What is the Orange Book?

The United States leads the world in biopharmaceutical innovation and access because we have a unique intellectual property (IP) system that strikes a balance between innovation and affordability. A key part of the policy foundation is the Hatch-Waxman Act.

Hatch-Waxman, formally known as The Drug Price Competition and Patent Term Restoration Act of 1984, established a regulatory and IP framework that both fosters competition by facilitating the approval of generic drugs while incentivizing innovation. As a result, today, more than 90% of prescriptions for drugs are filled with generics. That's more than in any other country. One important piece of this framework is the Food and Drug Administration's (FDA) Orange Book and the Hatch-Waxman patent process.

The Orange Book provides information on approved drugs and related patents and exclusivities. When an innovator submits an FDA application for the approval of a new drug, they are required by statute to include information on certain patents that claim that drug substance, drug product or uses of that product. Once the drug has been approved, the FDA publishes this patent information in the Orange Book. This patent listing is fundamental to the Hatch-Waxman framework and provides benefits to both the innovator company and generics and serves to resolve any patent disputes before marketing of the generic drug.

Benefits of Orange Book Patent Listings:

Transparency to the existence of relevant patents for drugs, drug products and methods of use

Early, efficient, and orderly resolution of patent issues prior to marketing of the proposed generic product, when generics can incur damages

Incentives for patent challenges through potential exclusivity for generic applicants

How the Orange Book fits in the Hatch-Waxman framework:

- Generic applicants must indicate to the FDA whether there are unexpired patents in the Orange Book listed for the relevant innovator product. If there are, the generic applicant must say whether they will wait until patent expiration to market their product or whether they allege the patent is invalid or would not be infringed by their product and provide notice to the innovator company.

- The innovator company can then file a lawsuit for a patent infringement.

- If the innovator files a suit within 45 days of receiving notice, the FDA cannot grant final approval to the generic applicant for 30 months (unless the generic wins the case sooner). This gives time for the court to hear the case before the marketing of the generic product.

- If there is no court decision after the 30-month mark, and assuming no FDA approvability issues, the generic can come to market.

Orange Book Uncertainty

The biopharmaceutical industry has for years sought clarity from the FDA on some ambiguity in its approach to patent listings, namely on whether certain types of patents should or should not be included in the Orange Book.

One area of confusion is around patents claiming drug delivery devices. The industry has repeatedly requested guidance on the issue, but the **FDA has not provided the clarity sought**. Instead, the FDA has stated that they are convening a multidisciplinary workgroup to review Orange Book listings and evaluate the need for changes on what is or is not included.

Some critics claim that patents are frequently improperly listed in the Orange Book, ignoring that there are already systems in place to challenge listings.

In 2003, Congress implemented a way within Hatch-Waxman litigation to challenge patents allegedly improperly listed.

Additionally, in 2016, FDA updated a procedure for any person to see a correction of patent information in the Orange Book.

If an innovator company does not file a patent in the Orange Book then generic companies lose the benefit of the patent being in the Hatch-Waxman process and a generic company marketing its product would lead to more complicated litigation with potential damages and the possibility of being prohibited from marketing its product. For this reason, failure to list required patents is a grounds for FDA to refuse to approve an innovator application.

Hatch-Waxman and the Orange Book are important components of an IP framework that has been a clear success, enabling vast access to generic medications and incentivizing innovation.