Dechert LLP

2025 Life Sciences Day

Key Takeaways:

Key Appeals Shaping Life Sciences Litigation and Regulation

- **Rule 702 and Expert Testimony:** Appeals pending in the Zantac and Paraquat litigations demonstrate how courts' application of "new Rule 702"—revised effective December 2023—can lead to disparate results and influence venue selection for future plaintiffs. For example, if the Delaware Supreme Court affirms the lower court's ruling which permitted plaintiffs' experts' opinions, future plaintiffs may flock to Delaware. *EcoFactor v. Google*, an *en banc* Federal Circuit will navigate the tension—often seen in life sciences cases—between the court's role as gatekeeper and the jury's role as factfinder.

- **Expansion of Liability:** In several pending appeals, plaintiffs seek to expand liability for corporate defendants using novel theories. *Gilead v. Superior Court* presents unique circumstances that are unlikely to be repeated, but drug development companies should evaluate their risk if California's highest court affirms the intermediate court's view that a company has a duty of reasonable care in deciding whether and when to commercialize an available alternative to its own FDA-approved drug. In *Medical Marijuana v. Horn*, the U.S. Supreme Court will soon resolve whether civil RICO permits recovery when personal injuries result in downstream injuries to business or property; if it does, that could be another new theory of liability asserted against life science companies.

- **Thermonuclear Verdicts:** High damages verdicts, particularly in jurisdictions like Philadelphia, may reflect a growing anti-corporate sentiment among jurors. If those verdicts are affirmed on appeal, Pennsylvania may become an increasingly popular jurisdiction for product liability and personal injury plaintiffs. This is particularly true so long as Pennsylvania maintains its law requiring companies registered to do business in the state to submit to general personal jurisdiction there (an issue the Pennsylvania Supreme Court recently declined to address in *Nemeth v. Syngenta*).

- **Constitutional and Procedural Issues:** In light of the U.S. Supreme Court's recent decision in *Royal Canin U.S.A. v. Wullschleger*, corporate defendants may want to insist on early deadlines for amending complaints in order to avoid late amendments that force remand to state court. The Court's other forthcoming decisions may give clarity about whether individual whistleblowers can no longer pursue False Claims Act cases absent a congressional amendment overhauling the procedure (*Zafirov v. Florida Medical Associates*) and whether federal class actions can be certified where some class members lack any Article III injury (*Labcorp v. Davis*).

Capital Raising and Asset Monetization Strategies for Life Sciences

- **Venture Capital and Crossover Rounds:** Venture capital funding has stabilized, and investors have largely become more "rational" as compared to the frenzy of 2020 and 2021. The spotlight is on validated science for high potential product candidates, in particular GLP-1s for obesity and a growing number of emerging indications. Crossover rounds are crucial as a company sets itself up for an IPO – validating valuations, boosting IPO demand, and building momentum for an IPO. However, this momentum also means investors will expect a near-term IPO, intensifying pressure to execute on that plan.

- **Post-IPO Challenges:** Transitioning to a public company involves more than just compliance matters: stock price swings can impact stakeholders, employee relations, business partners, and management's focus. A clear plan for news flow, hitting upcoming milestones, and maintaining post-IPO momentum is crucial for success.

- **Monetizing IP:** Licensing IP related to product candidates or platform technology continues to be the go-to strategy for biotechs to monetize their IP and fund research and development. In 2024, there were over 500 reported licensing and collaboration deals, with biologics, later-stage assets, and GLP-1 targeted therapies playing a key role in maintaining industry momentum. Royalty monetizations, involving the sale of future royalty streams under a license agreement tied to one or more marketed products, have generally increased in recent years but remain a niche financing option for biotechs. Companies must focus on IP portfolio quality to attract investors and ensure successful financing rounds and IPOs.

- **Market Trends and Administration Impact:** Current administration policies on FDA/NIH budgets, tariffs, antitrust, and a potentially patent-friendly environment will shape strategic decisions in capital raising and asset monetization.

Licensing, Funding, and Litigating Life Sciences Disputes

- **Earnout Provisions and Litigation:** Delaware courts are seeing a rise in litigation involving life sciences acquisitions and former shareholder suits against acquirors. Courts are evaluating earnout provisions, with less buyer-friendly rulings, hewing less to the express terms of the agreements and contractually-structured provisions and assessing best efforts in breach of contract and equitable claims. Companies should consider hedging with contractual promises on acquired products to mitigate these risks and maintain commercially reasonable efforts in line with business judgment.

- **Monitor Commercially Reasonable Efforts Case Law:** Companies should have regular monitoring in place from outside counsel on jurisdictionally-specific case law regarding patent licensing and acquisition agreements to avoid litigation and ensure effective drafting for obligations placed on buyers and sellers as well as licensees and licensors.

- **Best Practices Training Programs for Effective Communication and Documentation:** Emphasizing importance of company-wide training and alignments on data preservation and document management is crucial to mitigating litigation risk and potential exposure for contractual liability. This includes balancing payments, managing joint committees, and maintaining strong relationships, particularly in university collaborations.

Trends in Competition Challenges to Drug Pricing

- **Novel Theories of Harm:** The FTC, state AGs, and private plaintiffs are pursuing aggressive antitrust theories that challenge fundamental tenants of life sciences companies such as rebates to pharmacy benefit managers (PBMs), the acquisition and enforcement of IP rights, and continued innovation on existing product lines.

- **Complexity of Drug Pricing and Rebating:** The disaggregation of stakeholders with varying incentives makes drug pricing complex. This can lead to counterintuitive results, such as larger rebates to PBMs not translating to lower out of pocket costs to end consumers. The FTC and state AG's are intensifying their scrutiny of these unique aspects of drug pricing for alleged anticompetitive harm. Pharmaceutical companies can mitigate antitrust risk by focusing their negotiations with PBMs on obtaining access to formularies as opposed to exclusive status and structuring their agreements to avoid disincentives for generic drugs.

- **Increased Scrutiny of IP Acquisition and Enforcement:** Patent rights fuel innovation in life sciences, yet recent cases have alleged antitrust violations stemming from the successful acquisition and enforcement of patent rights. One such case worth following is *Carefirst v. Amgen* in the E.D. Va. regarding IP Amgen acquired for Enbrel®. In addition, the FTC and Congress have been active in alleging anticompetitive practices stemming from listing certain types of patents in the Orange Book. A recent Federal Circuit decision in *Teva v. Amneal* adopts a narrow view of patents that can be listed, particularly those related to drug-device combinations. To mitigate risk, pharmaceutical companies should reevaluate their Orange Book patents and policies in view of this new precedent.

- **Attacks on Continued Innovation:** The FTC, Congress, state AGs and private plaintiffs have also alleged antitrust violations stemming from continued innovation on existing products. These broad allegations of wrongdoing via "patent thickets" and "product hopping" test the traditional level of coercion necessary prove anticompetitive behavior. In addition, these theories disregard the significant innovations that occur after discovery of a new compound that provide meaningful benefits to patients. Pharmaceutical companies can mitigate risk by avoiding conduct that can be characterized as a "hard switch," documenting the room for improvement in existing products, and documenting the clinical benefit of improved products to patients.

Life Sciences in Philadelphia – Fireside Chat Q&A with Dr. Patrick Oates of PHL Life Sciences

- **Economic Significance:** The life sciences industry is a major economic driver in Philadelphia, generating approximately US$62 billion of direct economic impact for the state and employing 88,000 people in the city. There are renewed efforts to attract more life sciences businesses to be headquartered in Philadelphia itself in an effort to further enhance the economic impact.

- **Philadelphia's Leadership in Life Sciences:** Philadelphia is a leading hub for cell and gene therapy, supported by top-tier research and medical institutions like Penn, Jefferson, CHOP, Drexel, and the Wistar Institute. Its strategic location and a highly skilled talent pool drawn from these institutions and innovative pharmaceutical companies strengthen its position. The city, does, however face challenges in securing venture capital funding compared to Boston and Silicon Valley.

- **Collaboration and Communication:** Continued growth of the life sciences sector in Philadelphia will require unified efforts and clear communication among a range of stakeholders, including industry leaders, hospitals, universities, and government officials. The Parker and Shapiro Administrations appear engaged in growing the industry, especially because of its impact on workforce development. Highlighting the sector's benefits and opportunities is essential,

particularly in engaging local and state officials to support strategic growth and attract investment. Some of the more prominent life sciences companies can further embed themselves in the community by fostering local engagement.