Congressional Research Service
Informing the legislative debate since 1914

IN FOCUS

June 12, 2025

# Pharmaceutical Patent Disputes: Biosimilar Entry Under the Biologics Price Competition and Innovation Act (BPCIA)

Patent rights play an important role in the development and pricing of pharmaceuticals, including biological products (biologics). Patent law seeks to encourage innovation by granting the patent holder 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 drugs and biologics 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 their own licensed versions of the "brand-name" biologic, which are called "biosimilars" (or, in some cases, "interchangeables"). These competing versions generally drive down prices.

It is not always clear whether the patents covering a brand-name biologic are valid or applicable to a potential biosimilar competitor. Thus, legal disputes may arise over these patents. Under the Biologics Price Competition and Innovation Act (BPCIA), Pub. L. No. 111-148, tit. VII, such disputes are subject to specialized procedures, which can affect whether and when a biosimilar version of the biologic may enter the market.

This In Focus provides an overview of the procedures for patent disputes relating to biologics (or "large-molecule" drugs). The analogous procedures for small-molecule drugs are covered in a companion product, CRS In Focus IF13028, *Pharmaceutical Patent Disputes: Generic Entry for Small-Molecule Drugs Under the Hatch-Waxman Act*. 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 Biologics

Drugs are substances used in the diagnosis, cure, mitigation, treatment, or prevention of human disease. Biologics are drugs produced by or derived from living organisms, such as viruses, toxins, antibodies, vaccines, blood components, or proteins. Given their organic origins, biologics are generally large, complex molecules; in contrast, nonbiological drugs are typically artificially synthesized, small-molecule chemicals.

Biologics, like small-molecule drugs, 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, biologics must be licensed by FDA under Section 351 of the Public Health Service Act (PHSA). Obtaining licensure of a new biologic from FDA is costly and time-consuming, requiring multiple rounds of clinical trials to demonstrate to FDA that the biologic is safe, pure, and potent.

To encourage the market entry of biosimilars, federal law provides an abbreviated regulatory pathway to obtain a biosimilar license from FDA. Under the BPCIA, a biosimilar manufacturer can file an abbreviated biologics license application (BLA) to obtain FDA's permission to market a biologic by demonstrating that it is biosimilar to an already-licensed biologic. In other words, instead of doing their own clinical trials to demonstrate safety, purity and potency, biosimilar manufacturers need only demonstrate that their product is "highly similar to" an already-licensed biologic with "no clinically meaningful differences" between the brand-name and biosimilar versions.

## General Patent Dispute Procedures

Patents can be obtained on almost any new and useful invention made by humans. Many different aspects of new biologics may be patented, such as active ingredients (e.g., a genetically engineered monoclonal antibody); methods of using the biologic to treat particular diseases; methods used to manufacture or store biologics; or technologies used to administer a biologic (e.g., injection 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).

## BPCIA's "Patent Dance" Procedures

The BPCIA contains specialized procedures for patent disputes relating to biosimilars. These procedures are triggered by the filing of a BLA seeking FDA approval of a biosimilar version of an already-approved biologic, as opposed to by traditional acts of patent infringement (such as actually making or using the patented invention). In

some cases, these processes may facilitate early resolution of patent disputes before the biosimilar is marketed.

The BPCIA's patent dispute procedures are often called the "patent dance." The patent dance is a complex scheme through which biosimilar manufacturers exchange information with the brand-name biologic manufacturer—which the BPCIA calls the "reference product sponsor" (RPS)—in preparation for two stages of potential patent litigation. The Supreme Court has held that biosimilar manufacturers cannot be judicially compelled to engage in the patent dance, so a biosimilar applicant may choose whether to initiate the patent dance.

Unlike the analogous provisions for small-molecule drugs, the PHSA does not require brand-name biologic manufacturers to provide any patent information to FDA as part of their initial licensure applications. As a result, comprehensive patent information is not included in the Purple Book, FDA's database of approved biologics. In part for this reason, the patent dance is necessary for the parties to determine the relevant patents. (Under the Biological Product Patent Transparency Act of 2020, brand-name biologic makers are now required to report to FDA patents identified during the patent dance, which are then listed in the Purple Book. However, no patent information is submitted to FDA until a patent dance takes place.)

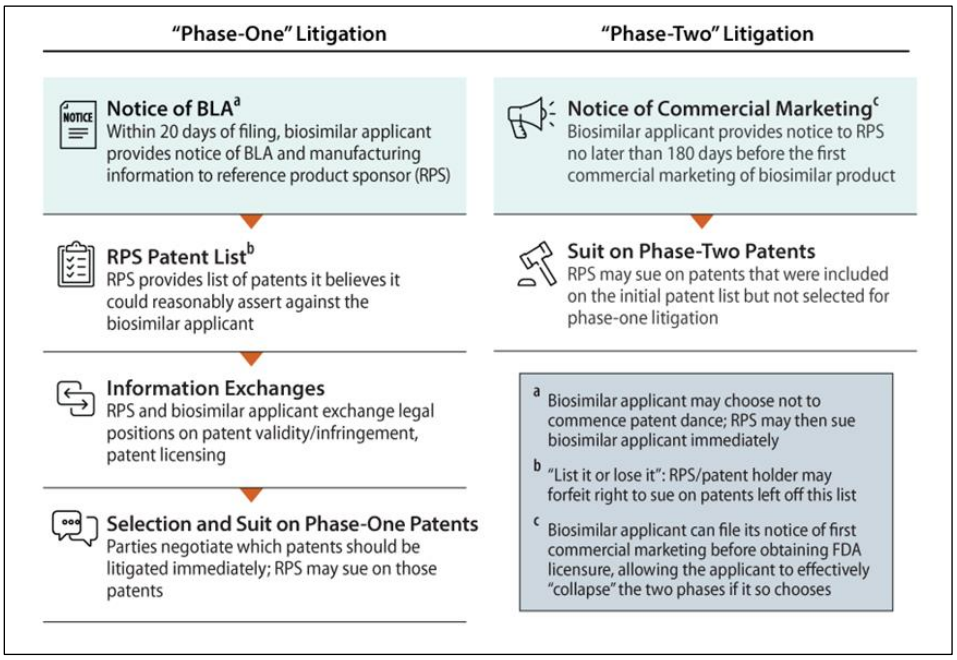
To initiate the patent dance, the biosimilar applicant must provide its BLA application and information about how the biosimilar is manufactured to the RPS no later than 20 days after FDA accepts the application. Based on this information, the RPS provides a list of patents that it may assert against the biosimilar applicant. The parties then engage in a series of back-and-forth information exchanges designed to identify and negotiate over what they believe to be the most relevant patents and each side's legal positions on the validity and infringement of those patents.

The patent dance process unfolds over roughly six to eight months. At the conclusion of the patent dance (if successful), the parties have identified a set of patents that may be litigated immediately in so-called "phase one" litigation. Other patents identified by the RPS may be asserted later on in "phase two" litigation. Phase two litigation is designed to occur closer to the actual market launch of the biosimilar and begins when the biosimilar gives notice to the RPS that it intends to commercially launch its product. This notice must be provided no later than 180 days before the date of the actual launch. Because the biosimilar applicant may file this notice at any time after filing its BLA—it need not wait for FDA licensure—the applicant may choose to effectively "collapse" the timing of phase one and phase two litigation so that they roughly coincide.

Unlike the analogous provisions for small-molecule drugs, the BPCIA contains an express statutory penalty for failing to list relevant patents. If the biosimilar applicant chooses to commence the patent dance, the RPS must provide a list of patents for which it believes a claim of patent infringement could "reasonably be asserted." The patent holder may forfeit his right to sue on patents that "should have been" included on this list but were not.

**Figure 1** summarizes the patent dance process for patent disputes for biosimilars under the BPCIA.

**Figure 1. The "Patent Dance" Process**




**Source:** CRS; 42 U.S.C.§ 262(*l*).



**Kevin J. Hickey**, Legislative Attorney

## Disclaimer