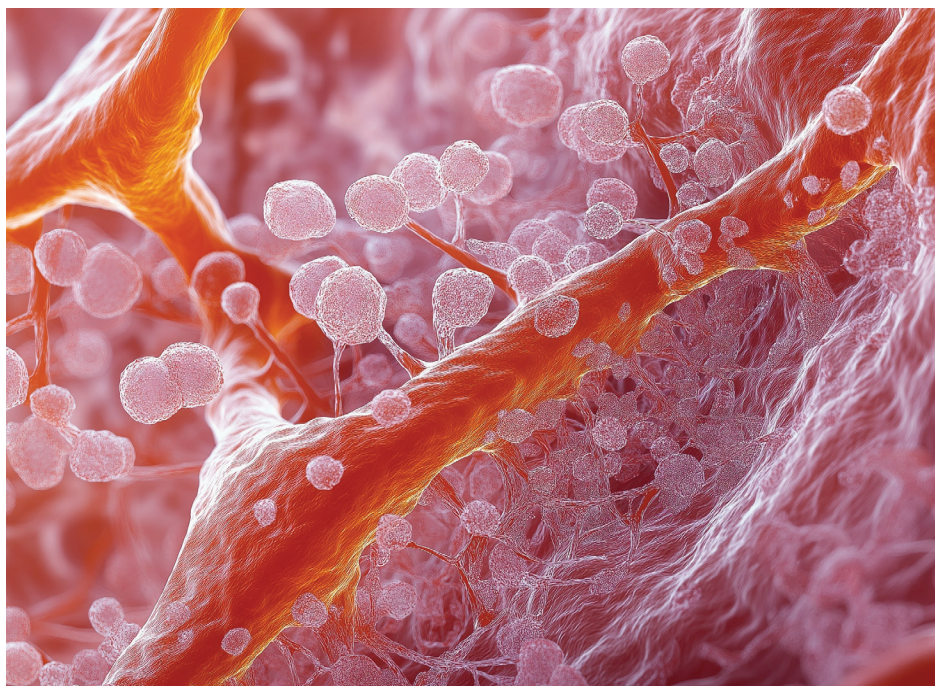


# Life Sciences Newsletter

UPDATES AND NEWS FROM THE BAKERHOSTETTLER LIFE SCIENCES TEAM

ISSUE 5 / MARCH 2026



## Dear Colleagues,

The changes that took place within the life sciences industry in 2025 have, as expected, continued to make an impact in 2026. Tariffs and supply chain issues continue to be top of mind for many in the industry, and personnel and policy changes within agencies such as the FDA and PTO continue to reshape how companies operate. As regulatory frameworks evolve and enforcement scrutiny intensifies, companies must navigate a landscape filled with risk, opportunity and rapid change. BakerHostetler's Life Sciences Industry team assists clients in mitigating risks and capitalizing on opportunities, whenever and wherever they arise. We hope that this newsletter will help you stay up to date on the ever-changing life sciences landscape.

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

## FDA UPDATES

### *FDA's Novel Regulatory Pathway for Personalized Therapeutics Is Taking Shape*

In February, the U.S. Food and Drug Administration (FDA) released [draft guidance](#) regarding its new regulatory process for personalized genetic medicines. The guidance is said to “describe considerations for generating substantial evidence of effectiveness and evidence of safety for individualized therapies based on a plausible mechanism framework.” The guidance notes that the plausible mechanism framework “outlines a set of recommendations to help developers of individualized therapies generate sufficient clinical safety and efficacy data to demonstrate that a drug or biological product is safe and effective for the intended use, and that the product can be manufactured to regulatory quality standards.” Although the guidance specifically discusses genome editing and RNA-based therapies, the general concepts may apply to other types of individualized therapies.

### *The BIOSECURE Act Is Now Law*

The BIOSECURE Act was signed into law Dec. 18, 2025, as part of the fiscal year 2026 National Defense Authorization Act. The law restricts federal agencies, contractors and grant recipients from procuring or using biotechnology equipment or services from what the statute calls biotechnology companies of concern. The law has broad implications for biopharma, medical device companies, contract development and manufacturing organizations, contract research organizations, genomic companies and even research institutions relying on federal funds. Life sciences companies across the supply chain are facing existential questions about their vendors, data flows and federal contracting eligibility. Contact Partner [Winston S. Kirton](#) or Senior Advisor [Adam Higgins](#) and listen to the [Regulatory Horizons podcast](#) to learn what life sciences companies should know about the BIOSECURE Act.



## 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.

### *White House and Congress Turn Focus to Health Policy*

On Jan. 15, the White House released a [fact sheet](#) outlining healthcare priorities and calling on Congress to turn those priorities into law. Congress also included a health policy package in appropriations legislation to finish funding the government for fiscal year 2026 and to prevent another shutdown at the end of January. See [BakerHostetler Insights](#) for a high-level summary of these policy developments, potential regulatory implications and considerations for healthcare stakeholders. Contact Partner [Jim Wiehl](#), Senior Advisor [Adam J. Higgins](#), Counsel [Catherine \(Kate\) S. Stern](#), Associate [Annie L. Adelman](#) or Associate [Tatyana Norman-Webler](#) for more information.

### *Supreme Court Rules President Lacks IEEPA Authority To Impose Tariffs*

The U.S. Supreme Court issued a landmark decision limiting presidential authority over U.S. trade policy, holding that the International Emergency Economic Powers Act (IEEPA) does not give the president unilateral authority to impose tariffs. In a 6-3 ruling, the Court concluded that Congress did not delegate general tariff-setting power through IEEPA and that the constitutional authority to impose duties remains vested in Congress under Article I, Section 8. See [BakerHostetler Insights](#) and contact Partner [Michael S. Snarr](#), Partner [Matthew W. Caligur](#), Of Counsel [Ronald J. Baumgarten Jr.](#), Counsel [Tung A. Nguyen](#) or Associate [James K. Perry](#) for more information.

## PATENT LAW UPDATES

### *Commerce Department's Proposed Change in Maintenance Fees Appears To Be Dead*

As noted in the December issue of the Life Sciences Newsletter, numerous conservative groups and lawmakers have strongly opposed the Commerce Department's consideration of changing patent maintenance fees to a percentage of the overall patent value. During a Feb. 10 Senate Appropriations Committee hearing, Secretary of Commerce Howard Lutnick said the department has no plans to pursue such fees. ([Committee Hearing](#) at 01:00:51 – 01:02:20.)

### *PTO Issues Memoranda Regarding the Use of Subject Matter Eligibility Declarations*

U.S. Patent and Trademark Office (PTO) Director John Squires issued two [memoranda](#) related to subject matter eligibility declarations and the use of these voluntary submissions to provide factual evidence relevant to the eligibility inquiry. The first memorandum was directed to the Examining Corps, and the second memorandum was directed to applicants and practitioners. The use of these declarations will hopefully assist

patent practitioners in obtaining patent coverage for subject matter that has been challenging over the past several years.

### *The District of Delaware Proposes Revised Local Rules, Including Changes to Its Patent Rules*

On Feb. 25, the U.S. District Court for the District of Delaware published proposed revisions to its [local rules](#), which were last modified Aug. 1, 2016. The proposed revised rules were recommended by the Lawyers Advisory Committee of the District of Delaware with approval of the court. Proposed revisions to Rule 3.2, "Patent Cases," include (1) attaching not only copies of the patents at issue but also "any re-examination certificates or certificates of correction" when filing an action and (2) expressly requiring submission of the District of Delaware's Supplemental Information for Patent Cases Involving an Abbreviated New Drug Application (ANDA) form along with any complaint or subsequent amended complaint in a Hatch-Waxman Act case. Read the IP Intelligence [blog](#) and contact Associate [Jeffrey J. Lyons](#) or Associate [Michael E. Neminski](#) for more information.



## LIFE SCIENCES TEAM MEMBER SPOTLIGHT

This issue's spotlight is on Partner [Janis Penman](#), who is BakerHostetler's Washington, D.C., office business leader and a member of the firm's Policy Committee. She is also the business development leader and hiring partner for the office.

### Describe your practice

I am a corporate lawyer who advises clients on all aspects of their businesses, from helping them negotiate commercial contracts and providing day-to-day business counseling to advising them on capital raising activities and mergers and acquisitions. Although I have represented clients in many industries over the course of my almost 30-year career, I have a significant amount of experience working with life sciences companies, with a particular interest and experience in the pharmaceutical and medical device areas. My clients include startup enterprises, companies in the emerging and growth stages, and large multinational corporations, each of which has unique legal needs.

### What do you like most about your job?

I really enjoy my role as a strategic advisor to my clients. In many cases, I work closely with company founders or the corporate development team, which allows me to help my clients navigate market risks and assist them with long-term business planning. This ability to collaborate with those engaging in the day-to-day operation of, and long-term planning for, these businesses makes me a better legal advisor and facilitates pragmatic, out-of-the-box thinking that can be invaluable in helping my clients succeed in a highly competitive and rapidly evolving business environment.

### Fun fact about yourself

I spent many years competing in equestrian competitions around the country with my two thoroughbreds. Although I love being a lawyer, I initially thought I would become a professional musician and almost headed to a conservatory to major in music performance instead of the liberal arts college where I ended up.

## IN THE NEWS/EVENTS

BakerHostetler released the third annual [BakerHostetler IP Perspectives](#), which provides a concise selection of key intellectual property developments shaping the year ahead. Below is a summary of the topics covered.

### *Social Media Copyright Enforcement Is Surging*

Brands are increasingly facing copyright claims tied to music, images and influencer content. The assumption that content available on social platforms is free to use continues to cause costly mistakes. With statutory damages reaching up to \$150,000 per work, rights holders are aggressively enforcing their claims. Tools such as BakerHostetler's Sounding Board™ help companies audit posts, identify noncompliant audio and reduce risk through proactive policies.

### *AI Generated Content Presents New Ownership Questions*

As businesses turn to generative artificial intelligence (GenAI) for names, logos and creative assets, they're encountering new questions. Who owns the output? What is protectable? U.S. Copyright Office rulings and recent case law reaffirm that human creativity – not artificial intelligence – is required for copyright protection. Meanwhile, GenAI created trademarks may be registrable, but clearance remains critical to avoid conflicts with existing marks.

### *AI Is Transforming Trademark Enforcement*

AI tools now serve as both sword and shield in policing brand misuse. From predicting trademark disputes to scanning global marketplaces for counterfeits, AI powered monitoring systems are helping companies detect infringement earlier and enforce their rights more efficiently. As digital commerce accelerates, automated brand protection is shifting in importance from optional to essential.

### *PTO Policy Shifts Are Reshaping Patent Strategy*

The PTO's 2025 reforms dramatically tightened access to *inter partes review* (IPR). Institution rates have fallen from higher than 65 percent to roughly 10 percent, making IPRs the exception rather than the rule. At the same time, the agency is encouraging stronger enforcement in federal court and the International Trade Commission, signaling a renewed emphasis on the power and value of patents in competitive strategy.

### *IP Strategy Is Now a Core Business Strategy*

Whether navigating transactions, evaluating software and AI assets, or conducting diligence, businesses increasingly recognize that IP cannot be an afterthought. Strategic alignment between IP and business goals – supported by advisers with both legal and technical depth – has become essential for protecting innovation and minimizing risk.



## IN CASE YOU MISSED IT

In December, BakerHostetler released its fourth issue of the BakerHostetler Life Sciences Newsletter. Issue 4 can be accessed [here](https://www.bakerlaw.com/life-sciences-newsletter).

FOR MORE INFORMATION OR TO BE ADDED TO THE DISTRIBUTION LIST, PLEASE CONTACT RON KERN AT [RKERN@BAKERLAW.COM](mailto:RKERN@BAKERLAW.COM).