ANALYSIS

The FDA and Patent Office React to Biden's Call to Action on Drug Patents

The president directed the U.S. Food and Drug Administration (FDA) and the U.S. Patent and Trademark Office (PTO) to propose ways the two agencies could collaborate towards this end. The agencies responded with a joint proposal to change how patents protecting drugs are examined, prompting responses from a wide range of industry participants.

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Special Sections

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In July 2021, President Joe Biden issued an Executive Order that took aim at increasing competition in the pharmaceutical industry. The President directed the U.S. Food and Drug Administration (FDA) and the U.S. Patent and Trademark Office (PTO) to propose ways the two agencies could collaborate towards this end. The agencies responded with a joint proposal to change how patents protecting drugs are examined, prompting responses from a wide range of industry participants. This article reviews the proposed initiatives and the industry response, and outlines what to expect next.

Current Practice and Agency Roles

Pharmaceutical innovator companies that research, develop, and bring new drugs to market work with both the FDA and the PTO. Innovators must seek FDA approval before they can market a drug, and they typically go to the PTO to seek patent protection for the drug as well. When the FDA is asked to approve a proposed drug, it focuses on the safety and efficacy of the product. The details of the regulatory process will differ somewhat depending on whether the product is a so-called "small molecule" drug that is chemically manufactured, or a "biologic" that is made using a biological system, but the fundamental purpose of FDA review is the same. The PTO's review of patent applications has a different purpose: its basic goal is to determine whether patent applicants have made novel inventions meeting the statutory requirements for patent protection. To make that call, patent examiners with technical backgrounds review each application against what was already known in the field, or "prior art." And applicants in this process have a duty to provide examiners with material information to aid their examination. These processes happen on separate tracks: a drug patent can issue before the drug it covers is FDA-approved. Given the time it takes to complete them, patents covering a drug—which, like all patents, typically expire 20 years after an application is first filed—may have lost years of statutory patent protection before the drug can even be marketed.

Despite their separate roles, the agencies have certain responsibilities that bring them into contact with each other's domain. For example, the FDA is responsible for a publication, known as the "Orange Book." The Orange Book lists patents that cover approved small-molecule drugs, at least according to the drug sponsors who submit patent information to the FDA. The FDA and the PTO also communicate with one another when a company files an application with the PTO to extend the term of a patent that covers its drug to make up for effective patent term when the patented drug was under FDA review. This extended term is known as "Patent Term Extension."

Congress has created abbreviated FDA-approval pathways for companies who want to market generic versions (of small-molecule drugs) or biosimilar versions (of biologics) of an existing FDA-approved product. But the law does not allow a generic or biosimilar manufacture to evade patent protection. To that end, in the same statutes that create abbreviated approval pathways—the Hatch-Waxman Act for small-molecule drugs and the Biologics Price Competition and Innovation Act (BPCIA) for biologic drugs—Congress devised ways to streamline the resolution of patent disputes. In addition, under the 2012 America Invents Act (AIA) Congress created processes to challenge the validity of patents at the PTO after their issuance.

The Executive Order and the Agencies' Proposed Initiatives

The president's Executive Order calls the FDA and the PTO to action. The Order expresses concern that "patent and other laws have been misused to inhibit or delay—for years and even decades—competition from generic drugs and biosimilars, denying Americans access to lower-cost drugs." These two key agencies are now tasked to collaborate to ensure that the systems in place incentivize innovation while also addressing barriers to generic drug and biosimilar entry. Acting on the President's direction, the FDA wrote to the PTO on September 10, 2021 to propose measures that would permit the FDA's input in patent examination and open the door for more collaboration between the agencies moving forward. The PTO responded on July 6, 2022, echoing many of the FDA's sentiments and outlining specific initiatives which formed the basis for the agencies' joint proposal.

The proposed changes fall into two main categories: changes that could affect patent examination in the near term, and plans for future agency collaboration. The near-term changes relate to prior art searching and patent applicants' disclosure obligations to the PTO and the FDA, and will be largely addressed through patent examiner training. The plans for agency collaboration center on increased information-sharing between them on topics such as generic drug labeling, Patent Term Extension, and use of AIA proceedings to challenge biopharmaceutical patents. These initiatives have been the subject of public comment as discussed below.

The PTO's letter also included proposals that do not involve the FDA and are not open to public comment. Rather, the PTO gave notice of what it is contemplating internally in response to the Executive Order. For example, the PTO stated that it plans to "introduce more examining time into the patent examination system," particularly for large patent families, "consider applying greater scrutiny to continuation applications in large families and/or the use of declaratory evidence to overcome rejections," and "revisit obviousness-type double patenting practice."

Public Comments

The public comment period for the proposed FDA-PTO initiatives began Nov. 7, 2022, and ended March 10, 2023. The agencies received over 90 comments from various industry, academic, and public-interest stakeholders.

For example, leading trade organizations for pharmaceutical innovator companies—Pharmaceutical Research and Manufacturers of America (PhRMA) and Biotechnology Innovation Organization (BIO)—submitted comments calling for caution. They urged the agencies not to change a patent system that is already working. According to PhRMA, "IP protections are more important than ever to protect investment in biopharmaceutical R&D" given the increasing cost of bringing drugs to market and the increasing risk that those drugs will fail to launch. PhRMA notes that the drug-labeling policies are already tilted toward the interests of generic drug manufacturers because generics are permitted to omit

patent protected indications, even if in reality the generics are substituted for branded drugs for those indications. Both organizations point out that the proper balance between innovation and competition was already struck with the Hatch-Waxman Act and BPCIA.

Unsurprisingly, comments from trade organizations representing generics and biosimilar manufacturers see things differently. These comments generally supported the proposed FDA-PTO initiatives. Common refrains (for example, from the Biosimilars Forum) include an emphasis on the high costs of challenging drug patents, both in terms of litigation costs and prescription drug spending. And some (such as Initiative for Medicines, Access & Knowledge (I-MAK)) argue the average period of market exclusivity for a biologic is simply too long.

Some of the proposed initiatives are less controversial than others. For example, PhRMA raised no objection to proposed patent examiner training (based on FDA-PTO collaboration) on public FDA resources that may be used to identify prior art, although BIO expressed skepticism over whether FDA regulatory dossiers would be fruitful sources for prior art.

However, both PhRMA and BIO pushed back against proposals for the FDA and the PTO to collaborate on efforts to ensure that information submitted to each agency is consistent, that the PTO has all relevant information submitted to the FDA, and that patent applicants are aware of their disclosure obligations. Here, PhRMA and BIO argue that creating a new infrastructure to determine inconsistent statements "is unwarranted" given that the duty to disclose already exists, backed by significant sanctions for dishonest conduct at the PTO (through the defense of inequitable conduct) that provide a sufficient deterrent for such conduct. The organizations further cite a lack of evidence to corroborate any allegations of widespread inconsistent statements by innovators, as well as the complexity associated with information sharing in an area that involves highly sensitive, proprietary information that is protected by statutory confidentiality requirements.

The innovator-focused trade organizations resist initiatives calling for FDA-PTO collaboration where such collaboration would be unnecessary or beyond the scope of a given agency's mandate. On generic drug labeling, for example, both PhRMA and BIO agree that FDA's role in listing patents in the Orange Book should remain ministerial, and the PTO should remain uninvolved in patent listing.

What Happens Next

The FDA and the PTO are assessing the public comments, and they may choose to either extend the comment period further to solicit more feedback or to confer internally to digest the feedback. If any changes are made to FDA and PTO policies, that could take several months, and may require more structured guidance and rulemaking procedures. Nevertheless, we may expect to see some changes in line with the PTO's internal initiatives, which may affect patent protection for FDA-approved medications. In short, the President has called for action, and affected participants in this space need to monitor what actions these agencies may take.

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