Top 15 Healthcare and Life Sciences Issues to Watch in 2023

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Introduction

Throughout 2022, the healthcare industry grappled with public health crises, economic and financial pressures and a dynamic regulatory environment. We expect 2023 to continue challenging industry stakeholders. Those best positioned to face legal and regulatory headwinds will be, in turn, best positioned to manage risk, reconfigure care delivery models and capitalize on market opportunities. We summarize below some of the most notable developments expected to impact healthcare in the new year.

The New *Arms* Race: How Retail Giants Will Reshape Primary Care in the Next Decade

Numerous mega-retailers have a new focus in expanding their market share: the healthcare sector. Similar to the impacts of retail leaders in other industries, these retailers and pharmacy giants have cultivated market share amidst a shift away from traditional brick-and-mortar healthcare providers to a virtual model that will fundamentally reshape the industry over the next decade.

Advancements in technology and the effects of COVID-19 have accelerated this shift, resulting in three emerging trends: (1) technology has prompted an increasing desire for more information when making purchases, including the ability to compare discrete options; (2) consumers who were previously unwilling to participate in remote healthcare services acclimated to them during the pandemic and (3) retail giants have cultivated brand familiarity that is expected to spur customer adoption of healthcare services by nontraditional actors, stimulating a virtuous cycle of company expansion and consumer adoption.

These patterns are evident in the increase in mega-retail company M&A activity over the last five years:

- **Amazon**'s pending acquisition of primary care provider One Medical, its 2020 launch of Amazon Pharmacy following its 2018 acquisition of PillPack and its recent development of Halo, its wearable fitness bracelet.

- **Walmart**'s 2019 launch of Walmart Health, which now operates more than 30 health centers in Supercenter Stores; its 2021 acquisition of telehealth provider MeMD Inc. and its partnership with Transcarent Inc., a healthcare platform that offers low-cost prescription drugs to self-insured employers and their employees.

- **Best Buy**'s 2021 acquisition of Current Health, a remote patient monitoring, telehealth and patient engagement platform, and its 2018 acquisition of GreatCall, a health and medical alert service.

- **Walgreens**'s 2020 launch of Walgreens Health, which operates "health corners" in ~100 Walgreens stores across the U.S.; its 2022 acquisition of a majority ownership in CareCentrix Inx., a post-acute care company and its 2021 acquisition of a majority ownership in VillageMD, a primary care provider that recently acquired Summit Health-CityMD.

- **CVS**'s 2018 acquisition of health insurance company Aetna, which has expanded to offer virtual primary care appointments.

These recent acquisitions demonstrate the shift to a new technology-driven model for delivery of healthcare services from consumers' homes and regular retail pharmacies and point toward larger healthcare industry changes to come.

Healthcare Consolidation in the Crosshairs

While much attention has been paid to antitrust review of horizontal health system and hospital mergers, in 2023, stakeholders also should expect to see increased scrutiny of vertical integration. In particular, in late 2021, the Federal Trade Commission (the "FTC") voted to withdraw its approval of the vertical merger guidelines it jointly issued with the Department of Justice in 2020, with the majority of FTC Commissioners asserting that those guidelines "suffer[ed] from serious deficiencies" including overreliance on purported procompetitive benefits of vertical mergers at the expense of diminished market competition. Also in 2021, the FTC indicated that physician practice transactions remain top of mind by issuing orders to six health insurance companies to provide information that will allow the agency to study the effects of physician group and healthcare facility consolidation that occurred from 2015 through 2020.

Further complicating matters, state lawmakers are increasingly seeking to exercise robust oversight over healthcare transactions: these laws allow state agencies to work

alongside federal antitrust enforcers to analyze potential anticompetitive effects of healthcare consolidation and, moreover, allow states to review smaller—often vertical—transactions that do not meet federal reporting thresholds. For example, in 2021, Oregon adopted the Equal Access to Care Act, which expressly provides the Oregon Health Authority (the "OHA") with review and approval authority over healthcare mergers and acquisitions. In 2022, California adopted the California Health Care Quality and Affordability Act, which, among other things, established the Office of Health Care Affordability (the "OHCA"), whose portfolio is to collect data informative to the legislature and the public regarding healthcare expenditures. Unlike the OHA, the OHCA does not have the authority to block or challenge healthcare transactions; notwithstanding, healthcare entities will be required to provide the OHCA with written notice of any potential agreement or transaction that will occur on or after April 1, 2024, raising concerns over timing of transactions, premature disclosure, confidentiality and cost.

Provider entities and healthcare investors alike should prepare to navigate an increasingly complex regulatory environment with new, untested transaction hurdles at both federal and state levels.

The Future of Healthcare Data: Implications of the American Data Privacy and Protection Act

The U.S. digital health market is predicted to reach $240.7 billion by 2026, fueled in large part by a dramatic surge in telehealth and mobile healthcare. Digital health companies face an ever-changing landscape of piecemeal data privacy regulation, including the Health Insurance Portability and Accountability Act of 1996, the Federal Trade Commission Act and the Food, Drug, and Cosmetic Act, as well as state laws. Earlier this year, the House Energy and Commerce Committee approved the American Data Privacy and Protection Act (the "ADPPA"), a landmark federal privacy bill with significant bipartisan support. The ADPPA covers a variety of sensitive data types, including "any information that describes or reveals the past, present or future physical health, mental health, disability, diagnosis, or healthcare treatment of an individual." While the ADPPA would not apply to health data already covered by HIPAA, it would apply to all health data *not* subject to HIPAA regulation—for example, health data controlled by certain tech companies and app developers in the digital-health space.

Though the ADPPA was not passed during the 2022 lame-duck congressional session, the bill provides important insights into the broad-reaching data oversight lawmakers and regulators may seek to exercise in the near future. To prepare, companies and investors operating in the digital-health space may wish to assess how increased regulation might impact health-data usage and liquidity, review and revise existing data privacy risk and compliance protocols and stand up procedures to address enhanced

individual data privacy rights, including broad consent, access, deletion and portability rights.

Implementation of the Inflation Reduction Act: What Life Sciences Investors Need to Know

The Inflation Reduction Act (the "IRA"), signed into law by President Biden on August 16, 2022, seeks to lower prescription drug costs, which will significantly impact investors in life sciences companies. Notably, the bill: (1) requires the Department of Health and Human Services (the "HHS") to negotiate maximum prices for certain Part B and Part D prescription drugs and biologics; (2) caps out-of-pocket spending on prescription drugs for Medicare Part D beneficiaries and (3) requires drug manufacturers to pay a Medicare rebate for raising prices over the rate of inflation. Given the expected negative impact of HHS negotiations on manufacturers of successful products, investors should assess whether and how targets have developed or implemented mitigation plans. Further, even though the IRA may lead to increased drug purchasing by eliminating the beneficiary share in the catastrophic phase and capping out-of-pocket spending, corresponding increases in manufacturer revenues may be offset by the additional cost-sharing that will be required when patients exceed their out-of-pocket maximum. Finally, because manufacturers will be required to pay a rebate for raising prices above the inflation rate, investors should evaluate the starting prices of a target's drugs and whether the target has adjusted pricing strategies in light of recent legislative developments.

Artificial Intelligence for Life Sciences and Healthcare Companies

The utilization of AI in medical devices has drastically increased over the last five years, and this pace is likely to continue in 2023 as medical device companies develop new ways to leverage machine learning. A key issue to watch is the increased implementation of dynamically updating AI, which can continuously learn and adapt in real time based on new input data. Medical devices designed to continuously update challenge the Food and Drug Administration's (the "FDA") traditional regulatory framework based on approval or clearance of a static, unchanging device.

In 2019, the FDA issued a discussion paper describing a potential "total product lifecycle" regulatory approach to premarket review for artificial intelligence and machine learning-driven software modifications. In January 2021, the FDA issued its Artificial Intelligence/Machine Learning ("AI/ML")-Based Software as a Medical Device ("SaMD") Action Plan to respond to stakeholder feedback. In the Action Plan, the FDA expressed its intent to issue draft guidance to address Predetermined Change Control Plans. In these plans, developers would anticipate likely modifications to the AI/ML SaMD and provide the methodology used to implement those changes in a controlled manner with appropriate risk-mitigation measures. The FDA review would include premarket risk

assessment of the AI/ML SaMD that establishes how patient risks would be continually managed throughout the product lifecycle and set expectations for the manufacturer to monitor any changes. The total lifecycle framework would also require manufacturers to provide continued transparency about the function and modifications of the AI/ML SaMD post-approval through the collection and monitoring of real-world data and subsequent reporting to the FDA.

The FDA has been slow to refine and implement the AI/ML regulatory framework. Although the FDA initially indicated it would issue the guidance on Predetermined Change Control Plans in 2021, it has not yet done so. The guidance is on the Center for Devices and Radiological Health's B-List of priorities for 2023, which means it will be issued as resources permit.

FTC Antitrust Developments and Impacts on M&A

The FTC continued in 2022 to reassess and expand its approach to antitrust enforcement, including "reactivating the full set of authorities that Congress granted" the agency and "updating [its] tools to ensure they better correspond to new market realities."

In particular, the FTC continued to expand use of its reinstituted prior approval and prior notice policy, including applying the policy to consent agreements with merging parties and purchases of divestiture assets from challenged transactions. These policies effectively require merging parties to FTC-contested acquisitions to provide prior notice and seek the FTC's approval for at least 10 years before closing future transactions affecting the market in which a violation was alleged (and in some cases, broader markets), regardless of whether or not those transactions are HSR-reportable. In addition, the FTC intends to require all divestiture buyers to obtain the FTC's approval before they can sell divested assets for at least 10 years following the purchase.

FTC Chairwoman Lina Khan made clear that private equity firms will be an area of significant focus for prior notice and approval provisions in future settlements. The agency cited healthcare as one industry in which private equity firms have been particularly active in recent years, including elder and disability care, anesthesiology, emergency medicine, hospice care, air ambulances and opioid treatment centers. Chairwoman Khan commented that private equity's "focus on short-term profits in the healthcare context can incentivize practices that may reduce quality of care, increase costs for patients and payors, and generate appalling patient outcomes."

Chairwoman Khan expanded further on the agency's more proactive approach to antitrust enforcement in recent testimony before the U.S. Senate Committee on the Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights.

Chairwoman Khan stated that the agency intends to "plac[e] greater weight on assessing both non-horizontal and forward-looking competitive harm" and will aim to "tackle problems at the[ir] incipiency" by addressing competition concerns *before* markets are dominated by only a few firms. In her statement, Chairwoman Khan reiterated that the FTC continues to "prioritize deterring and stopping anticompetitive conduct in the healthcare sector" and highlighted recent Agency intervention in hospital mergers, pharmaceutical industry practices and other healthcare-related markets. This suggests a likelihood of more FTC challenges to healthcare transactions in the year ahead.

Healthcare PE Portfolio Companies Face Close Scrutiny over Potential for Interlocking Boards

Regulatory focus on private equity investors in the healthcare space is nothing new—but antitrust authorities are increasingly joining the fray. In June 2022, Deputy Attorney General Andrew Forman outlined the Department of Justice (the "DOJ") Antitrust Division's enforcement priorities to push back on increased consolidation in the healthcare space.

One tool in the DOJ's kit is Section 8 of the Clayton Antitrust Act of 1914, which prohibits a "person" from serving on the board of two corporations that are "competitors." Regulators have taken the position that sponsor-affiliated directors serve on behalf of the sponsor—and, therefore, two boards could be impermissibly interlocked as a result of the board service of different individuals affiliated with a single sponsor. While the Act defines a "person" to include corporations and associations and does not explicitly mention alternative corporate structures like LLCs, regulators have been pushing to expand the application of Section 8 more broadly.

Regulators have leveraged Section 8 against sponsors in various industries. For example, in response to the DOJ's concerns, a director who simultaneously served on the boards of both Definitive Healthcare Corp. ("Definitive") and ZoomInfo Technologies Inc. ("ZoomInfo") was forced to resign from Definitive's board. Definitive and ZoomInfo control specific intelligence platforms used by various third-party teams across the United States. Thus, healthcare industry investors should be conscientious of Section 8's constraints—and whether antitrust authorities may view two portfolio companies as "competitors"—when considering current board membership and future investments.

Healthcare SPAC Outlook in 2023: A Prognosis

The SPAC boom seems to be coming to an end. Use of special purpose acquisition vehicles reached a record high in 2021 as an attractive way to bring private companies to the public market more quickly than the traditional IPO process. There were 450 SPAC IPOs with an aggregate investment of $124.1 billion and 161 U.S. de-SPAC transactions

with an aggregate value of $341 billion in the first three quarters of 2021. Volatile stock markets and increased regulation from the SEC and stock exchanges have slowed this trend, resulting in only 76 SPAC IPOs with an aggregate investment of $12.4 billion, and 74 U.S. de-SPAC transactions with an aggregate value of $38.6 billion in the same quarters of 2022. Despite the dampened outlook for SPACs, both healthcare-industry-focused SPAC IPOs and de-SPAC transactions have demonstrated more durability than those in almost any other sector. Even with this resilience, healthcare SPACs will not be immune to further decreased IPO and de-SPAC transaction volume in 2023.

The SPAC downturn in 2022 was fueled by multiple factors: (1) proposed regulatory and listing exchange requirements that made it more difficult to successfully close a de-SPAC transaction; (2) rule changes to align with requirements for traditional IPOs; (3) a shrinking pool of available private entities that would make viable public companies; (4) the impacts of the instability in the global economy and record high inflation, including difficulties obtaining debt and equity financing to pay the consideration for these transactions and (5) public market apprehension caused by poor post-closing stock performance by many high-profile de-SPAC transactions. Recent developments, however, may help ease fears of new regulation that make de-SPAC transactions less appealing, including the recent IRS announcement that complete liquidating distributions for SPACs will be exempted from the otherwise applicable 1% excise tax on stock repurchases by public companies that was previously expected to become applicable in 2023.

Despite these headwinds, the healthcare sector has become one of the most sought-after for de-SPAC transactions. SPACs with healthcare targets accounted for the second-highest number of de-SPAC transactions in the United States in the first nine months of 2022: 19 healthcare de-SPAC transactions worth $6.6 billion, representing approximately 25% of aggregate SPAC deal volume and 17% of aggregate de-SPAC deal value, compared to 20.8% of aggregate SPAC deal volume and 13% of aggregate de-SPAC deal value in 2021. These data indicate that SPACs may continue to play a notable role in the healthcare sector, despite the general trend away from SPACs, albeit a smaller one than seemed likely during the frothy years of 2020 and 2021.

Another side effect of these headwinds is that there are now public healthcare companies that face operational challenges and poor stock performance that has been worsened by the market downturn that are likely ripe for take-private transactions. While this creates new opportunity for private buyers, such buyers will need to navigate the conflicts and potential litigation stemming from the de-SPAC transaction process, as well as likely differing views with respect to valuations as between the companies and buyers.

Over-the-Counter Drug Innovation Opportunities

Recent significant changes in the over-the-counter ("OTC") drug regulatory regime bring new opportunities for innovation. The 2020 Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") reformed the OTC drug regulatory regime by creating an expedited mechanism for the FDA to update and issue OTC drug monographs. Companies may now obtain authorization (starting October 1, 2023) for new OTC active ingredients or dosage forms (and obtain 18 months of marketing exclusivity in certain circumstances) without having to submit costly and time-consuming new drug applications.

Separately, in June 2022, the FDA issued a proposed rule that, if finalized, would provide a pathway for additional categories of drugs to be switched from prescription to OTC status. The proposed rule would authorize use of an additional mechanism (such as mobile apps) for consumers to self-select OTC drugs without the supervision of a healthcare practitioner. Although the proposed rule has the potential to expand opportunities for OTC drug development, the industry has criticized certain aspects in comments submitted to the agency. For example, the industry has challenged the proposal to allow for continued, simultaneous marketing of an identical prescription drug even after approval of the new OTC switch drug (which would curtail economic incentives to pursue an OTC switch).

Realizing the Promise of the 21st Century Cures Act: Healthcare Information Interoperability, EHR Competition and Penalties for Information Blocking

The 21st Century Cures Act (the "Cures Act") is widely known for its impact on the drug and device approval process, but a substantial, often underemphasized, portion of the Cures Act seeks to advance electronic health record ("EHR") interoperability. In 2020, the Office of the National Coordinator for Health Information Technology (the "ONC") promulgated a final rule (the "Rule") that, among other things: (1) defined "information blocking" as a practice that "interferes with, prevents, or materially discourages access, exchange, or use of electronic health information" and prohibited covered entities from engaging in information blocking; (2) created common-sense exceptions to the information-blocking prohibition and (3) required certified EHRs to adopt application programming interfaces—code enabling data communication between software products—allowing patients to easily access, exchange and use their health information.

Since publication of the Rule, the ONC has received hundreds of complaints of potential information blocking; federal enforcement of the Rule, however, has stalled. Although the Office of the Inspector General (the "OIG") has authority under the Cures Act to issue a civil monetary penalty up to $1 million per instance of information blocking by

(i) certified health information technology vendors, (ii) health information networks or (iii) health information exchanges, the OIG has not yet finalized its 2020 proposed rule outlining how its investigations will be performed for such entities, creating an "enforcement gap." Complicating matters, the range of potential penalties for provider entities remains unclear: the Cures Act states that the HHS shall subject providers to "appropriate disincentives," but does not define such disincentives or specifically provide the HHS with additional authority to enact such disincentives. Providers thus have an opportunity to audit their Cures Act compliance platform, including existing processes for evaluating and documenting patient record requests, ahead of the forthcoming penalty announcements.

Earlier this year, HHS Secretary Xavier Becerra stated that information blocking Rule enforcement will be a major focus of the agency. Industry stakeholders, who have struggled to maintain control over their data ecosystems, are signaling surrender in the face of the tide of interoperability and preparing for enforcement efforts to ramp up in 2023.

What an End to the Public Health Emergency May Mean for Modernizations to Care Delivery

The end of the federal COVID-19 Public Health Emergency (the "PHE") will incite a reckoning as the U.S. grapples with the future of care delivery following pandemic-era accommodations that expanded telehealth and pharmacists' scope of practice, among other things. Since January 2020, the HHS has maintained certain flexibilities and waivers permitting a surge in telehealth usage alongside a Trump-era executive order that permanently expanded some telehealth services beyond the PHE. Simultaneously, in response to provider shortages, pharmacists assumed a more integral role in care delivery, resulting in increased COVID-19-related direct patient care responsibilities that may continue to evolve to include wellness screenings, telepharmacy counseling, diagnosis of acute conditions and prescription of medications. It remains to be seen whether the federal and state barriers to telehealth that were temporarily relaxed in response to the PHE, including reimbursement, will be reimposed and, if so, to what degree. Given the prolonged pandemic, however, and increased utilization of telehealth, a longer-term shift by government regulators towards enabling broader access to such services is both feasible and pragmatic, so long as fraud and abuse, data privacy and security and data licensing and ownership issues are considered. One notable telehealth development is the passage of the Consolidated Appropriations Act of 2023, which extends Medicare telehealth flexibilities through 2024, granting regulators more time to determine which flexibilities should be made permanent. However, unless Congress intervenes to enact further extensions or make the changes permanent, the federal system will largely revert to pre-PHE restrictions. Likewise, some states have begun

expanding pharmacists' scope of practice to encompass direct clinical care, which may be considered a step towards modernizing the U.S. healthcare system.

Civil and Criminal Enforcement by the DOJ's Consumer Protection Branch Targeting Life Sciences Companies

The Department of Justice Consumer Protection Branch (the "CPB") is increasingly targeting corporate entities, including life science companies, for civil and criminal enforcement, a point it has emphasized in a recent inaugural report regarding corporate enforcement actions. The CPB's involvement in matters that traditionally have been addressed by regulators like the FDA significantly ups the stakes for targeted companies because of the CPB's ability to bring criminal prosecutions and to seek large monetary fines. For example, following an FDA investigation, the CPB obtained over $40 million in criminal fines from an endoscope manufacturer for failing to ship revised cleaning instructions and submitting untimely reports of product-associated infections. The CPB also secured over $22 million from a surgical gown manufacturer for mislabeled surgical gowns and corresponding misrepresentations.

In light of increased CPB enforcement, investors in pharmaceuticals and medical devices should carefully consider whether the target: (1) potentially has exposure due to conduct that could attract the CPB's attention; (2) is monitoring CPB enforcement precedent and has an appropriately resourced and effective compliance program and leadership that makes compliance a leading priority and (3) has appropriate strategies for interacting with regulators and responding to government investigations when they arise.

DOJ Focused on Pursuing Individual Criminal Liability of Healthcare and Life Science Executives

Deputy Attorney General Lisa Monaco announced in a September 2022 speech that individual accountability is the DOJ's "first priority" in criminal enforcement. Executives at healthcare and life science companies are likely to be a central target of this focus. The Responsible Corporate Officer doctrine (the "RCO")—often known as the *Park* doctrine—gives the DOJ a tool to use against executives in pharmaceutical and device manufacturers in certain circumstances. Under the RCO doctrine, an executive can be held criminally liable for a misdemeanor and potentially sentenced for up to a year in prison if the company she serves committed an FDCA violation and the executive could have prevented the violation but failed to do so. For example, two executives of Acclarent were acquitted in July 2016 of felony charges relating to the promotion of a device but were convicted of misdemeanor violations; they were ultimately fined and did not receive any prison time. In 2020, the former chief executive officer of Indivior PLC pled guilty as an RCO related to the marketing of an opioid addiction treatment and was sentenced to six months in prison. The DOJ has also

pursued other theories of criminal liability. In February 2022, the former CEO of Rochester Drug Cooperative was convicted of conspiracy to unlawfully distribute opioids under the Controlled Substances Act, which carries a mandatory minimum sentence of 10 years. Given this heightened scrutiny of senior executives, companies should periodically review their compliance programs and should make updates and enhancements as appropriate.

Chapter 11 Remains Viable Option for Companies Facing Mass Litigation

Lawsuits are part of the cost of doing business in the healthcare and life sciences industries. Usually, these legal costs are manageable, but sometimes large-scale litigation involving products liability or other claims threatens to overwhelm an otherwise healthy company. In such circumstances, companies should consider strategic reorganization under Chapter 11. While bankruptcy is generally seen as a worst-case scenario and may seem an odd choice for a solvent company with strong operations, it can be an effective way to "rip off the Band-Aid" and resolve mass litigation all at once. Bankruptcy provides the advantage of consolidating various suits into a single forum before a sophisticated judge that understands both the underlying claims and the impact such suits have on the health of the company. Recent examples of this strategy include the bankruptcy of Johnson & Johnson's subsidiary LTL Management (facing claims related to talc products) and Endo International (facing opioid claims). This trend has been on the rise in 2021 and 2022 and, as credit markets tighten heading into 2023, bankruptcy is likely to continue to be a beneficial forum for operationally healthy companies to surgically address mass litigation.

Major Supreme Court Cases to Watch in 2023

The Supreme Court is poised to issue a number of potentially groundbreaking decisions impacting healthcare companies and their stakeholders in its 2022–2023 term:

Pfizer v. United States Department of Health and Human Services (Cert. petition filed Oct. 7, 2022).

Pfizer sought to establish copay assistance programs to help cover out-of-pocket costs for its drug tafamidis. In an advisory opinion, however, the HHS stated that these programs could violate the Anti-Kickback Statute (the "AKS") for patients covered by Medicare. The AKS makes it illegal to "induce" the purchase or recommendation of federally insured medicines. Pfizer has argued, unsuccessfully so far, that "inducement" requires a degree of corrupt intent—because tafamidis is the only drug used to treat a particular heart condition, its copay-assistance program would not wrongfully induce physicians to prescribe it. Pfizer has filed a petition for certiorari. If the Court takes the case, it will set up an important battle over the scope of the AKS with significant ramifications for other expensive drugs used to treat rare conditions.

Health and Hospital Corporation of Marion County, Indiana v. Talevski (Oral arguments heard Nov. 8, 2022).

The case concerns a lawsuit by the family of Gorgi Talevski against the Health and Hospital Corporation of Marion County (the "HHC"). The family asserts that the HHC violated provisions of the Federal Nursing Home Reform Act (the "FNHRA"). The Supreme Court will first determine whether individuals can sue for violations of their rights under the FNHRA. If that law does not provide relief, the Court will determine whether a violation can be redressed under the Civil Rights Law, Section 1983. If the Court finds Section 1983 inapplicable, there will be serious implications for similar statutes like the Medicare and Medicaid Act (the "Act"). Like the FNHRA, the Act does not contain language creating a private cause of action, leaving Section 1983 as the only avenue for relief in federal courts. A decision rejecting the use of Section 1983 here would throw similar claims under the Act into state courts.

Amgen Inc. v. Sanofi (Cert. granted Nov. 4, 2022)

Amgen sued Sanofi for patent infringement over competing medications used to lower cholesterol, arguing that Sanofi's drug employs antibodies that are functionally similar to a group of antibodies allegedly covered by Amgen's patent. At issue is a highly technical question of patent law involving the scope of the "enablement requirement" under 35 U.S.C. §112. Broadly speaking, the enablement requirement mandates that a patent provide enough information for the invention to be made and used—but the parties dispute whether that includes the full scope of possible embodiments of the invention. This issue has particular importance for so-called pharmaceutical patents that are intended to cover a full genus of antibodies. If the Supreme Court applies a more robust enablement requirement, it may make patent claims for broad antibody therapies less certain, making this a case to watch for the life sciences industry.

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Please do not hesitate to contact us with any questions.

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