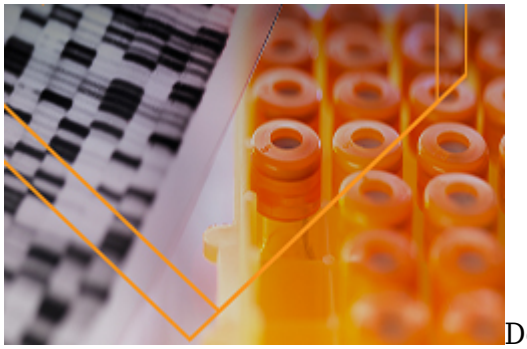
2020 Year in Review: Securities Litigation Against Life Sciences and Healthcare Companies

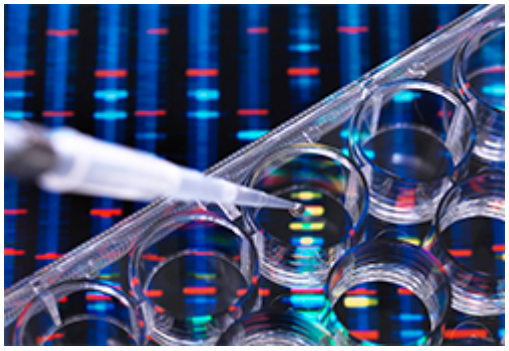


Despite the turmoil and disruption of 2020, plaintiffs' lawyers and courts appear to have adapted readily to our "new normal." Although at lower rates than previous years, plaintiffs' firms continued to file securities class actions against publicly traded pharmaceutical, biotechnology, medical device and healthcare product and services companies in 2020, while courts continued to issue detailed, substantive decisions in these actions. The number of class action filings in state and federal courts from last year shows a 22% decline from a record level in 2019 – a decrease for the first time since 2016, but still far higher than the 1997-2019 average.

In Goodwin's fifth annual Year in Review publication, we focus on active jurisdictions that are geographic epicenters for life sciences and healthcare companies: the First Circuit and the District of Massachusetts; the Second Circuit and New York District Courts; and the Ninth Circuit and California District Courts. In our analysis, we summarize key decisions issued in these jurisdictions during 2020 in class actions against life sciences and healthcare companies, as well as cases to watch in 2021.

Read the Report.

Goodwin's Clinical Trials Service Offering



Given the breadth of clinical-stage companies that the Goodwin FDA and Healthcare teams advise, our regulatory attorneys together with our commercial contracting, products liability and insurance attorneys play an integral role in counseling clinical-stage companies on matters related to the conduct of clinical trials.

Learn more about our clinical trials service offering **here**.

Q&A with Goodwin's Andrew Harrow: Exploring the Pharma Deals Outlook in 2021

COVID-19 put into perspective the importance of the pharma industry to the global economy. Goodwin London Life Sciences partner **Andrew Harrow** reflects on 2020's impact on the pharma sector, particularly biotech, and discusses what 2021 might look like for industry deals and investment. Full article **here**.

2nd Virtual Goodwin + KPMG @ JPMorgan Symposium – Day Two Recording

Goodwin's 2nd Annual Goodwin + KPMG @ JPMorgan Symposium kicked off Day Two of our Symposium with an overview of the effects of the pandemic on the biopharma market by Dale Raine, Managing Director and Co-Head of the European Healthcare Investment Banking at Lazard in conversation with Goodwin Life Sciences Corporate partner, Graham Defries. This chat was followed by a panel discussing global life sciences outlook, partnerships and M&A opportunities, and whether Europe will continue to be a focus for 2021 and beyond. The Symposium wrapped up with a fireside chat featuring the Carl Hansen, CEO and Tryn

Stimart, CLO of AbCellera in conversation with Goodwin Life Sciences partner Deepa Rich, discussing drug discovery and the accelerated adoption of AI and machine learning in our new reality, and their path to one of the largest IPOs in biotech history.

View the Video

2nd Virtual Goodwin + KPMG @ JPMorgan Symposium – Day One Recording

Goodwin held the 2nd Annual Goodwin +KPMG @ JPMorgan Symposium on Wednesday, January 27th and Thursday, January 28th. The Symposium kicked off with industry luminary, Noubar Afeyan, Chairman and Co-Founder of Moderna sitting down for a fireside chat with Vice Chairman, Global Chair of M+A and Goodwin partner, Stuart Cable.

Following the fireside chat, there were three industry focused panels. The first panel, "The COVID Catalyst: Driving Innovation Mainstream," discussed how COVID-19 boosted innovation across the continuum whether it be devices, therapeutics, diagnostics, supply chain, or the dissemination of needed products and services on a worldwide scale. The second panel, "COVID Gives Digital Health a Shot in the Arm," addressed how digital health came into the spotlight in 2020 as a result of increased demand for virtual health. The first day wrapped with the panel, "How the 2020 SPACs Revolution Will Impact the IPO Market for 2021 and Beyond," focused on the rise of SPACs in 2020 and how that will affect the IPO market moving forward.

View the Video:

Got a Broad Chemical Patent? Be Wary.

 Idenix's Pharmaceuticals' patent (U.S. Patent No. 7,608,597) was invalidated for having a genus that was "too broad." The trial judge ruled that the patent did not enable a person of skill in the art to select a single compound from the "billions and billions" of compounds encompassed by the genus. On appeal, the Federal Circuit upheld the trial judge's ruling of non-enablement. On January 19, 2021, the Supreme Court of the United States (SCOTUS) declined to review the Federal Circuit's decision to invalidate Idenix's patent.

This decision is likely to have effects across the pharmaceutical and biotech field. The Federal Circuit's ruling may narrow the scope of generic protection granted to pharmaceutical companies for novel drug scaffolds. Chemical genus claims are often used to deter "fast followers" from making small modifications to a drug's design to avoid patent coverage. In their amici briefs, both GlaxoSmithKline and Amgen argued that this narrowing would result in a decrease in innovation across the pharmaceutical space.

Idenix's patent claimed a method of treating Hepatitis C virus (HCV) infection by administering a class of synthetic nucleosides, β-D-2′-methylribofuranosyl nucleosides, also known as a "2'-methyl-up nucleosides". Idenix's patent covered any 2′-methyl-up nucleoside which fell within the claimed chemical genus that was effective in treating HCV. Idenix sued Gilead Sciences, alleging the '597 patent's claimed genus encompassed the compound sofosbuvir, an active ingredient in Gilead's hepatitis C drugs Sovaldi and Harvonis. In 2016, a Delaware jury agreed and awarded Idenix $2.5 billion. However, the district judge set aside the jury's verdict, ruling the patent was invalid on enablement grounds. The judge contended this genus was too broad, and the patent did not enable a person of skill in the art to select a single compound from the "billions and billions" of compounds encompassed by the genus.

On appeal, the Federal Circuit determined the patent did not provide "meaningful guidance" or "useful blaze marks" to direct a person of skill to specific effective hepatitis C therapeutics within the claimed genus. That a person of ordinary skill in the art would not know, without undue experimentation, which 2′- methyl-up nucleosides would be effective for treating HCV. The court concluded that the working examples present in the patent were "very narrow, despite the wide breadth of the claims at issue" and were insufficient to enable such a broad genus.

Merck & Co. acquired Idenix Pharmaceuticals for $3.85 billion in 2014.

Moving from the Informed Consent to Approved Labeling: Preparing for Risks in

Product Marketing & Use Webinar Recording

On February 3, 2021 Goodwin FDA Regulatory partner, **Julie Tibbets**, Products Litigation + Counseling partner, **Nilda Isidro**, and Risk Management & Insurance counsel **Brian Mukherjee** discussed what drug and biologic companies with late-stage product candidates can do to best position their products to mitigate the risks that come with transitioning from clinical trials to marketing and sales.

Our speakers – leaders in life sciences regulatory compliance, product litigation preparedness, risk management, and insurance – highlighted best practices surrounding pharmaceutical promotion, preparing for risks inherent in the marketing and sale of prescription drugs, and the ways in which insurance can help mitigate those risks. This webinar identified key takeaways for companies that are nearing FDA approval and are poised to launch their commercial products.

Click **here** to view the slides and webinar recording.