

Retaining Patent PROFITS; When patents expire, profits fall. But, there are some strategies to get more mileage out of branded pharmaceuticals.

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The principal consequences for an expired patent holder are that its product loses market share and considerable profitability in a very brief period. Fortunately, for the holders of expiring patents, innovative strategists can create options to forestall the company's loss of profits—specifically the preemptive launch of a generic, layering innovations, and line extensions.

Once a brand-name manufacturer loses patent protection for a profitable and popular product, generic substitutes capture the majority of the market because they are typically priced 25% to 70% lower than their brand-name equivalents.

The experience of [Bristol-Meyers Squibb \(BMS\)](#) typifies the dramatic impact that generic products can have on competition after patent expiration. The patent on BMS's Glucophage, which had sales over \$2 billion in 2001, expired in January of 2002. One month later, more than 85% of that drug's market share had been taken by generic alternatives.

Strategy 1: Preemptive launch of a generic

To combat loss of revenues to new competitors, a drug originator can introduce its own generic prior to its drug's patent expiration. Using an "authorized generic," the branded pharmaceutical company gives permission to a preferred generic firm, or its own generic subsidiary, to sell and possibly to manufacture an authorized version of the drug. This authorized generic is then launched on the same day as the first generic competitor, thereby effectively eliminating the 180 days of marketing exclusivity provided by the Waxman-Hatch Act of 1984.

Brand-name pharmaceutical companies also have the unique ability to market a generic version of a patented drug before the expiration of the patent. They approach customers with a generic version of their own patented drug at a substantially reduced price for a contract period that extends beyond the patent expiration. Customers are attracted because such contracts make irrelevant any concerns that they have about the availability or quality of a future competitor's generic substitute, and because such contracts cut their drug costs immediately. Despite its short-term revenue forfeiture from the loss of monopolistic profits, the brand-name firm also benefits. It "locks-in" customers at a higher-than-generic price for a set period following patent expiration when the likely alternative is to lose those customer accounts altogether.

For example, Upjohn succeeded in retaining control of 90% of the generic market for its patented drug Xanax by introducing its own generic over-the-counter version one month before the Xanax patent expired. Upjohn was aware that it is a common practice among pharmacies to stock the first generic substitute that becomes available and to stay with that generic even in the advent of a second generic. Effectively, Upjohn traded one month of sales at its high patent drug price for years of generic drug sales at 90% of its previous level, albeit at a substantially reduced price.

An authorized generic also makes sense from the perspective of the theory of complementary assets. A patent-holder and an independent generic manufacturer can share benefits from an exchange of capabilities: the preservation of the pharmaceutical company's market power and the avoidance of duplicative commercialization investments, specifically those associated with manufacturing, marketing, and distributing a generic. Branded firms generally regard their production facilities as far too valuable for the manufacturing of high-margin, patented drugs to commit them to generics. Symbiotically, generics manufacturers, which commonly have excess production capacity awaiting the release of drugs from patent protection, pin their survival on access to the markets that the branded firms have controlled. By partnering to produce an authorized generic, the complementary assets of branded and generics firms can be optimally deployed for mutual benefit.

Strategy 2: Layering innovations

The second pre-expiration strategy for pharmaceutical manufacturers involves layering patents one upon another by patenting innovations on a base drug to maintain an exclusive market position. The result is an enhanced product that enjoys a monopoly market guaranteed by additional periods of patent exclusivity. The FDA grants such periods in recognition of significant innovations, including alterations in active ingredients, strength, dosage form, route of administration, or conditions of use. Other forms of patentable innovation involve alternative delivery methods for a drug, such as offering a tablet, a time-release capsule, an injectable, or an ointment as a substitute for an original patented capsule.

FDA exclusivity periods range from six months to seven years, but all have the same effect in that no generic drugs can be approved during the protected time span. In 1996, [AstraZeneca](#) obtained three years of exclusivity based on the patenting of a preservative added to the drug Diprovan. This exclusivity was granted as the patent protection on Diprovan expired and delayed the approval of a generic version submitted by Sicor, a subsidiary of Teva Pharmaceuticals USA.

Manufacturers of brand-name pharmaceuticals have one more special extension option available. Since 1998, the Department of Health and Human Services has given makers of more than two dozen brand-name drugs an extra six months of market exclusivity as an incentive for them to conduct clinical trials to determine how well their medicines work in children. Pediatric clinical trials typically cost the patent holder several million dollars, but can protect many millions of dollars in additional sales as was the case with the ulcer drug Prilosec that earned \$11 million a day under extended patent protection for [AstraZeneca](#), the patent-holder.

Strategy 3: Line extensions

Another strategy for pharmaceutical companies is to promote revised versions of the original drugs through line extensions. The goal is to switch current users to a new version of the drug before generic introductions of the old versions can appear on the market. [Eli Lilly](#) negated much of its lost revenues from the patent expiration on Prozac by getting FDA approval for Sarafem, which is a new name for fluoxetine, the active chemical in Prozac. Likewise, Merck's prostate drug Proscar was the principal consequences for an expired patent holder are that its product loses market share and considerable profitability in a very brief period.

approved by the FDA to help hair loss in men, under the name Propecia. [GlaxoSmithKline's](#) antidepressant Wellbutrin was given the additional name, Zyban, and marketed as a cigarette smoking-cessation medication.

[Forest Labs](#) used a line extension when it abandoned its antidepressant drug Celexa, even though it had two years of patent protection remaining. Its 2,300 sales representatives were retrained to promote Lexapro, which is nearly identical in chemical composition to Celexa. In its

first six months on the market, Lexapro grabbed 10% of the \$8 billion antidepressant market. Lexapro is a “me-too” drug, i.e., a slight modification on an existing drug that allows its maker to seek a new commercial patent to replace sales lost when the initial patent expires. This highly successful strategy of [Forest Labs](#) was different from one that involves the layering of patents because the intent was not to extend the life cycle of the base product but rather to replace the original with a “new” drug that would begin a new lifecycle of its own.

In an interesting twist on line extensions, holders of expiring patents can apply to the FDA for approval to make new claims that help reposition a familiar drug. This tactic worked for BMS when it repositioned Excedrin as Excedrin Migraine and for [Johnson & Johnson's McNeil Consumer Healthcare](#) when Motrin was promoted as Motrin Migraine Pain, despite the fact that the active ingredients in both products remained the same.

The potential of pre-expiration strategies

The preemptive launch of a generic product by the patent holder is particularly promising when the firm can contractually commit major purchasers of the product for multi-year periods. Locking-in important purchasers helps to guarantee a sizable income stream for the patent holder, keeps its production costs low, and dissuades generic firms from entering the market because it makes economies of scale more difficult to achieve.

Layering innovations usually forces a patent holder to face a scaled down version of its original R&D decision, namely, should the firm invest in a new undertaking given the market potential that a new or distinguishably improved product provides. The layering decision usually involves lower risks of product failure and market rejection. However, it also usually forecasts lower financial returns than the initial product investment because consumer and competitor options have likely changed in their favor during the interim time period.

Creating a line extension is attractive when market niches have been identified that would welcome a tailored version of the product. Since such extension must usually be financially self-sufficient, a patent holder would want to attend to the needs of a market splinter only when the number of customers was sufficient in size or financial wherewithal to support the additional costs incurred by the firm in developing and marketing a specialized version of the product.

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