USPTO and FDA Continue to Focus on Patent Quality in the Pharmaceutical Industry

 After a recent reminder from the U.S. Patent and Trademark Office (USPTO) regarding the duties of disclosure and reasonable inquiry during examination of a patent application and a Request for Comments (RFC) on the USPTO initiatives to ensure "robustness and reliability" of patent rights,[1] the Director of the U.S. Patent and Trademark Office published a third notice in less than four months. The latest notice is in conjunction with the Food and Drug Administration (FDA) to further the discussion surrounding the patent practices of the pharmaceutical industry (**87 Fed. Reg. 67019** (November 7, 2022)). Specifically, the notice is of a public listening session and request for comments (PLS/RFC).

Against the backdrop of President Biden's Competition Executive Order (EO) that calls for action "to help ensure that the patent system, while incentivizing innovation, does not unjustifiably delay generic drug or biosimilar competition beyond that reasonably contemplated by applicable law," as well as Congressional and public interest in this goal, the stated purpose of the present notice of the PLS/RFC is to obtain public input for areas of joint USPTO-FDA collaboration and engagement with respect to the pharmaceutical industry to promote greater access to medicines for American families.

In particular, the USPTO and FDA are seeking feedback from a broad group of stakeholders, most notably, patients and their caregivers, patient advocates, representatives from regulated industry, including companies that sell branded medicines, generic drugs and biosimilars, healthcare organizations, payers and insurers, academic institutions, public interest groups, and the general public.

The background of the notice of the PLS/RFC describes the response to the EO and details certain communications between the USPTO and the FDA in furtherance of its objectives. More specifically, in a letter from the USPTO to the FDA, initiatives for collaboration were outlined including exploring joint USPTO-FDA public engagements, providing examiners with training on publicly available FDA resources, exploring consistency in representations made to the USPTO and the FDA, revisiting patent term extension (PTE) practice, exploring the policies surrounding the use of "skinny labels," and being open to discussing "patent thickets," "evergreening," and "product hopping."

Further, in the current notice, the USPTO states in a footnote that this collaborative PLS/RFC is in parallel with the USPTO's initial RFC. The initial RFC included new USPTO initiatives to advance the EO; such initiatives include seeking input on enhancing processes for information disclosure statements and the identification of key prior art, considering applying greater scrutiny to continuation patent applications and use of declaratory evidence during patent prosecution, revisiting terminal disclaimer practice and procedures for third party input during prosecution, and conducting a comparative analysis of the prosecution and grant of "pharmaceutical and biological patents" in the United States versus other countries.

Although the USPTO notice on disclosure requirements and the initial RFC include all technologies, it is clear that the focus of the USPTO/FDA's inquiries are related to the pharmaceutical and biologics industries.

More specifically, with respect to the PLS/RFC, its inquiries include considering what FDA resources may be available to USPTO examiners to assess patentability, e.g., determining whether inconsistent statements were made to the USPTO and the FDA, using AIA proceedings to address the patentability of claims in pharmaceutical and biotechnological patents, revisiting PTE practices, understanding "skinny label" practice, and generally promoting greater availability of generic products. The PLS/RFC also seeks input on the questions posed in the USPTO letter to the FDA mentioned above.

The in-person PLS at the USPTO is scheduled for January 19, 2023, from 10 am to 5 pm (ET), for which preregistration is needed to speak. Written comments to the PLS/RFC will be accepted until February 6, 2023, with the comments to the initial RFC of the USPTO extended until February 1, 2023.

Stakeholders are encouraged to participate and we will monitor how the USPTO and the FDA respond to these hotly debated topics that impact almost every American.

[1] See **87 FR 45764** (July 29, 2022) and **87 FR 60130** (October 4, 2022), respectively. See also ***USPTO Publishes Notice Calling Out Pharmaceutical Industry***, Goodwin Life Sciences Perspective blog, July 29, 2022; and ***USPTO Doubles Down Calling Out Pharmaceutical Industry***, Goodwin Life Sciences Perspective blog, October 19, 2022, respectively.

Avoiding Misbranding: Words Matter When Describing the Regulatory Status of 510(k) Cleared Devices and Registered Device Establishments

When it comes to discussing medical devices regulated by the U.S. Food and Drug Administration (FDA), words such as "approved" and "cleared" cannot be used interchangeably as these terms carry a particular meaning. Similarly, creating an impression of approval of a device establishment or its devices because the establishment is registered with FDA

also is prohibited. Long-standing regulatory provisions, **21 C.F.R. § 807.97** and **21 C.F.R. § 807.39**, set forth, respectively, the FDA's position that approval and clearance are not interchangeable and that device establishment registration does not denote approval of the establishment or its devices. Importantly, these provisions also highlight the consequences to industry for misusing terms when discussing the regulatory status of a device or a device establishment.

When seeking to market a new device for which a premarket notification must be submitted to the FDA demonstrating that the device to be marketed is substantially equivalent to a legally marketed device, the submitter must obtain an order of substantial equivalence from the FDA, which is commonly referred to as a 510(k) *clearance*. Conversely, to market a new device for which a premarket approval application must be submitted to the FDA, the applicant must obtain FDA's *approval* of the application. While FDA review and FDA action occur for both types of medical devices, the outcomes of clearance and approval are distinctly different and carry legal consequences. Specifically, 21 C.F.R. § 807.97 states that "[a]ny representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding." Additionally, 21 C.F.R. § 807.39 states that "[a]ny representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

We researched Warning Letters in **FDA's Warning Letter Database** and found that FDA issued four Warning Letters citing violations of § 807.97 since 2017 and thirteen Warning Letters citing violations of § 807.39 since 2017.

Many of the representations that FDA found to be misleading under § 807.97 were straightforward violations, such as language on product websites stating that cleared devices are "FDA approved," or listings of device clearances under the heading "FDA Approvals." In one instance, FDA found the website to be misleading under both § 807.39 and § 807.97 because the company claimed the device had been cleared by the FDA, when in fact it was marketing a 510(k) exempt device for an indication that would require a de novo authorization which the company had not obtained, and the website claimed the company maintained an active listing, which was hyperlinked to the company's FDA Establishment Registration and Device Listing for only the 510(k) exempt device.

In response to the COVID-19 public health emergency, FDA issued twelve Warning Letters related to representations regarding masks and antibody tests that were found to be misleading under § 807.39. In virtually all of these instances, company websites displayed unofficial "certificates of FDA registration" issued by third parties which claimed to certify that the manufacturer had completed FDA Establishment Registration and Device Listing. These certificates often incorporated unauthorized reproductions of FDA's logo and motifs of the U.S. flag, giving the impression of official government documents. FDA consistently found the display of these certificates to be misleading, even when they included ostensible "disclaimer" language stating that the certificates did not denote FDA endorsement or approval. FDA repeatedly found that these disclaimers did not adequately limit or otherwise mitigate the misleading impression of the certificates because they were phrased, designed, and placed in a manner where they could be easily overlooked.

These Warning Letters present a cautionary tale to all sponsors intending to market new medical devices. While sponsors may be tempted to claim their devices are approved by the FDA following the agency's review of a premarket notification or upon completion of FDA Establishment Registration and Device Listing, § 807.97 and § 807.39 make clear that such claims will constitute misbranding. Sponsors can avoid § 807.97- and § 807.39-related Warning Letters and associated liability by carefully reviewing all of the language on their marketing materials and websites to ensure that none of their representations create the impression of official approval based on

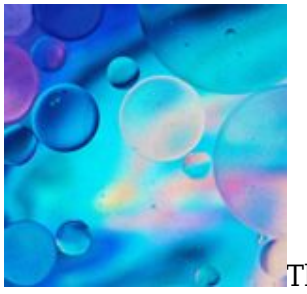
reference to a premarket notification submission or establishment registration.

Five Key Regulatory Considerations for Virtual Ketamine Clinics

 The off-label use of ketamine to treat anxiety, depression, and other behavioral health disorders —coupled with the COVID-19 telehealth era—has spurred the opening of virtual ketamine clinics nationwide. Some clinics offer a full suite of health care services, including telehealth visits, prescribing, pharmacy dispensing, and counseling services, while others are focused on more niche areas like group coaching sessions. In the wake of public reports detailing investigations into a number of digital health companies prescribing controlled substances, it is more important than ever to ensure your business model complies with the various regimes regulating the use of ketamine to treat behavioral health issues.

Read the client alert **here**.

Antitrust & Competition Life Sciences Quarterly Update Q3 2022

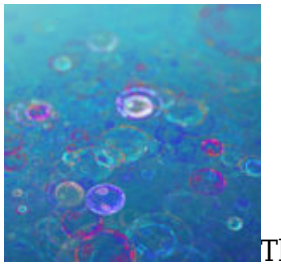
 The third quarter in the life sciences space showed that business is generally proceeding as usual, with large pharma players successfully acquiring or licensing in clinical stage assets without running into antitrust delays. That said, even these inherently procompetitive deals appear to be receiving at least some attention from the agencies. As such, being ready for scrutiny should help avoid extensive and costly reviews. Indeed, a recent trio of mergers within the sickle cell disease space shows the importance of adequate preparation and engagement.

Antitrust agency activity in other sectors is also instructive. The FTC's challenge to the Meta/Within merger could portend difficulties for the life sciences space, but recent court defeats could temper

the agencies' appetite for challenges based on novel and/or more aggressive theories, including potential competition.

Read the Goodwin Insight **here**.

FDA Announces Total Product Life Cycle Advisory Program (TAP) Pilot



The U.S. Food and Drug Administration's ("FDA" or "the Agency") Center for Devices and Radiological Health ("CDRH") recently announced the launch of its Total Product Life Cycle Advisory Program ("TAP") Pilot. The first phase of this voluntary initiative, called TAP Pilot Soft Launch, will be conducted during fiscal year ("FY") 2023 with enrollment beginning on January 1, 2023.

The Agency committed to establishing the TAP Pilot as part of the MDUFA V reauthorization, and the Agency's long-term vision for TAP is "to help spur more rapid development and more rapid and widespread patient access to safe, effective, high-quality medical devices of public health importance." As part of the TAP Pilot, the FDA will provide strategic engagement for such devices by:

- Improving participants' experiences with the FDA by providing for more timely premarket interactions
- Enhancing the experience of all participants throughout the device development and review process, including FDA staff
- Facilitating improved strategic decision-making during device development, including earlier identification, assessment, and mitigation of device development risk
- Facilitating regular and solutions-focused engagement early in device development between FDA review teams, participants, and other stakeholders, such as patients, providers, and payers
- Collaborating to better align expectations regarding evidence generation, improve submission quality, and improve the efficiency of the premarket review process

Read client alert **here**.