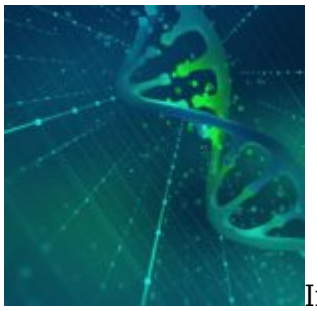
Lawsuit Filed Challenging FDA Final Rule Regulating Laboratory Developed Tests

On May 29, 2024, a lawsuit was filed in the U.S. District Court for the Eastern District of Texas, challenging the U.S. Food and Drug Administration's **final rule** concerning the regulatory status of laboratory developed tests ("LDTs") under the Federal Food, Drug and Cosmetic Act ("FDCA"). As detailed in our prior analysis (**here**), the final rule amended the FDA's existing regulations to make explicit the agency's interpretation that LDTs are "devices" under the FDCA, and established a five-stage plan to phaseout the agency's current general policy of "enforcement discretion" with respect to LDTs.

With the final rule's July 5 effective date looming, two entities—a trade association and a laboratory—filed suit in federal court to overturn the final rule. In this Insight, we briefly summarize the legal theories advanced in the lawsuit and likely next steps.

Read the full alert **here**.

Designating a Platform Technology: FDA's Long-Awaited Draft Guidance



In newly released **Draft Guidance** from the U.S. Food and Drug Administration (FDA) entitled, *Platform Technology Designation Program for Drug Development*, the FDA addresses its new designation program for platform technologies, which is intended to bring efficiencies to drug development, manufacturing, and review processes for applications that incorporate designated platform technologies.

Read the full alert **here**.

The Appeals Review Panel's In Re Xencor Decision: The USPTO Provides Its Position on Written Description and Means-Plus-Function Claims

 On May 17, 2024, an Appeals Review Panel (ARP) of the United States Patent and Trademark Office ("USPTO") released its decision in ***Ex parte Chamberlain*** (referred to in Federal Circuit proceedings as *In re Xencor*; "**Chamberlain**"). The ***Chamberlain*** decision provides some clarity on the USPTO's position on written description requirements for Jepson and means-plus-function claims in the life sciences space. Importantly, it suggests that carefully drafted means-plus-function claims are a potential path for Applicants to claim antibodies broadly by use of functional language (i.e., by their targets) once again.

The two claims considered in ***Chamberlain*** are functional claims to an antibody styled as (a) a Jepson claim (claim 8) and (b) a means-plus-function claim (claim 9). In the ***Chamberlain*** decision, officially dated May 21, 2024, the ARP maintains the Patent Trial and Appeal Board's ("PTAB") rejection of both claims for lack of written description, reverses the rejection of claim 9 for indefiniteness, and reverses the Examiner's obviousness-type double patenting rejections of claims 8 and 9 (not addressed in this publication).

Read the full alert **here**.

FDA Finalizes Rule and Sets Course to Phase In Oversight of Laboratory Developed Tests

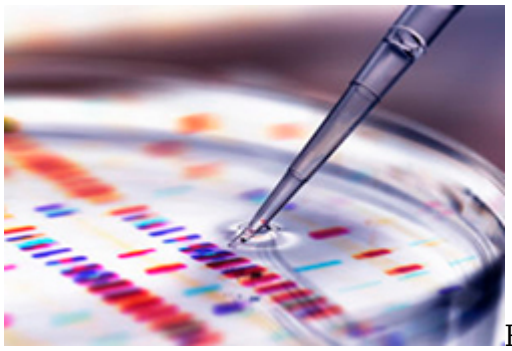
 On May 6, 2024, following more than a decade of discourse

with interested stakeholders on potential approaches to regulation of laboratory developed tests (LDTs), the U.S. Food and Drug Administration (FDA) published its **final rule** setting forth its framework for oversight of LDTs. The final rule and accompanying policy to phase out the agency's general policy of "enforcement discretion" for LDTs comes roughly six months after FDA published its **proposed rule** that outlined the agency's proposed approach to increasing oversight over LDTs. As detailed in our prior analyses of the proposed rule (see **here** and **here**), FDA proposed to implement a **phaseout policy** that would, across five stages and within four years, apply to clinical laboratories offering tests as LDTs the same regulatory requirements applicable to in vitro diagnostics (IVDs).

The proposed rule received more than **6,500 comments**, and while FDA did not change its amendments to the regulation or meaningfully modify the phaseout timeline, FDA has significantly modified its phaseout policy to extend full or partial enforcement discretion to additional categories of LDTs, creating a framework whereby the agency intends to take a more targeted enforcement approach, particularly in the near-term, to addressing LDTs.

You can read our more in our **Insight**, where **Steven Tjoe**, **Matt Wetzel**, and **Sukrti Thonse** highlight the key features of the final rule and five-stage phaseout policy. Be sure to bookmark our dedicated **LDT Resource Page** to stay informed on the latest news and analyses on LDTs.

2nd BCLT Advanced Life Sciences Institute



Rapid advancement in life sciences technologies has made keeping up with the legal implications more important than ever. Join the **Berkeley Center for Law and Technology** for the **2nd BCLT Advanced Life Sciences Institute**, where you will learn from the experts about cutting-edge issues impacting your life sciences practice.

The programming will share key insights and best practices related to the rapid rise of AI in the life sciences and new trends for licensing, deals, and life sciences funding models. Expert will review key developments in the law (Section 112, obviousness-type double patenting), anti-counterfeiting and patient safety, and the ever-complex interplay of regulatory and IP exclusivities. Finally, don't miss in-depth discussions on future pandemic preparedness and use of trade secrets v. patents for portfolio protection!

The Advanced Life Sciences Institute will be launched virtually through **B-CLE** on May 21 and 22.

Registration is free and available to all, and CLE will be offered.