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Patent Listing in FDA's Orange Book

For over 40 years, the U.S. Food and Drug Administration (FDA) has maintained a resource formally titled *Approved Drug Products with Therapeutic Equivalence Evaluations*. This frequently updated publication—available as a searchable online database—is more commonly called the "Orange Book" after the color of the print version's cover.

The Orange Book

The Orange Book lists all of the nonbiologic (a.k.a. "small-molecule") drugs approved by FDA to be marketed in the United States. (Biological products, which are drugs derived from living organisms—such as vaccines, blood components, and monoclonal antibodies—are listed in a separate FDA publication known as the "Purple Book.") Along with information about the approved drugs (e.g., dosages and forms), the Orange Book includes FDA's therapeutic equivalence evaluations—that is, the approved products that are pharmaceutically equivalent and bioequivalent to another approved product (e.g., a generic form of a brand-name drug). Finally, the Orange Book includes information on patents and regulatory exclusivities that may protect a brand-name drug from generic competition.

The Orange Book serves as an important resource for health care providers and the pharmaceutical industry. Providers may use the Orange Book to determine the regulatory status of a product (e.g., whether a drug has been approved by FDA or if an approval has been withdrawn). Pharmacists may use the Orange Book to determine whether a therapeutically equivalent generic form of a drug is available to substitute when they fill a prescription written for a brand-name drug.

For drug manufacturers, the Orange Book's information on a drug's patents and regulatory exclusivities can be critical to whether and when generic competition occurs. (For more information, see CRS Report R46679, *The Role of Patents and Regulatory Exclusivities in Drug Pricing*.)

Pharmaceutical Patents

Patents are a form of intellectual property that protect new inventions. To obtain a patent, an inventor must file a patent application with the U.S. Patent and Trademark Office (USPTO). USPTO reviews the application and grants a patent only if the claimed invention meets the statutory requirements. A patent's term lasts for about 20 years.

Like any other invention, pharmaceutical-related innovations must be new, useful, nonobvious, and sufficiently described to be patented. For example, if a person synthesizes a new chemical with potential use for treating human disease, she may obtain a patent on that chemical itself (an active-ingredient patent). Pharmaceutical manufacturers often obtain many other types of drug patents beyond the active ingredient, including patents on methods of using a drug, drug formulations, devices to administer a drug, and methods of making a drug. A single brand-name drug may thus be protected by multiple patents, which may expire at different times.

Patent Listing in the Orange Book

Only certain types of pharmaceutical patents are included in the Orange Book. By statute, a company seeking FDA approval of a new drug must include in their new drug application (NDA) any patent that either (1) "claims the drug" and "is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent"; or (2) "claims a method of using such drug for which approval is sought." If the drug is later approved by FDA, the patent information in the NDA (along with any updates) is listed in the Orange Book with the drug.

FDA regulations provide that "[p]rocess patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates" must *not* be included in an NDA. As a result, these types of patents should not be listed in the Orange Book per FDA regulations.

Brand-name and generic drug manufacturers have disputed in court whether certain patents should be listed in the Orange Book. In *Jazz Pharmaceuticals v. Avadel CNS Pharmaceuticals*, the U.S. Court of Appeals for the Federal Circuit held that a patent on a computerized risk evaluation and mitigation strategy (REMS) system for a drug should not have been listed in the Orange Book. With respect to patents on drug devices, the U.S. Court of Appeals for the First Circuit held in *In re Lantus Direct Purchaser Antitrust Litigation* that a patent on a device for injecting a drug should not have been listed in the Orange Book, and the Federal Circuit reached the same conclusion in *Teva v. Amneal Pharmaceuticals* regarding patents on metered-dose inhalers. A 2022 report from FDA and a 2023 report from the Government Accountability Office reveal varied stakeholder views on these issues, with some calling for FDA to clarify the rules for listing REMS and device patents in the Orange Book.

The FDA's "Ministerial" Role

FDA does not actively police the patents listed in NDAs to ensure that they in fact claim the drug or a method of using the drug. FDA maintains that it lacks expertise in patent law and that its role with respect to Orange Book patents is only "ministerial." In other words, FDA lists the patent information provided by drug companies in the Orange Book without independently verifying that it meets the statutory and regulatory requirements. Some stakeholders have criticized this approach based on concerns that that NDA filers may list inapplicable patents in the Orange Book to deter generic competition.

FDA does have an administrative process through which any person who "disputes the accuracy or relevance of patent information" in the Orange Book may notify FDA and seek correction of the patent information. FDA will only change the patent information in the Orange Book if the NDA holder agrees to amend or correct the information in response to the patent listing dispute.

The Orange Book and Generic Entry

Prior to generic entry, the brand-name drug may be the only available version of a product. Generic competition tends to bring down the price of a drug, in some cases sharply.

The process for generic drug approval is governed by the Hatch-Waxman Act of 1984 (P.L. 98-417), as amended. Under Hatch-Waxman, a drug company may seek FDA approval for a generic version of an approved brand-name drug by filing an abbreviated new drug application (ANDA). An ANDA must make one of four certifications with respect to each patent listed in the Orange Book:

- *Paragraph I*: Certifies that there are no patents listed for that drug in the Orange Book.
- *Paragraph II*: Certifies that all the patents listed in the Orange Book for that drug are expired.
- *Paragraph III*: Certifies that the ANDA filer does not challenge the patent(s) listed in the Orange Book.
- *Paragraph IV*: Certifies that the ANDA filer challenges the patent(s) listed in the Orange Book as invalid or not infringed (i.e., inapplicable).

FDA may approve ANDAs with paragraph I or II certifications immediately. If the generic applicant makes a paragraph III certification, FDA may not approve the ANDA until the patents at issue have expired. If the generic applicant makes a paragraph IV certification and the NDA filer timely sues in court for patent infringement, this triggers the "30-month stay." FDA cannot approve the ANDA for 30 months, unless the court resolves the patent dispute earlier (so-called "patent linkage").

In considering whether and when to file an ANDA, generic drug companies will assess the expiration date, scope, and validity of patents listed in the Orange Book. They may weigh, for example, the costs and benefits of challenging a patent under paragraph IV or instead waiting for a patent to expire under paragraph III. Orange Book patents can thus affect when generic competition begins for a drug.

It is generally in the interest of NDA holders to list all relevant patents in the Orange Book. While patent holders may still sue in court for infringement of drug patents that are not listed in the Orange Book, the ANDA filer need not certify as to unlisted patents and the 30-month stay would not apply. In that case, FDA could approve the ANDA on its own schedule, unless a court ruled otherwise.

The FTC and Orange Book Patents

In September 2023, the Federal Trade Commission (FTC) issued a policy statement concerning some drug manufacturers' alleged "improper listing of patents" in the Orange Book. The intent of the statement was to notify drug makers that "the FTC intends to scrutinize improper Orange Book listings to determine whether these constitute unfair methods of competition in violation of Section 5 of the [FTC] Act." FTC argued that improperly listed patents "may disincentivize investments in developing a competing product and increase the risk of delayed generic and follow-on product entry, reducing patient access to more affordable prescription drugs and increasing [health care] costs."

In November 2023, FTC announced that it had used FDA's administrative process to challenge more than 100 patents as improperly listed in the Orange Book, including patents relating to drug-delivery devices such as asthma inhalers and epinephrine autoinjectors. FTC also sent notice letters to drug companies informing them of FTC's view that these patents were improperly listed in the Orange Book. In response, several drugmakers opted to delist (i.e., remove) patents challenged by FTC; other drugmakers maintained that their patents were properly listed in the Orange Book.

FTC's Orange Book-related actions continued through 2024 and 2025. In April 2024, FTC announced that it had challenged an additional 300 Orange Book patents as improperly listed and sent new warning letters to drug companies concerning 20 different brand-name drugs. These new challenges include patents relating to asthma and COPD inhalers and patents on devices to deliver injectable weight-loss and diabetes treatments. In May 2025, FTC challenged an additional 200 Orange Book patents relating to 17 different drug products. Several hundred patents have been removed from the Orange Book following FTC's actions.

Issues for Congress

The types of patents required to be listed in the Orange Book and their effect on generic entry under the Hatch-Waxman Act ultimately derive from statutes Congress created and could amend, should it choose to do so.

One issue concerns responsibility for monitoring Orange Book patent listings. Due to FDA's ministerial role with respect to Orange Book patents, disputes over Orange Book patent listings are more often decided by courts in Hatch-Waxman or antitrust litigation. Congress may consider whether to impose more responsibilities on FDA, FTC, or the courts, or whether to expand current procedures for challenging Orange Book patents before FDA or in court.

Another issue is whether additional clarity is needed on the types of patents that may be listed in the Orange Book. Congress updated the statute on the types of patents that should be listed in 2021 (P.L. 116-290), and FDA has also issued and updated its regulations on these issues. Even so, disputes continue over whether certain patent types (e.g., REMS or drug-delivery devices) should be listed.

A third issue Congress might consider is the relationship between Orange Book patents and the 30-month stay. Congress could consider, for example, whether the 30-month stay should apply only to certain patent types (e.g., active ingredient patents).

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