

Pharma Lifecycle Management and Brand Defense Strategy

Strategic and Tactical Options for Continuing Your Product Success Story

HEALTHCARE MARKETING
DR. UMBACH & PARTNER

www.umbachpartner.com

Training + Consulting

Pharma-Lifecycle-Management-and-Brand-Defense-Strategy

20 July 2014

Terminology

The term "product lifecycle" in this presentation extends beyond the official patent-protected period and includes the years directly following the loss of market exclusivity.

"There is life to a brand even after patent expiry"

Goal: Maintain Success

Keep the brand at the top of its lifecycle curve in order to get more out of the assets.

Manage the Brand's late lifecycle so that we realize the brand's full medical and commercial value

Nature of Issue

Managing the loss of market exclusivity is a complex legal, regulatory and marketing challenge.

The situations in the various countries differ. This may require approaches on a national basis.



There is no "one size fits all"

Wake up call

Many big research-based pharma companies have experienced rude awakenings when generic companies took away most of their top product sales - virtually overnight.

They should have seen it coming.



Be prepared and take an active approach

The Company Portfolio

Research-based companies focus on innovation (taking the high road).

Goal: Launch new products and maximize their commercial potential.

Therefore, an innovative successor drug would best fill the gap. Ideally, it could shift the value created by the old brand to the new brand.

Situation Appraisal: Regulatory Authorities

Regulatory authorities have been making their own decisions about the approval of generic version of expensive drugs.

They may surprisingly grant marketing authorization to low-priced generic versions - due to national healthcare budget constraints in an increasingly cost-conscious environment.

Situation Appraisal: Patent Protection

History shows that even apparently iron-clad patents have not been safe.

Big pharma has sometimes paid settlements to avoid costly litigation and the possibility of losing years of exclusivity through questionable court action.

Types of Competitors

1) "Me-too products"

Other companies may legally "circumvent" the patent by producing similar products long before the patent expires

2) Generics from generic drug companies

Situation Appraisal: Generic Competition

Competing generic companies may initiate a downward price spiral in an attempt to dominate the market.

Aggressive generic companies are no longer waiting for patent expiration. Teva has launched over a dozen products "at risk" in the United States prior to patent expiration. Many other generic companies have entered markets prior to patent expiry in Europe.

In some cases generic companies launched prior to the innovator's own product launch (Example: Amgen/Pfizer's rheumatoid arthritis agent Enbrel in China)

(Source: <http://www.pharmexec.com/pharmexec/Strategy/Rethinking-Product-Lifecycle-Management/ArticleStandard/Article/detail/805006>)

Option Overview

1) Short-term tactics

2) Develop strategic options

Short-Term Tactics 1

Litigation

Fight generic competitors in court

Discuss legal aspects with experienced patent lawyers familiar with these issues.

Ask: What is the likelihood of defending the company's rightful patent situation in court?

Possible patent infringement could concern:
Ingredients, formulation, manufacturing processes, production methods, indication, data protection, etc.

(Note: The generic companies usually win this game)

Short-Term Tactics 2

Once generics are on the market:

Reactive approach to discussing generics during calls with physicians:

When the doctor asks the sales rep, raise elements of doubt, but do not spend time on competitors

Range of Usual Strategic Options

- New dosage forms
- New pharmaceutical formulation
- Additional indications
- Supplementary Protection Certificate
- Combination product
- Switch to OTC-Status
- Competing solely on price
- Arrangements with payers
- Early entry strategy
- Portfolio management in formularies
- Original Generic

Note: Additional (ineffective or non-applicable) approaches can be found in the appendix

Supplementary Protection Certificate

Providing regulators with data on pediatric use may prolong market exclusivity by 6 months in the US

PIP = Paediatric Investigation Plan

PUMA = Paediatric Use Marketing Authorisation

Switch to OTC-Status

Ask Regulatory Affairs experts if an Rx-to-OTC switch is a viable option

Preconditions:

Regulatory approval and willingness to establish the brand name in the consumer market

Examples:

Antimycotics: Clotrimazol: Canesten[®]

Proton Pump Inhibitors: Omeprazol, Pantoprazol

Rx = Prescription only, OTC = Over The Counter

© Healthcare Marketing Dr. Umbach & Partner

www.umbachpartner.com

Competing Solely on Price

Typical, very-low price generic product strategy:
Prices can be 40 to 80% lower than the original.

One would act as a generic company fighting the established generic companies (that are fast, flexible and aggressive).

Other companies (e.g. Novartis) have set up their own generic division (Sandoz).

Arrangements with Payers: Deals with national governments

In Germany: "Rabattvertrag für Originale"
MSD made special arrangements with the German Statutory Sickness Fund (AOK) for the cardiovascular brands Lorzaar / Fortzaar and the anti-osteoporosis product Fosavan at a time when the brands still enjoyed patent protection.

Other options: Disease management programs

Source: Dr. Lukas Pfister, MSD, PM-Report June 2008

Early Entry Strategy

Partner with a generic drug company that sells an authorized generic version through licensing arrangements for about six months prior to patent expiry.

Then the generic drug company can independently sell their own product.

Early Entry Strategy: USA

Bayer and Barr Pharmaceuticals signed a contract: Barr sells an "authorized generic" version of Bayer's birth control pill Yasmin several years before the product's last patent expires.

Barr gets exclusive rights to sell the products in the US, and Bayer will supply the pills.

In return, Bayer will get a share of the sales.

Portfolio Management in Formularies

Smart portfolio management in
regional / provincial / hospital drug formularies

Example: "Bundling"

Responsible: National Key Account Managers

"Original Generic"

Introduce product in the form of second, separate brand - about 20% to 40% cheaper than the original

Consumer Market:

"Fighter Brand"

Example: Lufthansa und Germanwings

Example of "Original Generic"

Original: Valette[®]
from Jenapharm
Patent expiry in
January 2011

The company introduced: "Originalgenerikum"
Maxim[®] - "Das OC Generikum von Valette"

Flexible price strategy

Around 10 Euro cheaper.

They adapt to competitive price level

Example of "Original Generic"

Price Strategy by Dr. Kade

Utrogest[®] : Original

Progestan[®] : 17% cheaper

Fachanzeige von Dr. Kade in "gyn" Juni 2014
Both are Brands from Dr. Kade

Recommended Next Steps

Initiate a cross-functional team integrated in the existing structure:

- That will develop a comprehensive approach
- Is in charge of contacts with relevant stakeholders
- Pays attention to time line
- Makes recommendation to the management board asking for business planning decisions
(Involvement of the leadership team is essential)

Task Force: Objectives

- Understand lessons learned from previous cases
- Avoid pitfalls, such as "group think"
- Analyse the competitive environment
- Detect new entrants early
- Identify opportunities to exploit
- Evaluate risk return ratios of strategic options
- Estimate levels of resources needed

* There is no magic bullet.

Task Force: Proposed Members

- Strategic Marketing
- Market Research (for market intelligence)
- Medical
- Market Access
- Regulatory
- Legal

Preferably persons with experience in late lifecycle management to benefit from "corporate memory" (ideas and strategies that either worked or failed)

Note: Interest from the countries will be limited, because they are unlikely to reap the fruits of this endeavour (People will probably have moved to a different position by the year 2020).

Additional Recommendations,
Back-up Charts and
Background Information:

Please contact us:
umbach@umbachpartner.com