USPTO Emphasizes Searches of FDA Databases for Pharmaceutical Patent Applications

 In response to Biden Administration goals regarding increasing pharmaceutical competition and lowering drug prices, the USPTO recently released training provided to the USPTO examining corps on utilizing publicly available FDA and NIH databases for prior art searches. The goal of the training is to ensure that all relevant prior art is considered by examiners when assessing patentability. As with disclosures on **clinicaltrials.gov**, drug labels and drug approval information are publicly available and thus may qualify as prior art.

This training is related to initiatives outlined in President Biden's **Executive Order (EO) 14036** entitled "Promoting Competition in the American Economy," signed on July 9, 2021. In this EO, President Biden stated his administration's goal of increasing competition in the pharmaceutical space and lowering prescription drugs prices. As part of this goal, President Biden instructed the Commissioner of Food and Drugs to write a **letter** to the Director of the USPTO describing any relevant concerns of the Food and Drug Administration (FDA) with respect to USPTO procedures. In its **response** to the FDA letter, the PTO outlines several initiatives, including working with the FDA to develop training materials for the patent examining corps on searching publicly available FDA resources (e.g., FDA and NIH databases) for prior art and to assess the state of the art in the pharmaceutical and biopharma areas.

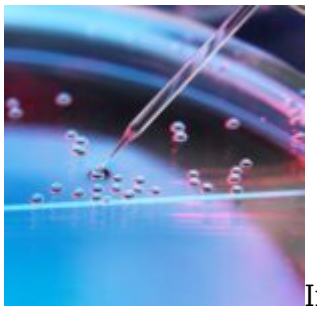
On March 20, 2024, the USPTO released new training materials ("**March 2024 Training Materials**") it developed in conjunction with the FDA for the examining corps regarding use of FDA and National Institutes of Health (NIH) databases to search for prior art. The March 2024 Training Materials outlines search strategies for use with various FDA and NIH public databases, including:

- **FDALabel** – FDALabel (current drug labels) contains "over 140,000 human prescription, biological, over-the-counter and animal drug label documents." This database allows for complex queries, including with structures, and "[m]ay be used to find information on indications, dosage and administration, contraindications (including warnings, adverse reactions, drug interactions, or information about use in particular populations of patients)."
- **Drugs@FDA** – Drugs@FDA gives examiners access to current and retired drug labels, along with non-label content such as FDA reviews, regulatory history, and approval letters. This database covers prescription brand-name drug products, generic drug products, therapeutic biological products, and OTC brand-name and generic drugs.
- **DailyMed** – DailyMed (current drug labels; operated by the NIH) contains labeling information on prescription drug and biological products for human use, OTC drugs and biological products, medical devices, medical gases, and prescription and nonprescription drugs for animal use. This database doesn't permit structure searches but does provide "publicly available" dates that can be used to establish the effective date of the disclosure.

Information available in this database includes usages/indication, dosage/administration and forms/strengths.

- **DailyMed Archive** – DailyMed Archive provides retired drug labels for prescription drug and biological products for human use, OTC drugs and biological products, medical devices, medical gases, and prescription and nonprescription drugs for animal use.

2023-2024 Key Trends and Updates: Securities Litigation Against Life Sciences Companies Webinar

 In this webinar, **Caroline Bullerjahn**, **Tucker DeVoe**, and **Justin Ward** from Goodwin, and **Frank Schneider** from Cornerstone Research will discuss key updates and recent trends concerning securities class actions filed against publicly traded pharmaceutical, biotechnology, medical device and healthcare product and services companies (collectively, "life sciences companies"), which continue to be a primary target of the plaintiffs' bar. While securities class action litigation against life sciences companies decreased slightly in 2023 compared to 2022, life sciences companies remain by far the most targeted sector for these suits, and the total number of securities class action suits filed against life sciences companies remains above the long-run historical average (40 filings in 2023 compared to 37 filings per year in from 1997-2022).

In addition to analyzing these overall trends, we will:

· examine data for class action filings in 2023 and trends based upon such data, focusing on filings against life sciences companies;

· review several significant, impactful recent decisions issued by federal courts particularly relevant to life sciences companies;

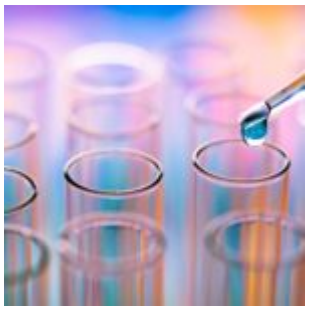
· provide in-depth analysis of the potential implications of these decisions, which involve challenges that life sciences companies often face; and

· discuss practical steps you can take to make informed choices related to your business, including your public disclosures.

This program is pending one hour CLE credit in California, New York, New Jersey, and/or Pennsylvania.

This webinar is scheduled for Wednesday, April 3rd from 2:30 – 3:30 PM ET. Please **register** here.

FDA's Laboratory Developed Test (LDT) Final Rule Under OIRA Review; Subcommittee on Health to Hold Hearing on Regulation of Diagnostic Tests

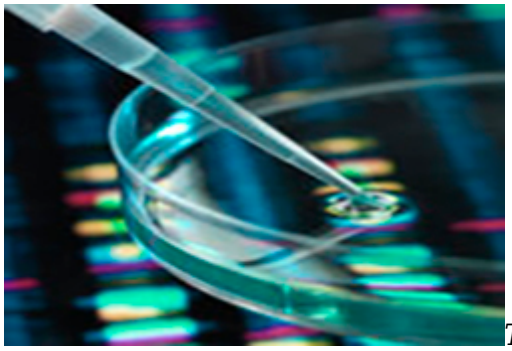


On March 1, 2024, the Office of Information and Regulatory Affairs ("OIRA"), Office of Management and Budget ("OMB"), Executive Office of the President **received** the final version of FDA's rule on regulation of laboratory developed tests ("LDTs") for administrative review. Having swiftly moved to OIRA review in under 5-months from the publication of the **proposed rule** and under 3-months from the end of its comment period, the rule has undoubtedly been a top priority for the FDA. Further, as of the date of this post, OIRA has **scheduled** four back-to-back meetings with interested stakeholders, all of which are to be held the week of March 18th. All of this signals that the final rule remains on track for potential issuance in April 2024, the target date for final action on the rule as we previously discussed **here**.

Further, on March 14, 2024, the House Energy and Commerce Committee Chair and Subcommittee on Health Chair announced a subcommittee hearing titled "Evaluating Approaches to Diagnostic Test Regulation and the Impact of the FDA's Proposed Rule." The hearing is scheduled for Thursday, March 21, 2024 at 10:00 AM ET. Additional information on attending or viewing the hearing is available **here**.

Be sure to bookmark our dedicated **LDT Resource Page** to stay informed on the latest news and analyses on LDTs.

Major Life Sciences Licensing Deal Trends in China in 2023

 *This is the first of two articles focused on 2023 life sciences deals in China. The second article, which is coming soon, looks at trends in M&A.*

In 2023, there were 240 reported life sciences licensing deals in China, an increase of almost 50% compared to 2021.

That includes 70 out-license deals involving Chinese companies licensing drugs and technologies to foreign companies, with a disclosed aggregate deal value surpassing US$35 billion.

It also includes 170 in-license deals involving Chinese companies licensing drugs and technologies from other Chinese companies or from foreign companies. This represents a 32% increase compared to 2021 — and a 58% increase compared to 2022 (more than making up for the 2022 dip in deals).

Read the full alert **here**.

USPTO's New Guidance on AI-Assisted Inventions: The Impact on the Use of AI in the Life Sciences

 On February 12, 2024, the US Patent Office and Trademark Office (USPTO) released the Inventorship Guidance for AI-assisted Inventions (**the Guidance**). We previously discussed the Guidance **here**.

Following up on the Guidance, the USPTO released two examples illustrating what the USPTO considers proper inventorship analyses for AI-assisted inventions. Each example sets forth different fact patterns and walks through an analysis of whether one or more human individuals qualify as inventors. Acknowledging that life sciences companies are increasingly employing AI systems to help

identify molecular targets and/or design therapeutic molecules, one of the two examples focuses on the use of AI to develop therapeutic molecules: Developing a Therapeutic Compound for Treating Cancer (**Example 2**).

Life sciences companies using AI-assisted systems should carefully consider whether their current R&D efforts allow for natural persons to provide a significant contribution such that the resulting efforts may properly identify a human inventor.

Read the full alert **here**.