BakerHostetler

Life Sciences Newsletter

UPDATES AND NEWS FROM THE BAKERHOSTETLER LIFE SCIENCES TEAM

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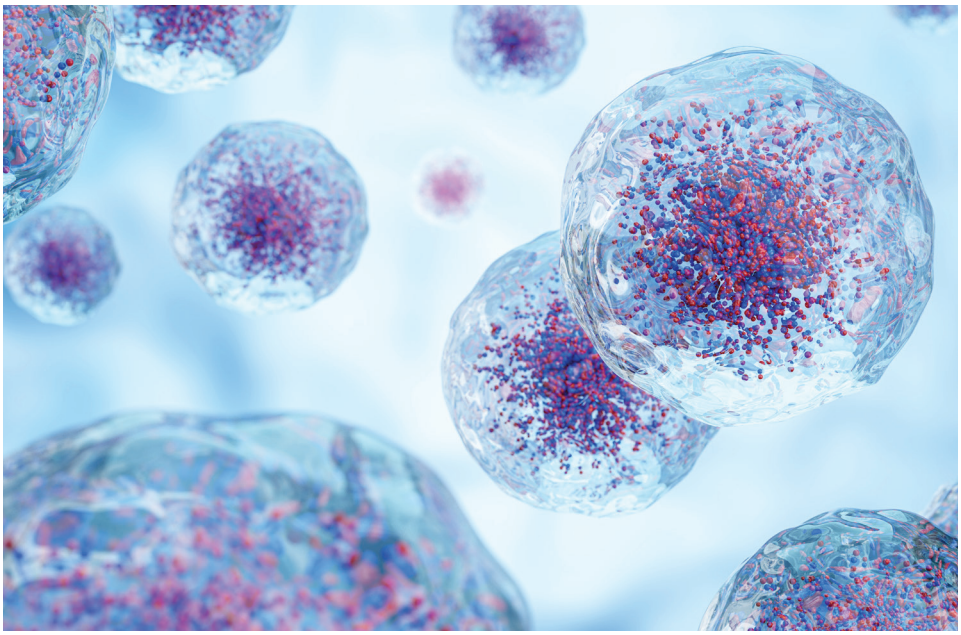

Dear Colleagues,

For a life sciences company to bring its scientific and technological advancements to the marketplace, it must navigate a complicated maze of laws, regulations and rules, as well as a fierce competitive landscape, an unpredictable political environment and a volatile economy. BakerHostetler has a team of attorneys that 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 Announces Plan to Phase Out Animal Testing Requirement for Monoclonal Antibodies and Other Drugs

On April 10, the U.S. Food and Drug Administration (FDA) announced that it "is taking a groundbreaking step to advance public health by replacing animal testing in the development of monoclonal antibody therapies and other drugs with more effective, human-relevant methods." The FDA noted that the "animal testing requirement will be reduced, refined, or potentially replaced using a range of approaches, including AI-based computational models of toxicity and cell lines and organoid toxicity testing in a laboratory setting (so-called New Approach Methodologies or NAMs data)." See the FDA's press release for more information.

Federal Court Rules that FDA's Intent to Regulate Laboratory-Developed Tests Exceeds Its Statutory Authority

In 2024, the FDA issued its final rule to amend its regulations to include *in vitro* diagnostic products within the definition of devices under the Federal Food, Drug, and Cosmetic Act (FDCA). Within the final rule, the FDA also announced that laboratory-developed tests would be enforced like other *in vitro* diagnostic products. In March, however, the U.S. District Court for the Eastern District of Texas held that the FDA's intent to treat these laboratory-developed tests as medical devices and regulate them under the FDCA exceeds the FDA's statutory authority. The court noted that "[l]aboratory-developed tests are offered as *services* [and] [u]nlike a drug or device, which is a manufactured and packaged article of commerce with user instructions, a laboratory-developed test service is a proprietary methodology performed by only the developing laboratory." *Am. Clinical Laboratory Ass'n v. U.S. Food & Drug Admin.*, No. 4:24-CV-479-SDJ, 2025 WL 964238, at *3 (E.D. Tex. Mar. 31, 2025) (emphasis in original). The court further noted that "[t]he FDCA's text makes clear that the 'devices' within its purview do not include professional medical services" (*id.* at *13), and "laboratory-developed test services are not 'devices' under [21 U.S.C.] § 321(h)." (*Id.* at *16).

FDA Issues Draft Guidance on Replacing Color Additives in Drug Products

On May 27, the FDA released a new draft guidance, "Replacing Color Additives in Approved or Marketed Drug Products," that outlines regulatory expectations for manufacturers and applicants seeking to replace color additives in drug products. See the alert for more information or contact partner Winston S. Kirton.

GOVERNMENT UPDATES/ON THE HILL

All eyes are on Washington to see how the campaign promises unfold and what executive orders are put in place. 2025 promises to be a year of structural change and intense debate on everything from taxes and life sciences to financial services and energy policies. 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.

PATENT LAW UPDATES

Inherent Anticipation of Product-by-Process Claims Requires a Showing That the Product Is Necessary Produced

In *Restem, LLC v. Jadi Cell, LLC*, the U.S. Court of Appeals for the Federal Circuit affirmed the Patent Trial and Appeal Board's ruling that claims directed to stem cells produced by a specific process (product-by-process claims) were not inherently anticipated by a prior art reference that Restem argued disclosed the same process. 130 F.4th 941 (Fed. Cir. 2025). According to the court, "Restem's argument conflates the anticipation and infringement analyses for product-by-process claims by improperly shifting the analysis from whether the prior art discloses the claimed product to whether the prior art discloses the claimed process." (*Id.* at 947). The court noted that in determining the validity of a product-by-process claim, "the focus is on the product and not on the process of making it." (*Id.*). The court held that substantial evidence supported the finding that cells produced by the prior art process would not necessarily have the required cell marker expression profile, and therefore the claims were not inherently anticipated. (*Id.*).

A Claimed Solution to an Unknown Problem Is Not Necessarily Non-Obvious

ImmunoGen sought to patent claims directed to methods of treating specific cancers using an antibody-drug conjugate, wherein the claims specified the dose to be administered to the subject. ImmunoGen argued that "[t]here was no motivation to solve the problem of ocular toxicity" in the prior art, and therefore the claimed dosing limitation could not have been obvious. *ImmunoGen, Inc. v. Stewart*, 130 F.4th 1328, 1333 (Fed. Cir. 2025). The Federal Circuit disagreed and stated "that the *specific* problem the inventors of the '809 application purported to solve via the claimed dosing regimen was unknown does not necessarily mean that the dosing regimen itself was not obvious." (*Id.*) (emphasis in original). Based on the evidence of record, the court affirmed the district court's ruling that the claims were obvious.

USPTO Cuts the Time It Takes for a Patent To Issue

On May 13, the U.S. Patent and Trademark Office (USPTO) started to accelerate the time between issue notification and the issue date of a patent, cutting the time frame from about three weeks to two weeks – roughly 33 percent shorter. See Partner Tayan Patel's blog post for more information.

Patent Eligibility Restoration Act of 2025 Introduced in the House of Representatives

On May 1, the Patent Eligibility Restoration Act of 2025 (PERA) was introduced in the House of Representatives. PERA maintains the existing categories of eligible subject matter under Section 101 (process, machine, manufacture and composition of matter) and addresses "inappropriate judicially created eligibility limitations by creating clear rules for what is eligible." PERA is said to "restore patent eligibility to important inventions across many fields while also resolving legitimate concerns over the patenting of mere ideas, the mere discovery of what already exists in nature, and social and cultural content that everyone agrees is beyond the scope of the patent system." See the press release for more information.information.

SUPPLY CHAIN UPDATES

Ongoing Disruptions in the US Medical Products Supply Chain

In 2025, the U.S. healthcare and life sciences sectors continue to face significant supply chain challenges. From pharmaceuticals to personal protective equipment, disruptions continue to strain medical products (including drugs, biological products and medical devices as well as active pharmaceutical ingredients and raw materials plus the parts, components or ingredients used to manufacture them) manufacturers and stakeholders nationwide. Key issues include:

- Policy shifts such as tariffs.
- Heavy reliance on foreign manufacturing.
- Limited domestic production capacity.
- Rising costs and logistical delays.
- Geopolitical unrest.

Federal Government's Response

In January, the U.S. Department of Health and Human Services proposed the 2025-2028 Draft Action Plan aimed at building a more resilient U.S. supply chain. Key initiatives include:

- Boosting Domestic Manufacturing: Incentives for U.S.-based production of critical medical goods.
- Improving Transparency: Real-time data sharing across the supply chain.
- Strategic Stockpiling: Enhancing the Strategic National Stockpile with diversified sourcing.
- Public-Private Partnerships: Coordinated efforts to streamline procurement and logistics.

Manufacturers' Response

Medical products manufacturers continue to focus on mitigating risk by implementing:

- Manufacturing network rationalization strategies.
- Third-party management and oversight optimization.
- Inventory management improvements.
- Multiyear resiliency programs.

Key Takeaways

- Communication and collaboration between government and industry stakeholders is a must.
- Manufacturers of medical products must continue to diversify sourcing strategies.
- Risk-based planning must incorporate uncertainty.
- Incentives for U.S.-based production must be clear and meaningful.

Manufacturers do not have to go it alone. Contact Partner Winston S. Kirton for advice and counsel.

TAX UPDATES

Hatch-Waxman Litigation Expenses Are Deductible Ordinary Business Expenses, Not Capital Expenditures

Actavis filed Abbreviated New Drug Applications (ANDAs) seeking FDA approval to market and sell generic versions of branded drug products. As a result of the ANDA filings, Actavis was sued for patent infringement pursuant to the Hatch-Waxman Act. Actavis treated its litigation expenses as ordinary and necessary business expenses and deducted them on its tax returns in the years the expenses were incurred. The IRS, however, considered these expenses as capital expenditures and argued that the expenses were incurred in order to facilitate the creation of intangible assets – FDA approval of Actavis' ANDAs. The Federal Circuit agreed with Actavis and held that Hatch-Waxman litigation expenses are deductible ordinary business expenses, not capital expenditures. *Actavis Laboratories FL, Inc. v. United States*, 131 F.4th 1345, 1353 (Fed. Cir. 2025).

Tax Bill Proposes Trillions in Tax Cuts and Significant Tax Increases, Including Domestic Research and Development Expensing for Life Sciences Companies

On May 14, the House Ways & Means Committee completed its Markup of tax legislation, which includes nearly $6 trillion in tax cuts and approximately $2 trillion in tax increases. The Markup, among other things, allows domestic research and development expensing. The Markup, for example, would suspend the capitalization of domestic research or experimental expenditures for amounts paid or incurred in taxable years beginning after Dec. 31, 2024, and before Jan. 1, 2030. A taxpayer, however, may elect to capitalize and amortize the expenditures by filing an election with its tax return, which is important for some taxpayers who benefit more from FDII (which permanently lowers their tax rate) when they capitalize (a mere timing issue) research and development expenditures. Foreign research or experimental expenditures still must be capitalized and amortized over a 15-year period. See the alert from our Tax team or contact Partners Jeff Paravano or Peter Roskam for more information.

LIFE SCIENCES TEAM MEMBER SPOTLIGHT

This issue's spotlight is on Partner Stephen Ruscus, who serves as co-leader of the firm's national Government Contracts team.

Describe your practice

I'm the co-leader of the firm's national Government Contracts team and think of myself as a broad-based government contracts practitioner, with a specialization in life sciences government contracts and pricing. I counsel life sciences companies across the full spectrum of government contract services – obtaining contracts, protecting contract awards, complying with new and existing requirements, training, compliance reviews, mandatory and voluntary disclosures, contract disputes, claims, terminations and debarment and suspension issues, etc.

What do you like most about your job?

While I counsel life sciences companies across the full spectrum of government contract services, some of my favorite parts of my practice include collaborating with other BakerHostetler life sciences partners – government contracts diligence in corporate transactions as well as contracts and pricing inputs in transition services agreements and novations of government contracts, government contracts intellectual property collaborations with BakerHostetler IP lawyers, investigation support to BakerHostetler's extensive life sciences White Collar team, risks statements in SEC filings, and work with the Labor and Employment team on unique equal opportunity and other labor-related government contract provisions. I've been blessed to practice in an area that is constantly evolving.

Fun fact about yourself

I used to play bass guitar in a band back when the Doobie Brothers sat at No. 1 on the charts

IN THE NEWS/EVENTS

- BakerHostetler has been named one of the "Top 10 Patent Firms" as well as "An Award-Winning Law Firm 2025" for the jurisdiction of North America – Northeast by *The Patent Lawyer* magazine.
- BakerHostetler has once again achieved outstanding results in BTI's "Most Recommended Law Firms" report, which spotlights law firms that have earned the most recommendations from corporate counsel. In the overall ranking, our firm earned a "Leader" commendation, the second-highest ranking possible. In the size-based category, BakerHostetler scored a "Highly Recommended" in the Largest Law Firms category (1,000-2,000 attorneys).
- The Food and Drug Law Institute held its annual conference May 15-16. While the FDA's participation and attendance were limited, the conference was an overall success. Key to that success was various stakeholders addressing the current uncertainties facing FDA-regulated companies across sectors. Partner Winston S. Kirton served on the conference planning committee and led a panel discussion titled "Global Supply Chain Threats in FDA-Regulated Industries," and Partner Lee Rosebush presented on a panel titled "Compounding, Drug Shortages and Regulatory Challenges." Kirton's session explored the threats disrupting global supply chains for FDA-regulated products, including policy shifts, increased tariffs on China, natural disasters and the ongoing geopolitical climate. Rosebush's panel engaged in a lively discussion on the merits of compounding medicines to address drug shortages and the need for stronger communications between the FDA and stakeholders in the compounding sector.
- BakerHostetler's Federal Policy team furthered its reputation for gathering high-profile politicians to discuss hot-button issues at the 36th Annual Legislative Seminar, held May 21 at the Hilton Washington DC Capitol Hill hotel. Partner Peter Roskam, leader of the Federal Policy team, and Senior Advisor Heath Shuler assembled members of Congress from both sides of the aisle, including Sens. John Barrasso and Tim Kaine and Congressmen Raja Krishnamoorthi, Bryan Steil, Kevin Hern, Ted Lieu, David Schweikert and Jim Himes. Nearly 240 firm clients attended, eager for firsthand updates on topics ranging from taxes to healthcare and every crucial policy debate in between. The event was preceded by an annual client dinner, where Sen. Steve Daines served as the keynote speaker. The formal sit-down meal was held at the Anderson House, a 120-year-old mansion designated a National Historic Landmark.

IN THE NEWS/EVENTS *continued*

- On June 3, Partner Stephen Ruscus presented a webinar titled "Life Sciences Government Contracting: R&D to Commercial Item Procurements" that highlighted key differences between major types of life sciences government contracts and programs across multiple agencies and multiple phases of the product life cycle. The session highlighted key compliance considerations, emerging issues arising under the new administration and continuing issues relating to IP, domestic sourcing, supply chain government contract issues and limitations on the use of non-U.S. persons/entities in the performance of government contracts.
- BakerHostetler welcomes White Collar, Investigations and Securities Enforcement and Litigation Partner Ryan Hedges (a former federal prosecutor) and Commercial Litigation Partner Bradley Pensyl to the firm and Life Sciences Industry team.
- BakerHostetler attorneys discuss a number of IP issues in BakerHostetler's 2025 IP Perspectives podcast series, including a discussion of obviousness-type double patenting and the Federal Circuit's *Allergan* decision.
- On June 17, BakerHostetler will host a reception in celebration of the BIO International Convention at Mooo.... Seaport in Boston.
- Partner Stephen Ruscus will be speaking at the 19th Annual Big Four Pharmaceutical Pricing Boot Camp, June 23-24.

IN CASE YOU MISSED IT

In March, BakerHostetler released its first issue of the BakerHostetler Life Sciences Newsletter. Issue 1 can be accessed here.

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