Getting Loss of Exclusivity Right:

A Perspective on Best Practices for Patent Expiry Planning

Between 2011 and 2015, nearly 100 brand name medications – including several blockbusters – stand to lose patent protection. With proper planning and implementation, brands can fight to maximize the duration of the relationships they have worked so hard to build. Both the brand and patient will benefit from such end-of-lifecycle strategies.

By Karen Carr

These days, we see article after article predicting dark times ahead for pharmaceutical manufacturers due to patent expiries of major revenue producing brands in their portfolios. In 2011, 12 brand name pharmaceuticals faced first-time competition from generic or Rx-to-OTC market entries. US sales revenue alone at risk on products including Lipitor®, Zyprexa®, Caduet®, Solodyne® and eight others was forecasted at approximately $10 billion dollars.¹

This year, blockbusters Lexapro®, Seroquel®, Geodon®, Plavix®, Singular®, Actos®, Provigil® and 18 other brands will face potential first-time competition unless, at least for some, litigation aimed at protecting their exclusivity is successful or new patent applications are returned with favorable response from the FDA. By 2015, yet another 57 therapies can anticipate possible first-time generic or Rx-to-OTC entries.²

The cliff looms large. As a partner to several brands that will now or will very soon face loss of exclusivity (LOE), we’ve been asking ourselves, “How can we best help our partners prepare?” What can be done between now and the end of commercial support to fully capitalize on the equity built and the trusted relationships earned? In short, how can we see these relationships through to their most positive and rewarding outcomes?

We know that many patients prefer to continue treatment with a branded versus generic product therapy, presuming cost and access are not barriers.³ Moreover, numerous specialist groups, including cardiologists and neurologists, are concerned that the allowable range for bioequivalence in generics is too wide – for example, in patients who are taking medication to control problems like arrhythmias or seizures, since even a slight variation in effectiveness can have a serious effect on a patient’s health.⁴ Two studies published in 2007 in the journal, Neurology, found that patients who switched from a brand-name product to a generic one had more seizures or higher hospitalization rates. An American Academy of Neurology (AAN) position paper states in part that “The AAN opposes generic substitution of anti-convulsant drugs for the treatment of epilepsy without the attending physician’s approval.” And for patients with the heart arrhythmia known as atrial fibrillation who are at risk for stroke, “if the levels [in a generic] are too high it could result in bleeding,” says James A. Reiffel, a cardiologist and professor of clinical medicine at Columbia.

So, for brands facing LOE, it begs the question, “Just how ‘inevitable’ does the inevitable have to be?” What can
branding, marketing and communications experts do to help maintain a brand’s potential revenue on the road leading up to, through and (if appropriate) beyond patent expiry – while helping physicians and their patients access and benefit maximally from its value?

The answer lies in some of the very same best practice approaches used in launch-, midlife- and mature-stage product and device marketing and customer relationship planning. Let’s look at their application to LOE:

Peri- and Post-LOE Business Case and Value Driver Alignment: Just as is true with new product launches, lead time is everything in LOE planning. As decisions are made to pursue (or not) revenue continuity, product or service enhancements, partnerships, reformulations, repackaging or the like, the team who will be accountable for implementing the plan should be engaged to participate in the research needed to understand their implications from the customers’ perspective. Specifically: Within what existing branded and generic competitive environment will the patent expiration and any new product introduction occur? What are the expected windows for limited- and then multi-source generic competition of the retiring brand? What will be the timeline and revenue targets for any replacement Rx or Rx-to-OTC therapies? How will these compare to models for the retiring brand? How will these timelines be rationalized across the peri- and post-LOE period? Will new sales models or distribution channels be introduced? How should the above drive the retiring and any “new” brand’s value proposition, positioning and messaging?

Brand, Customer and Marketing Program Planning: With the aforementioned answers in hand, the work of program and channel architecture, branding (and/or rebranding), positioning, customer segmentation and key messaging should begin with the same rigor applied in pre-launch, launch and in-market stages. First, research into core customer groups’ drivers, barriers, opportunities and reasons to believe in and engage with the intended LOE value story should be conducted. The research needs to focus on understanding what will be needed in the way of financial incentives for consumers, potential...

Brand Plans in Action

The makers of Provigil® and Nuvigil® are using the Provigil.com homepage to proactively drive patient consideration of Nuvigil®.

Novartis is using the online channel to actively educate patients about how “Diovan® is different” and that there is no generic version of Diovan®.

The makers of Diovan® are proactively positioning Get on Track™, “a comprehensive online support system committed to helping you manage your blood pressure over time,” as a core component of the value proposition and differentiator to other generic blood pressure medications.

Lipitor®’s $4 co-pay card program – Lipitor For You – is prominently displayed to patients at point of care.
alternative distribution channels, retail partnerships and payer agreements. Additionally, insights into customer segmentation, prioritization, interaction and relationship wants and preferences should be explored. Lastly, at this stage, existing and new potential sales, marketing and relationship support program assets can be tested to gauge their best leverage in the LOE phase. The summation of this work provides clear direction on how to craft an “ideal experience” for all participants in the LOE ecosystem, while driving optimal return on program investments. See related table for key considerations included in this step.

**Advertising, Promotion and Relationship Management Program Architecting:** Once the LOE brand ecosystem and customer inter-relationships are identified, the well-known relationship management continuum (Awareness → Consideration → Action → Loyalty) provides a useful framework for architcting the customer experience – the next step in planning. This approach enables the brand and its agencies to think through when, where and what pieces of the proposition customers will learn about, engage with and continue to relate with the brand and/or new options leading up to and beyond loss of exclusivity.

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### Key LOE Planning Considerations

**Patients:**
- What will patients know about or understand regarding the relative therapeutic and pill + benefits of the branded versus generic product(s)?
- How may out-of-pocket cost increases of up to 30%\(^\dagger\) after LOE impact patients’ desire topersist with the brand versus switch to a generic alternative?
- Similarly, how will access restrictions, such as step therapy, prior authorization, and/or no coverage or at lower tier affect patient loyalty?

**Healthcare Professionals:**
- What will prescribers perceive regarding the clinical efficacy of the brand versus generic or OTC alternatives?
- Will access be limited?
- How will specialty distribution be affected?
- To what extent will formulary impact prescriber writing (or switching) behavior?
- How can the availability of continued patient support be leveraged as a value to physicians, their patients and caregivers?

**Pharmacies:**
- Given managed care systems that reward generic versus branded dispensing, what value proposition will help drive continued pharmacy loyalty to a branded product?
- How might new or existing partnerships be initiated to support patient acquisition and retention objectives?
- Can point-of-fill education be utilized to drive a better informed pharmacist-patient conversation?

**Payers:**
- In our increasingly outcomes-focused healthcare environment, what elements beyond pricing should be part of the value story for payers?

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Once defined, and as development of mass, digital, in-office, point of care and pharmacy assets begin, consideration to the following should be given: For how long and via what channels will existing rebates, savings cards, support programs and other acquisition and retention strategies continue? When and how in the journey should migration of existing patients into the LOE ecology be facilitated? What will be the core content and calls-to-action for patients, prescribers, pharmacists, distributors and payers, and through

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which channels will these be delivered? What new channels and content will be needed, and what will be the content retirement plan for in-market assets?

Ongoing Market and Program Monitoring & Measurement: The old adage “what gets measured gets managed” is perhaps never truer than throughout the LOE phase. In the constrained timeframe that marks a brand’s end-of-life opportunity, success is measured in days and months, not years, and every opportunity to adjust and optimize must be maximized. Data capture for every metric in the marketing funnel should be implemented from the outset. An integrated key performance indicator dashboard should be created for broad distribution to all accountable for the program’s performance. And regular key stakeholder analysis should begin the day the first communication is launched. Key considerations in LOE measurement planning include: What will be the key performance indicators and how will they be gathered? At what intervals will they be reported and evaluated as program elements are launched over time? What third-party partner data will be integrated, and how will this happen? Who are the key “need to know” stakeholders and by what means will results be shared?

Assuredly, each brand’s LOE scenario is unique, driven by complex dynamics specific to its business, market and customer environments, number of and speed with which generics will enter the market, delivery mechanisms and many other factors. Equally certain, generics will gain ground in the market. Managed care will favor them on tier. Accountable care organizations will incentivize their use and dispensing. And cost and access will drive patients to their use.

In the meantime, we believe those with intentions of maximizing the duration of the hard fought relationships they have created should begin planning now to implement end-of-life strategies that will benefit the brands and the patients they benefit.

References:

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