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Life Sciences Landscape: 2023 Mid-Year Industry Update

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The first half of 2023 has brought significant changes for businesses in the life sciences industry—from AI-powered vaccine advancements to developments in intellectual property law to shifts in real estate and the workplace. Attorneys within our multidisciplinary team provide insight into what has transpired so far this year and what lies ahead.

Drug Pricing, Negotiations, and Reimbursement – Timothy W. Jenkins and Maria Tripplaar

The Inflation Reduction Act (IRA), signed into law in August 2022, impacted a wide range of tax laws and touched many aspects of government. Significantly, part of the IRA provides Medicare with the ability to negotiate the prices of certain high-cost, qualifying single-source drugs. For the consumer, this means that Medicare will be able to negotiate directly with drug companies to lower the price of some of the most expensive Medicare Part D drugs. This was seen by many as an incredible achievement for the Biden administration, but was highly controversial within the pharmaceutical community, where the IRA was seen as a blow to the industry.

In March 2023, the Centers for Medicare & Medicaid Services (CMS) issued initial guidance about the Medicare Drug Price Negotiation Program.[1] The guidance allows for significant stakeholder input and has substantial due process built into the framework. CMS has also provided an extensive timeline to determine which Medicare drugs will be eligible for negotiation, conduct the negotiation, and then incrementally publish the maximum fair prices for the selected drugs. In 2026, the maximum fair prices for 10 selected drugs will become effective, with an additional 15 drugs in 2027, an additional 15 drugs in 2028, and an additional 20 drugs in 2029.

Unsurprisingly, Merck, one of the largest developers and manufacturers of prescription medications, sued the federal government on June 6, 2023, over the Medicare drug price negotiation program, and claimed that it is "tantamount to extortion." Specifically, in its lawsuit, Merck cites the Fifth Amendment to the U.S. Constitution, which states, in part, "nor shall private property be taken for public use, without just compensation." Merck has asked the U.S. District Court for the District of Columbia for an injunction to stop the program from going into effect. According to a statement on its website, Merck detailed its concerns that the program will have a negative impact on biopharmaceutical innovation and harm patients.[2] Moreover, the company stated:

> As we detail in our complaint, the Fifth Amendment requires the U.S. government pay "just compensation" if it takes property for public use. However, the IRA allows the government to obtain innovations without providing fair value for them. Under the IRA, the government will take Merck's patented innovations by coercing the company to provide third parties with access at prices the government sets.

Merck has also alleged a violation of the First Amendment with free speech implications.

Shortly after Merck filed its lawsuit on June 10, the U.S. Chamber of Commerce filed its own legal challenge. Subsequently, on June 21, the National Infusion Center Association (NICA), Global Colon Cancer Association (GCCA), and Pharmaceutical Research and Manufacturers of America (PhRMA) also filed a lawsuit in the U.S. District Court. We expect that other pharmaceutical companies, such as Biogen and Novartis (which have also raised public complaints), will soon file lawsuits.

Finally, on July 3, the CMS, Health and Human Services (HHS) published a notice in the Federal Register soliciting comments from industry partners, as required by the statute for CMS to consider certain data from primary manufacturers as part of the negotiation process. This is an ongoing and evolving process, and continues to move forward.

2023 Life Sciences Transactions Landscape – Ryan J. Udell

Earlier this year, following our attendance at the annual J.P. Morgan Health Care Conference, we wrote about a mix of changing development focus, market conditions, and geopolitical forces at work in the life sciences industry that pointed to a strong year for M&A after a difficult 2022. We predicted that the continuing limited availability of private equity

1 https://www.cms.gov/files/document/fact-sheet-medicare-drug-price-negotiation-program-initial-guidance.pdf

2 https://www.merck.com/news/the-inflation-reduction-acts-negative-impact-on-patient-focused-innovation-value-and-access/

funding and the capital markets would favor Big Pharma and Big Biotech, with historic levels of cash on their balance sheets and a need to restock their pipelines as drugs roll off patent. We also thought that so-called mega-mergers would remain out of favor due to the active antirust regulatory environment in the United States, among other things.

As we take stock, through the end of the second quarter of 2023, approximately $93 billion in M&A deals have been announced, putting this year on track to be in the top five years for M&A (and double the deal value for the first half of 2022). Most of these transactions tended to be structured without contingent consideration, indicating that the market has adjusted to the large valuation differences that existed over the past two years (and are mainly later-stage, de-risked assets – Phase 2 or later). The targets were also overwhelmingly public, likely due to a combination of funding and investor pressure and private investors' willingness to accept the new valuation environment (and a willingness to continue to wait out the reopening of the IPO window). The therapeutic areas were principally oncology and immunology, but also other areas of focus for acquirers included ophthalmology, renal, and cardiovascular.

We expect that for the second half of 2023 life sciences M&A will remain robust, given that similar market and regulatory conditions should persist. Therefore, we should see more Big Pharma bolt-on and tuck-in acquisitions of later-stage assets to restock the pipeline, as opposed to mega-mergers or assets that still need significant clinical development.

On the capital-raising front, we expect to see a larger crack open of the IPO window later in the year or in the first half of 2024 (it cannot get much more closed, with only three IPOs in the United States this year thus far). Private fundraising is accelerating, indicating that the investment environment is starting to normalize (with more measured bets in traditional therapeutic areas) after the unprecedented (and many would say unsustainable) pace in speculative technologies through the COVID-19 years. While the market resets, there is hope as breakthroughs in large patient (and large dollar) areas continue, including Alzheimer's, immunology, weight loss, and diabetes, ultimately fueling more interest and investment.

Here's to a strong and productive rest of 2023!

Data Protection and Privacy – Philip N. Yannella and Gregory Szewczyk

Life science companies face a rapidly evolving landscape of privacy and data security legislation, particularly in the United States. Consider that, in just the past three years, 12 U.S. states have passed or implemented comprehensive privacy laws. A particular challenge for life sciences companies is determining the extent to which these privacy laws apply to their companies, as certain kinds of data are generally exempt. For example, HIPAA-covered data and clinical trial data are not subject to U.S. state privacy laws. But life science companies often collect other personal information from consumers—such as via over-the-counter sales, website tracking, or other B2C channels—that are subject to U.S. state privacy laws.

The collection of consumer health data is a particular focus of regulatory, litigation, and legislative scrutiny. The Federal Trade Commission has aggressively targeted consumer health companies for their use of online tracking technologies that capture health-related information and share it with advertisers. Numerous class action lawsuits have focused on this same kind of data-sharing via chatbots or Meta Pixel. Additionally, several states have passed more focused laws that may impact life sciences companies. For example, Washington State recently passed the My Health My Data Act, which seeks to regulate the collection and processing of consumer health data, which is defined broadly, and provides a private cause of action. Life science companies that do not operate in Washington, but store consumer health data in Amazon Cloud servers based in Washington, may be within scope of the law. Nevada and Connecticut have implemented similar laws.

The privacy and data security risks for life science companies will only increase as companies roll out mobile health applications for consumers, utilize artificial intelligence, launch genetic sharing initiatives, and implement IoT-based medical devices—which may trigger compliance obligations under FDA cybersecurity regulations, U.S. privacy laws, and breach notification laws. Innovation is a hallmark of the life sciences industry, but that carries with it new risks in today's complex world of data regulation.

Hot Topics in IP – AI, Patents, Litigation, and More – Caryn Borg-Breen, Ph.D., Charley F. Brown, Scott D. Marty, Ph.D., Jonathon A. Talcott, and Catherine I. Seibel

Artificial Intelligence – Charley F. Brown

In an era characterized by rapid advancements in biotechnology, the development of the LinearDesign algorithm by Baidu Research signals a shift in the design and optimization of vaccine sequences. This novel AI algorithm, capable of quickly designing highly stable COVID-19 sequences, has reportedly resulted in a significant increase in antibody response, achieving a 128-fold enhancement. This breakthrough is poised to have substantial implications for regulatory approval. The FDA's traditional approval processes may require some degree of adaptation to appropriately assess this new category of AI-derived vaccines. The FDA recently acknowledged the dynamic nature of AI technology and the need to understand its impact on the safety and efficacy of new drugs. In a recently released discussion paper, the agency seeks to engage with interested parties, such as pharmaceutical companies, ethicists, academia, patients, and patient groups, and global counterpart regulatory and other authorities, on using AI/ML in drug and biologic development.

The use of the LinearDesign algorithm simultaneously unveils uncharted territory in patent law, particularly regarding inventorship. The involvement of AI in the conception and design process raises compelling questions about traditional notions of human inventorship in intellectual property rights. The U.S. Patent and Trademark Office (USPTO), following traditional guidelines, only recognizes human entities as inventors. The introduction of AI-developed vaccines could potentially prompt a reconsideration of these longstanding guidelines, thereby reshaping our understanding of inventorship in the era of AI. Consequently, this could incite far-reaching implications for future vaccine patent applications and the broader legal landscape surrounding AI-generated inventions.

Patent Eligibility – Scott D. Marty, Ph.D., and Catherine I. Seibel

In June 2022, the U.S. Supreme Court denied certiorari in *American Axle v. Neapco*, a case that many inventors and practitioners had hoped would be a vehicle for clarifying the scope of patentable subject matter under 35 U.S.C. § 101. Many have commented that the Supreme Court's decisions in this area in recent years have created a difficult-to-implement framework for patent eligibility. In 2019, the U.S. Patent and Trademark Office (USPTO) issued guidance in an attempt to untangle the issue, but even with that effort, the judicial landscape of Section 101 remains murky.

In reaction to this frustration and lack of clarity, and specifically citing the Supreme Court's refusal to take on American Axle, Senator Thom Thillis (R-N.C.) introduced the Patent Eligibility Restoration Act of 2022 (PERA) last fall. PERA has support from both sides of the aisle, as Senator Chris Coons (D-D.E.) signed on as a PERA cosponsor. PERA aims to rewrite the language of 35 U.S.C. § 101 to specifically define concepts that are not patent-eligible.

Of particular interest to the life sciences community, PERA's exceptions include a process that occurs in nature wholly independent of, and prior to, any human activity; an unmodified human gene, as that gene exists in the human body; and an unmodified natural material, as that material exists in nature, among other exceptions. The way the bill is currently

written, the patent eligibility provisions of Section 101 are only limited by the enumerated exclusions, arguably in an attempt to create a more definitive scope of patent eligibility. PERA has already drawn widespread commentary and, in some instances, criticism, and the bill faces a long journey to become law (and that journey could include major revisions to the bill).

Recent developments in this area demonstrate that the uncertainty regarding patentable subject matter is here to stay for the time being, at least until the Supreme Court decides to take action or, more likely, when PERA eventually becomes law. However, patent eligibility continues to be a closely watched and frequently litigated issue in the life sciences industry.

Written Description and Enablement in Therapeutics – Scott D. Marty, Ph.D., and Catherine I. Seibel

In a recent unanimous ruling, the U.S. Supreme Court provided guidance for what is required to satisfy the enablement requirement under 35 U.S.C. § 112(a). In *Amgen v. Sanofi*, the Supreme Court found that petitioner Amgen's patent claims directed to a genus of antibodies were invalid for lack of enablement, meaning that the patent did not sufficiently enable a person of ordinary skill to implement the claimed invention. The Court affirmed that the patent was invalid because the claims did not describe the full scope of the antibody genus according to its structure, but instead recited functional language.

As narrowly applied to patents covering antibody therapeutics, the opinion demonstrates that merely identifying a binding target is not sufficient to enable all other antibodies that also bind to the same target. In this respect, the opinion is a tidy companion to the Federal Circuit's decision in *Juno Therapeutics, Inc., et al. v. Kite Pharma, Inc.*, No. 20-1758 (Fed. Cir. 2021), where claims to biologics lacking target-binding structural elements failed to have an adequate written description. In many cases, the sufficiency of the written description goes hand in hand with the sufficiency of the enablement requirement, and both are important in making sure that the patents adequately describe and enable the claims.

In a broader sense, the *Amgen v. Sanofi* opinion reinforced the importance of ensuring that an appropriate balance be struck between writing broad claims to maximize protection, but making sure those claims are still supported by the disclosure in the patent application. In the words of the Court, "the more a party claims… the more it must enable," and Amgen's specification fell short of satisfying the enablement requirement. The decision reflects the courts' increasing focus on support for functionally defined genus claims in the life sciences. That lesson is an important takeaway for all patents, not just those concerning therapeutics. If the specification fails to provide enough guidance to implement the invention across all claimed embodiments, it will likely be found invalid for lack of enablement.

The Dawn of the Unified Patent Court – Jonathon A. Talcott

In breaking news, the much-anticipated launch of the Unified Patent Court (UPC) for European patents finally occurred on June 1, 2023, as did the option to select unitary effect at grant to become a Unitary Patent (UP).

The UPC now has jurisdiction over all UPs and "conventional" European patents (EPs) designated to the 17 participating EU Member States that have ratified the UPC Agreement (UPCA). That is, unless the EPs are "opted out" of the new court's jurisdiction, which can occur during a seven-plus-year "transition" period, which opt-out can be withdrawn during that time. Spain, Croatia and Poland are not participating, with other EU Member States have signed the UPCA but have not yet fully ratified it. The United Kingdom originally participated in the UPCA but then withdrew as part of Brexit.

One key advantage of the UPC over national litigation, of course, is that damages, injunctions, and other remedies will extend across borders. The UPC will therefore be useful if infringing activities arise in a number of countries, which is typical for life sciences patents. UPC litigation is designed to be quicker and less costly than multiple national litigations, with first-instance decisions on both infringement and validity generally to be issued within 12 months of the initiation of

proceedings. Thus, for companies trying to clear market entry, the UPC offers the potential for central patent invalidation. On the other hand, existing national litigation offers more predictability in terms of timelines and outcomes.

With the advent of the UPC and UPs, life sciences companies with operations in Europe should proactively account for this new system. They should shape their patent filing and litigation strategies according to these untested waters in what is essentially the largest remake of the European patent system in history. Strategic considerations include assessing the location of the manufacturing site of a product's active pharmaceutical ingredient and jurisdictions where the most significant sales occur. And while the UPC will have exclusive jurisdiction for infringement and validity disputes over UPs, UPC litigation will sit alongside national European patent litigation for EPs that have not opted out—at least during the seven-year transition period. Weighing the pros and cons of these parallel venues will, therefore, be critical to a successful patent portfolio. Our Life Sciences Group will continue to monitor the results of this new European dynamic as it unfolds.

COVID-19 Patent Litigation – Jonathon A. Talcott

Perhaps not surprisingly given their impact, Pfizer and Moderna have recently faced a number of lawsuits over their COVID-19 vaccines for alleged patent infringement. Of course, Moderna may have started the trend, filing its own infringement suit back in 2022 against Pfizer (and its partner, BioNTech) promptly after Moderna revoked its pledge not to enforce its patents during the pandemic. As parallel litigation between these companies ferments in the United States, Germany, and the Netherlands, the United Kingdom's High Court has set the first trial in this heated battle for next April.

Since Moderna sued Pfizer, Alnylam, CureVac, Moderna, and now Arbutus Pharma have all sued various combinations of BioNTech, Pfizer, and Moderna for patent infringement, primarily on technology relating to how the mRNA vaccine is delivered (*e.g.*, either modifications to the mRNA or the lipid matrix used for delivery). These lawsuits are all in their early stages, with trial dates (if any) likely to occur within the next 12–18 months.

It has been reported that Pfizer earned roughly $37.8 billion from sales of its COVID-19 vaccine, Comirnaty, last year, while Moderna made approximately $18.4 billion from its vaccine, Spikevax. With that much at stake and the six-year "lookback" period for patent damages, we expect to see even more COVID-19 vaccine-related patent litigation in the coming months as more information about these proprietary vaccines comes to light, and as it becomes more savory to sue on this issue with the waning of the pandemic. What's more, biotechnology inventions (including the COVID-19 vaccine) are often covered by several patents, many of which are not readily identifiable through public searches. Therefore, companies in this space should take extra precautions in freedom-to-operate approaches to the market. We expect to learn more about the successes and failures of these cases over the next year.

The Latest on PTAB* Fintiv *Denials – Caryn Borg-Breen, Ph.D.

Ten years have passed since the America Invents Act took effect. By now, it is clear that IPR challenges, which hit a zenith in 2015–2016, are on the decline. This is particularly true in the pharmaceutical space, where yearly challenges to Orange Book–listed patents have fallen by an order of magnitude since 2015. Although there are many potential reasons for the decline, a key factor has been concern about discretionary denials following the *NHK/Fintiv* decisions. Recent U.S. Patent and Trademark Office (USPTO) data and clarifications of the *Fintiv* decision show that *Fintiv* denials have declined significantly and are likely to remain low.

In June 2022, the USPTO released a study showing that, as of June 2022, more than 80 percent of petitioners had been sued by patent owners in another venue (mostly Western or Eastern District of Texas and District of Delaware) prior to filing their petitions. After *Fintiv* was designated precedential, discretionary denial was raised in about 40 percent of all cases in which a petitioner was sued by a patent owner in another venue. From Q3 of 2020 to Q2 of 2021, denials occurred at a high rate. However, since Q2 of 2021, discretionary denial has occurred only in a minority of cases (25 percent or

less) in which it was raised. Overall, *Fintiv* denials make up substantially less than 10 percent of cases filed, whether it was raised, since Q2 of 2021. The rate of denials is similar for Orange Book–listed patents. The *Sotera* decision, designated precedential in Q1 of 2021, is a big reason behind the reduction in discretionary denials. In *Sotera*, the PTAB granted institution despite a parallel proceeding because the petitioner had filed a stipulation stating that it would not pursue in a parallel district court proceeding the same grounds as in the petition or any grounds that could have reasonably been raised in the petition.

In June 2022, USPTO Director Katherine Vidal also issued a memorandum clarifying *Fintiv*. The director announced that the PTAB would no longer deny institution (1) where the petition presents "compelling evidence of unpatentability," (2) where the parallel proceeding is an ITC proceeding, or (3) where the petitioner stipulates (following *Sotera*) that it will not pursue in a parallel district court proceeding the same grounds as in the petition or any grounds that could have reasonably been raised in the petition. In addition, the director announced that when considering the speed with which a parallel proceeding would go to trial, the PTAB will consider the median time-to-trial in the district. If it is around the same time or after the projected statutory deadline for the PTAB's final written decision trial date, this factor will weigh against discretionary denials under *Fintiv*. Since June 2022, data shows that *Fintiv* denials continue to be on the decline as petitioners continue to make use of *Sotera* stipulations.

In March 2023, the USPTO Director issued further guidance on *Fintiv* in an opinion vacating and remanding a PTAB institution decision in *CommScope Technologies LLC v. Dali Wireless, Inc*., IPR2022-01242. This opinion clarifies that PTAB panels must first undertake the *Fintiv* factor analysis and should proceed to apply the compelling merits standard only upon concluding that *Fintiv* factors 1–5 favor denial of institution under § 314. USPTO Director Vidal's clarifications of *Fintiv* suggest that *Fintiv* denials will continue to be in the minority.

PTAB's Proposed Rule Changes

On April 20, 2023, the PTAB published an Advance Notice of Proposed Rulemaking "to better align the practices with the USPTO's mission to promote and protect innovation and investment in the same, and with the congressional intent behind the American Invents Act (AIA) to provide a less-expensive alternative to district court litigation to resolve certain patentability issues while also protecting against patentee harassment." The proposed changes touch on many aspects of PTAB practice. Comments must be submitted by June 20, 2023.

Discretionary Denials. The USPTO is considering changes that would provide for denial of institution based on certain conditions and circumstances (and exceptions). These include denials of (1) petitions filed by "certain for-profit entities," (2) petitions challenging "under-resourced patent owners where the patentee has or is attempting to bring a product to market," (3) petitions challenging patent claims previously subject to a final adjudication (pursuant to 28 U.S.C. 1295(a)(1)) upholding the patent claims against patentability challenges (either in another forum or in a different post-grant proceeding before the PTAB), (4) serial petitions, (5) petitions that raise previously addressed prior-art arguments, (6) parallel petitions, and (7) petitions challenging patents subject to ongoing parallel district court litigation.

Threshold Definitions. The USPTO is considering changes that would provide definitional clarity to the criteria evaluated under *Fintiv*. A first proposed change is to define "substantial relationship" between entities more broadly to encompass relationships falling outside the common law mean of "real party in interest" and requiring early disclosure of such relationships to the PTAB. A second proposed change is to define "substantial overlap" between claim sets to be when at least one challenged claim is "substantially the same," meaning that any differences between the claim and a claim set to which the claim is being compared are not material to patentability. A third proposed change is to define "compelling merits" to mean that the evidence of record at the institution stage would be highly likely to lead to a conclusion that one or more claims of the challenged patent are unpatentable.

Administrative Changes. The USPTO is considering changes that would require PTAB petitioners to (1) stipulate that they have not filed and will not file other petitions to the challenged claims, (2) justify the filing of multiple petitions in a separate paper, and (3) file all settlement papers when seeking dismissal. Other proposed changes include permitting petitioners to (4) pay additional fees to gain higher word count limits in petitions and (5) separately brief discretionary denial issues.

The Latest on Non-Compete Agreements – Meredith S. Dante

For decades, one of the key ways that companies, particularly life sciences companies, have protected proprietary information and defended against unfair competition is through the use of noncompete agreements. Whether in connection with the sale of a business, or as part of the regular onboarding process, many life sciences companies utilize restrictive covenants with at least a portion of their workforces. In the last decade, non-compete agreements have been under attack in various states, with legislation passed that narrows the use of these kinds of agreements. In January 2023, the Federal Trade Commission issued a Notice of Proposed Rulemaking, which essentially seeks a categorical ban on non-compete agreements. And, even in the wake of the FTC's announcement, state legislatures remain active in this space, passing legislation that continues to limit the use of non-compete agreements.

So, what now? What should life sciences companies be doing or thinking about, given the patchwork of state laws and proposed federal rules that would void non-compete agreements altogether? There are a few things to consider and steps that companies can take now to protect against the increasing scrutiny of non-competes (and potentially a ban). The first is an assessment of existing agreements. Figuring out where these covenants reside (offer letter, employment agreement, equity documents, severance plans, or agreements) is an important step in assessing what, if any, impact existing state laws or a federal ban would have on the organization, as well as strategizing for the future. The second is analyzing who the company has sign non-competes and then assessing whether such a practice is necessary. For example, not everyone at a company should necessarily be signing a non-compete; they can sign a confidential information agreement and that would be sufficient to protect the company's legitimate business interests. Figuring out who should sign what kind of agreement—non-compete, non-solicitation, and confidential information—can help define a more viable strategy in an increasingly challenging legislative environment. This is particularly true for organizations with remote workers in various states (and even all states) across the country. Finally, craft a strategy for what agreements the company wants to utilize and with whom, and start the process now with new hires, as new consideration is often necessary to support restrictive covenants. Make sure any agreements are updated to reflect current law and also contain appropriate severability clauses.

Protecting confidential and proprietary information is always top of mind, and there are ways to ensure companies have legally compliant contracts as part of their overall protection strategy. It is never a bad idea to do a periodic review of those agreements, and the new state laws and proposed federal rules are an opportunity to do a refresh.

Benchmarking and Other Antitrust Updates – Stephen J. Kastenberg and Karli Lubin

Benchmarking is widespread among corporations, but the uncertainty around the limits of appropriate benchmarking consistent with the antitrust laws has only become blurrier. Earlier this year, the U.S. Department of Justice (DOJ) withdrew three antitrust policy statements that provided guidance on the legal limits of information sharing. The policy statements were issued jointly with the Federal Trade Commission, which has not withdrawn them. One of the withdrawn policies included a "Safety Zone" for information exchanges. Under the Safety Zone, absent extraordinary circumstances, the agencies would not challenge information exchanges that met the following criteria: (1) The exchange was managed by a third party; (2) the information collected was more than three months old; (3) there were at least five participants reporting data for each statistic, and none of the participants' data constituted more than 25 percent of that statistic on

a weighted basis; and (4) the information was sufficiently aggregated to prevent recipients from identifying the source of any specific information on pricing. The DOJ stated that the withdrawn policy statements are "overly permissive" with respect to information sharing because of significant changes in market realities since the issuance of the guidance. The DOJ is particularly concerned about advancements in technology used to analyze shared data, noting that high-speed, complex algorithms can now process huge quantities of older data to glean insights about the strategies of a competitor.

There are also an increasing number of civil suits involving allegations of price or wage fixing resulting from information exchanges that appear to exchange aggregated data but allegedly contain data identifiable to the competitors participating in the exchange. Life sciences and other companies need to tread carefully as to what benchmarking they undertake, and it would be helpful in light of evolving legal standards and government positions for companies to take a fresh look at their participation in benchmarking and similar data exchanges, particularly around pricing, production, and employment compensation, benefits, and other terms and conditions of employment.

The Importance of ABAC in Diligence – Henry E. Hockeimer, Jr.

Because critical discovery and life science processes occur globally, transactions involving acquisitions in the life science industry can be conducted anywhere. As such, performing comprehensive due diligence is paramount. A key component of due diligence is ensuring that the acquired company has a robust anti-bribery and anti-corruption (ABAC) program. In assessing this, a determination should be made that not only an ABAC program exists but other key questions must be asked.

1. Where does the acquired company conduct business?
2. Is its customer base private, state-owned, or a combination?
3. Does the company have any agreements with third-party intermediaries?

Among other broad-ranging due diligence matters, we assist companies in performing ABAC due diligence at the acquisition stage, and we also help to ensure that ABAC policies are in place and comprehensive. We also assist with the comprehensive training of employees. Proper due diligence is imperative for any transaction, especially in the life sciences sector. There are various legal risks that need to be identified, carefully analyzed, and addressed in a timely manner.

Morphing Into a Life Science Use – Opportunities and Challenges for Office Building Owners and Prospective Lab Users – Bart I. Mellits

Both owners of office buildings and potential life science tenants should be aware of developments in the real estate industry, and the office market in particular. An ongoing trend that is changing the face of real estate is the country's increasing demand for life sciences and laboratory space. Industry leaders and forecasters have commented that this increased demand for lab space has seen billions of dollars in institutional investment in recent years, signaling a shift in how we provide life science space and where we do it. With that as a background, the COVID-19 pandemic has instilled in a new generation of Americans a heightened awareness of health and wellness and spurred the commercialization of university-level life science research. However, with the pandemic, also came the rise of remote work, which, in turn, has lowered office demand and occupancy rates. Now, layered on top of this stress are higher interest rates and lower property values, which are contributing to the pressure on office building owners. One potential avenue of relief for owners is to convert their troubled conventional office buildings into a laboratory/life science use. This can supplement

the market for life science space, but such conversions are not so easy.

Life science users have several special requirements that differentiate them from typical office tenants, and landlords must make significant modifications to their buildings to accommodate these tenants. This can be especially difficult for older buildings with outdated configurations and infrastructure. If owners want to attract lab tenants, owners will have to analyze their building and determine if it is a suitable candidate for conversion. Among the features that life science tenants desire are the following:

1. Increased ceiling heights;
2. Center-to-center column spacing to allow for standard laboratory bay design;
3. Reinforced structural capacity to minimize vibrations and to handle heavier loads of lab equipment;
4. Accommodation of the enhanced safety and security needs of tenants, including fume hoods, biosafety cabinets, safety showers and eyewashes, and waste disposal systems;
5. Advanced and enhanced mechanical, electrical, and plumbing/fire protection (MEP/FP) systems, which may include the segregation of fire-rated control areas
6. Larger loading docks;
7. Redundant power supply/back-up generator; and
8. Increased roof capacity for additional HVAC equipment. In addition to these physical features, both landlords and tenants must confirm that applicable zoning, building code, and other regulatory requirements have been met or are able to be satisfied.

While converting buildings to life science use can be challenging, there is some assistance in the marketplace. First, there are myriad government programs, subsidies, tax credits, and grants at the federal, state, and local levels enhance and promote life science development and life science companies at various stages in the life cycle. In addition, from the landlord's view, rents for lab users remain high, and many of these leases can be for longer terms. Depending on the building, conversion of an existing office building can have the added benefit of an already usable existing infrastructure, perhaps only needing upgrades, as opposed to ground-up construction. Moreover, many existing buildings already have entitlements in place, thus avoiding a sometimes risky and costly entitlements process.

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