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IN FOCUS

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Pharmaceutical Patent Disputes: Generic Entry for Small-Molecule Drugs Under the Hatch-Waxman Act

Patent rights play an important role in the development and pricing of pharmaceutical drugs. Patent law seeks to encourage innovation by granting the holder of a valid patent a temporary monopoly on an invention, potentially enabling the patent holder to charge higher-than-competitive prices. In the pharmaceutical industry, these higher prices are designed to enable makers of new "brand-name" drugs to recoup the costs of research and development (R&D) required to discover and test a substance believed to be useful in treating human disease. After the period of valid patent exclusivity ends, other companies may make approved generic versions of the drug, which generally drive down prices.

It is not always clear whether the patents covering a drug are valid or applicable to a potential generic version. Thus, legal disputes over whether these patents should prevent or delay generic entry are common. Under the Hatch-Waxman Act of 1984, Pub. L. No. 98-417, such disputes are subject to specialized procedures, which can affect whether and when generic versions of a drug may enter the market.

This In Focus provides an overview of the procedures for patent disputes relating to nonbiologic (or "small-molecule") drugs. The analogous procedures for biological drugs are covered in a companion product, CRS In Focus IF13029, *Pharmaceutical Patent Disputes: Biosimilar Entry Under the Biologics Price Competition and Innovation Act (BPCIA)*. For a more comprehensive review of these issues, see CRS Report R46679, *The Role of Patents and Regulatory Exclusivities in Drug Pricing*.

FDA Regulation of Drugs

Drugs are substances used in the diagnosis, cure, mitigation, treatment, or prevention of human disease. Nonbiological drugs do not derive from living organisms and are generally artificially synthesized, small-molecule chemicals. In contrast, biologics (or "large-molecule" drugs) are generally more complex substances derived from living organisms, such as viruses, toxins, antibodies, vaccines, blood components, or proteins.

Both drugs and biologics are subject to a premarket approval process administered by the U.S. Food and Drug Administration (FDA). Before they can be marketed or sold in the United States, nonbiological drugs must be approved by FDA under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Obtaining FDA approval of a new drug requires multiple rounds of clinical trials to demonstrate to FDA that the drug is safe and effective. These trials are time-consuming and expensive; estimates of the average total R&D expenditures to bring a new drug to market range from hundreds of millions to several billion dollars.

To encourage the market entry of generic drugs, the Hatch-Waxman Act created an abbreviated regulatory pathway for generic drug approval. Under Hatch-Waxman, generic drug manufacturers seeking FDA approval can file an abbreviated new drug application (ANDA) that relies on a brand-name drug's information to demonstrate safety and efficacy. In other words, instead of doing their own clinical trials, generic drug makers need only show that their product is pharmaceutically equivalent and bioequivalent to a previously approved brand-name drug.

General Patent Dispute Procedures

Patents can be obtained on almost any new and useful invention made by humans. In the pharmaceutical field, many different aspects of new drugs may be patented, such as active ingredients, methods of treatment, drug manufacturing methods, drug formulations, or technologies used to administer drugs (e.g., inhaler devices).

To obtain a patent, the claimed invention must be novel, useful, and nonobvious, and the inventor must be the first person to file a patent application with the U.S. Patent and Trademark Office (PTO). If the PTO grants the patent, the patent holder generally has the exclusive right to make, use, sell, and import the invention for a set term—usually 20 years from the date that the patent application was filed. Any other person wishing to make use of the invention during this period needs permission from the patent holder or risks legal liability for patent infringement.

To enforce the patent, the patent holder may sue alleged infringers in federal court to seek injunctions, damages, and other remedies. Patents are presumed to be valid, but accused infringers may defend against such claims by asserting noninfringement (i.e., what they did was not covered by the patent) or invalidity (i.e., the PTO should never have issued the patent because, for example, the invention was not new).

Hatch-Waxman Patent Dispute Procedures

The Hatch-Waxman Act contains specialized procedures for many patent disputes regarding generic drugs. These procedures are triggered by the act of filing an ANDA seeking FDA approval of a generic version of a drug, as opposed to by traditional acts of patent infringement (such as making or using the patented invention). Under certain circumstances, the law treats an ANDA filing as an "artificial" act of patent infringement, which allows for early resolution of patent disputes before a generic drug is actually marketed. Hatch-Waxman's procedures can affect whether and when a generic drug can be approved by FDA

and marketed, and thus when a brand-name drug becomes subject to generic competition.

Patent Listing in the Orange Book

An FDA publication known as the "Orange Book" lists certain information on all nonbiologic drugs approved by FDA for sale in the United States. In addition to serving as an important resource for health care providers and the pharmaceutical industry, the Orange Book also contains information about certain patents covering the drugs. Under the Hatch-Waxman Act, new drug manufacturers must list all patents that claim the drug or a method of using that drug as part of their application for FDA approval. FDA then includes this patent information in the Orange Book. For more information, see CRS In Focus IF12644, *Patent Listing in FDA's Orange Book*.

Hatch-Waxman Act Patent Certifications

When a generic drugmaker files an ANDA, it must make one of four certifications with respect to each patent listed by the brand-name drug manufacturer in the Orange Book:

- (I) there are no patents listed;
- (II) the patent has expired;
- (III) the generic applicant will delay seeking final FDA approval until the patent expiration date; or
- (IV) the patent is invalid or not infringed.

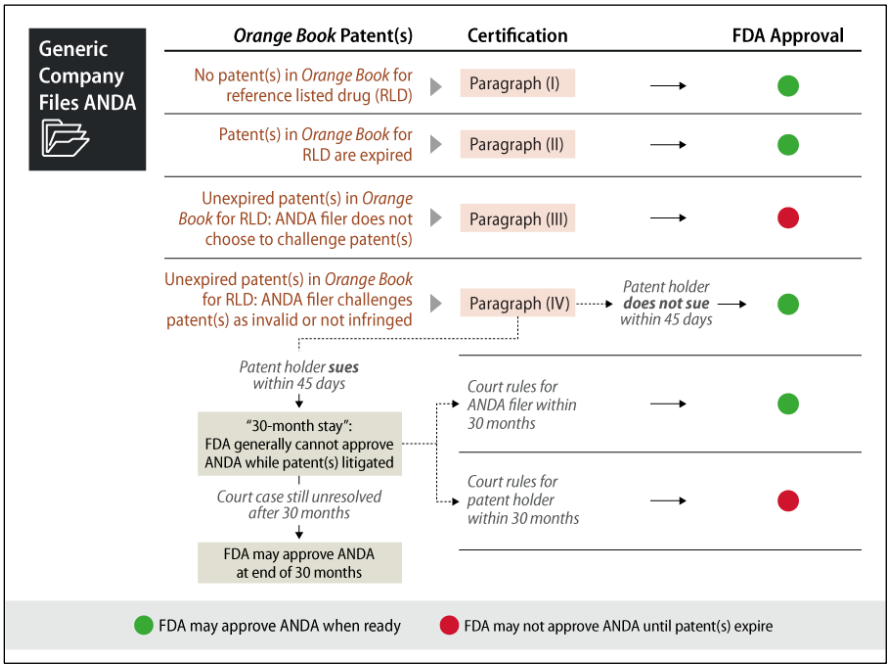
Through the final option—called a "paragraph (IV) certification"—the applicant takes the position that the patent listed in the Orange Book should not prevent it from marketing a generic version. If the generic manufacturer makes a paragraph (IV) certification, it must notify the patent holder and the brand-name drug manufacturer, who then have 45 days in which to bring a patent infringement lawsuit against the generic applicant. This often results in litigation between the brand-name and generic drugmakers.

If the patent holder timely files suit after a paragraph (IV) certification, FDA generally cannot approve the generic drug application for 30 months while the parties litigate their patent dispute. This period, known as the "30-month stay," is an important protection for brand-name drug manufacturers because it may operate to preclude generic entry for a time while the patent case is litigated.

If the courts determine that the patent is invalid or not infringed during the 30-month period, FDA can approve the ANDA as of the date the court enters judgment. If the courts instead conclude that the patent is valid and infringed, then FDA generally cannot approve the ANDA until the patent expires. If the case is still pending after 30 months, FDA may approve the ANDA. The generic manufacturer can then choose whether to await an outcome in the litigation or to launch their product "at risk" (i.e., without a final legal determination on the patent issues).

Figure 1 summarizes the process for patent disputes for generic drugs under the Hatch-Waxman Act.

Figure 1. Patent Dispute Procedures for Generic Drugs Under the Hatch-Waxman Act



Source: CRS; 21 U.S.C. § 355(j).

Note: ANDA = abbreviated new drug application.

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