Loss of exclusivity doesn’t have to be the end of branded drug revenue streams. Three strategies for preserving meaningful value well into the post-patent-loss future are outlined.

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Between 2014 and 2020, a combined total of $259 billion in worldwide pharmaceutical sales are at risk from patent expiration, with $70 billion at risk in 2016 and 2017 alone. Scary numbers, especially when common wisdom holds that, practically speaking, loss of exclusivity (LOE) could mean the end of a product’s value…and revenue stream.

LOE almost always causes a precipitous decline in sales for small molecule drugs—on average, brand unit share dips to 16% by the time generics have been on the market for one year. However, it’s not the end of the line—focused efforts can preserve meaningful value for the brand. LOE is a natural milestone in a product’s lifecycle which—similar to market launch—should be strategically planned for and managed. Even when a pharmaceutical company exhausts all options to extend a product’s patent life (reformulations, new indications, etc.), revenue opportunities remain. A key is early action: a company should consider starting the LOE planning process two years before the anticipated patent expiry date.

Three value-extending strategies

Three LOE strategies have shown demonstrable success in extending a small molecule drug’s value. These revenue-generating strategies can be executed as standalone options or in combination, as illustrated by Pfizer and AstraZeneca’s successful LOE strategies for their branded products Lipitor and Nexium, respectively (see the case studies on page 4).

1. PRESERVE BRAND EQUITY AND PATIENT LOYALTY. To slow brand erosion and continue sales momentum, a company may decide to shift its focus from core marketing and sales activities designed to maximize sales prior to LOE to a new set of activities intended to drive patient acquisition and retention to maximize sales through the LOE period—even if that means sacrificing some revenue in the pre-LOE window. This strategy taps into established brand equity and patient loyalty and drives increased awareness of the branded product’s ongoing availability. For example, three to six months...
before LOE, a company could start to lessen reliance on reimbursement from health plans by transitioning patients to a copay card to drive affordability and reduce patient out-of-pocket (OOP) expenses to levels equivalent to those with generics. This may help maintain sales volume and reduce the velocity of profit erosion. A company also might drive patient retention by creating enrollment programs (e.g., mail-order, copay cards) that collect patient information and help facilitate targeted interactions (e.g., refill notices) and remind patients that the branded product is still available even after generics have launched.

These and other similar tactics may help drive larger margins by keeping patients on branded therapy in a cost-effective manner. Overall, our experience has shown that effective deployment of tactics like these can drive anywhere from a 2x to a 20x return on investment, depending on the approach taken.

When evaluating a strategy to preserve brand equity, a branded drug company should be mindful that pricing pressures increase as the number of generic competitors rises—generic-to-brand price ratios tend to remain above 50% when only one or two generics are available but dip below 25% with five or more generics. This dynamic may impact its choices around marketing investment levels and tactics. Specifically, if there are five or more generic competitors in the market, it may not be attractive to pursue this strategy because a branded company’s costs may be too high and the revenue they can preserve too low to be viable.

Also, this isn’t a one-and-done decision—the number of generic competitors is likely to increase or decrease over time so companies should continue to reevaluate their decision to continue in the brand. If the market becomes too saturated with generics and the price gets too low, companies may need to “turn off” this strategy, choose another option or, as explained later, “sunset” the brand. Alternatively, if generic competitors drop out of the market, it may be worthwhile to increase investments over time.

2. CREATE AN OVER-THE-COUNTER (OTC) FORMULATION. Some drug manufacturers may choose to create an OTC version of their branded product to maintain and/or grow volume post-LOE. An OTC formulation strategy may help a company to decelerate value erosion post-LOE, maintain current customers and acquire new ones, and protect the branded product’s long-term revenue stream. An OTC strategy is also attractive because it allows a company to gain access to a broader base of potential patients and removes reimbursement hurdles from the equation.

Companies that pursue an OTC strategy often need to invest more in the product for additional trials, regulatory approval and, potentially, reformulation. These important steps can prove to be challenging as regulators consider patient safety when using the product without a physician’s supervision. Even after overcoming these challenges, a company may have to invest in new retail sales channels and marketing programs to gain share. Fortunately, it may be able to do this cost-effectively via a partnership with others who already have developed the channels.

3. LAUNCH A GENERIC. A branded drug company may be able to profit directly from patients who migrate to a generic alternative by offering a generic. While this may seem counterintuitive, the company can manufacture a generic version of the branded drug or partner with another party to do so. Variations of this strategy include:

- **Branded generic**: Leverage existing product supplies and approvals to create a generic product to be sold by the branded company.
- **Authorized generic**: Use existing product manufacturing capacity to provide a private-label company with the same product.
- **Licensed generic**: Contract with a generic competitor to produce a generic version of the branded drug; this allows the competitor to enter the market earlier than it would be allowed to otherwise.

This strategy can allow the branded company to retain a higher portion of product value with relatively low implementation costs. However, companies need to thoroughly understand the anticipated generic landscape before implementing the strategy. The launch of a new generic must be carefully timed so that the product isn’t the first to market (and, therefore, the first to introduce price competition for the brand) but is launched early enough to capture a significant share of the generic market.

One of the best times for a branded company to launch a generic is when a generic company has effectively challenged the brand’s patent and is granted 180 days of market exclusivity. In situations like these, the generic launched by the originator company has been able to capture 30-50% of generic drug sales. This strategy is more attractive when the total number of generic entrants is expected to be relatively low (less than five) —once that number increases, the new generic drug’s price and market share may be too low to justify the approach.

As a side note, a company that chooses to implement one of the three revenue-generating LOE strategies may move forward using in-house resources or by collaborating with an external partner. Options could include co-promotions with royalty streams, out-licensing, or contracting with a company that has experience managing LOE events to maximize profit post-LOE. Externalization can benefit companies by helping them maintain focus on their core business while allowing them to access best-in-breed capabilities from across the industry.

### The last resort: Sunset the brand

If the highlighted three LOE strategies aren’t a match for your product’s attributes and company’s broader capabilities and business
objectives, there is a fourth option—sunset the brand. In this approach, companies continue to manufacture the product but suspend all marketing and sales investments and adjust inventory levels to account for the decline in demand.

To effectively sunset a product, the company should review all of the ongoing cost drivers and determine the best path forward to minimize the expenditures required to maintain a presence in the market. For example, it may be possible to reduce the number of SKUs and, in turn, reduce manufacturing and inventory costs. It is also important to understand that products approach the point of sunset at different rates. Product and market dynamics may help determine the right time to sunset a brand—for example, a higher number of generic competitors may accelerate the process.

Consult the brand affinity checklist

One overarching criterion that can help to determine the optimal path(s) to effective LOE management is brand affinity, the level of customer engagement and comfort with the brand. Applying the answers from the brand affinity checklist (see Figure 1) can help to guide strategic decision-making and increase the effectiveness of LOE planning.

If brand affinity is high, then both preserving and maximizing the brand and switching to OTC may be attractive LOE options. To evaluate whether switching to OTC is viable, a company should answer this key question: Would the current Rx product—or a modification thereof—satisfy the FDA’s strict OTC approval criteria? Considerations include the ease of symptom identification, product safety profile, potential for misuse or abuse, regimen complexity, and patients’ ability to self-manage the disease. If the answer is yes, a two-pronged Rx and OTC LOE strategy may be appropriate. If the answer is no, it may be better to double-down on the Rx strategy.

A company also should consider the intensity of market competition before moving forward with either of these options. For example, it may be difficult for a company to benefit from pursuing an OTC strategy if it is unable to lock in a period of exclusivity to drive OTC volume. Further, the effectiveness of differentiation and loyalty tactics is dampened when the market offers more treatment options.

If brand affinity is low, then the most likely options are to launch a generic or sunset the brand. Launching a generic is the more resource-intensive of these two approaches and its success is highly dependent on speed to market because the company will have greater opportunity to capture market share by locking in contracts with distributors and wholesalers. Therefore, the strategy should only be deployed if a company has the internal capabilities or the third-party relationships to get to market quickly and capture wholesaler/pharmacy contracts to drive volume.

Finally, when deciding whether to execute an LOE strategy in-house or with an external partner, companies need to consider myriad variables, including organizational capabilities, risk tolerance, portfolio (whether similar products allow for an optimization play across products), and the commercial attractiveness of a longer-term play in generics.

Two years and counting down

No matter which LOE strategy a company chooses to pursue, planning should commence two years prior to the anticipated LOE date. An early start is essential to allow the organization time to develop and deploy its LOE strategy before the LOE date. Generally speaking, if a company waits until after LOE to...
deploy its LOE strategy it is too late and the impact of any LOE efforts will be greatly diminished. As illustrated in Figure 2, a typical planning and execution timeline is segmented into pre-LOE, peri-LOE, and post-LOE periods. Among important considerations:

» The peri-LOE period, six months before to six months after LOE, is the primary time to launch the selected LOE strategy in the market.
» Efforts to build and implement a preserve/maximize brand equity strategy should begin one-to-two years before LOE to build programs and launch the offering in the final six months of exclusivity.
» Companies choosing the OTC option will need to begin work earlier than those producing an authorized generic because OTC product approval has a longer lead time than other, more marketing-centric, approaches.
» Externalizing a product typically has a one-to-two-year time horizon.

Manage the milestone, generate value

Product LOE isn’t something that happens to a pharmaceutical company, it is a milestone event with significant forward visibility. A company can continue to generate value and revenue from its LOE brands but proactive management is required to do so. Strategic planning should begin two years before LOE, but, for companies already within that two-year window, all is not lost—although the urgency to act now and accelerate planning efforts is definitely greater.

Finally, LOE strategy can and should evolve over time to address changing business priorities and market conditions; companies should continuously monitor, evaluate, and adapt their strategy as needed during not only the pre- and peri-LOE periods but also throughout the post-LOE period—you never know when something may change in the generic landscape.

Case Study: Pfizer’s Lipitor—Always Cover Your Bases

Lipitor, a statin launched in 1996 to treat high cholesterol, was facing loss of exclusivity in November, 2011. Lipitor was Pfizer’s top-selling drug (global peak sales of $13 billion) and accounted for one-sixth of Pfizer’s revenues in 20108. Given the magnitude of impact the Lipitor LOE would have on Pfizer’s bottom line, the company launched a comprehensive strategy focused on winning by 1) driving customer stickiness and brand loyalty to keep patients on branded Lipitor, and 2) launching an authorized generic to capture a portion of the generic atorvastatin market.

To maximize branded Lipitor performance, Pfizer invested heavily in direct-to-consumer (DTC) advertising in the two years leading up to Lipitor’s LOE, spending more than $270 million on Lipitor advertising in 2010 and $220 million in 201110. In the year of its LOE (2011), Lipitor was the most heavily promoted drug on television7. When Lipitor lost exclusivity, Pfizer also launched other DTC brand preservation tactics, such as a consumer copay card program that lowered the patient copay to $4 a month (versus $10 for generic atorvastatin) and a specialty pharmacy partnership to enable direct mail order fulfillment of Lipitor prescriptions8.

Further, Pfizer partnered with Watson to sell its authorized generic, a Pfizer-manufactured atorvastatin. This approach allowed Pfizer to benefit from generic competition and, at six months post-LOE, the Pfizer-Watson product had achieved 30% of generic atorvastatin share11.

The Lipitor LOE strategy was considered a success—Pfizer extended the value of the brand and slowed generic erosion. In 2012, Lipitor maintained—20% of US pre-LOE annual sales of over $5 billion12. “We kept three times more share than has traditionally occurred” after patent expiry for a big drug, Pfizer’s CEO Ian Read said in an interview. “We added hundreds of millions of dollars of profitability to the company, as well as enabling patients to stay on the brand11.”

Case Study: AstraZeneca’s Nexium—A Tale of Two Dosages

Nexium, a proton pump inhibitor launched in the US in 2005 to treat gastrointestinal reflux disease, was facing loss of exclusivity in May 201114. Nexium was AstraZeneca’s second-biggest product by revenue at the time15. In 2013, global sales of Nexium reached $7.8 billion, and the product was ranked sixth in sales volume worldwide16.

AstraZeneca successfully leveraged consumer marketing campaigns to brand Nexium as “The Purple Pill.” Brand loyalty, a strong safety profile, and ease of symptom identification opened the aperture for the types of LOE strategies AstraZeneca could pursue.

Nexium, like many other drugs in the gastrointestinal (GI) space, was produced in two doses, which presented an opportunity for a two-pronged strategy. First, AstraZeneca continued to raise awareness and brand recognition for Nexium through DTC advertising15,16. As part of this strategy, AstraZeneca launched a copay card for patients to lower the cost of branded prescription Nexium and make it easier for patients to stay on the branded product at the pharmacy17. In parallel, AstraZeneca partnered with Pfizer in 2012 to develop an OTC formulation for the lower dose; the pair successfully obtained FDA approval in 201418. While AstraZeneca brought the product to the table, Pfizer brought extensive experience in consumer health and the capabilities needed for success in the OTC market. AstraZeneca’s two-pronged LOE strategy for Nexium was a success. Despite generic competition, prescription Nexium maintained $900 million in US revenue in 2015, nearly 50% of its revenue the year prior19—a value that exceeded analysts’ expectations20. The Nexium OTC partnership also was considered a win: AstraZeneca was able to continue to focus on its core prescription business while gaining access to industry-leading consumer health and OTC capabilities.

AstraZeneca said the deal would help the company “realize the substantial, long-term value of [the] brand and potentially other brands in [AstraZeneca’s] portfolio13.” Nexium OTC launched in the US in May 201422, generated $210 million in US sales through the end of 201523, and is described as one of the largest and most successful Rx-to-OTC switches14.

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