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From the PTO to The FDA: What to Consider When Branding Clinical Trials

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The legal implications of branding generally arise for companies during the process of selecting a company name and any initial product or service names. For drug development companies, however, careful consideration should also be paid to the implications of branding a clinical trial.

Our experience and observations suggest that branding clinical trials has become more prevalent. While it may seem unnecessary to brand a clinical trial because of its limited duration and pre-market nature, the long road to market for therapeutics makes building a recognizable house brand or product name challenging for companies before regulatory approval. As a result, companies are turning to the clinical trial process as an early-phase opportunity to establish a brand identity, raise public awareness of the company's mission, and create market familiarity with the company's technology and discovery objectives.

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Each month in the U.S. around 800 clinical trials are commenced and around 80 trademark applications are filed that use the phrase "clinical trial(s)" in the specification of goods or services. These applications typically cover Class 9 (applications or software for clinical trials), Class 35 (recruiting for clinical trials), or Class 42 (medical research). The number of trademark applications related to clinical trials has steadily increased from 2018-2020, with filing volume spiking significantly from May 2020-July 2020. The spike in applications was followed by a corresponding increase in clinical trials from August 2020-November 2020, suggesting that companies are applying for trademarks relating to clinical trial activity several months before trials actually begin.

Branding agencies tout the benefits of an effective clinical trial branding campaign in improving participant recruitment and retention for the trial, drawing investment, and increasing citations in third-party studies and research literature, all of which could contribute to the success of clinical development and regulatory approval of potentially life-saving therapeutics. Further, while these potential benefits of clinical trial branding may not directly establish enforceable rights in a name or address regulatory concerns, by serving the goals of the trial itself and increasing public awareness and stakeholder involvement, they warrant paying legal attention to the trial name that is adopted.

Trademark and regulatory attorneys representing drug development companies are surely familiar with the dual-track process of naming a potential drug, which involves scrutiny of the name by both the U.S. Patent and Trademark Office (USPTO) and Food & Drug Administration (FDA). Not all, however, may be attuned to the unique considerations of branding a clinical trial name. We touch on some of these considerations in the discussion that follows, including the importance of performing trademark clearance, the challenges and benefits of protecting a clinic trial name, and the independent regulatory considerations that drug development companies should evaluate when branding a clinical trial.

Trademark Availability

Before a company adopts a trademark or files a trademark application, it is advisable to perform trademark clearance to assess whether the proposed mark is available. Without performing proper clearance, the company is vulnerable to a potential challenge from a third party with pre-existing rights. For clinical trial names, a challenge could interrupt the clinical trial and even disturb its

methodology if it affects participant recruitment or retention, creating a major inconvenience for the company conducting the study.

Some may question the need for trademark clearance of a clinical trial name. After all, this name is often used only before commercial launch, with a separate name used to identify the drug candidate itself. Moreover, a company behind a clinical trial is not providing a commercial "good" or performing a "service" under the clinical trial name, at least not in a typical trademark sense, simply by conducting clinical trials for the company's own benefit. Nevertheless, a clinical trial name could still create marketplace confusion if, for example, it is confusingly similar to a third-party clinical trial name, drug name, or the house mark of a company in the same or a related field. As a practical matter, the importance of thorough clearance is particularly great if the clinical trial name will be marketed or promoted widely.

Trademark clearance often begins with a preliminary (or "knock-out") search of several options and then follows with an in-depth (or "full") search of a narrower list of choices. If a preliminary search does not reveal any clear or obvious conflicts, the recommended next step is often to order an in-depth search. An in-depth search, generally conducted by a vendor, will provide a more comprehensive report of potentially conflicting trademark filings as well as a deeper dive into marketplace uses of similar marks, domain names, and drug names. Some vendors also offer a pharmaceutical-specific extension that searches various pharma-related sources and provides information to help reduce the risk of rejection of the name by regulatory agencies.

After assessing potential risks, a company's attention may turn to whether and how to protect the name of its clinical trial.

Trademark Protectability And Registration

Whether a company is concerned with protecting its clinical trial name may depend on how extensively it plans on promoting the trial and the trial's expected duration. Trademark protection for a trial of relatively short duration that is not promoted extensively is probably less important than a longer or more heavily promoted trial, and the degree of distinctiveness of the trial name may also bear on this question, as it tends to do with trademarks generally.

Drug development companies concerned with protecting their clinical trial name in the U.S. must navigate the requirement that a mark be used in commerce in the ordinary course of trade. Ordinarily, trademark owners can "plant a flag" on a new trademark by filing an intent-to-use application with the USPTO, which establishes a priority date ultimately secured by effectively proving use of the trademark to the USPTO and obtaining a trademark registration. But how can a drug development company prove "commercial" use of a clinical trial name when the trial itself is not per se commercial?

For one, a drug development company's own clinical trial activity will generally not be protectable as a "service" under trademark law, if it is for the company's own commercial benefit, as opposed to clinical trials performed by third-party research organizations for a drug development company's benefit. *See*, TMEP §1301.01(a)(ii) ("Performing research and development, or other routine or expected activities, in the production or sale of one's own goods, and not for the benefit of others, are not services for purposes of service-mark registration.") As clinical trials are generally conducted to support FDA approval, they are an expected, routine, and even mandated activity not separately registrable from the principal activity of providing therapeutics. *See*, TMEP §1301.01(a)(iii). As a result, drug development companies may be precluded from registering a clinical trial name as a service mark.

A more viable way for a drug development company to register its clinical trial name may be in association with pharmaceutical preparations or other "goods" under study, even without traditional commercial use. It is now well established that a trademark used with clinical trials can satisfy the use-in-commerce requirement so long as it is in the "ordinary course of trade," which is generally considered the case for pre-market testing of therapeutics for the purpose of seeking regulatory approval. Because of the years long regulatory hurdles faced by drug development companies before obtaining the approval needed for commercial launch, the use-in-commerce requirement is satisfied by, for example, shipping drug samples to laboratories for clinical trials (*G.D. Searle & Co. v. Nutrapharm, Inc.*, 1999 WL 988533 (S.D.N.Y.)) and pre-clinical trials conducted in the U.S. and clinical trials overseas by a U.S. company (*Alfacell Corporation v. Anticancer, Inc.*, 2002 WL 31121389 (TTAB)). In practice, any legitimate and non-token cross-border use (state or international) of a mark for purposes of testing potential therapeutics should, and generally does, satisfy the use-in-commerce requirement for securing a U.S. registration.

The feasibility of registering a clinical trial name as a trademark for a good may be an open question and is, to our knowledge, not as well established as registering a house mark or drug name based solely on pre-market clinical trials. But the logic of permitting registration of a house mark or drug name based solely on pre-market trials should apply with equal force to clinical trial names, provided that the trial name appears

in a manner sufficiently associated with the therapeutic being shipped or tested, such as by appearing on the drug candidate label, packaging, clinical trial protocol, or other materials distributed to a clinical site for conducting a trial.

In the absence of a registration, a company may seek to rely on common law rights to protect a clinical trial name. In the U.S., one can build a protectable brand based on use alone, and thus spare the expense of an application that may not ultimately register if the USPTO's technical requirements for proving commercial use cannot be satisfied.

Filing for trademark protection outside the U.S. presents a more straightforward path to registration, as commercial use is not a prerequisite to registration in most foreign jurisdictions. An applicant in the European Union, for example, may obtain an EU registration without showing use and the registration will not become vulnerable to challenge by a third party for non-use for a period of five years, at which point the trial may have run its course in any case.

Regulatory Considerations

Clinical trial protocols, informed consent, and participant recruitment materials are subject to review and approval by an institutional review board (IRB) or independent ethics committee. As such, it is important to consider the clinical trial name early during clinical development to ensure consistency in all the relevant clinical trial documents. Depending on the clinical trial design, clinical trial sponsors should take care that the trial name or branding does not compromise the trial blinding plan, introduce bias in study groups, or compromise the trial's data integrity. Company sponsors must also avoid clinical trial names that suggest the investigational product is safe or effective, or otherwise beneficial to study subjects. Sponsors should also consider how the trial name will change as an investigational drug product progresses from Phase 1 to Phase 3 or Phase 4 clinical trials, and the potential confusion with other clinical trials.

The FDA regulates investigational drug products (including the brand name of the drug if eventually approved) as well as the conduct of clinical trials used to support FDA approval. Until a drug product is approved by the FDA, clinical trial sponsors should not make any claims regarding the safety or efficacy of an investigational drug product. Accordingly, clinical trial names should avoid making or suggesting any such claims (including implied claims) regarding the investigational drug product. Use of positive quality names or names that incorporate product-specific attributes, such as PREVENT, SAFE, or RESTORE, will raise questions or be rejected by the FDA and/or the IRB, which could delay clinical trial timelines. To the extent the clinical trial name is based upon or impacts the naming of the drug product, sponsors need to understand that the proprietary drug name is subject to FDA review and approval, which typically does not occur until the FDA is close to granting an approval for the drug product, at which time there is a chance that the FDA will reject the proposed drug name for non-compliance with the FDA drug nomenclature rules. Also, when developing a name for a clinical trial that includes trial sites in different countries, clinical trial sponsors should also consider applicable regulations and regulatory review or approval processes in foreign jurisdictions.

Further, use of positive quality names or names that make implied claims about the investigational drug product may complicate disclosures in the event of a failure to meet clinical trial endpoints or a serious adverse event. For privately held companies that are anticipating accessing public markets through an initial public offering, disclosures to the U.S. Securities and Exchange Commission (SEC), including disclosures in the offering documents or prospectus, use of such positive quality names can be problematic and create confusion to purchasers of the company's equity, which may increase the company's exposure to shareholder lawsuits.

Conclusion

All told, while branding a clinical trial may be helpful in building public awareness and interest, legal considerations abound. Drug development companies should evaluate and closely consider potential trademark availability risks and protectability challenges before adopting a potential trial name. Further, in branding a trial name, drug development companies should take view of the impact on clinical trial related materials that require IRB and FDA approval; FDA regulations on clinical trials, drug advertising and promotion, and drug nomenclature; and the company's public disclosures and SEC filings.