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IN FOCUS

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Pharmaceutical Patenting Practices: A Legal Overview

Pharmaceutical manufacturers frequently obtain intellectual property (IP) rights in their products. IP law provides exclusive rights in a particular invention or product for a certain time period, potentially enabling the rights holder (e.g., a brand-name drug manufacturer) to charge higher-than-competitive prices. If rights holders are able to charge such prices, they may have an incentive to lengthen the period of exclusive rights. Some commentators allege that pharmaceutical manufacturers have engaged in patenting practices that unduly extend the period of exclusivity. These critics argue that these patenting practices are used to keep drug prices high, without any benefit for consumers or innovation. Defenders of these patenting practices contend that patents are generally necessary to allow manufacturers to recoup their investments in research, development, and regulatory approval, and that concerns regarding these practices are either overstated or unjustified. This In Focus provides an overview of the relevant legal background and describes four such alleged patenting practices.

Legal Background

FDA Regulation of Pharmaceutical Products

The U.S. Food and Drug Administration (FDA) must approve new drugs and biologics (i.e., pharmaceutical products derived from biological materials, such as a virus or blood component) prior to their being marketed in interstate commerce. The approval processes for drugs and biologics are similar, but distinct.

To obtain FDA approval, a drug manufacturer must submit a new drug application (NDA) that demonstrates, among other things, that the drug is safe and effective for its intended use. The clinical studies necessary to establish safety and efficacy are often expensive and lengthy; the average cost to develop a new drug has been generally estimated to be between $1 billion to $3 billion, and the average length of the FDA approval process is over twelve years. To encourage competition and lower drug prices through generic drug entry, the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman) created a streamlined approval process that allows generic drugs to be approved through an abbreviated new drug application (ANDA) that establishes the drug's safety and efficacy by relying on FDA's prior approval of a drug with the same active ingredient. In certain circumstances, the generic's ANDA filing constitutes an act of "artificial" patent infringement, allowing the brand manufacturer to sue the generic drug manufacturer.

Similarly, a biologic may only be marketed in the United States after FDA approves a biologics license application (BLA). To approve a BLA, FDA must determine that the biologic is "safe, pure, and potent," and that the production and distribution processes are designed to ensure the same. Like Hatch-Waxman, the Biologics Price Competition and Innovation Act of 2009 (BPCIA) created an abbreviated process to encourage early market entry of sufficiently similar biologics by relying on FDA's prior approval of a biologic. A biological product is sufficiently similar if it is "biosimilar" to or interchangeable with an approved biologic. The BPCIA also created a process for biologic and biosimilar manufacturers to resolve patent disputes following the filing of an abbreviated BLA.

Patent Law Basics

Patents, which are available for a wide variety of inventions beyond pharmaceuticals, grant the patent holder the right to exclude others from making, using, selling, or importing a patented invention within the United States for a defined term of years (generally, twenty years from the date a patent application was filed). A person who does so without the patent holder's permission infringes the patent and is potentially liable for monetary damages and other legal remedies. Patent exclusivity allows the patent holder to recoup any expenses incurred during research and development, and is intended to incentivize innovation. The exclusivity may also shield patentees from competition, thus allowing them to charge higher-than-competitive prices for goods protected by patents. Patent incentives are said to be particularly necessary for products like pharmaceuticals, which are costly to develop but may be easily copied once marketed.

Pharmaceutical patents may cover many different features of a drug or biologic beyond the active ingredient itself. Such "secondary patents" may claim, among other things:

1. formulations of the drug or biologic (e.g., an administrable form or dosage);
2. methods of using the pharmaceutical (e.g., to treat a particular disease);
3. methods of manufacturing or technologies used to make the pharmaceutical;
4. methods or technologies for administrating the pharmaceutical; or
5. other chemicals related to the active ingredient, such as intermediaries.

Pharmaceutical Patenting Practices

From the patent holders' perspective, the practices described below are appropriate uses of the legal rights granted by their patents. Critics, however, view these practices as harmful strategies that exploit the patent system in ways that Congress did not intend.

"Evergreening"

Evergreening, also known as patent "layering" or "life-cycle management," is a practice by which drug innovators allegedly seek to prolong their patent monopoly on pharmaceuticals by obtaining additional patents as former patents expire. Because different aspects of pharmaceutical products are patentable, dozens of patents can protect a single pharmaceutical product from competition.

Critics of evergreening maintain that secondary patents are often for minor improvements or ancillary aspects of a pharmaceutical product, and effectively extend patent protection of the original product beyond the term set by Congress. Defenders contend that any additional patents cover important innovations and/or improvements to existing products, and that so-called secondary patents must meet the same patentability requirements and examination procedures as any other patent.

"Product Hopping"

"Product hopping" is the process by which a brand manufacturer uses its current dominant market position to encourage doctors, pharmacists, and consumers to "hop" from one drug, protected by soon-expiring patents, to a newer version of the same (or similar) drug with later-expiring patents. The new version of the product may be, for example, an extended release form, a new dosage, a different route of administration (e.g., capsules to tablets), or a minor chemical change. The brand manufacturer may encourage the transition through a marketing campaign or discounts and rebates. Product hopping tends to take one of two forms: a "hard switch," where the brand manufacturer removes the original product from the market, or a "soft switch," where the brand manufacturer leaves the original product on the market.

Critics of product hopping contend that the new product usually adds little or no clinical benefit, and the change occurs only to avoid generic competition by eliminating the market for the original product by the time of expected generic entry. Defenders maintain that manufacturers have legitimate reasons to create and patent new products, and that the new products often do have clinical benefits (for example, fewer side effects or better patient compliance).

"Patent Thickets"

In the pharmaceutical context, the term "patent thickets" describes a brand manufacturer's practice of amassing a large number of patents relating to a single product, thereby discouraging competitors from entering the market, or making it too costly and risky to do so. For example, one recent study of the top twelve drugs by gross U.S. revenue found that manufacturers obtained an average of seventy-one patents on each drug. Concerns about patent thickets have commonly been raised regarding biologics, as compared to small molecule chemical drugs. This may be, at least in part, because manufacturing a pharmaceutical using living cells is often complicated, offering many potential opportunities for patenting innovative processes or tools (although the underlying naturally occurring biological material itself might be not be patentable). For example, a company producing a biologic could attempt to patent the use of a different medium for cell growth or an adjustment to the dosing.

Critics contend that these patent thickets are created by patenting minor or secondary innovations, yet effectively delay competition because generics or biosimilars must challenge or design around every patent, which can be expensive or difficult. Defenders maintain that the patents on these products reflect the type of innovations that the patent laws were designed to incentivize, and that each patent has been determined to be valid through the patent examination process.

"Pay-for-Delay" Settlements

Through the procedures established by Hatch-Waxman and the BPCIA, brand manufacturers may initiate patent litigation when generic (or biosimilar) manufacturers submit abbreviated applications for products covered by certain unexpired patents. Some brand manufacturers have settled such litigation by paying (or otherwise compensating) generic manufacturers in return for the generic manufacturers agreeing to delay market entry. The Supreme Court has held that this practice, referred to as a "reverse payment" or "pay-for-delay," may in certain circumstances be a valid exercise of patent exclusivity, but in other circumstances may violate the antitrust laws.

Critics allege that brand manufacturers use pay-for-delay to protect weak patents from invalidation; because pay-for-delay agreements terminate the litigation, questions of patent validity and infringement remain open. Thus, critics contend that pay-for-delay adversely affects competition by allowing the brand manufacturer to (1) avoid the risk that its patents will be invalidated, (2) delay the market entry of generic competition, and (3) effectively extend its exclusive right to market the listed drug. Defenders maintain that these settlements are a legitimate way to reduce the cost and risk associated with litigation; they point out that the overwhelming majority of lawsuits settle across all areas of the law. Moreover, defenders argue that the litigation could end with the brand manufacturer prevailing, which would generally bar competition until the end of the patent term. By settling the litigation, defenders contend, generic entry before the end of the patent term is often guaranteed.

Combinations of Practices

Although presented here separately, critics contend that these practices are sometimes used concurrently. For example, some brand manufacturers may combine product hopping with pay-for-delay settlements, by using a pay-for-delay settlement to delay generic entry while the brand manufacturer switches the market to a new product protected by patent exclusivity.

Conclusion

For data sources, more details, and specific market examples of the particular practices, please see CRS Report R46221, *Drug Pricing and Pharmaceutical Patenting Practices*, coordinated by Kevin T. Richards.

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