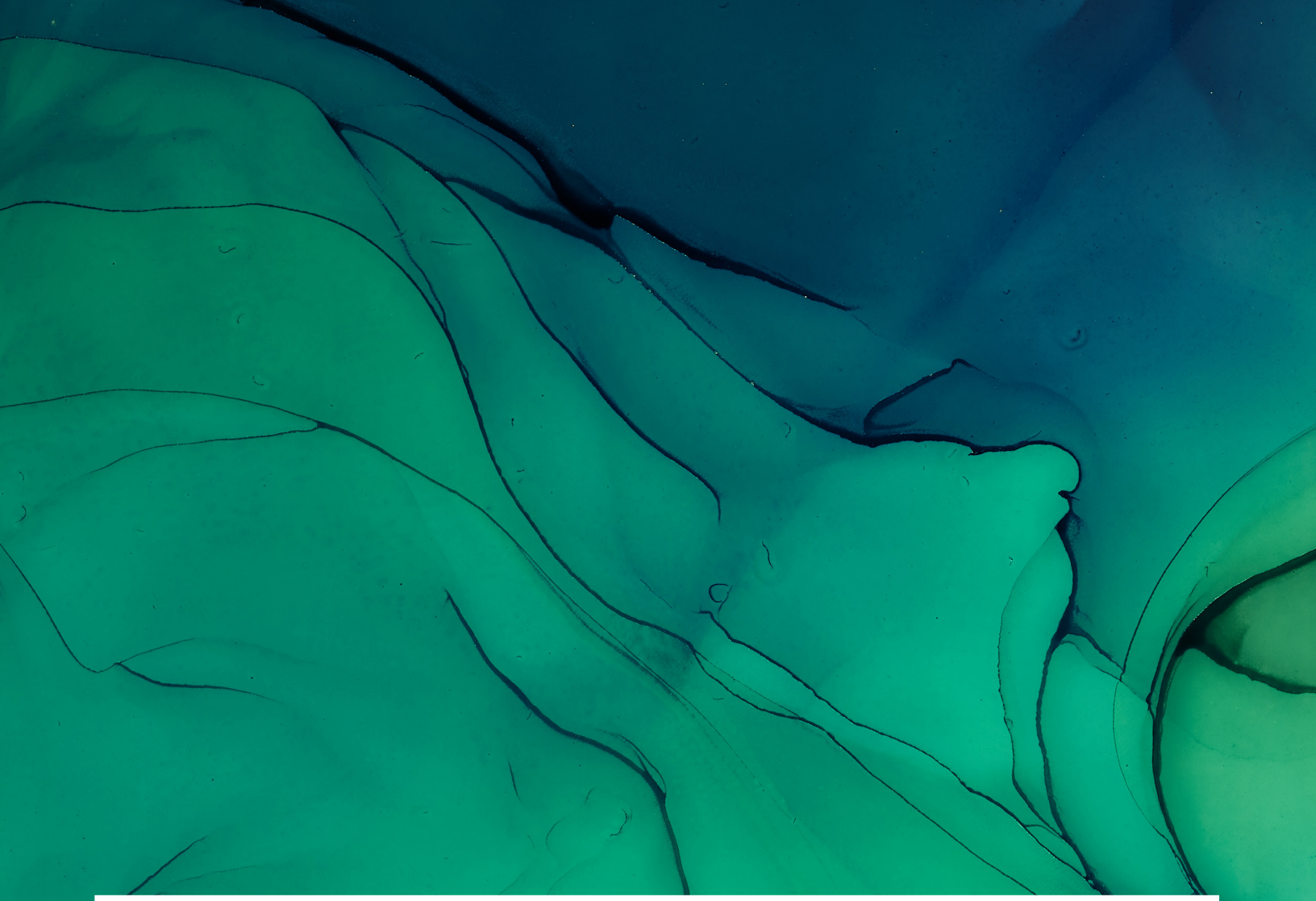

LIFE SCIENCES INDUSTRY UPDATE

2024 Mid-Year Report

Ballard Spahr LLP

ATTORNEY ADVERTISING

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LIFE SCIENCES LANDSCAPE: 2024 MID-YEAR INDUSTRY UPDATE

ARTIFICIAL INTELLIGENCE IN LIFE SCIENCES

By Charley F. Brown

Life sciences companies are forming AI-driven strategic collaborations with tech giants, creating synergy that promises to revolutionize the industry. Companies like NVIDIA, Microsoft, Google, and AWS are at the forefront of these partnerships, leveraging their advanced AI capabilities to enhance various aspects of life sciences operations.

For instance, NVIDIA's BioNeMo drug discovery cloud service allows biopharma firms to develop and customize generative models, accelerating the drug discovery process, and providing a scalable solution for companies looking to innovate rapidly.

Microsoft is also playing a significant role in transforming drug discovery and development through its AI technologies. By partnering with Novo Nordisk and Novartis, Microsoft is applying its GenAI tools to streamline research and development efforts, making the drug discovery process more efficient and cost-effective. These collaborations harness Microsoft's extensive suite of AI-driven services, such as Copilot and Microsoft Azure, to drive advancements in precision medicine and personalized health care solutions. The integration of AI in these processes is expected to reduce time-to-market for new drugs and improve overall patient outcomes, showcasing the profound impact of these strategic alliances.

Similarly, Google and Amazon Web Services (AWS) are contributing to the AI-driven transformation of the life sciences sector. Google's Target and Lead Identification Suite and Multiomics Suite are designed to accelerate drug discovery and facilitate the sharing of vast genomic data, enhancing precision medicine efforts. AWS, with its comprehensive cloud services, is collaborating with companies like Amgen and Pfizer to integrate AI into drug manufacturing and regulatory processes. These partnerships illustrate a broader industry trend where the convergence of AI and life sciences is fostering innovation. The combined expertise of tech giants and biopharma companies is setting the stage for unprecedented advancements in life sciences, making these collaborations crucial for the future of the industry.

FRAMEWORK PROPOSED FOR USE OF BAYH-DOLE MARCH-IN RIGHTS

By Scott D. Marty, Ph.D.

Since President Biden signed the Inflation Reduction Act into law August 16, 2022, all eyes have been on the implementation and effect on President Biden's effort to lower drug costs. The Biden-Harris administration has announced additional actions to lower health care and prescription drug costs. One of those actions includes what is known as "march-in" rights under the Bayh-Dole Act. That is, when an invention is made using taxpayer funds, under certain circumstances, the government may exercise a right to "march-in"—to unilaterally sublicense privately owned patents to other applicants under certain circumstances. To date, the government has never exercised march-in rights under the Bayh-Dole Act.

The Bayh-Dole Act at 35 USC § 203 specifically provides for the government's ability to unilaterally sublicense privately owned patents created using government funding, and the contractor (often the patent owner) or its assignee has failed to take steps to put the invention into practical application, to use the invention to alleviate health or safety needs, to meet requirements for public use specified by federal regulations, or if such action is necessary because the contractor has not complied with the preference for U.S. industry.

On December 7, 2023, in conjunction with a fact sheet released by the Biden-Harris administration, the administration announced new action to lower health care and prescription costs by promoting competition. On the same day, the U.S. Department of Commerce's National Institute of Standards and Technology (NIST) released a request for information, along with a proposed framework for agencies, for the exercise of march-in rights, which specify for the first time that price can be a factor in determining that a drug or other taxpayer-funded invention is not accessible to the public. The proposed framework made it clear that price can serve as a basis for exercising march-in rights. This came as a bit of a surprise in view of the prior administration's proposed rule that would have prevented the government from exercising this authority on the basis of high price alone.

The proposed framework requires that a federal agency consider three questions when analyzing whether to exercise the government's march-in rights. First, the invention in question must be subject to the Bayh-Dole Act, namely it must have been first conceived or reduced to practice through federally funded work. Second, the government must determine whether a statutory criterion has been met. Third, march-in must support the policy objective of the Bayh-Dole Act. As for the second criterion, the draft framework provides numerous factors to consider, including the practical application of the march-in rights, health and safety needs, and public use requirements. Public comments were accepted until February 6, 2024.

As one might expect, the many commenters about the proposed framework included the Federal Trade Commission, ranking members of the Senate HELP Committee, trade associations, nonprofit advocacy groups—such as the Bayh-Dole Coalition, Council for Innovation Promotion, and the Incubate Coalition—as well as universities, investors, and other interested parties. The comments have resulted in at least three letters from Congress to the Biden administration. Commenters have expressed concern that permitting pricing as a trigger for march-in rights would stifle commercialization of federally funded inventions and foster uncertainty around drug development. Others have expressed concerns that the exercise of march-in rights would not actually have the desired effect of increasing competition or lowering prices due to the patent thickets around most drug products, the steep requirements for regulatory approval, and the overall vagueness of how pricing factors into the framework.

While both supporters and opponents of the proposed framework view them as having a broad scope, march-in rights can be exercised only on patents that result from federally funded research, and they can enable generic entry only if all patents on a drug were federally funded and regulatory approval is obtained. Whether the government exercises its march-in rights for the first time remains to be seen, but one can be assured that the discussion is ongoing.

PATENT ELIGIBILITY RESTORATION ACT ADVANCES

By Catherine I. Seibel

On June 22, 2023, the U.S. Senate released the Patent Eligibility Restoration Act of 2023 (PERA), a bill that modifies the language of 35 U.S.C. § 101 and eliminates all judicially created exceptions to patent eligible subject matter. The bill was introduced by Senators Thom Tillis and Chris Coons to clarify the current legal framework for determining subject matter eligibility, which they claim has led to unpredictable outcomes and the undermining of American innovation.

By way of background, Section 101 broadly defines what subject matter is eligible for a patent in the United States, but, over time, courts have created several exceptions to eligible subject matter. Accordingly, courts currently assess subject matter eligibility under the framework established by *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014) and *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012). Under this framework, even if a claim is directed toward a category of eligible subject matter under Section 101, a court must also ask if the claim nonetheless is also directed to one of the judicial exceptions. If it is, the court must ask whether the claim recites significantly more than the exceptions. As a result, most courts' analyses of this issue hinge on the judicial exceptions to eligible subject matter.

The act proposes several changes to the law. First, PERA eliminates all judicial exceptions to patent eligibility. Second, PERA amends Section 101 to state that "[a]ny invention or discovery that can be claimed as a useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, is eligible for patent protection," provided it meets other patentability requirements such as novelty and nonobviousness. Third, PERA enumerates several narrow statutory exceptions to eligibility, including unmodified human genes and a mental process performed solely in the mind of a human being.

Proponents of PERA contend that the current legal framework and the judicial exceptions to Section 101 have not just created uncertainty in the law, but overly restrict what can be patentable. Stakeholders in the technology and biotech industries in particular have argued that the judicial exceptions to eligible subject matter have stifled innovation and investment, especially in fields like artificial intelligence, pharmaceuticals, and medical diagnostics. For proponents, PERA will restore patent eligibility in many fields while providing clarity over patentability of ideas, laws of nature, and content that is beyond the scope of the patent system.

A hearing was held on January 23, 2024, before the Committee on Intellectual Property (a subcommittee of the Senate Judiciary Committee) to discuss the proposed legislation and hear positions both in support and in opposition to the bill. As expected, supporters testified that PERA would make the patent system more predictable and conducive to technological advancements and competition, particularly because it would bring U.S. standards in line with the eligibility criteria of other countries. While the bill seems widely supported across the patent community, some critics of the legislation contended that overly broadening patent eligibility could clutter the patent system with low-quality patents and actually stifle innovation.

In terms of next steps, the full Senate Judiciary Committee will review and debate PERA and may amend it before sending it to the Senate floor, and eventually to the House of Representatives for additional debate and review. Interested stakeholders will have several more opportunities to weigh in, and the text may change over the numerous forthcoming steps in the legislative process. But if PERA is passed, there is no doubt that it will significantly impact the U.S. patent system.

SENATORS PUSH PREVAIL ACT TO ADDRESS PATENT LAW CONCERNS

By Kenneth H. Sonnenfeld, Ph.D.

In 2011, Congress passed the America Invents Act (AIA), which created mechanisms for third parties to challenge patent validity. Under the AIA, the validity of newly issued patents may be challenged in the U.S. Patent and Trademark Office (USPTO) on prior art, sufficiency of description, and other grounds if a petition raising such issues of validity is filed within nine months of grant using the post grant review (PGR) procedure. After nine months from grant, a PGR may no longer be filed, but a third party may challenge a patent by filing a petition for inter partes review (IPR), where a petitioner can challenge invalidity by providing grounds that the claims of the issued patent are invalid as not being novel or are obvious in view of written publications or published patents or patent applications.

Under the current statute there are relatively few restrictions on who may file a petition for PGR or IPR, provided that the real party in interest is identified. In addition, under the current statute, the party petitioning for a finding of invalidity through a PGR or IPR need only prove the claims are invalid by a preponderance of the evidence, compared to the clear and convincing standard of evidence required to prove invalidity in a district court proceeding. According to the USPTO, during about the first 10 years of experience with IPRs and PGRs, about 32% of patents challenged by an AIA proceeding were at least partially invalidated by the USPTO (see https://www.uspto.gov/sites/default/files/documents/ptab__aia_fy2022_roundup.pdf). In AIA proceedings that went to a final written decision, over 80% invalidated one or more patent claims. *Id.* In view of the relatively high rate of patents being invalided by AIA proceedings and the corresponding uncertainty as to the strength of U.S. patents, on July 10, 2023, Senators Coons, Tillis, Durbin, and Hirono introduced the Promoting and Respecting Economically Vital Innovation Leadership (PREVAIL) Act.

The PREVAIL Act cites to congressional findings of the importance of patents to the economic success of the United States and that "[r]eliable and effective patent protection encourages United States inventors to invest their resources in creating new inventions." Intellectual property-intensive industries are cited as generating tens of millions of U.S. jobs and account for a third of the U.S. gross domestic product. Citing to unintended consequences of the AIA, the PREVAIL Act proposes changes to the patent statute to address several problems the authors of the bill believe weaken U.S. patents. Among the proposed changes are creating a code of conduct applicable to the Director of the USPTO and the Administrative Patent Judges (APJs) who decide AIA proceedings. One such change would be that an APJ who participates in a decision to institute a PGR or IPR shall be ineligible to hear the review. Although there are several procedural changes directed at reducing the number of

potential patent challenges, three proposed substantive changes could significantly reduce the number of invalidity findings. The first significant change would be applying the presumption of validity to previously issued claims of a patent challenged through either an IPR or PGR. Along with the presumption of validity, the second substantive change would increase the burden to prove invalidity in both IPR and PGR proceeds for previously issued patent claims from a preponderance of the evidence to clear and convincing evidence. The third substantive change would codify a rule change from 2018 requiring claims to be interpreted as they would be in a court action rather than using the broadest reasonable interpretation standard.

An informative summary of the PREVAIL ACT may be found at https://www.coons.senate.gov/imo/media/doc/prevail_act_fact_sheet.pdf.

JUDICIAL DECISIONS IMPACT THE SCOPE OF THERAPEUTIC PATENT CLAIMS

By Margaret Bolce Brivanlou, Ph.D.

Recent judicial decisions have limited patent applicants' ability to claim large and small molecule inventions by their function, creating a challenge to cover a competitor's therapeutic based on discovery of a therapeutic activity. Enablement and written description are bedrock statutory patent law requirements that the patent specification must describe and teach someone in the field how to make and use the full scope the patent claim. Over a year ago, the U.S. Supreme Court decision in *Amgen v. Sanofi* (598 U.S. 594 (2023)) clarified and emphasized the enablement standard in patent law for claims to biologics, and likely other inventions as well.

Amgen had patents covering antibodies that bound a specific "sweet spot" on PCSK9 and were effective in treating hypercholesteremia. Both Amgen and Sanofi developed anti-PCSK9 antibodies, which came to market around the same time, and Amgen asserted its patents against Sanofi's anti-PCSK9 antibody, attempting to keep it off the market. After years of litigation, the Court sided with Sanofi, confirming that Amgen's patent specification with 26 antibody examples and structural analysis of the antibody-PCSK9 binding did not enable the genus of antibodies falling within Amgen's claims. Dismissing Amgen's argument that the specification provided a roadmap for using routine methods to produce the group of antibodies, the Court found the specification to be essentially a "research assignment" or "hunting license," suggesting that the enablement requirement necessitated disclosure of many more antibodies having the claimed function.

Since the decision last year, federal courts and the USPTO have expressly followed *Amgen* to hold claims to functionally defined biologics unpatentable. For example, the Federal Circuit, in *Baxalta Inc. v. Genetech, Inc.* (81 F.4th 1362 Fed. Cir. 2023) invalidated Baxalta's patent for antibodies that bind Factor IX and its increased procoagulant activity, finding the claims were essentially indistinguishable from those in *Amgen*.

These decisions reinforce the challenge to enforce patent claims covering more than the specific therapeutic even if the inventor had identified a groundbreaking therapeutic mechanism leading to a class of new therapeutics. Patent applicants are exploring new approaches to obtaining and enforcing claims that could cover a functional class of molecules—including "means plus function" claim strategies that cover the molecule disclosed in the specification and its "equivalents" (*In re Chamberlin*, Appeal 22-1944 (PTAB)). We will monitor as courts vet the scope and enforceability of these and other strategies for claiming functionally defined classes of molecules. We provide counsel on clients' patent portfolios, as well as implications for those of third parties potentially relevant to therapeutic products.

OVERTURNING OF *CHEVRON* LIKELY TO AFFECT REGULATORY OUTLOOK

By Kate A. Belinski and Katlyn E. Koegel

Ending the doctrine of *Chevron* deference, the Supreme Court's decision in *Loper Bright Enterprises v. Raimondo* and *Relentless, Inc. v. Department of Commerce* earlier this summer changed the regulatory landscape for the next generation. While it is still too early to appreciate the full impact of the decision, three main effects are anticipated for the life sciences industry: (1) shifts in agency resources and a focus on informal guidance; (2) an increase in challenges to divisive Food and Drug Administration (FDA) decisions; and (3) supplemental challenges to agency authority under the Inflation Reduction Act (IRA).

The Court's *Loper* decision implies that executive agencies' findings of fact should be afforded "due respect" if supported by "substantial evidence." While lower courts may no longer defer to an agency's reasonable interpretation of legal questions, they may consider an agency's technical expertise as it relates to factual determinations. For the FDA, Centers for Medicare & Medicaid Services (CMS), and myriad other agencies, there is an incentive to focus resources on accumulating "substantial evidence" to support their positions instead of issuing formal regulations. In the same vein, agencies are likely to rely more heavily on informal guidance documents, leaving industry actors to discern whether to follow the informal guidelines, wait for Congress to issue unambiguous statutes, or try to resolve uncertainties in court.

Second, prior decisions based on *Chevron* do not have "special justification" for overruling the holdings, but reliance on *Chevron* is "an argument that the precedent was wrongly decided." For the life sciences industry, this opens the floodgates to potential litigation, particularly applied to the FDA's assertion of jurisdiction over medical products and administration of exclusivities. In previous product jurisdiction cases, courts deferred to the FDA, which justified its exercise of authority by citing its mission to protect public health. In exclusivity cases, the FDA justifies its choice between manufacturers through statutory interpretation and policy considerations. Without *Chevron*, these choices are now in the hands of the judiciary—and it is still unclear how different courts will interpret and apply statutes.

Finally, as challenges to the constitutionality of the IRA continue to play out in the courts, rejected contenders might have another avenue to fight the drug selection and negotiation process. If the statutory scheme is upheld, actors can still challenge agency implementation of the IRA on the basis of statutory ambiguity. However, since the IRA expressly exempts some agency determinations from "administrative or judicial review"—a provision which itself might be held unconstitutional—it is unclear whether these challenges will succeed. One thing is clear: With *Chevron* overturned, actors dissatisfied with agency regulations now have the power to seek judicial redress with no fear of deference.

MERGERS AND ACQUISITIONS: NUMBER OF LIFE SCIENCES DEALS RISES, DOLLAR VALUE LAGS

By Ryan J. Udell

It was the best of times (for mid-sized M&A) and the worst of times (for large deals) for the life sciences sector so far this year. While deal volume (by announced deals) remains robust, dollar value trails.

Through mid-year, we remain on track for a record number of $1 billion plus acquisitions. With strong balance sheets—hundreds of billions of dollars of "dry powder"—and staring down the abyss that is the patent (revenue) cliff, late stage assets became front and center in the first half-year of deal making. Well over half of the $1 billion-plus deals announced were for clinical stage assets, which is significantly higher than the "pandemic period." While capital continues to become easier to access, it continues to be a bumpy road that will likely not smooth out until we have a more definitive read on inflation, interest rates, and the larger economy. There is also the small matter of an election in the fall and continued, complex geopolitical forces at play (*e.g.*, China, Russia v. Ukraine, the Middle East). So smaller biotechs continue the trend of being open for M&A business (and other strategic alternatives). With many willing buyers and sellers, it is natural to see a robust market for such assets. Thus far, Novartis, Merck, AbbVie, and Novo Nordisk have been the most active buyers.

Strong regulatory headwinds in the United States and elsewhere continue to discourage so-called mega-mergers in general and particularly in the life sciences market. Indeed, through mid-year, no biopharma M&A transactions have been announced with values over $10 billion. Interestingly, CDMO and pharma services deal volume are up substantially and have accounted for approximately 50% of deal count year-to-date.

Therapeutic areas that have seen the most activity include obesity, as well as the usual suspects oncology, neurology, cardiovascular, dermatology, and ophthalmic. However, both oncology and neurology are trending down through the first half of the year.

All of this was largely what we had expected when we provided our outlook at the beginning of the year after attending the JP Morgan Healthcare Conference. We appear to be entering a new market of more but smaller, and we expect that to continue through the end of the year. Stay tuned for our report after JP Morgan 2025 to see if we were right!

CAPITAL MARKETS: LIFE SCIENCES IPOS TRENDING STRONGER

By Brian D. Short

The U.S. capital markets for life sciences businesses have shown resilience and adaptability in the face of economic uncertainties and evolving regulatory landscapes.

Initial public offerings (IPOs) for life sciences companies have seen an uptick to date in 2024. However, it has not been the big opening of the IPO market that many had expected earlier in the year. The third quarter is also normally a slow IPO period, as investment banks avoid road shows and pricing during the summer months. This year poses an additional challenge with the U.S. presidential election in November, and we expect investment banks to avoid such activity during the weeks surrounding the election.

Even though we are not likely to realize the number of IPOs that many expected for this year, 2024 is trending stronger for life sciences IPOs compared to last year. In addition, the market is viewing the industry more favorably, and IPO candidates should continue to prepare for a potential IPO and life as a public company.

ANTITRUST COMPLIANCE AND NONCOMPETE AGREEMENTS DRAW AGENCY SCRUTINY

By Stephen J. Kastenberg, Elizabeth P. Weissert, and Meredith S. Dante

In recent months, antitrust enforcement agencies, including the Federal Trade Commission (FTC) and the Department of Justice (DOJ) Antitrust Division, have engaged in rulemaking and investigations that could have a significant impact on the life sciences industry. In particular, the enforcers continue to focus on competition in the labor markets, merger activity, and the health care and prescription drug industries.

On April 23, the FTC issued a final rule that would prevent most employers from enforcing noncompete agreements against workers in almost all circumstances, with only limited exceptions for existing noncompetes with senior executives and noncompetes made in connection with the bona fide sale of a business. The final rule becomes effective September 4, 2024, but has already been challenged. On April 24, the U.S. Chamber of Commerce filed suit in federal court in Texas alleging the FTC lacks authority to issue the rule, and other challenges followed. On July 3, the U.S. District Court for the Northern District of Texas granted motions for a preliminary injunction to prevent the FTC's rule banning noncompete clauses from taking effect, but the court's order only applied to the named plaintiffs—not nationwide. The court has indicated it will issue a final order on the merits by August 30, possibly enjoining the noncompete rule nationwide.

On July 9, the FTC issued an interim staff report on pharmacy benefit managers (PBMs). The FTC has been conducting an investigation into PBMs since 2022 through its authority under Section 6(b) of the FTC Act. The interim report details the FTC's preliminary finding about how increasing vertical integration and concentration has enabled the six largest PBMs to manage nearly 95 percent of all prescriptions filled in the United States. The FTC has indicated it intends to continue the investigation and provide further updates.

On March 5, at a workshop focused on the impact of private equity investment in the health care market, the DOJ, FTC, and U.S. Department of Health and Human Services (HHS) announced the launch of a public inquiry into private equity ownership in the health care field. Then, on May 9, the DOJ announced that it has created the Health Care Monopolies and Collusion (HCMC) Task Force within its Antitrust Division to pursue investigations, and, where warranted, civil and criminal enforcement in the health care industry.

In December 2023, the FTC and DOJ issued revised merger guidelines, which guide the agencies' review of mergers and acquisitions to determine compliance with federal antitrust law. Some of these changes target firms that might seek to use a merger to engage in a portfolio leveraging strategy by cross-market bundling their products. Guideline 6 provides that the agencies will examine "whether one of the merging firms already has a dominant position that the merger may reinforce, thereby tending to create a monopoly [and] whether the merger may extend that dominant position to substantially lessen competition or tend to create a monopoly in another market." This issue played out when the FTC challenged Amgen's

acquisition of Horizon Therapeutics. *FTC v. Amgen Inc. and Horizon Therapeutics plc* (Civ. Action No. 1:23-cv-03053 in N.D. Ill.). This challenge resulted in a September 1, 2023, consent order, pursuant to which Amgen was prohibited from bundling any Amgen products with Horizon's medications. Many of these changes also target private equity acquisitions, in particular roll-up acquisitions, where a buyer acquires multiple companies in the same industry. For example, Guideline 8 provides that if a proposed "transaction is part of a firm's pattern or strategy of multiple acquisitions, the Agencies consider the cumulative effect of the pattern or strategy[.]"

The FTC has also been focused on brand pharmaceutical manufacturers' listing of patents in the FDA's Orange Book. Patents listed in the Orange Book trigger the Hatch-Waxman regulatory scheme governing the process for challenging for patent infringement generic drugs under FDA approval consideration. On September 14, 2023, the FTC issued a policy statement warning pharmaceutical companies that make and sell brand-name drugs that they could face legal action if they improperly list patents in the FDA's Orange Book. Then, on November 7, 2023, the FTC issued notice letters to 10 drug manufacturers challenging more than 100 patents relating to brand-name asthma inhalers, epinephrine autoinjectors, and other drug products as allegedly improperly or inaccurately listed in the Orange Book. And on March 22 this year, the FTC filed an amicus brief in *Teva Pharmaceuticals USA, Inc. v. Amneal Pharmaceuticals, Inc.* (Civil Action No. 2:23-cv-20964 in D.N.J.) arguing that Teva had improperly listed patents in the FDA's Orange Book. On June 10, the U.S. District Court for the District of New Jersey found the inhaler patents were improperly listed in the FDA's Orange Book, a ruling being appealed to the Federal Circuit.

STATE AGS TAKE A LEAD ROLE IN GOVERNMENT ENFORCEMENT AND INVESTIGATIONS

By Mike Kilgarriff

Life sciences and health care companies frequently face government enforcement actions. The perception that state Attorneys General rarely address health-related or life science issues changed following nearly $50 billion in settlements related to opioids and vaping over the past few years. State AGs frequently leverage their unfair and deceptive trade practice laws to address significant health concerns. In the wake of historic settlements, state AGs are using those same tactics to provide oversight and enforcement to ensure compliance with data privacy and health care regulations.

The following cases highlight the extensive range of state AG actions in the life sciences, encompassing data breaches, improper billing, unethical marketing, and patient safety violations:

- Centene Corporation
  - States involved: Ohio and Mississippi
  - Issue: Mismanagement of pharmacy benefits, resulting in improper billing practices
  - Settlement: $143 million to resolve disputes over pharmacy benefits management practices
- MultiCare Health System
  - State involved: Washington
  - Issue: Hiring a neurosurgeon with a history of performing unnecessary surgeries, leading to fraudulent billing
  - Outcome: Ongoing litigation with the DOJ and state authorities, highlighting issues of patient safety and compliance with medical billing standards

State AGs have broad authority over data security and breach matters, with many states enacting comprehensive privacy laws and requiring companies to notify authorities after breaches. Below are examples of the investigations and settlements state AGs pursued in data breach enforcement actions:

- DNA Diagnostics Center
  - States involved: Pennsylvania and Ohio
  - Issue: Data breach affecting 2.1 million individuals, including exposure of personal information from legacy data

  - Settlement: $400,000 and implementation of stronger data security measures, including annual security risk assessments and updated data policies

- Inmediata
  - 30 states involved
  - Issue: Exposure of health information of 1.5 million consumers
  - Settlement: $1.4 million and overhaul of data security and breach notification practices (October 2023)
  - More details: Allegations of violating HIPAA and state breach notification laws

- Nationwide Radiology Provider (New York)
  - New York State Attorney General: Letitia James
  - Issue: Failure to protect personal and health care data of over 92,000 patients.
  - Settlement: $450,000 settlement, November 2023.
  - More details: Data stolen in a ransomware attack included patient IDs, health insurance ID numbers, dates of service, provider names, types of radiology exams, and diagnoses.

Genetic testing company 23andMe recently became a target of state Attorney General enforcement following a data breach. On October 6, 2023, 23andMe disclosed that unauthorized access to their "DNA Relatives" feature led to the exposure of customer profile information, including names, sex, birthdates, locations, and genetic ancestry. Even more troubling, the breach appeared targeted at individuals with specific genetic heritage. In a letter made public by the Connecticut Attorney General, it was revealed that 23andMe did not submit a breach notification required under Connecticut law, which mandates notification without unreasonable delay and within 60 days of discovering the breach. The Connecticut Attorney General also raised concerns about 23andMe's compliance with the Connecticut Data Privacy Act (CTDPA), questioning the company's consent processes and the protection of sensitive personal information.

In addition to the Connecticut Attorney General's investigation, 23andMe faces at least 30 lawsuits related to the data breach and has requested that federal cases be consolidated into multidistrict litigation. The breach has also drawn congressional scrutiny, with Senator Bill Cassidy requesting information about 23andMe's security protocols and response efforts.

This year, cybersecurity incidents like the 23andMe breach are becoming more common. Pharmaceutical and health care organizations use patient data to deliver personalized treatments and efficient care, but digitalization raises significant privacy and cybersecurity challenges. The life sciences sector must prioritize building cyber resilience to protect the sensitive health information it handles daily from increasing cyber-attacks and data privacy concerns. Consumer health data, R&D intellectual property, and clinical trial data are particularly vulnerable. To the extent organizations lag behind in addressing potential risks, state AGs are likely to be at the forefront of investigations, seeking redress on behalf of consumers in their states.

IMPORTANT CONSIDERATIONS FOR JOINT VENTURE DEVELOPMENT OF LABORATORY AND RESEARCH SPACE

By Bart I. Mellits and Sara A. McCormick

With increasing frequency, we see private real estate developers and investors enter into joint venture arrangements for the development of laboratory and research space. Below, we've outlined a few important considerations when structuring these arrangements:

1. Strategic Alignment. Ensuring that the goals and strategic objectives of both parties are aligned is crucial. The life sciences company may prioritize long-term operational needs and specialized infrastructure, while the developer might focus on financial returns and project timelines.

2. Financial Arrangements and Funding. Specialized requirements of life science users, often including high-tech, state-of-the-art facilities, generally result in higher development costs. Similarly, competition for prime locations (particularly in established "clusters" with proximity to talent, academic institutions, and other life science companies) can also mean higher land acquisition costs. These high costs are a key reason that the joint venture structure is attractive in the life sciences sector. Understanding and agreeing on the capital requirements and financial contributions of each partner is essential. This includes initial funding, ongoing operating expenses, and contingencies for cost overruns. The parties must come to agreement on funding expectations, including mandatory contribution amounts, timing, and consequences for failures to contribute.

3. Regulatory and Compliance Issues. Navigating the regulatory landscape to obtain necessary permits and approvals, including any necessary zoning approvals, can be complex and time-consuming. The partners need to understand their responsibilities in this process, which should be laid out clearly in the venture operating agreement. Similarly, ensuring that the facility meets all industry-specific regulations, including biosafety standards and environmental regulations, is critical.

4. Design and Construction Specifics. The life sciences company will have specific technical and operational requirements, such as specialized HVAC systems, clean rooms, and laboratory spaces. These must be clearly communicated and integrated into the design and construction phases. The developer should have specific expertise in the life sciences sector, with an understanding that this type of development is often complex, requires tenant-specific customization, and tends to have a longer development timeline than in other sectors. Because the life sciences sector is subject to rapid changes in technology and market demand, the parties should think creatively about creating flexible and adaptable spaces.

5. Intellectual Property and Confidentiality. Safeguarding the life sciences intellectual property during the design, construction, and operational phases is critically important. Sensitive information and proprietary processes should be protected through nondisclosure and other legal mechanisms.

6. Governance and Decision-Making. As with other types of joint ventures, establishing a clear governance structure, including roles and responsibilities and decision-making processes, is of upmost importance for every partner in the venture. While some members may think they want to be involved in each and every decision, this might be too cumbersome in practice. Typically, the operating agreement will call for the day-to-day management to be handled by one member (which may shift from the developer to the operator after construction is complete), while the other member(s) have decision-making authority with respect to so-called "major decisions" only. The major decisions are often the subject of negotiations.

7. Transfer Rights and Exit Strategy. The operating agreement for the joint venture should include clear agreements regarding timelines and conditions under which members may transfer their interests or the venture can be dissolved or the assets liquidated, as well as the potential for buyouts, including terms under which one partner can buy out the other or sell its stake. For example, during construction, the life sciences company may want to try to prohibit transfers by the developer. On the other hand, the specific identity of the life sciences company may be a key component of the underwriting by the other member(s) of the venture, who may want to limit the life sciences company's ability to transfer its interest in the venture.

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