WE WORK FOR HEALTH

POLICY BRIEF:

PRESERVING THE INTEGRITY OF INTELLECTUAL PROPERTY PROTECTIONS

Intellectual property protections include patents the U.S. Patent and Trademark Office grants to innovators for inventions. For pharmaceutical products, patents can be granted for innovations such as:

- the active ingredient of a drug product
- a drug method of use
- drug formulation
- methods of making or manufacturing a drug product, or
- a device used for a drug's administration

Once a drug is approved by the Food and Drug Administration (FDA), certain patents can be listed publicly in FDA's Orange Book to protect against unlawful market competition by providing notice of patents and inclusion in the Hatch-Waxman framework.

WHAT ARE ORANGE BOOK PATENT LISTINGS?

The Federal Food, Drug, and Cosmetic Act requires any drug developer that submits a drug for FDA review to also submit patent information for the drug to be published in the Orange Book after FDA approval. FDA regulations also prohibit certain patents from being listed.

The patents required to be listed **in the Orange Book include patents that claim:**

1. the drug's active ingredients, formulation or composition (drug substance patent or drug product patent); or
2. an approved method of use for such drug.

FDA regulations preclude the following types of patents from being listed **in the Orange Book:**

1. manufacturing process patents,
2. patents claiming packaging, metabolites, and intermediates.

Why does an Orange Book patent listing matter for drug developers?

- To help protect that drug from unlawful market competition and enable the developer to resolve patent issues prior to generic drug market entry.
- Listing a patent in the Orange Book provides transparency and predictability for the innovator and generic manufacturers as it allows generic drug developers to know that patents exist, which patents, and how many will need to be challenged and proven to be invalid or not infringed for the generic to enter the market prior to patent expiration.
- The Hatch-Waxman Act provides the appropriate balance of patent protections and regulatory exclusivity for innovator drugs and access to generic drugs. Specifically, as part of that balance, the Hatch-Waxman Act requires generic drug developers to prove innovator patents are invalid or not infringed in order to market a generic drug prior to expiration of the innovator patent.

What is the process for addressing improperly listed patents?

- The Hatch-Waxman Act provides a mechanism to address patents that are alleged to be improperly or inappropriately listed in the Orange Book.
- FDA regulations also provide a process for correcting patent listings alleged to be improperly listed.

FTC'S OVERREACH AND CAMPAIGN TO UNFAIRLY ERODE IP PROTECTIONS

The FTC has recently been targeting Orange Book patent listings – ultimately seeking to strip innovators of IP protections in Hatch-Waxman in favor of allowing generic manufacturers to copy innovative products earlier than current law envisions.

- In September 2023, FTC issued a Policy Statement threatening innovators that Orange Book patent listings "that do not meet the statutory listing criteria undermine… the competitive process and may constitute an unfair method of competition in violation of Section 5 of the FTC Act." [1]
- Since then, FTC has targeted more than 400 patents listed in the Orange Book that it claims are "junk listings."
- The issue is that the FTC does not have the expertise to make such determination and has demanded that companies delist these patents from the Orange Book.[2,3] These challenges focused on drug products with drug-delivery devices such as injection devices or inhalers.
- The FTC's tactics are intended to strip away legal IP protections provided by the Hatch-Waxman Act intended for innovators and would remove the transparency and premarket patent issue resolution many generic manufacturers rely on.

FDA HAS FAILED TO TAKE ACTION

- There are certain types of patents for which FDA has not provided clear direction regarding whether innovators should list or not list in the Orange Book. These patents include:
  1. patents claiming drug-delivery devices, and
  2. patents covering risk evaluation mitigation systems (REMS). This is the case even after repeated requests from industry for FDA to provide guidance on the device issue.
- By not acting, FDA has created ambiguity regarding the listing requirements for patents including such claims.
- The FTC has exploited this lack of regulatory clarity by making sweeping assertions of "sham" patent listings in the Orange Book and taking actions that jeopardize the ability of innovators to leverage the IP protections provided under current law.

WHAT CAN CONGRESS DO?

Protect and uphold IP protections for innovators and promote transparency for generic competition in the Hatch-Waxman framework by pressing FDA to clarify the types of patents that can and cannot be listed in the Orange Book. Clarifying the types of patents claiming drug-delivery devices that are required to be listed in the Orange Book would provide greater certainty in what patents to list and will uphold the IP protections intended by the Hatch-Waxman Act. Clarity also assures that the right balance to spur innovation and competition among drug developers the Hatch-Waxman Act intended.

FOR MORE INFORMATION ABOUT PATENTS AND INTELLECTUAL PROPERTY, VISIT WEWORKFORHEALTH.ORG/IP

1. https://www.ftc.gov/news-events/news/press-releases/2023/09/ftc-issues-policy-statement-brand-pharmaceutical-manufacturers-improper-listing-patents-food-drug
2. https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-challenges-more-100-patents-improperly-listed-fdas-orange-book
3. https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-expands-patent-listing-challenges-targeting-more-300-junk-listings-diabetes-weight-loss-asthma