is a singularly unique and important individual who can be easily subjected to unwarranted harassment and abuse. He has a right to be protected, and the courts have a duty to recognize his vulnerability." *Mulvey v. Chrysler Corp.*, 106 F.R.D. 364, 366 (D.R.I. 1985).
- As a result, Iacocca didn't have to testify

Mike Vilensky, *Once Too Big to Testify, CEOs Feel Backlash to 'Apex Doctrine*,' October 9, 2024, Bloomberg Law.

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How is the apex doctrine changing?

- **Eliminating apex doctrine:**
  - Washington Supreme Court says doctrine undermines right to access courts. We don't need special rules for CEOs:
    - Similar decisions in CO, CT, MO, NY, NC, and OK
    - "[T]he apex doctrine's influence has reached its zenith and has begun to decline." *BlueMountain Credit Alter. Master Fund L.P. v Regal Ent. Group*, 465 P.3d 122, 132 (Colo. App. 2020)
- **Codifying apex doctrine:**
  - Georgia recently amended its rules of court to include apex doctrine after its Supreme Court had rejected the doctrine
  - Doctrine is also codified in CA, FL, TX, MI, and WV

P. Andrew Smith, *The Apex Doctrine is Helpful Even Where it is Not Formally Adopted*, ABA Pretrial Practice & Discovery, March 9, 2023.

How is the apex doctrine changing?

- **Reconfiguring the apex doctrine test:**
  - General rule against deposition no longer applies
  - Courts will make fact-based decision looking at:
    - Does the CEO have special or unique knowledge?
    - Are there less burdensome means of getting that information?
  - This fact-based inquiry can lead to contrary results for the same CEOs:
    - Mark Zuckerburg deposition rejected in 2022 privacy lawsuit, but allowed in 2024 lawsuit related to its AI model
- **Know you can be deposed and act in a way that you can defend if you're deposed**

Lionel Lavenue, Joseph Myles and Maram Al-Shaer, *The apex doctrine and depositions of high-level executives: the divide among circuit courts*, Reuters, March 14, 2023, available at https://www.reuters.com/legal/legalindustry/apex-doctrine-depositions-high-level-executives-divide-among-circuit-courts-2023-03-14/ (last visited 11/26/2024); Mike Vilensky, *Once Too Big to Testify, CEOs Feel Backlash to 'Apex Doctrine*,' October 9, 2024, Bloomberg Law.

Crystal ball

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Uncertainty

Any questions?

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