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

CORPORATE LAW

Considering 'Dexit': A Comparative Review of Key Issues in the Corporate Laws of Delaware, Nevada and Texas

The recent announcement that leading venture capital firm Andreessen Horowitz (AH) had decided to redomicile its primary business entity, AH Capital Management, from Delaware to Nevada caught the attention of many and has brought to a crescendo a public conversation about "Dexit" (exit from Delaware) that has been getting louder in recent years. AH made an intentionally noisy exit, publishing a memorandum detailing its reasons for leaving Delaware and the various advantages it saw in moving to Nevada, while also indicating that it gave due consideration to Texas. There are several substantive differences impacting the scope of fiduciary duties, dispute resolution processes and minority stockholder rights in Delaware, Texas and Nevada. For example, while all three states have adopted the business judgment rule, Nevada and Texas offer greater potential to shield corporate fiduciaries from liability for breaching their fiduciary duties. See BakerHostetler Insights and contact associate Jennifer Dare and partner Steven Goldberg to learn more.

FDA UPDATES

FDA's 'PreCheck' Program: New Pathway to Acceleration of US Drug Manufacturing

The U.S. Food and Drug Administration (FDA) has announced FDA "PreCheck," a new regulatory program intended to streamline the development and approval of domestic pharmaceutical manufacturing facilities. This initiative is part of the federal government's broader effort to strengthen U.S. supply chain resilience and reduce reliance on overseas drug production. The program intends to offer drug manufacturers a more predictable and collaborative regulatory pathway with the potential to shorten timelines for establishing U.S.-based facilities. See the Health Law Update and contact associate Laura Macherelli and partner Winston S. Kirton for more information.

FDA Launches New Priority Review Voucher Program for Biopharmas

The FDA announced a pilot program designed to accelerate the review of drugs and biologics. The Commissioner's National Priority Voucher (CNPV) pilot program reduces drug and biologic review times from 10-12 months to just 1-2 months. The CNPV will use a collaborative tumor board style review process to accelerate approvals for companies aligned with critical U.S. national health priorities. See here for more information.

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. 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.

Is Major Health Legislation The Next Issue to be Addressed by Congress?

Congress returned after Labor Day from its summer recess, and the big question on Capitol Hill is what's next after the first half of the year was devoted entirely to Republicans' One Big Beautiful Bill Act. Health policy is likely to be a significant part of that answer, as powerful lawmakers remain interested in bipartisan legislation addressing pharmacy benefit manager practices, Medicare Advantage and potentially other health reforms. That policy package, which nearly became law in catch-all legislation at the end of last year, will also test another important question: Is there any appetite for bipartisanship in this Congress? Democrats feel burned by the reconciliation process and the bill's impact on federal health programs, and they are more concerned with enhanced tax credits for Affordable Care Act plan premiums, which expire at the end of 2025. There's also the end of the fiscal year looming in September, and the expiration of current appropriations is likely to deepen tensions and perhaps even cause a government shutdown. Can health policy leaders overcome the toxic politics and put a deal together later this year on major health legislation? Contact senior advisor Adam Higgins for more information.

Sen. Thom Tillis Announces Retirement

Sen. Thom Tillis, R-N.C., chairman of the Senate Judiciary Committee's Intellectual Property (IP) subcommittee, has announced that he will not seek reelection in the 2026 midterms. Earlier this year, Tillis announced that he would serve as chair of the subcommittee for the 119th Congress and will look to "usher[] in meaningful change within the IP space," including "reforming patent eligibility via the Patent Eligibility Restoration Act."

PATENT LAW UPDATES

Commerce Department Considering Changing Maintenance Fees to a Value-Based System

According to a *Wall Street Journal* article, Commerce Department officials are considering a change to patent maintenance fees. Currently, patent owners pay approximately $2,000, $4,000 and $8,000 in undiscounted maintenance fees at 3.5 years, 7.5 years and 11.5 years, respectively. Under the new proposal, patent owners would be charged 1 percent to 5 percent of their overall patent value. Patent owners are watching this proposed change closely.

Federal Circuit Decides Its First-Ever Derivation Proceeding

In *Glob. Health Sols. LLC v. Selner*, the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) addressed its first-ever derivation proceeding under the Leahy-Smith America Invents Act of 2011 (AIA). In doing so, the Federal Circuit explained the differences and similarities between pre-AIA interference proceedings and AIA derivation proceedings, noting that "to meet its *prima facie* burden in an AIA derivation proceeding, the petitioner must produce evidence sufficient to show (i) conception of the claimed invention, and (ii) communication of the conceived invention to the respondent prior to respondent's filing of that patent application." *Glob. Health Sols. LLC v. Selner*, No. 2023-2009, 2025 WL 2446374, at *5 (Fed. Cir. Aug. 26, 2025). The Federal Circuit also noted that "[t]o prevail in [an AIA derivation proceeding], a first-to-file respondent [] need only prove that his conception was *independent*." (*Id.* at *5). See the blog post and contact partner Ron Kern for more information.

Federal Circuit Confirms that Enablement of an Anticipatory Prior Art Reference Is Distinct from Enablement Under Section 112

In *Agilent Techs., Inc. v. Synthego Corp.*, the Federal Circuit addressed the difference between the enablement standard for an anticipatory prior art reference (under 35 U.S.C. § 102) and that for an applicant/patentee's own disclosure (under 35 U.S.C. § 112).

For an anticipatory prior art reference to be enabling, the reference must "teach a skilled artisan – at the time of filing – to make or carry out what it discloses in relation to the claimed invention without undue experimentation." *Agilent Techs., Inc. v. Synthego Corp.*, 139 F.4th 1319, 1327 (Fed. Cir. 2025) (quoting *In re Morsa*, 803 F.3d 1374, 1377 (Fed. Cir. 2015)). But the Federal Circuit confirmed that the prior art reference need not enable the challenged claim in its entirety. Rather, "the reference need only enable a single embodiment of the claim." *Agilent Techs.*, 139 F.4th at 1327. Furthermore, the prior art reference need not enable one skilled in the art to actually use the invention. (*Id.* at 1329).

For the applicant/patentee's own disclosure to be enabling, on the other hand, "the specification must enable one skilled in the art to 'use' the invention." (*Id.*) (quoting *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1325 (Fed. Cir. 2005)). And as the Supreme Court stated, "the specification must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable." *Amgen Inc. v. Sanofi*, 598 U.S. 594, 610 (2023). Thus, the Federal Circuit confirmed that the enablement of an anticipatory prior art reference and enablement under Section 112 "are two separate inquiries." *Agilent Techs.*, 139 F.4th at 1328-29.

SUPPLY CHAIN UPDATES

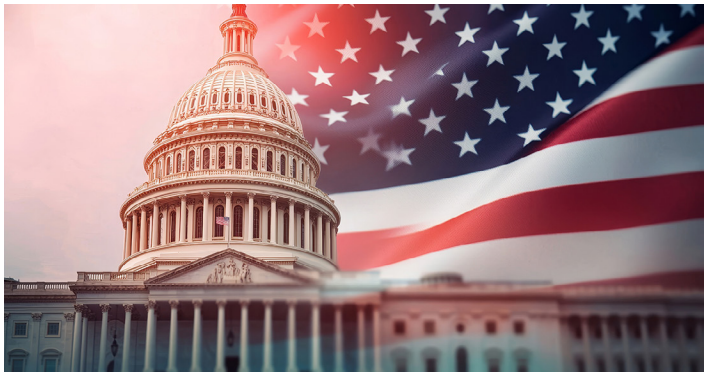
Ongoing Disruptions in the US Medical Products Supply Chain

Supply chain disruptions have become a significant challenge for the U.S. FDA-regulated products industry, affecting the availability of pharmaceuticals, medical devices and food. These disruptions are caused by various factors, including U.S. policy shifts, geopolitical tensions, natural disasters and pandemics. The future of global supply chains remains uncertain, but ongoing industry efforts aim to enhance resilience and ensure the continuous supply of critical products. Partner Winston S. Kirton has recently launched a podcast series to discuss the supply chain disruptions and the industry efforts aimed at mitigating their effects.

In his first podcast, Winston discusses how companies can address supply chain challenges resulting from policy shifts and whether these disruptions in the supply chain will affect the availability and safety of essential medical products.

In his second podcast, Winston dives into how the FDA-regulated products industry is responding to these disruptions.

In his latest podcast, Winston and head of the firm's International Tax group, J. Brian Davis, unpack the sweeping tax reforms introduced by the One Big Beautiful Bill Act signed into law on July 4, 2025.



TAX UPDATES

Passage of the 'One Big Beautiful Bill Act' Legislation and Its Effect on Research and Development

On July 4, President Donald Trump signed wide-ranging tax legislation, P.L. 119-21 (the Legislation), which includes net tax cuts of $4.5 trillion and spending cuts of $1.2 trillion, for a cost compared with current law of approximately $3.3 trillion over the 10-year budget window. The Legislation will affect nearly every sector of the economy, including research and development.

Since 2022, taxpayers have been required to capitalize and amortize U.S.-based research or experimental expenditures ratably over a five-year period and non-U.S.-based research or experimental expenditures ratably over a 15-year period. These include costs to develop or improve a product, including software. Examples of costs are the salaries of the persons engaged in the research or experimentation efforts, overhead incurred to operate and maintain the facility, and materials and supplies that are consumed in the course of the research or experimental activities. The requirement to capitalize and amortize these costs has been a source of contention since 2022.

The Legislation permanently suspends the capitalization of domestic research or experimental expenditures for amounts paid or incurred in taxable years beginning after Dec. 31, 2024. However, a taxpayer may elect to capitalize and amortize the expenditures by filing an election with its tax return. This is an important election for some taxpayers, who benefit more from foreign-derived intangible income (FDII) – which permanently lowers their tax rate – when they capitalize (a mere timing issue) R&D 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 Bradley Pensyl, who is a commercial litigator and member of the Life Sciences Industry team.

Describe your practice

I am a commercial litigator and trial lawyer who has a natural curiosity for different markets, different types of claims and different clients. Although I am a generalist by nature – "If you can litigate one thing, you can litigate anything" is the mentality that my mentors engrained in me – I love working on a team with specialists in the area where the particular case takes me.

What do you like most about your job?

First is, I love sports and competition. Being a litigator has always felt, to me, like the closest feeling you can get to being on a basketball court or a baseball field. I love the camaraderie of a team of people working together to achieve a common goal, especially when that goal involves beating the other side for a client.

Second is that my role gives me the privilege to learn all kinds of crazy stuff about really nerdy things. I spent three years learning every piece of data from the Celebrex and Bextra studies that Pfizer conducted. I loved every second of it. I spent seven years learning how the American Dream Mall in the Meadowlands in New Jersey was financed. I know it's weird, but I loved it all. I led three trials involving the ins and outs of making improvements to sewer and water systems in municipalities in Pennsylvania and Iowa. That is probably the weirdest of all, but yes, I enjoyed it. I'm weird.

Fun fact about yourself

One of the most fun things I have done in my life is coaching my twin daughters' CYO basketball teams from third through seventh grades. I took the position so seriously that I vividly recall hearing questions such as "Did you seriously just spend three hours on a game plan for a fifth-grade basketball game?" "Did I really see you arguing with a nun in the hallway before the game?" and "Hang on, am I hearing this correctly – that you were ejected for arguing with a ref the other night?" (A guilty plea to all of the above.)

IN THE NEWS/EVENTS

Partner Winston S. Kirton launched a new podcast series to discuss the supply chain disruptions and the industry efforts aimed at mitigating their effects.

Episode List:

- The first podcast features a conversation between Winston and Mark Abdoo, U.S. FDA Associate Commissioner for Global Policy and Strategy Access the first.
- The second podcast highlighted a discussion between Winston and Nordic Global Strategies' Mara Burr on how supply chain disruptions have become a significant challenge for the U.S. FDA-regulated products industry.
- The third podcast unpacks the sweeping tax reforms introduced by the One Big Beautiful Bill Act signed into law on July 4, 2025.

Partner Jason Hoffman published an article in *Law360* that breaks down the three key venues where patent claims are commonly invalidated – district court, the U.S. International Trade Commission, and the Patent Trial and Appeal Board – and explains what each type of invalidity actually means. Contact Jason for more information.

Partner Lee Rosebush and associate Marc Wagner will present at the National Association of Specialty Pharmacy's 2025 Annual Meeting and Expo, which will run Sept. 14-17 in Denver, Colorado. Titled "Supply Chain Resilience: 503Bs as a Drug Shortage Channel," the session will focus on the regulatory and market landscape for drug shortages as well as the 503B pathway to compounding or repackaging drug products, 503B capabilities, and partnering with a 503B before and during drug shortages.

IN CASE YOU MISSED IT

In June, BakerHostetler released its second issue of the *BakerHostetler Life Sciences Newsletter*. Issue 2 can be accessed here.

FOR MORE INFORMATION OR TO BE ADDED TO THE DISTRIBUTION LIST, PLEASE CONTACT RON KERN AT RKERN@BAKERLAW.COM.