Key Takeaways

Skadden

Navigating the Evolving Pharmaceutical Landscape of FDA Regulation, Patent Strategy and Antitrust Risk

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Key Points

- Policy priorities under current leadership at the FDA are focused on reforming the Investigational New Drug application process and encouragement of innovation in rare diseases. The USPTO is seeing lower institution rates for *inter partes* review and increasing procedural hurdles, meaning that fewer patents are successfully being challenged through that route. The FTC has announced a continued focus on healthcare with a new Healthcare Task Force and has weighed in on private litigation over biosimilar competition.
- Given the current regulatory and litigation landscape, life sciences companies should consider conducting a holistic evaluation of patent, FDA regulatory and antitrust strategy when planning to submit a drug product or biologic for FDA approval. They may also want to revisit or refresh the strategy at key inflection points in the product's life cycle.
- Pharmaceutical companies should consider coordinating FDA and USPTO submissions through a single cross-functional review process.

On September 23, 2026, Skadden attorneys Leslie Demers, Julia York and Rachel Turow discussed the continued scrutiny of life sciences companies by regulators and legislators. They covered how recent developments at the U.S. Food and Drug Administration (FDA), U.S. Patent and Trademark Office (USPTO) and the Federal Trade Commission (FTC) reflect changing regulation and enforcement priorities, and what risks life sciences companies should consider weighing when developing and marketing products.

Recent Developments at the FDA, USPTO and FTC

The panel began with a discussion of recent developments at the three regulatory bodies.

At the FDA, under the leadership of Acting Commissioner Kyle Diamantas, the agency has signaled an interest in restoring predictability to agency operations and innovation for rare diseases, including:

- Launching the Expedited Investigational New Drug (IND) pilot under Operation TrialBlazer.
- Creating a new framework for psychedelic drugs.
- Reauthorizing the Prescription Drug User Fee Act VIII program.
- Issuing guidance on substantial evidence of effectiveness.

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The agency has also named new center directors at the Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research, and named its first deputy commissioner for technology and artificial intelligence.

As for the USPTO, under its new director, John Squires, the agency has become increasingly pro-patent, with several changes seen as strengthening patent holders' rights. Rates for *inter partes* review (IPR) — the main administrative process for contesting a patent's validity — have plummeted from roughly 67-68% in fiscal years 2023 and 2024 down to 47% year-to-date in fiscal year 2026, according to analysis of data from the USPTO.

New discretionary factors, focused on U.S. manufacturing and small businesses, also now allow the USPTO director to deny institution before petitioners even get a hearing on their prior art. In addition, in 2025 the USPTO introduced the "settled expectations" doctrine as a stand-alone basis for denying IPR institution, based on the length of time a patent has been in force and the resulting reliance interests.

Finally, healthcare remains an enforcement priority for the FTC, the primary federal antitrust enforcer in the pharmaceutical industry. In March 2026, FTC Chairman Andrew Ferguson announced the formation of a Healthcare Task Force to:

- Lead enforcement and advocacy initiatives.
- Identify new priority areas.
- Strategize on investigations.

Biosimilar competition is one area of advocacy, evidenced by the FTC's *amicus* briefs submitted over the summer of 2026 in monopolization cases relating to the biologics Stelara and Enbrel:

- In the Stelara case, the FTC addressed the standard applicable to monopolization where the plaintiffs alleged that the defendant had monopolized the market for Stelara (ustekinumab) by acquiring patents and asserting them against biosimilar manufacturers.
- In the Enbrel case, the FTC argued that acquisitions of pending patent applications that were later issued by the USPTO and subsequently asserted against biosimilars to Enbrel (etanercept) are not immune from antitrust scrutiny.

In addition, the FTC settled administrative litigation against Express Scripts, Inc. (February 2026) and Caremark Rx LLC (July 2026) over insulin formulary, rebate and compensation practices.

Federal and State Legislation, and Policy

The panel also addressed recent developments in policy set by federal and state legislation, focusing on three pieces of federal legislation specific to the pharmaceutical industry, all of which were introduced with bipartisan support:

- **The Drug Competition Enhancement Act (S. 1040)** would expand the scope of unfair methods of competition under Section 5 of the FTC Act to include "hard switches" as well as "soft switches" that "unfairly disadvantage the listed drug" in a manner that impedes generic competition.
- **The Biosimilar Red Tape Elimination Act (S. 1954)** would amend Section 351(k) of the Public Health Service Act to remove extra requirements for showing interchangeability, which would lower the regulatory hurdles for biosimilars to reach interchangeable status.
- **The Medication Affordability and Patent Integrity Act (S. 2658)** would require companies to certify that they are submitting the same information "material to patentability" to both the USPTO and the FDA. If this advances, patent prosecution teams and FDA regulatory counsel will need to consider coordinating their submissions carefully.

Life sciences companies may want to continue to monitor these bills, all of which have been placed on the Senate legislative calendar and are awaiting floor consideration.

Private Litigation

The panel next turned to the U.S. Supreme Court's June 2026 decision in *Hikma Pharmaceuticals USA Inc. v. Amarin Pharma, Inc*. The issue presented was whether a generic manufacturer can be held liable for indirect infringement when pharmacists dispense its product for patented uses.

Hikma's "skinny label" for its icosapent ethyl product carved out Amarin's patented cardiovascular risk reduction indication but retained the hypertriglyceridemia indication, which is not patent-protected. Even with that carve-out, the U.S. Court of Appeals for the Federal Circuit had held that Hikma's marketing amounted to induced infringement, pointing to advertising statements calling the product "generic Vascepa" and a website describing a broader therapeutic category for the product.

On June 4, 2026, the Supreme Court ruled 9-0 that Amarin had failed to plausibly state a claim that Hikma actively induced infringement, thereby preserving the skinny label approval pathway under the Hatch-Waxman Act.

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Recent Developments in Pharma Patent Litigation

Ms. Demers discussed several recent private patent cases that have important implications for pharmaceutical and life sciences companies.

First, in *C.R. Bard, Inc. v. Atrium Medical Corp*., the district court had held that patent misuse bars claims where a license agreement requires payment even after a U.S. patent expires because it improperly attempts to expand a patent's limited scope. On appeal, however, the U.S. Court of Appeals for the Ninth Circuit held that the doctrine bars royalties for using an expired patent but not every payment after a U.S. patent expires. A minimum payment under a U.S.-Canadian license therefore continued after the U.S. patent expired, because the Canadian patent was still in force.

Ms. Demers next turned to *Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals of New York, LLC*, in which the Federal Circuit held that a patent can be listed in the FDA's Orange Book only if it claims the drug's active ingredient. In contrast, patents covering only parts of a delivery device without the drug, such as an inhaler's dose counter, do not qualify for the Orange Book.

The discussion continued with two cases that set the limits of disclosure requirements: *Amgen Inc. v. Sanofi* and *Teva Pharmaceuticals International GmbH v. Eli Lilly and Co.* In *Amgen v. Sanofi*, the U.S. Supreme Court unanimously invalidated broad functional antibody claims backed by only 26 examples, showing that the more a patent claims, the more it must enable. By contrast, the Federal Circuit in *Teva v. Lilly* upheld claims for using a known group of antibodies to treat migraines because the antibodies and the methods for making them were already well understood.

Ms. Demers concluded the discussion with *REGENXBIO Inc. v. Sarepta Therapeutics, Inc*., in which the Federal Circuit held that engineered host cells containing recombinant nucleic acid molecules are patent-eligible because they are "markedly different from anything occurring in nature." The decision reinforces that claims to man-made biological compositions can clear the Section 101 threshold when the claimed product is not formed in nature.

Recent Developments in FDA Regulatory Litigation

Ms. Turow provided an overview of recent FDA regulatory litigation, beginning with the observation that following the Supreme Court's decision in *Loper Bright*, courts are increasingly scrutinizing the FDA's interpretations of its statutory authority.

One example is *Norwich Pharmaceuticals, Inc. v. Kennedy*, in which the U.S. Court of Appeals for the District of Columbia Circuit held that a first Abbreviated New Drug Application (ANDA) filer's failure to obtain tentative approval forfeits 180-day exclusivity only if a change in approval requirements was the but-for cause of the delay. The court rejected the FDA's decades-old "multiple sufficient causes" test, gave the agency no deference and remanded for the FDA to apply the but-for standard.

In *Eli Lilly and Co. v. Kennedy*, the district court upheld the FDA's definition of "protein" as requiring more than 40 alpha amino acids but vacated the FDA's determination that retatrutide is not "analogous" to a protein. The court found the FDA's bright-line approach effectively read "analogous product" out of the statute. Lilly has appealed to the U.S. Court of Appeals for the Seventh Circuit, and the stakes are significant because a Biologics License Application carries 12 years of exclusivity, compared with five years for an NDA.

In *Outsourcing Facilities Association v. FDA*, the U.S. Court of Appeals for the Fifth Circuit upheld the FDA's removal of semaglutide from the drug shortage list as being consistent with the Administrative Procedure Act. The court found that the agency rationally relied on manufacturer production and inventory data over compounders' anecdotal evidence.

Recent Developments in Pharmaceutical Antitrust Litigation

Ms. York concluded the webinar with a discussion of recent developments in antitrust litigation in the pharmaceutical industry. The cases reflect that the potential for antitrust exposure for pharmaceutical companies extends across the entire product life cycle, from drug development and patenting through market access and pricing.

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Ms. York began with a case relevant to drug development. In the recently settled *Government Employees Health Association v. Actelion Pharmaceuticals Ltd*., the district court concluded that genuine disputes of material fact existed over whether Actelion's Tracleer Risk Evaluation and Mitigation Strategy (REMS) program justified its refusal to sell samples of the drug to prospective generic manufacturers and whether that justification was pretextual.

On antitrust risks in patent procurement, the court in *CareFirst of Maryland Inc. v. Johnson & Johnson* recently determined that genuine disputes over whether J&J intended to defraud the USPTO precluded summary judgment on the plaintiff's *Walker Process* monopolization claim, although the parties agreed that the case had essentially been decided in J&J's favor by virtue of the court's decision granting summary judgment on the question of the acquisition of certain patents. (CareFirst has appealed to the Fourth Circuit.)

Antitrust risk can also arise out of conduct before the FDA; in *In re Lantus Direct Purchaser Antitrust Litigation*, the district court granted purchasers partial summary judgment on their claim that Sanofi improperly submitted a device patent in the Orange Book, and the case appears headed to trial in January 2027.

Recent cases also confirm that antitrust claims related to the settlement of patent litigation also remain a source of potential exposure. In *In re Amitiza Antitrust Litigation*, a jury found Takeda liable in May 2026 over a 2014 settlement and awarded about $885 million before trebling. Takeda has said it will challenge the verdict.

Finally, restrictions on distribution and pricing practices are also drawing antitrust challenges. In *Teva Pharmaceuticals USA Inc. v. Corcept Therapeutics, Inc*., Teva alleged that Corcept used an exclusive specialty pharmacy relationship to unlawfully block generic substitution for Korlym. The court allowed Teva's federal antitrust claims to proceed to discovery, and summary judgment motions were filed in mid-October 2026.

In *Regeneron Pharmaceuticals, Inc. v. Amgen Inc*., Regeneron's challenge to Amgen's rebating practices for Enbrel and Otezla resulted in a jury verdict in Regeneron's favor in May 2025; post-trial motions remain pending.

Final Thoughts

The discussion at the webinar demonstrates that regulatory strategy, patent strategy and antitrust considerations are all critical aspects of the pharmaceutical product life cycle and should be viewed from a holistic perspective.

Companies should therefore consider a coordinated strategy across these disciplines throughout the different phases of drug development, approval and marketing, and continue to monitor the regulatory, legislative and litigation environment as legal and policy conditions continue to change.