BakerHostetler

Life Sciences Newsletter

UPDATES AND NEWS FROM THE BAKERHOSTETLER LIFE SCIENCES TEAM

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Dear Colleagues,

We've reached the end of a year of significant change in the life sciences space. This year we have seen changes to key intellectual property positions within the new administration, including a new director of the USPTO, ongoing disruptions in the U.S. medical products supply chain, passage of the One Big Beautiful Bill Act, and numerous changes in FDA programs intended to accelerate drug approval and U.S. manufacturing. As we move on to 2026, all signs point to continued change and growth in the life sciences space. We thank you for your tireless efforts and dedication to the life sciences space and your role in improving the lives of patients.

We wish you a happy holiday season and all the best for the new year!.

RON KERN, Ph.D., partner, Intellectual Property Practice Group and Life Sciences Industry team

Jacqueline Romero, Former US Attorney for the Eastern District of Pennsylvania, Joins BakerHostetler's Premier White Collar Team



Jacqueline Romero has joined BakerHostetler's Philadelphia office as a partner in the firm's Litigation Practice Group and a member of the White Collar, Investigations and Securities Enforcement and Litigation team. Her arrival marks BakerHostetler's third white collar partner addition in 2025.

Jacqueline served as the U.S. Attorney for the Eastern District of Pennsylvania from 2022 to 2025 and has more than 25 years of experience working for the federal government, including as an assistant U.S. Attorney, senior counsel to the U.S. Treasury Department and a trial attorney for the U.S. Department of Justice. Jacqueline's time in the federal government included 19 years of handling federal healthcare investigations under the False Claims Act; the Anti-Kickback Statute; the Controlled Substances Act; and the Food, Drug and Cosmetics Act in the pharmaceutical industry and hospital, university, pharmacy, compounding pharmacy and clinical settings.

Jacqueline's arrival strengthens BakerHostetler's Life Sciences Industry team and one of the nation's strongest white collar practice teams.

GOVERNMENT UPDATES/ ON THE HILL

Trump Administration Resource Center

All eyes are on Washington to see how the campaign promises unfold and what executive orders are put in place. BakerHostetler's Trump Administration Resource Center is your one-stop resource for updates, analyses and guidance provided by BakerHostetler attorneys and senior advisors – all designed to help businesses prepare for and respond to this changing environment. Sign up to receive notifications when updates are added. Contact the Federal Policy team if you have questions.

FDA UPDATES

FDA's National Priority Voucher Program: A New Era of Expedited Review

The Food and Drug Administration (FDA) has introduced the National Priority Voucher program, an initiative designed to accelerate the review of therapies that address critical public health needs. Under this program, sponsors developing drugs for designated national priorities such as pandemic preparedness, antimicrobial resistance or emerging biothreats can receive a voucher that shortens the FDA review timeline to as little as one to two months. This represents a significant departure from traditional review cycles, which often span 10 to 12 months.

While the program offers clear advantages for qualifying products, its eligibility criteria remain somewhat opaque, creating both opportunity and uncertainty for biotech companies and investors. Early indications suggest that a priority designation will hinge on factors such as unmet medical need, potential for broad public health benefit and alignment with federal health security objectives. For startups and established companies alike, this could mean rethinking pipeline strategies to align with these priorities – potentially unlocking faster market access and competitive advantage.

For stakeholders, the key takeaway is strategic positioning, as companies that can demonstrate alignment with national health imperatives may gain unprecedented speed to market. However, with limited guidance on implementation and voucher transferability, careful regulatory planning will be essential. As the FDA refines this program, expect heightened interest from venture capital and partnerships focused on high-impact therapeutic areas.

Contact Partner Winston S. Kirton for more information.

FDA Announces ANDA Prioritization Pilot Program

In an effort to support U.S. generic drug manufacturing and testing, the FDA announced a pilot prioritization program for the review of abbreviated new drug applications (ANDAs). The goal of the program is to spur and reward investment in U.S. drug manufacturing and research and development and to strengthen the domestic pharmaceutical supply chain by providing faster reviews for generic companies that test and manufacture their products in the U.S. Under this program, ANDA applicants that conduct any required bioequivalence testing in the U.S. and whose products are made in the U.S. using exclusively domestic sources for active pharmaceutical ingredients are eligible for priority review.

FDA Announces a Novel Regulatory Pathway for Personalized Therapeutics

FDA officials outlined a novel regulatory pathway called the "plausible mechanism pathway" that is designed to offer a new way to market personalized therapies. It is said that the pathway "could trigger a seismic shift in how bespoke gene-editing therapies are developed and approved."

FDA Releases Draft Guidance Relating to Biosimilars Approval

The FDA released draft guidance describing considerations regarding a comparative clinical study or studies with efficacy endpoints intended to support a demonstration that a proposed therapeutic protein product is biosimilar to a reference product for the purpose of submitting a biologics license application.

FEDERAL TRADE COMMISSION

FTC Sharpens Scrutiny of Noncompete Clauses in Health Care

In the wake of judicial setbacks to its proposed nationwide noncompete ban, the Federal Trade Commission (FTC or commission) has pivoted toward a more targeted enforcement strategy. In doing so, the commission has placed the health care sector squarely within its crosshairs. On September 10, FTC Chairman Andrew Ferguson announced that the commission had issued warning letters to several large, albeit unidentified, health care employers and staffing firms urging them to reassess the legality of their noncompete agreements under Section 5 of the FTC Act. The letters suggest a strategic pivot toward case-by-case enforcement against employers whose noncompete agreements the FTC deems violate Section 5.

Section 5 gives the commission broad power to seek injunctive relief (not damages) against vaguely defined "unfair methods of competition," including coercive or exploitative conduct in employment contracts and other practices that negatively impact competition, even where those practices do not violate traditional antitrust laws like the Sherman Act. Previously, the FTC had sought to use its rulemaking authority to promulgate a "noncompete rule" that would have virtually banned or invalidated most noncompete agreements. In April 2024, the FTC voted to adopt the final noncompete rule.

In August 2024, a federal court in Texas issued a nationwide injunction blocking the FTC's noncompete rule. Although the FTC initially pursued an appeal of the court's ruling, it formally withdrew its defense of the rule by September 2025. But despite abandoning the rulemaking effort, the agency has emphasized, to be clear, that its retreat from regulation does not signal a retreat from enforcement. In a recent statement, Ferguson pledged to "aggressively enforce the antitrust laws against noncompete agreements," including by "patrolling our markets for specific anticompetitive conduct that hurts American consumers and workers."

The health care sector appears to be the starting point for the commission's enforcement push. Noncompete clauses are widely used in health care employment contracts, often extending to nurses, physicians and other frontline providers. These agreements typically limit where a clinician can work after

leaving a job and frequently cover wide geographic areas and extended time periods. Critics argue that these agreements can suppress wages and mobility and also can exacerbate access-to-care issues in underserved communities, particularly in areas where noncompete agreements can effectively limit employment options.

The FTC's letters reflect these concerns, warning that while narrowly tailored noncompete agreements may serve legitimate business interests, overly broad or unjustified restrictions on health care workers can constitute unfair methods of competition under Section 5. The FTC has expressed particular concern about the impact of such agreements on patient access to care, especially in rural areas where workforce shortages are already acute.

Noncompete clauses are also facing increased scrutiny from state regulators. Reflecting a broader national trend, Pennsylvania has enacted the Fair Contracting for Health Care Practitioners Act (act), which limits employers' ability to impose post-employment restrictions on certain health care professionals, including medical doctors, doctors of osteopathy, certified registered nurse anesthetists, nurse practitioners and physician assistants.

The act makes noncompete agreements longer than one year void and unenforceable. Noncompete clauses lasting up to one year may still be enforced if the practitioner resigns voluntarily. However, those agreements become unenforceable if the employer terminates the practitioner's employment, even for cause. The act defines "employer" broadly to include any person or group that employs a health care practitioner at a facility or an office. Crucially, it applies to both nonprofit and for-profit health care employers, requiring them to comply with new restrictions on noncompete clauses for covered practitioners.

Both nonprofit and private health care organizations in Pennsylvania must now consider the act when drafting post-employment restrictions for covered practitioners. Employers in the health care industry must also be cognizant of the FTC's renewed scrutiny of noncompete agreements it deems overly broad, coercive or lacking justification. Employers would be wise to review their employment agreements to ensure any noncompete clauses are narrowly tailored and defensible under antitrust principles. Agreements that apply broadly to nonexecutive staff, lack geographic or temporal limitations, or fail to serve a legitimate business interest may be vulnerable to federal and state enforcement. Likewise, agreements that impede a practitioner's ability to treat or accept patients may be prohibited, and organizations should take good care to avoid agreements that may restrict patient care continuity. Stay tuned.

This article was published on October 8 in *The Legal Intelligencer*. Contact Partner Carl Hittinger or Associate Devin Redding for more information.

PATENT LAW UPDATES

John Squires Takes Over as USPTO Director

The U.S. Senate confirmed John Squires to serve as the next director of the U.S. Patent and Trademark Office (USPTO), and since taking the role, Squires has addressed numerous topics, including subject matter eligibility and patent reviews, head on.

Subject matter eligibility

In *Ex parte Guillaume Desjardins*, the USPTO issued an Appeals Review Panel decision that reversed the Patent Trial and Appeal Board's finding that claims directed to training of machine learning models were ineligible under 35 U.S.C. § 101. *Ex parte Guillaume Desjardins*, Appeal 2024-000567 (Sept. 26, 2025). The decision, which was authored by Squires, indicated that patent examiners and review boards should limit their reliance on § 101. The decision states, for example, that "[u]nder a charitable view, the overbroad reasoning of the original panel below is perhaps understandable given the confusing nature of existing § 101 jurisprudence, but troubling, because this case highlights what is at stake." (*Id.* at *9). The decision notes that "[e]xaminers and panels should not evaluate claims at such a high level of generality" (*id.*) and "[t]his case demonstrates that §§ 102, 103 and 112 are the traditional and appropriate tools to limit patent protection to its proper scope. These statutory provisions should be the focus of examination." (*Id.* at *10).

Although the claims at issue are directed to computer-implemented methods of training a machine learning model, this decision, together with other actions taken by Squires, signals a promising shift in how the USPTO will address subject matter eligibility in other areas, including the life sciences space.

Institution of IPR and PGR proceedings

Director Squires reclaimed a direct role in deciding whether to institute Inter Partes Review (IPR) and Post-Grant Review (PGR) proceedings. This change, effective October 20, is among a series of significant reforms that began in late March and have steadily altered the rules of engagement for patent owners and challengers alike. See BakerHostetler's IP Intelligence blog post and contact Partner Robert L. Hails Jr. or Partner Jason F. Hoffman for more information.

Delegating Discretionary Denial Review Authority to Deputy Director Stewart

Squires confirmed that the USPTO will continue its discretionary review program for patent reviews. Shortly after taking office on September 23, Squires delegated responsibility for discretionary denial decisions to Deputy Director Coke Morgan Stewart, and just three days later, the USPTO issued 21 new decisions. See BakerHostetler's IP Intelligence blog post and contact Partner Robert L. Hails Jr. or Partner Jason F. Hoffman for more information.

The Patent Eligibility Restoration Act

On October 8, the U.S. Senate Committee on the Judiciary's Subcommittee on Intellectual Property held a hearing titled "The Patent Eligibility Restoration Act – Restoring Clarity, Certainty, and Predictability to the U.S. Patent System." Sen. Thom Tillis, R-N.C., the leader of the subcommittee, stated that the Patent Eligibility Restoration Act will be one of his top priorities during his remaining time in office.

As part of the hearing, Squires submitted written testimony and urged Congress to reaffirm a broad interpretation of patent eligibility under Section 101. The director wrote that "[p]atentable subject matter was once summarized as *'anything under the sun made by man.'* Save for perpetual motion machines and the judicial exceptions, the principle was broad, clear, and inclusive. That principle should remain the guiding star today." The director's written testimony further stated that the misuse of Section 101 could disqualify the kinds of advances America needs most:

> Section 101 should not be misused as a blunt instrument to exclude entire technological fields. To do so risks disqualifying exactly the kinds of advances America needs most —advances in artificial intelligence, biotechnology, and data science. Artificial intelligence in particular illustrates the stakes: without reliable patent protection, AI start-ups cannot secure the venture capital needed to compete against state-backed giants in China and elsewhere. Eligibility is the difference between an ecosystem of American innovators and a future where leadership in AI is ceded abroad.

Commerce Department's Proposed Change in Maintenance Fees Getting Pushback

As noted in the September issue of the Life Sciences Newsletter, Commerce Department officials are considering a change to patent maintenance fees, in which patent owners would be charged a percentage of their overall patent value. Since the announcement, numerous conservative groups and lawmakers have strongly opposed the change. Patent owners continue to watch this proposed change closely.



LIFE SCIENCES TEAM MEMBER SPOTLIGHT

This issue's spotlight is on Partner Jennifer L. Mitchell, who is BakerHostetler's California Digital Assets and Data Management leader and co-leader of the Media and Telecommunications Industry team.

Describe your practice

As BakerHostetler's California Digital Assets and Data Management leader, I help clients navigate the complex landscape of global and U.S. federal and state privacy matters. Having worked at an international medical device and healthcare company as a global privacy officer prior to joining the firm, I have a special passion for advising clients on strategies to comply with privacy requirements applicable to health information, which is treated with heightened sensitivity under applicable laws, as well as providing practical guidance on how to support their business's data use objectives. This includes, for example, drafting privacy policies, designing consent strategies, advising on technical website and ad tech implementation, and negotiating data processing addenda with vendors. We are also supporting an increasing number of privacy regulatory investigations at the federal and state levels.

What do you like most about your job?

Privacy compliance advisory work offers an incredible amount of variety because every client's privacy requirements and strategy are different. I love that my work is intellectually challenging and ever-evolving with new technologies and new laws. I also find a great deal of satisfaction supporting our clients in an area that can appear daunting for the nonspecialist and helping make their work less stressful.

Fun fact about yourself

I have been skydiving twice, snowmobiled on glaciers and hiked through lava tubes. I am less interested in adventure sports these days!

IN THE NEWS/EVENTS

BakerHostetler welcomes Partner Susan Natland, Partner Jessica Sganga and Partner Kate McMorrow, who have joined the firm's Intellectual Property Practice Group in Los Angeles. Adding this experienced group aligns with the firm's strategic plan to achieve a full-service platform on the West Coast. The West Coast office now mirrors the firm's strengths in complex mega litigation, IP, digital assets and data management, mergers and acquisitions, securities, and labor and employment.

Partner Winston S. Kirton was elected to the 2026 Healthcare Businesswomen's Association Nominating Committee, where he will help identify and shape the next generation of leaders who will drive growth and innovation in the healthcare industry.



IN CASE YOU MISSED IT

In September, BakerHostetler released its third issue of the BakerHostetler *Life Sciences Newsletter.* Issue 3 can be accessed here.