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Looking Back, Moving Forward: A Year in Life Sciences

Polsinelli Life Sciences Spotlight | Volume 1

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Contents

Clients & Friends,

Welcome to the inaugural issue of the Polsinelli Life Sciences Spotlight.

As we embark on 2025, we are thrilled to provide an overview of legal and business issues at the forefront of the life sciences industry.

A common refrain in life sciences circles is that "it takes a village" – advances are made only with collaboration among numerous stakeholders, including those receiving this newsletter. At Polsinelli, we value those relationships, as it is these relationships that help our clients achieve their business and scientific goals.

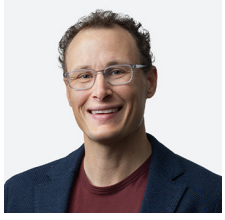
Polsinelli works with clients across subsectors of the life sciences industry and participates in a range of life sciences and health care events. Our next event will be a Polsinelli-hosted reception at the upcoming J.P. Morgan Healthcare Conference, and we hope to see you there.

We host many other events throughout the year, as you'll see in the newsletter. If you have not joined us for one of these events in the past, please do so in 2025.

As you engage the newsletter, please let us know if you have suggestions for future topics or features. And please reach out if we can provide additional color on any of the topics raised.

We look forward to continuing to bring you industry insights that will help you – and us – champion innovation.

Enjoy,



Rick Jordan

Lead, Life Sciences Industry Group
Co-Chair, Venture Capital and Emerging Growth Companies

Policy Opportunities in 2025 Washington

Tim Perrin
Senior Policy Advisor
Public Policy
Washington, D.C.

Shortly after his inauguration in 2009, President Barack Obama famously claimed that "elections have consequences." His win in 2008, combined with Democrats securing Congressional majorities that November, resulted in a unified government – one party controlling the executive and legislative branches – that enacted the sweeping Affordable Care Act (ACA) in 2010. Perhaps Obama should have said that "elections create opportunities." Similarly, with Republicans winning control of the White House and the U.S. Senate in November 2024, as well as maintaining their majority in the U.S. House of Representatives, they are looking to generate opportunities within the life sciences and health policy space in 2025.

These public policy opportunities are expected to stem from campaign discourse extolling private sector efficiency and innovation as virtues or standards to be emulated within federal programs. Policy initiatives consistent with these two themes will likely be advanced through a combination of the legislative process and executive branch action. With a Republican back in the White House, the direction for most of these policy opportunities will originate from within President-elect Donald Trump's second-term administration.

Much has been written about the individuals President-elect Trump has proposed to lead the federal departments and agencies within his administration. Many, if not most, of his picks are considered outside the Washington norm. Sending the message that the federal government will not operate 'business as usual,' Trump has tapped individuals who will serve as "disruptors." Although the Washington stakeholder community is concerned by the potential for uncertainty, by shaking things up, the incoming Trump administration will open new policy opportunities for stakeholders in the life sciences space.

So how should industry stakeholders react when the typical political and policy landscapes are in a state of flux? To succeed in this unified government environment for at least the next two years – until the 2026 Congressional mid-term elections - industry stakeholders must demonstrate to policymakers that their products or services can improve the way the federal government governs. This is where the themes of efficiency and innovation come into play.

Finding efficiencies within the .gov ecosystem is the initial emphasis touted by the Trump transition team. The formation of the "Department of Government Efficiency" (DOGE) epitomizes the intent of this effort. Although DOGE is an unofficial entity and can only make recommendations to Congress and the administration about the areas of waste, fraud and abuse within federal

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programs to cut, this Trump 2.0 initiative makes clear that anything inefficient (e.g., systems, programs, products, services, etc.) will be viewed unfavorably by the administration and Congressional Republicans.

The flip side of this is that things that demonstrably create efficiency will have the opportunity to be considered by policymakers. One other data point makes this effort particularly interesting: some Democratic populists on Capitol Hill who favor an economics-first approach to politics are viewing the DOGE effort as a political opportunity. Politics sometimes makes for odd bedfellows, so it is possible we could see some unlikely bipartisanship emerge on efficiency issues.

Secondly, the Republican-controlled government will celebrate innovation – especially within the life sciences and health care spaces. Agencies including the Centers for Medicare and Medicaid Services (CMS), the National Institutes of Health (NIH), the Food & Drug Administration (FDA), and the Advanced Research Projects Agency for Health (ARPA-H) will be headed by leaders open to new ways of solving costly, long-term problems. Even though the Center for Medicare and Medicaid Innovation (CMMI, or also called the CMS Innovation Center) was established in the ACA by Democrats, Republicans during Trump's first term came to view the agency as an effective laboratory to evaluate whether new payment models would save the Medicare program money and improve patient outcomes.

While CMS will continue carrying out coverage and reimbursement policies, existing incentive programs within the Medicare inpatient and hospital outpatient programs that promote the adoption of transformative therapies and treatments could be expanded. And agencies like CMS and FDA will be involved in determining how federal regulations and requirements, as well as trade and tariff policies, will impact health care product manufacturing and where that manufacturing is located.

President-elect Trump and his political appointees are receiving most of the focus in early 2025, but it is Congress that will be the agent of lasting policy change. By enacting policy changes into law, Congress can shape the policy for landscape for years to come and will use three primary mechanisms. As illustrated by Democrats in 2010 with the passage of the ACA, unified government allows Congress to use the budget reconciliation process, which allows Congress to enact budget-connect policy changes by simple majorities. Congressional Republicans began developing their reconciliation plans after the election results were known with the goal of enacting legislation in 2025 that will impact the size and scope of federal programs. Health care policies, including changes to Medicare and Medicaid, could be advanced through the reconciliation process. Secondly Congress may include health provisions in the annual appropriations bills. Federal programs that promote health care priorities could be emphasized, while inefficient federal programs could see decreased funding or be cut all together.

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Finally, because not every health care policy proposal impacts the budget, Congress could pass stand-alone legislation or a health-specific legislative package. With the narrow margins of party control in the Senate and the House, this procedural pathway may be an opportunity for Republicans and Democrats to work together.

While efficiency and innovation are themes that will guide political and policy action in 2025, policymakers in the administration and Congress will be looking to enact broad-based changes that impact the greatest number of people. Doing so means that decisions regarding life sciences policies will likely involve not only health care interests, but agricultural, environmental, manufacturing and taxation concerns as well. Framing issues with this in mind will maximize stakeholder investment in public policy advocacy.

Recent Life Sciences Deal Trends

Andrew J. Merken
Shareholder
Venture Capital and Emerging Growth Companies
Boston

When it comes to life sciences industry transactions, the business cycle is alive and well. After a spectacular second half of 2020 and all of 2021 – which took most everyone by surprise given COVID - the past three years have seen a marked decrease in the volume – though not the dollar value – of activity. The number of venture capital financings, Merger & Acquisition (M&A) transactions, licensing deals and Initial Public Offerings (IPO) dropped – in some cases fairly significantly – in 2022 through 2024. And while the new year has brought a renewed sense of optimism, there are still a number of unknowns, particularly on the regulatory front, that will impact 2025 and beyond.

Underlying the 2022-2024 slowdown was inflation, a rise in interest rates and a slackening economy. From a borrowing perspective, higher interest rates raised the cost of capital, requiring companies to lean less on debt and more on equity in financing their operations and transactions. At the same time, however, those same higher interest rates caused investors to cycle away from the stock market and to park more capital in bonds. As the IPO markets cooled, so did public market liquidity opportunities for venture capital investors, resulting in less new capital available for new investments. And as the economy slowed, venture capital investors were forced to reserve more capital to keep existing portfolio companies afloat, exacerbating the lack of funding available for new investments. By one estimate, US venture capital funding declined from $47 billion in 2021 to $34 billion in 2022 (a 22% decrease), to $25 billion in 2023 (an additional 27% drop), before increasing slightly to $27 billion in 2024. Drug discovery and therapeutics companies tended to be the most active recipients of VC funding.[1]

Interestingly, though, while the overall amount of capital invested decreased as did the number of deals, the average deal size increased. Investors pivoted toward later stage deals – Series B, C and D rounds - which tend to be less risky but which require more capital and, arguably, a number of well-known life sciences VCs transitioned to being growth equity investors in their most recent funds. Early-stage (Series Seed and Series A rounds) investing decreased. At all stages, pre-money valuations fell, with down rounds becoming more frequent and, often, dramatic.

M&A activity showed similar trends; in the US life sciences industry, M&A deals dropped in value from $180 billion in 2021 to $70 billion in 2022 (a 61% decrease) before increasing to $113 billion in 2023 and then decreasing again to $111 billion in 2024. The number of transactions also decreased, by 31% from 2021 to 2022 before increasing by a modest 5% in 2023 and then decreasing again by 23% in 2024. As with VC investing, though, the median average deal size increased during this same timeframe - from $110 million in 2021 to $160 million in 2022, before decreasing to $100 million in 2023 and increasing again to $199 million in 2024 – as did the trend of transactions favoring

1 https://www.jpmorgan.com/content/dam/jpmorgan/documents/cb/insights/outlook/jpm-biopharma-deck-q2-2024-final-ada.pdf

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later stage, less risky assets (late stage development/early commercialization) over early stage ones, in part because strategic acquirers looked to acquisitions to supplement declining revenue growth. The big winners in M&A were companies focusing on oncology, immunology and neurology. [2AB]

Licensing deals also decreased, from 215 in 2021 to 182 in 2022 (a 15% decrease) and then again to 134 in 2023 (an additional 26% decrease).[3]

Following a strong 2021 in which there were 99 life sciences IPOs that raised a total of $15.6 billion, 2022 saw only 17 life sciences IPOs ($2.4 billion) and only 13 IPOs in 2023 ($2.7 billion).[4] The flight to debt and the slowing economy were to blame, with the trickle-down effect of less IPO liquidity impacting the venture capital markets and lower stock prices of already-public companies making stock acquisitions more difficult. In addition, much like in venture capital and M&A, IPOs have been trending toward less risky later stage, clinical asset companies.

Looking ahead to 2025 and beyond, there are positive signs for life sciences transactions, including interest rates that decreased in the second half of 2024 – resulting in lower costs of borrowing and a renewed trend toward equity – and lower inflation which is expected to jump start the economy. In addition, venture capital fundraising has been active, setting the stage for more funding deals. Adding significant uncertainty, though, are expected changes in DC policy – in the short term, the uncertainty will likely restrain some of the renewed optimism, and in the long term could have significant consequences. *Will the FTC take a more lenient approach to antitrust regulation? Will interest rates continue to decrease or, as some have suggested, reverse course and increase again? Will the FDA's reach be proactively restrained or dramatically pivoted in areas such as vaccines and nutrition? Will the NIH pull back on its research grants? Under the Inflation Reduction Act, will HHS' negotiation of drug prices increase or even decrease? Will the Biosecure Act, which would prohibit entities that receive federal funds from using biotech equipment or services from a company associated with a foreign adversary (most notably, China) – be passed by the Senate and signed into law?* The answers to these questions remain to be seen, as does their impact on life sciences industry transactions. Regardless of the outcome, 2025 promises to be an interesting ride.

2A https://www.jpmorgan.com/content/dam/jpmorgan/documents/cb/insights/outlook/jpm-biopharma-deck-q2-2024-final-ada.pdf
2B https://www2.deloitte.com/content/dam/Deloitte/cn/Documents/life-sciences-health-care/deloitte-cn-lshc-global-life-sciences-sector-outlook-2024-en-240709.pdf
3 https://www.jpmorgan.com/content/dam/jpmorgan/documents/cb/insights/outlook/jpm-biopharma-deck-q2-2024-final-ada.pdf
4 https://www.jpmorgan.com/content/dam/jpmorgan/documents/cb/insights/outlook/jpm-biopharma-deck-q2-2024-final-ada.pdf

2024 Sampling of Representative Life Sciences Deals

JANUARY

- Polsinelli Represents Eat Mezcla, Inc. in $4 Million Series A Financing
- Polsinelli Represents Grubbly Farms in Series A Financing
- Polsinelli Advises Winnow AI in Sale to Aya Healthcare

FEBRUARY

- Polsinelli Represents Acadia Healthcare in Acquisition of Turning Point Centers
- Polsinelli Represents Hightop Health in Acquisition of Roots Behavioral Health
- Polsinelli Represents Elo Life Systems in $20.5 Million Series A-2 Financing
- Polsinelli Represents CPC in Acquisition of Drug Free Sport International
- Polsinelli Client Bond Pet Foods, Inc. achieves significant milestones in its Joint Development Agreement with Hill's Pet Nutrition

MARCH

- Client Verge Genomics and Ferrer Internacional Enter into ALS Development Collaboration with up to $122 Million in Upfront and Milestones Payment

MAY

- Polsinelli Advises Pathways Recovery Centers in Acquisition of Serenity Park Recovery Center

JUNE

- Polsinelli Represents Opya in Acquisition of Center for Autism Spectrum Therapy

JULY

- Polsinelli Advises Seaweed Bath Co. in the Acquisition of Andalou Naturals and Mineral Fusion

AUGUST

- Polsinelli Advises Nexus Group on Partnership With Beacon Behavioral Partners
- Polsinelli Advises KU Health in Acquisition of Liberty Hospital

SEPTEMBER

- Polsinelli Assists API Innovation Center in Obtaining First DPA Title III Award to Bolster U.S. Pharmaceutical Independence
- Polsinelli Represents Momo Medical in €6.5 Million Series A Financing
- Polsinelli Represents DERM-JES Holdings' Acquisition of DermTech
- Polsinelli Represents Endolith in $5.13 Million Series Seed Financing

OCTOBER

- Polsinelli Secures Litigation Victory For MSN Pharmaceuticals in Lawsuit Against FDA Involving a Generic Version of Entresto

NOVEMBER

- Polsinelli Counsels Avanos Medical in Qualifying for Separate Payment Under NOPAIN Act
- Polsinelli Advises ResQ Pharma in Obtaining PDUFA Date for LipidRescue™
- Polsinelli Advises Paramount Health Management in Acquisition of Life Launch Centers
- Polsinelli Represents Metro Physical & Aquatic Therapy in Recapitalization with U.S. Physical Therapy
- Polsinelli Represents Legacy Pharma Solutions in its Acquisition by Nutra-Med

Living in a Post-Chevron World – *Loper Bright* and the Impact on FDA-Regulated Industries

Chad A. Landmon
Hatch-Waxman and Biologics Litigation Chair
Washington, D.C.

Michael M. Gaba
Food and Drug Vice Chair
FDA Law
Washington, D.C.

Suzanne E. Bassett
Associate
FDA Law
Washington, D.C.

In June 2024, the Supreme Court issued its long-awaited ruling in *Loper Bright Enterprises v. Raimondo (Loper Bright)*[1] overturning the Court's Chevron[2] doctrine, which established judicial deference to administrative agency interpretations of ambiguous statutes. Under *Chevron*, a two-step framework applied in cases involving the interpretation of statutes administered by federal agencies. First, the reviewing court had to decide whether the statute was ambiguous. Second, if it was, the reviewing court was directed to "defer to the agency's interpretation" of the statute so long as that interpretation was "based on a permissible construction of the statute."

Under the new *Loper Bright* framework, courts "may not defer to an agency interpretation of the law simply because a statute is ambiguous." Instead, the Court held that the judiciary must "exercise independent judgment" to adopt a statute's "best reading," even when ambiguous. While the Court's opinion in *Loper Bright* states that prior cases that relied upon *Chevron* are undisturbed by the decision, it remains to be seen whether courts will consider these cases binding law.

For decades, *Chevron* deference played a significant role in courts repeatedly deferring to the Food and Drug Administration (FDA) and upholding its decisions, sometimes without a detailed consideration as to whether agency action was consistent with congressional purpose as outlined in the statutes. Many companies have seen courts' reliance on *Chevron* as a high bar in challenging FDA action, even when there may be a legitimate argument. The *Chevron* doctrine has been cited in thousands of cases, including several FDA cases, with disputes often being resolved in FDA's favor based upon perceived ambiguity in the relevant statute.

Since June, *Loper Bright* has been cited hundreds of times in briefs and other court documents as companies continue to bring challenges under the Administrative Procedure Act. While only a few cases related to FDA have been decided in the past six months, we have provided a summary of the cases we are continuing to follow in the new year that will likely have a major impact for FDA regulated companies:

- *Novartis Pharmaceuticals Corporation v. Becerra, et al.*, Case No. 1:24-cv-02234 (D. D.C.) – Novartis challenged FDA's approval of a generic version of Novartis's blockbuster drug ENTRESTO. The generic drug manufacturer, MSN Pharmaceuticals Inc., joined the suit as an intervenor-defendant and was represented by a team of Polsinelli

1 144 S. Ct. 2233 (2024).
2 *Chevron v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

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attorneys. Novartis argued that FDA's approval was unlawful because the Federal Food, Drug, and Cosmetic Act requires indications for a generic drug to be the "same as" the reference listed drug. Novartis argued that FDA's regulations that allow for the "omission" only allow for language to be removed and not the "modification" of language to avoid parts of the label that may be protected by patent. Novartis also argued that MSN's labeling rendered the drug less safe and effective and that the active ingredients in the generic product were not the same as ENTRESTO.

The D.C. District Court found that FDA did not act in an arbitrary and capricious manner by excluding the patent-protected indication and dosing regimen from MSN's labeling and deferred to FDA's "area of technical expertise." The court further found that FDA thoroughly explained its rationale in the Administrative Record and that FDA's scientific determinations on the active ingredients were reasonable and consistent with the evidence. In citing *Loper Bright*, the court preserved *Bristol-Myers Squibb v. Shalala*,[3] notwithstanding arguments from Novartis that *Loper Bright* nullifies it, finding that the D.C. Circuit interpreted the relevant statutory provisions itself and did not defer to FDA's interpretation. *Bristol-Myers* has been an important case for generic drug manufacturers holding that the statute permits changes to a generic's label to account for patent-protected indications.

- *American Clinical Laboratory Association et al. v. FDA et al.,* Case No. 4:24-cv-00479 (E.D. Tex.) – The American Clinical Laboratory Association (ACLA) filed a lawsuit challenging FDA's statutory authority to regulate Laboratory Developed Tests (LDTs) as medical devices. The Association for Molecular Pathology filed a similar lawsuit in August 2024, which was consolidated with the above case. ACLA asserts that FDA's Final Rule, which was published in May 2024, exceeds FDA's statutory authority and that FDA "acted arbitrarily and capriciously in violation of the Administrative Procedure Act." Although the lawsuit was filed before *Loper Bright* was decided, ACLA argues in its motion for summary judgment that FDA now "faces a heavy burden to justify its extraordinary position" under the *Loper Bright* standard and that FDA should not be afforded "respect" to its interpretation of the statute in part based on the agency's "late-breaking" assertion of a statute enacted in 1976. The parties' replies to the motions for summary judgment were due in December 2024, with a ruling from the court to follow shortly after. Oral arguments have yet to be scheduled. This lawsuit is likely to be one of the first challenges to an FDA regulation that will be decided under *Loper Bright*.

- *Eli Lilly & Co. v. Becerra et al.,* No. 1:24-cv-01503 (S.D. Ind.). - Eli Lilly filed a lawsuit in September arguing that FDA improperly classified its anti-obesity product retatrutide as a drug, rather than a biological product. In the complaint, Eli Lilly argues that an applicant must submit a biologics license application to obtain a

3 91 F. 3d 1493, 1499 (D.C. Cir. 1996).

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license of a "biological product," which Congress defined to include a "protein" or "analogous product." However, the statute does not further define "protein" or "analogous product," which Eli Lilly argues is an interpretive decision for the courts to decide under *Loper Bright*. This case is similar to previous lawsuits filed challenging FDA's classification for human cells, tissues and cellular tissue-based products (HCT/Ps). As *Loper Bright* has left the door open for companies to challenge these types of product classifications, similar challenges should be filed in the new year.

- *Jazz Pharmaceuticals Inc. v. Becerra et. al.,* No. 1:23-cv-01819 (D.D.C.) – Jazz Pharmaceuticals challenged FDA's determination that two drugs were not the same for purposes of the Orphan Drug Act when they are marketed for the same condition with the same "active moiety." Under the Orphan Drug Act, FDA is barred from approving another orphan drug that is the same drug for the same disease or condition during the seven-year exclusivity period for the first drug approved. Under FDA's longstanding regulatory definition of "same drug," an orphan drug is not considered the same drug if it is "clinically superior." In this case, FDA determined that, because of its once-nightly dosing regimen (compared to twice-nightly), Jazz's competitor was "clinically superior." The court rejected FDA's argument that the Agency's reading of the Orphan Drug Act was entitled to deference under *Loper Bright* but nevertheless ruled in FDA's favor, holding that this particular challenge was squarely within FDA's "area of special expertise" and thus FDA was entitled to a high level of deference.

Following *Loper Bright*, monitoring the FDA landscape and any changes the Agency takes to its regulatory approach as cases continue to be litigated is increasingly important. With the change in administration at the Department of Health and Human Services and FDA, *Loper Bright* will likely play a critical role in court challenges to any policy shifts that are implemented. In addition, advocating before FDA prior to its decisions being made is even more important in this post-*Chevron* environment, where FDA is more likely to be challenged in court and where having a robust factual record is likely to come into play in later court challenges.

Are Medical Device Disputes the Latest "Smartphone Wars" at the ITC?

Daniel F. Smith
Shareholder
ITC Section 337 Litigation and Trade Remedies
Washington, D.C.

Section 337 of the Tariff Act of 1930 directs the U.S. International Trade Commission (ITC) to investigate and block the importation of goods that infringe U.S. intellectual property rights or are the subject of other unfair acts. Complainants file petitions with the ITC alleging that certain imported products are involved with a specific unfair act. The ITC then investigates the claims and, if it finds a violation, may issue an exclusion order barring the importation of the offending goods.

Section 337 investigations have involved a wide variety of products, from simple consumer products such as phone cases, to sophisticated electronics including mobile phones and computers, to large-scale industrial products including wind turbines and jet engines, and even to seemingly taboo items such as tattoo machines and "not safe for work" products. The types of products at issue occasionally fall into a pattern, most notably the ITC's "smartphone wars" in the late 2000s and early 2010s. Internet of things devices have also become more common. Recently another category of products has been on the rise with complaints aimed at medical devices and other personal health and wellness products.

In 2024, the ITC received no fewer than nine complaints directed to medical devices and related products. This is more than 20% of all Section 337 complaints filed in 2024. In contrast, from 2021 through 2023 only 13 Section 337 complaints were directed to medical devices and similar products, approximately four per year. The cases filed in 2024 covered a diverse range of health products, including cochlear implants, skin care systems and cosmetics, and wearable products such as smart rings and smart glasses.

What's the reason for this uptick? One factor likely reflects the growing popularity of "medi-spas" and health and wellness wearables.[1] It is also likely that with numerous new competitors entering the market, the ITC's exclusionary remedy is more attractive to complainants seeking to protect their U.S. market share rather than seeking monetary damages in district court for their competitors' infringement.[2] Unlike in district court litigations, the Supreme Court's eBay decision does not apply to Section 337 Investigations, and a successful complainant at the ITC is not required to demonstrate that the equitable factors for an injunction favor issuing the Commission's exclusionary relief. However, showing the offending products infringe a valid patent claim is not all that is required to prove a violation. An ITC complainant is also required to prove that it or its licensee has established or is in the process of establishing an industry in the United States directed to products protected by the asserted patents. Mere

1 *See* https://brentonway.com/med-spa-marketing-stats-trends/ (projecting global medical spa market growth from $17.2B in 2023 to $19.5B in 2024 with compound annual growth rate of 13.2%).
2 Under 28 U.S.C. § 1659, parallel district court proceedings are subject to an automatic stay during the ITC investigation.

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patent ownership is not sufficient to avail oneself of the Commission's remedies. To establish the required domestic industry, the complainant is required to show it has significant domestic activities and investments directed to qualifying activities for its products, such as manufacturing, service and repair, customer support, engineering, research and development, or even licensing. Sales and marketing activities on their own are not sufficient to establish the required industry.

The ITC's recent final decisions have generally favored complainants. Of the thirteen investigations involving medical devices or related products instituted from 2021 through 2023, five ended with the Commission finding a violation and entering an exclusion order or the respondent voluntarily agreeing to stop importing. Three ended with settlements and only two ended with the Commission finding no violation.[3] Notable among the recent violations are two investigations involving Apple where the Commission excluded versions of the Apple Watch. In Inv. No. 337-TA-1266, the electrocardiogram functionality in the Apple Watch infringed two patents and in Inv. No. 337-TA-1276, the Apple Watch infringed two patents covering blood oxygen sensing technology. Although the Commission suspended the remedy in the 1266 Investigation because the PTAB previously determined the infringed claims were unpatentable, the Commission denied Apple's request to stay the remedies in the 1276 Investigation, and Apple is now subject to those orders unless the Court of Appeals for the Federal Circuit reverses the ITC's Final Determination or until the patents expire.

Will this trend of complainants filing complaints directed to medical device and adjacent products continue? Only time will tell. Medical Device companies should be prepared both to consider the ITC as part of their IP enforcement strategies as well as to learn more about defensive strategies at the ITC.

3 Three investigations have not reached a final decision. Two of those investigations are before the Commission after an ALJ found a violation. The ALJ's decision in the third investigation was due in December 2024.

CLIENT SPOTLIGHT

Q&A with SxanPro

A Q&A with **Ashlea Souffrou**, CEO and Founder of SxanPro,
a medtech company focused on healthcare supply chain optimization

Ashlea Souffrou, CMRP
Founder & CEO
SxanPro

What is the origin story of SxanPro? How did you come up with the idea for the company and the technology?

The idea for SxanPro was born out of real-life frustrations I witnessed in the healthcare supply chain. While working closely with hospitals, I saw firsthand the chaos and inefficiencies caused by incomplete inventory data, manual processes, and the inability to inventory items effectively. These challenges didn't just create operational bottlenecks; they directly impacted clinical and financial outcomes. I knew there had to be a better way—a solution that would give hospitals clarity and control over their inventory without requiring a massive overhaul of their existing systems. That's when we developed SxanPro, leveraging Unique Device Identification (UDI) to provide actionable, high-quality inventory insights quickly. It was about turning the possibility of clarity into a reality in one of the most complex systems imaginable.

Traditional inventory management systems often fall short in addressing critical gaps, such as identifying expired or recalled products, low or excessive supply, etc. What do you see as the biggest limitation of these systems, and how does SxanPro's technology directly address these issues?

The biggest limitation of traditional systems is the lack of unified, actionable data. Many rely on outdated item masters or manual input, which leaves room for errors, such as inconsistent naming, and blind spots, especially when it comes to tracking expired, recalled, or consigned items. SxanPro's technology bridges these gaps by capturing and enhancing inventory data using UDI, which creates clarity from chaos with a single, reliable source of truth for all things inventory. We provide hospitals with immediate visibility into their inventory health—whether it's identifying expired items, managing par levels, or having full transparency into inventory value, especially high-value supplies. By delivering insights hospitals can act on immediately, we ensure resources are optimized, risks are reduced, and patient care is prioritized.

How does your technology benefit hospitals beyond operational efficiencies?

Our technology helps hospitals recover costs by identifying unused or expired items that can be transferred to other locations, sold or credited by manufacturers, ensuring supplies are utilized before they become waste. Additionally, we alleviate the burden on clinical staff by taking manual inventory tasks off their plate, allowing them to focus on what truly matters—patient care. Hospitals also gain system-wide visibility into inventory, which improves decision-making and resource allocation across facilities. It's not just about doing more with less; it's about creating a system where resources are used responsibly and effectively.

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What role do you see UDI-based technologies like SxanPro playing in the future of healthcare supply chain management? How will hospitals evolve their inventory systems as more institutions adopt this kind of advanced, data-driven approach?

UDI-based technologies like SxanPro will become foundational to healthcare supply chain management. As the industry pushes for more transparency and accountability, hospitals will need systems that provide accurate, standardized data across the board. UDI isn't just about inventory—it's about building a smarter, interconnected supply chain that anticipates needs, minimizes waste, and drives better patient outcomes. As more institutions adopt data-driven approaches and prepare for AI integration, we'll see a shift from reactive inventory management to proactive strategies that align with value-based care. Hospitals will evolve into agile, tech-enabled ecosystems, capable of responding to challenges like shortages or recalls with precision.

As the healthcare industry continues to evolve, what do you see as the next big challenge in inventory management, and how is SxanPro positioning itself to help hospitals overcome these challenges in the future?

As the healthcare industry continues to evolve, we're not just looking at the next big challenge in inventory management—we're on the brink of the next big breakthrough. Hospitals are rapidly adopting innovative technologies and harnessing the power of data, paving the way for transformative advancements. With these tools, they're poised to achieve remarkable efficiencies, minimize waste, and improve patient care. At SxanPro, we're excited to be a part of this journey, helping hospitals unlock these possibilities and turning challenges into groundbreaking opportunities for the future of healthcare.

For hospitals still relying on traditional, manual inventory processes, what advice would you give them to make the transition to a more efficient, automated system like SxanPro?

Start small but think big. Transitioning doesn't have to mean overhauling everything at once. Identify pain points where manual processes are causing the most inefficiency or risk, and tackle those first. A solution like SxanPro is designed to integrate seamlessly into existing workflows without requiring IT or downtime. Take that first step toward freeing up your teams and creating a future where your inventory works for you, not against you. Focus on the long-term benefits—saving time, recovering costs, and improving patient safety. And most importantly, bring your team along on the journey. When people understand the why behind the change, they're much more likely to embrace it.

Anything else you want to share about SxanPro—or your journey and story?

SxanPro is deeply personal to me because it's not just about technology; it's about making a difference. I've always believed that innovation starts with listening—understanding the real challenges people face and creating practical solutions that solve them. Watching SxanPro grow and seeing the impact it's had on our hospitals has been incredibly rewarding. But I also know this is just the beginning. There's so much potential in healthcare to optimize resources, support clinicians, and, ultimately, improve outcomes for patients. That's what drives me every day, and it's why SxanPro exists.

Polsinelli advises SxanPro on intellectual property and corporate matters.

Polsinelli Client is Saving Your Bananas

J. Powell Carman
Shareholder
Corporate Mergers & Acquisitions
St. Louis

The Cavendish banana—the most-common species sold across the United States, Europe, and China, of what is widely considered the most popular fruit in the world — is at risk of going extinct from a deadly fungus. Elo Life Systems, a Research Triangle Park startup spun out of Precision BioSciences three years ago, is genetically engineering Cavendish bananas to make them resistant to the fungus, as was recently featured on *Science Friday.*

TR-4, also known as *Fusarium Oxysporum,* is a kind of fungus that attacks banana trees at the roots. Fungicides and other chemicals can't kill it, so farmers have few options when it invades their crop. TR-4 was first discovered in Southeast Asia about 50 years ago and by the late 2010s, was showing up in the soil of banana producing countries in LATAM. Several banana-producing nations, like Costa Rica, have enacted strict biosecurity measures to prevent its spread.

In April 2023, Dole planted Elo's gene-edited bananas to carry out a field trial on a plantation in Central America. Elo altered a handful of the fruit's 30,000+ genes to generate proteins that will defend it from the fungus. Elo is also using its computational biology and "molecular farming" platform designed to teach fruits and vegetables how to behave to create sustainable and healthier alternatives.

Elo, which raised $24.5 million in February 2023, is also creating an alternative to the increasingly popular zero-calorie monk fruit sweetener. At present, monk fruit is expensive to source, only grows in particular climates, and rots quickly. Elo uses watermelons and sugar beets, among other plants, as biofactories to grow mogroside (the monk fruit protein) and then extracts it to make a high potency, no calorie sweetener.

Polsinelli is advising Elo on financing and commercial partnerships.

Proposed Changes to Terminal Disclaimer Practice in Patent Applications Withdrawn after Industry Backlash

Blake A. Ronnebaum
Associate
Chemical Science
Patent Prosecution
Kansas City

In May 2024, the US Patent and Trademark Office (USPTO) proposed a major change to terminal disclaimer practice that was expected to upend the common patent prosecution strategy of filing multiple applications stemming from a single, original patent application. Under the proposed rule, a terminal disclaimer would be required to stipulate that if any claim is found unpatentable or invalid, then any other patents tied to that invalid claim by one or more terminal disclaimers would also be invalid and unenforceable. While the proposed rule was expected to issue in December 2024, patentees can breathe a sigh of relief, as the rule was recently withdrawn on December 4.

The USPTO proposed its new requirement in connection with terminal disclaimers filed to overcome rejections on grounds of nonstatutory double patenting. A nonstatutory double patenting rejection asserts that a pending claim is not patentably distinct over other patent claims already owned by the same applicant. In typical prosecution practice, a terminal disclaimer may be filed by the patent applicant to link one or more patents together in order to overcome this rejection. The effect of a terminal disclaimer is to prevent the application's patent term from extending beyond that of an already-issued patent. Under the proposed rule, a patent applicant that filed a terminal disclaimer would be required to agree that the patent subject to the terminal disclaimer is unenforceable if (1) any claim in a patent linked by a terminal disclaimer is found unpatentable or invalid over prior art in court or by the USPTO and appeal rights have been exhausted, or (2) a statutory disclaimer, filed by the patent owner to cancel one or more claims of a linked patent, is filed after any challenge based on anticipation or obviousness to that claim has been made. The USPTO asserted that the action was taken to prevent multiple patents directed to obvious variants of an invention from potentially deterring competition.

If implemented, the new rule would have greatly affected filing and prosecution strategies for applicants that tend to file many continuation applications. Essentially, the consequence of the potential rule would have made a continuation application only as strong as the weakest claim in the patent family. One successful invalidity challenge to a single broadly drafted patent claim could have had the effect of rendering an entire patent estate unenforceable under the proposed rule. The potential for a sweeping invalidation of an entire patent family linked by terminal disclaimer would have been a controversial deviation from current patent law, in which every claim of every issued patent is presumed to be valid and enforceable until an appropriate body (the Patent Trial and Appeal Board or a Federal Court) holds otherwise.

For applicants in life sciences industries, particularly in the pharmaceutical industry, this potential rule change could have had significant impacts. Pharmaceutical companies generally file several patent applications claiming different variations of their drug product to create a "patent thicket," which often makes it more difficult for generics to enter the market. The proposed rule would

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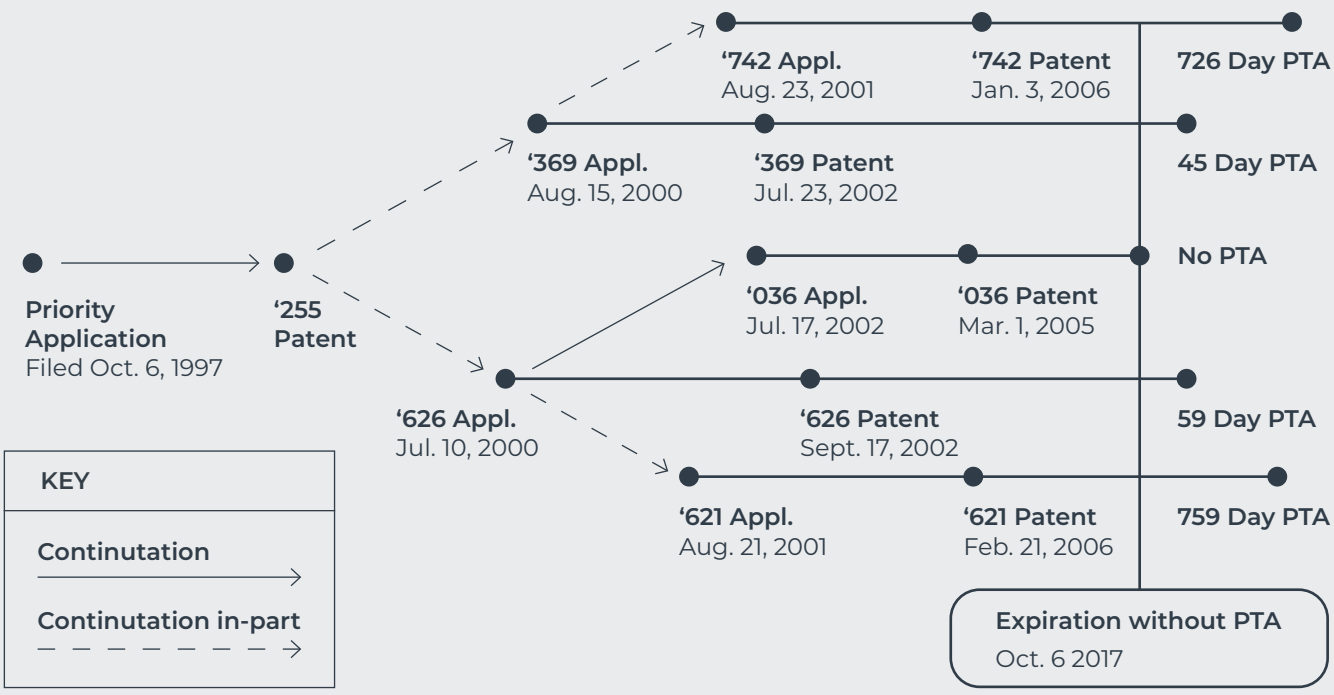
have made it much easier for a generic company to wipe out the entire patent estate of a branded drug to allow entry into the market. Startup companies in particular, who generally rely on continuation applications to help spread out the cost of building a patent estate over time, would have faced new vulnerabilities if the new rule was enacted.

The comment period ended on July 9. It's no surprise then that the proposed rule received about 349 comments from interested parties ranging from sole inventors to large companies. In total, 244 comments were submitted opposing the rule, 92 comments supported the rule, and 13 comments were neither expressly for or against the rule. Perhaps most notably among the commenters was Andrei Iancu, the former Director of the USPTO from 2018-2021. Director Iancu, joined by other former Directors and Deputy Directors of the USPTO strongly urged current Director Kathi Vidal to withdraw the rule. In an interview with *Law360*, Director Iancu opined that the next Trump administration would likely scrap the rule.

The proposed rule also came shortly after the Federal Circuit issued a decision in *In re Cellect*[1], which also affects terminal disclaimers. In *Cellect*, the patents at issue (shown in the diagram below) claimed priority to the same priority application, but all the patents expired at different times due to differing amounts of patent term adjustment (PTA) awarded at issuance. PTA is additional patent term added onto the issued patent to make up for delays in prosecution caused by the patent office.



1 *In re Cellect*, No. 2022-1292 (Fed. Cir. Jun. 14, 2023).

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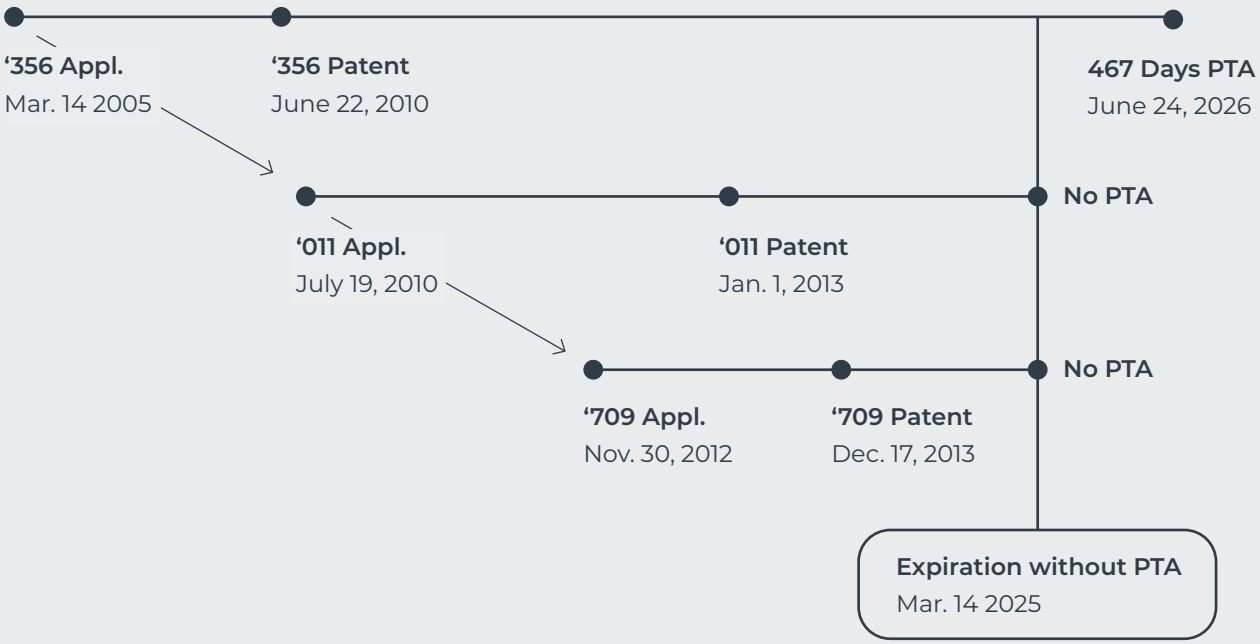
The Court in *Cellect* held that the relevant date for evaluating nonstatutory double patenting is the expiration date of a patent including its PTA (if any), as opposed to the expiration date of the patent without PTA. Because some of the patents in *Cellect* had expiration dates extending well-beyond the terms of other patents in the family, they could be used as references in a double patenting rejection against earlier-expiring patents in the family. The failure of the patentee in *Cellect* to file a terminal disclaimer resulted in the later-expiring patent being invalidated.

A Federal Circuit panel later came to a different conclusion than the *Cellect* panel and held in *Allergan USA, Inc. v. MSN Laboratories Private Ltd.*[1] that a first-filed, first-issued, and later-expiring patent could not be invalidated by a later-filed, later-issued, earlier-expiring patent for nonstatutory double patenting (see diagram below – the '356 patent cannot be invalidated by the '011 or '709 patents).[2] Taken together, these decisions do leave some open questions to be worked through as to strategies for using terminal disclaimers in large patent families, particularly when certain patents have received PTA.



In summary, although many changes have taken place over the past year regarding terminal disclaimer practice and nonstatutory double patenting, patent applicants can rest easier now that the USPTO's proposed rule has been withdrawn and left the current system intact.

1 *Allergan USA, Inc. v. MSN Laboratories Private Ltd.*, No. 2024-1061 (Fed. Cir. Aug. 13, 2024).
2 A petition for rehearing *en banc* in *Allergan* was filed, but was later withdrawn by agreement before a decision on the petition was rendered.

Artificial Intelligence and Machine Learning Patenting Pitfalls in the Life Sciences Industry

Benjamin J. Sodey
Counsel
Biotech and Life Science Patent Prosecution
St. Louis

Life sciences companies are increasingly using artificial intelligence/machine learning (AI/ML) technology in areas including drug discovery and development, personalized medicine, diagnostics, genomics, and proteomics. Consequently, life sciences companies seek patent protection for inventions developed using AI/ML. The use of AI/ML in an invention, however, raises potential patentability issues that may doom a patent in prosecution or litigation. Accordingly, life sciences companies should construct a robust patent strategy to address the AI/ML aspects of an invention throughout the development and production cycle. Such a strategy includes an understanding of the human contribution to the invention and AI/ML subject-matter eligibility concerns.

In February 2024, the United States Patent and Trademark Office (USPTO) issued guidance on inventorship and subject matter eligibility for AI/ML-assisted inventions.[1] The guidance applies to all U.S. patents and applications filed after February 13, 2024, and provides guidelines for determining whether and when a natural person may be named as an inventor on an invention made in whole or in part using AI/ML and what AI/ML-assisted inventions constitute patentable subject matter.[2]

Humans must be involved to identify "a specific problem to elicit a particular solution."

Conception of an idea is the key factor in determining inventorship and is often described as the *mental* act of invention.[3] A mental act is something only humans can perform. Therefore, when a natural person uses an AI/ML system to create an invention, the analysis of conception should focus on the human inventor's activities.[4]

The human must do more than merely recognize a problem to be solved. Solutions generated from AI/ML tools with generalized instructions may not be entitled to patent protection.[5] A human should have **a specific problem and a particular solution** in mind when creating or prompting the AI/ML tool.[6]

1 Inventorship Guidance for AI-Assisted Inventions, 89 Fed. Reg. 10043, 10043-44 (Feb. 13, 2024); 2024 Guidance Update on Patent Subject Matter Eligibility, Including on Artificial Intelligence, 89 Fed. Reg. 58128, 58128-58138 (July 17, 2024).
2 89 Fed. Reg. at 10044-45; 89 Fed. Reg. at 58128-29.
3 *Ethicon, Inc. v. U.S. Surgical Corp.,* 135 F.3d 1456, 1460 (Fed. Cir. 1998) ("Because '[c]onception is the touchstone of inventorship,' each joint inventor must generally contribute to the conception of the invention.") (quoting *Burroughs Wellcome Co. v. Barr Labs.,* Inc., 40 F.3d 1223, 1227-28 (Fed. Cir. 1994)); see also *Univ. of Utah v. Max-Planck-Gesellschaft Zur Forderung Der Wissenschaften E.V.*, 734 F.3d 1315, 1323 (Fed. Cir. 2013).
4 89 Fed. Reg. at 10046; *Thaler v. Vidal*, 43 F.4th 1207, 1213 (Fed. Cir. 2022) ("[O]nly a natural person can be an inventor, so AI cannot be."), cert denied, 143 S. Ct. 1783 (2023).
5 89 Fed. Reg. at 10048; see also *Burroughs Wellcome*, 40 F.3d at 1228 ("An idea is definite and permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan [the inventor] hopes to pursue.").
6 89 Fed. Reg. at 10048.

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In drug discovery, humans should be defining R&D project scope early in the process, such as identifying a particular class of compounds to research or a particular target upon which to focus. This is an example of a human having a "particular solution" in mind, so the resulting invention solving the particular problem can be considered "conceived" by the human inventor.[7]

Humans should be making "substantial contributions" to patent claims.

Where two or more inventors are involved, each joint inventor must contribute in some significant manner to the invention.[8] Humans who create an invention using an AI/ML system must likewise contribute significantly to the invention.[9]

In determining inventorship of AI/ML-assisted inventions, the *Pannu* factors apply.[10]

A potential joint inventor must have

1. "Contribute[d] in some significant manner to conception or reduction to practice;"
2. Made "a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention;" and
3. Done more than merely explain well-known concepts or the current state of the art.[11]

It follows that a single person who uses an AI/ML system to create an invention is also required to make a significant contribution to the invention, according to the Pannu factors, to be considered a proper inventor.[12]

Where an AI/ML-assisted invention has only one human inventor, that person must have recognition and appreciation of the **entire** invention.[13] Although each joint inventor does not need to contribute to every claim in a patent, in AI/ML-assisted inventions, at least one ***human*** must have significantly contributed to each claim.[14] This is consistent with the *Thaler* ruling that a patent application cannot include claimed inventions developed **only** by an AI/ML system.

Given that patent claims often involve multiple steps and/or components, tracking how humans contribute to the conception of specific claim elements is important. Similarly, company communications should recognize the significant contributions of humans to the inventions. Planning a patent claim drafting strategy during AI/ML development and involving experienced patent counsel earlier in the R&D process, and frequently throughout, are best practices.

Consider the contributions of, and potential ownership by, third parties.

A human who develops a key building block from which a claimed invention is derived may have contributed to conception of the invention, even if they were not directly

7 *Id.*
8 *Pannu v. Iolab Corp.*, 155 F.3d 1344 (Fed. Cir. 1998); see also *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1473 (Fed. Cir. 1997) ("'[A] joint inventor must contribute in some significant manner to the conception of the invention.").
9 89 Fed. Reg. at 10048 ("[A] significant contribution could be shown by the way the person constructs the prompt in view of a specific problem to elicit a particular solution from the AI system.").
10 Id.
11 *Pannu*, 155 F.3d at 1351.
12 89 Fed. Reg. at 10048.
13 *Id.* at 10047.
14 *Id.* at 10047-48.

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involved in each and every step leading to its creation.[15] Relatedly, individuals who *design, build or train* AI/ML systems with the goal of solving a specific problem to produce a particular solution could be considered inventors if their work is deemed a significant contribution.[16] Identifying wrong inventors in a patent application makes any patent issuing therefrom vulnerable to challenges, so initially identifying the correct inventors is important.

In the U.S., ownership of a patent or patent application "initially vests in the named inventors of the invention of the patent," unless they transfer their interest to another.[17] Only the inventor and those who derive title from the inventor (such as through a patent assignment agreement) may **own** a patent or patent application.

Tool developers can play crucial roles in inventorship of AI/ML-assisted inventions. Customers should ensure ownership of AI/ML outputs in agreements with such tool developers. Ownership terms should be carefully negotiated, balancing the developer's ability to provide services with the customer's interest to protect its underlying intellectual property (IP). Contracts with tool developers should include a clear, present assignment of all relevant IP rights and should also stipulate that the tool developer will provide any additional information or documentation necessary to prosecute or defend these IP rights.

Be prepared for patent eligibility challenges in prosecution and litigation.

The USPTO awards patents for "process[es], machine[s], manufacture[s], and composition[s] of matter."[18] The USPTO will not award a patent for "abstract idea[s], law[s] of nature, or natural phenomen[a]" without additional claim elements that add a technological improvement to the existing standard; the additional claim elements cannot be well-understood, routine, or conventional.[19] These nuances can be difficult to navigate, hence the need to involve skilled patent attorneys.

While the federal courts and the USPTO both agree that the complex two-step *Mayo/Alice* analysis first articulated by the U.S. Supreme Court governs eligibility, the USPTO often applies the two-step *Mayo/Alice* analysis differently than the federal courts. This USPTO/federal court split sometimes leads to conflicting determinations from patent examiners and judges reviewing the same or similar claims.

In its July 2024 guidance, the USPTO provided a few examples of patent claims involving AI/ML that may or may not involve patentable inventions.[20] These examples highlight the importance of including claim elements directed to specific tangible details to demonstrate patentability.[21] One USPTO example involves an AI model that analyzes glaucoma surgery patients to identify the risk of post-implantation

15 89 Fed. Reg. at 10049; see also *Dana-Farber Cancer Inst., Inc. v. Ono Pharm. Co.*, 964 F.3d 1365, 1373-74 (Fed. Cir. 2020) and 35 U.S.C. § 116(a) ("Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.").
16 89 Fed. Reg. at 10049.
17 *Beech Aircraft,* 990 F.2d at 1248. See also 37 C.F.R. § 3.73(a) ("The inventor is presumed to be the owner of a patent application, and any patent that may issue therefrom …").
18 35 U.S.C. § 101.
19 *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012); Alice Corp. Pty. Ltd. v. CLS Bank Int'l., 573 U.S. 208 (2014).
20 89 Fed. Reg. at 58131-38.
21 *Id.* at 58138.

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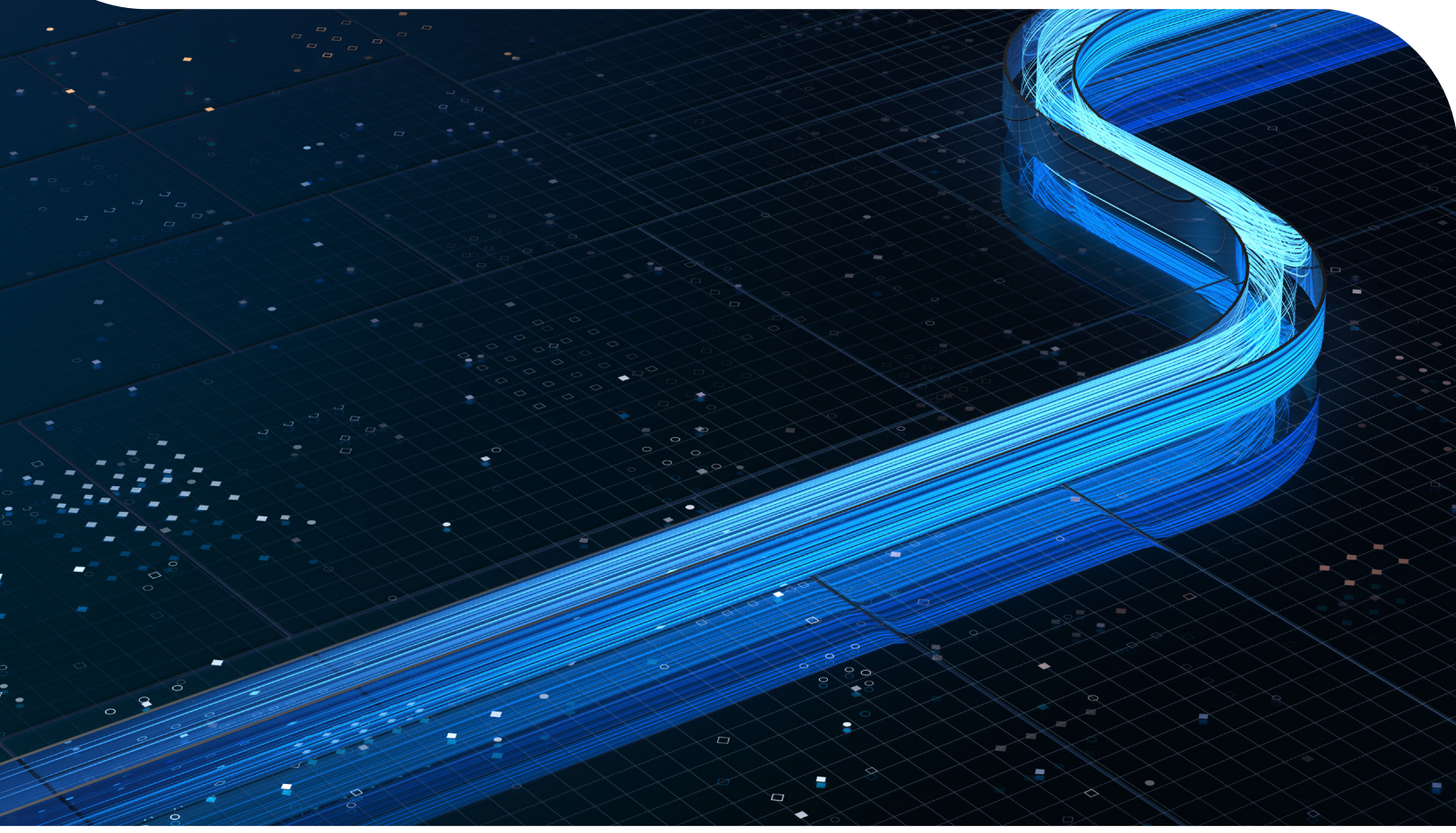
inflammation.[22] A patent claim that merely focuses on collecting a data set, identifying at-risk patients using a model trained on the data set and *prescribing* a treatment, was patent ineligible. On the other hand, *performing* treatment with a particular "Compound X" made the claim patent eligible because the claim included a treatment specific to a patient population identified by AI modeling. Although the specific selection of patients in need of treatment may not have been a result of human conception—particularly if the training on the data set was largely automated—integrating that information into a complete, patent-eligible invention that leads to a specific treatment would likely require a human contribution.

Life sciences companies creating AI/ML-assisted inventions should involve patent counsel who are well-versed on the *Mayo/Alice* analysis in both prosecution **and** litigation to help obtain patents that are allowed by the USPTO and that will survive challenges in court.

22 July 2024 Subject Matter Eligibility Examples, pages 29-35 (Example 49. Fibrosis Treatment) (https://www.uspto.gov/sites/default/files/documents/2024-AI-SMEUpdateExamples47-49.pdf).



Q&A with Portal Innovations

Polsinelli is proud to be a partner of Portal Innovations, a life sciences venture capital firm that offers capital and lab space to early-stage biotech and medtech startups. We recently sat down for a Q&A with **Anna Tomaszewski,** Senior Director of Business Development & Partnerships for Portal, to get insights into Portal's journey, their outlook on life sciences, and why our partnership matters to their mission and vision.

Anna Tomaszewski
Senior Director of Business Development & Partnerships
Portal Innovations

What is Portal Innovation's origin story?

Portal Innovations was born from deep understanding of the challenges faced by biotech entrepreneurs. Drawing on his extensive experience scaling startups and raising capital, John Flavin, Portal's CEO & Founder, recognized the untapped potential of biotech innovation coming from Midwest universities and companies. However, he also saw the critical gap in resources—access to capital, lab space, and integrated business and scientific teams—that founders need to turn their ideas into successful ventures.

Too often, entrepreneurs were forced to relocate to coastal hubs to access these resources, as John experienced firsthand with Pyxis Oncology. This inspired him to build a robust infrastructure within emerging markets, allowing talent and innovation to stay rooted locally and thrive nationally.

Portal's flagship location in Chicago was the first step in this vision, sparking rapid growth and paving the way for expansion into cities like Boston, Houston, Atlanta and beyond.

Why did Portal pick the cities it is in?

Portal selects cities based on several key factors that make them ideal for nurturing life sciences innovation, including:

- Leading academic and medical center institutions;
- High levels of NIH grant funding for life sciences research;
- A growing density of scientific and professional talent;
- Urban economies primed for growth at the intersection of IT and life sciences;
- Attractive live-work-play environments for talent recruitment and retention;
- State and local governments committed to prioritizing the life sciences sector;
- Limited early-stage venture capital presence;
- A lack of specialized lab infrastructure.

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What are some of the innovations that the companies in your ecosystem are developing?

- Grove Biopharma in Chicago — Protein-Like Polymers (PLPs): they are synthetic biologics that can be customized to engage intracellular targets with large, disordered interaction domains;
- March Biosciences in Houston — Engineered T cells (CAR-T) to treat T-cell cancers while avoiding cell fratricide and severe immunodepletion;
- Synaptrix in Atlanta — NOVABLOC: a procedure-based solution that delivers a novel type of electrical stimulation to relieve pain for 20+ days;
- Syntis Bio in Boston — A pill-deployed polymer to suppress nutrient absorption in the gut (bariatric surgery in a pill) and extend the half-life of oral drugs.

Why are partners like Polsinelli important to Portal's success?

Building a thriving life sciences ecosystem requires collaboration across various domains of expertise. Polsinelli's experienced and entrepreneurial attorneys play a critical role in guiding and supporting startups within Portal's ecosystem. Their partnership ensures that biotech companies have the legal foundation they need to navigate complex challenges and achieve success.

In addition to our partnership, Polsinelli is advising Portal Innovation on a range of legal matters, including intellectual property and tax planning.

A Busy Biotech Week Boston

This fall, Polsinelli participated in Biotech Week Boston, a week-long calendar of events focused on the life sciences and biotech community in Boston and beyond that attracted participants from all over the world. The firm partnered with Portal Innovations to kick off the week, hosting a panel on the Strategic and Legal Trends in the Boston Biotech Market featuring Tara Nealey, Ph.D. (Chair of Biotech and Life Sciences Patent Prosecution Practice), Brian Larivee (Counsel, Hatch-Waxman and Biologics Practice), Michael Gaba (Vice Chair of Food and Drug Law Practice) and Andrew Merken (Partner, Venture Capital and Emerging Growth Companies Practice). Polsinelli's presentation was followed by a panel highlighting non-profits making a significant impact in the life sciences sector including Termeer Foundation, Nucleate and Latinos in Bio and Women in the Enterprise of Science and Technology (WEST).

Pictured from left to right: Brian Larivee, Tara Nealey, Ph.D., Michael Gaba and Andrew Merken

Later in the week, Polsinelli attorneys participated in sessions hosted by Redefining Every Stage of Investment (RESI) Boston/Life Science Nation and covered topics including Landing Your Company in the Boston Life Science Ecosystem: US Patent Prosecution and Food and Drug Administration (FDA) Considerations for Non-US Companies (Nealey and Gaba), Venture Capital- (VC-) Proofing Your Intellectual Property (IP), Licensing and FDA Approvals (Nealey, Gaba, Kat Holliday of the Harvard Tech Transfer Office and Prashant Shah of o2h Ventures) and Family Offices – Perspectives on Early Stage Investments (Merken, John Abeles of Northlea Ventures, Michael Langer of T.rx Capital, John Parker of Springhood Ventures and Sunil Shah of o2h Ventures).

Pictured from left to right: Andrew Merken, Sally Wang, Karl Hess, Bryan Ennis, Tara Nealey and David Hsu

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Polsinelli also hosted dinner for a group of life science C-suite executives, investment bankers, VC investors, tech transfer office officials, consultants and public relations professionals. To finish the week, Nealey and David Hsu, Ph.D. (Electrical Engineering and Computer Science Patent Prosecution Practice) were joined by Bryan Ennis (Sware, Inc.), Sally Wang (HighLight Capital) and Karl Hess (Outcome Capital) in an engaging discussion on Technology Advances in Life Sciences followed by networking with members of Boston's biotech community.

Polsinelli enjoyed helping connect leaders in the life sciences ecosystem, and looks forward to participating again this year!

Perspectives from the Host of The *10 Minute* HealthBizCast

Bobby Guy
Shareholder
Corporate Mergers
& Acquisitions
Nashville

The *10 Minute* HealthBizCast is now in its 8th season and hosted by Polsinelli shareholder Bobby Guy. The podcast features interviews with executives and thought leaders in the healthcare and life sciences industries and focuses on the future of US healthcare. Season 8's focus is on "rapid, incremental change."

At *The 10 Minute* HealthBizCast, we think that the coming revolution in life sciences is going to change US healthcare in remarkable ways. In fact, we think this revolution is one of the five major trends that will shape healthcare over the next decade. Several of our guests on Album 8, which began in September 2024 and will finish in January 2025, discuss biotech, diagnostics, and health data issues.

We kicked off the album with an interview with Baxter Lee, CFO of Clearwater, a leader in cybersecurity and compliance, discussing his views on how to adapt to the continuous targeting of healthcare data and how to increase protection – a problem that will require a rapid shift to address.

Track 3 featured Hans Keil of Nurture Genomics. Nurture is working to diagnose actionable genomic conditions in children with a mission to convert sickcare into wellcare -- preempting disease before it becomes entrenched.

Bill Brown of Genomind talks to us on Track 7 about his company's work to break barriers in the field of personalized medication management or pharmacogenomics. Genomind has the potential to dramatically change the trial-and-error methods of prescribing drugs by looking at DNA compatibility, and Bill talks about this, as well as the difficulties of finding a payor source for advanced diagnostics.

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The theme running through many of our life sciences interviews is the opportunity to dramatically change patient outcomes and experience, if only our conventional medical systems (and payor sources, including Centers for Medicare and Medicaid Services (CMS)) would provide more support and less resistance.

Another of the other consistent themes that we encounter across every album, especially when interviewing leaders from the healthcare provider space, is how many inefficiencies they see that are blue sky opportunities for the life sciences industry – challenges just waiting to be seized by healthcare entrepreneurs.

We are excited to continue exploring these themes, and new ones that are sure to arise, as we finish Album 8 and then launch Album 9 in Spring 2025.

The *10 Minute* HealthBizCast Guests

Baxter Lee
CFO
Clearwater

Hans Keil
Nurture Genomics

Bill Brown
Genomind

The ***10 Minute*** **HealthBizCast** is available on all streaming platforms.

To sign up for the mailing list and to receive information about when we're launching new albums, **click here**.

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Subscribe to stay up-to-date on all our Life Sciences industry events and updates.

SUBSCRIBE

Reception during the JP Morgan Conference

Monday, January 13

RSVP

Webinar: Part One: President-Elect Trump Told Robert F. Kennedy Jr. to "Go Wild on Health." *What Might That Mean for the FDA?*

Wednesday, January 15

RSVP

Reception during the BIO International Convention

Monday, June 16

RSVP

Editorial Board

Polsinelli's multidisciplinary Life Sciences team provides clients with a full-service approach through every lifecycle stage and can serve as outside counsel for any legal need including those unique to the industry.

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