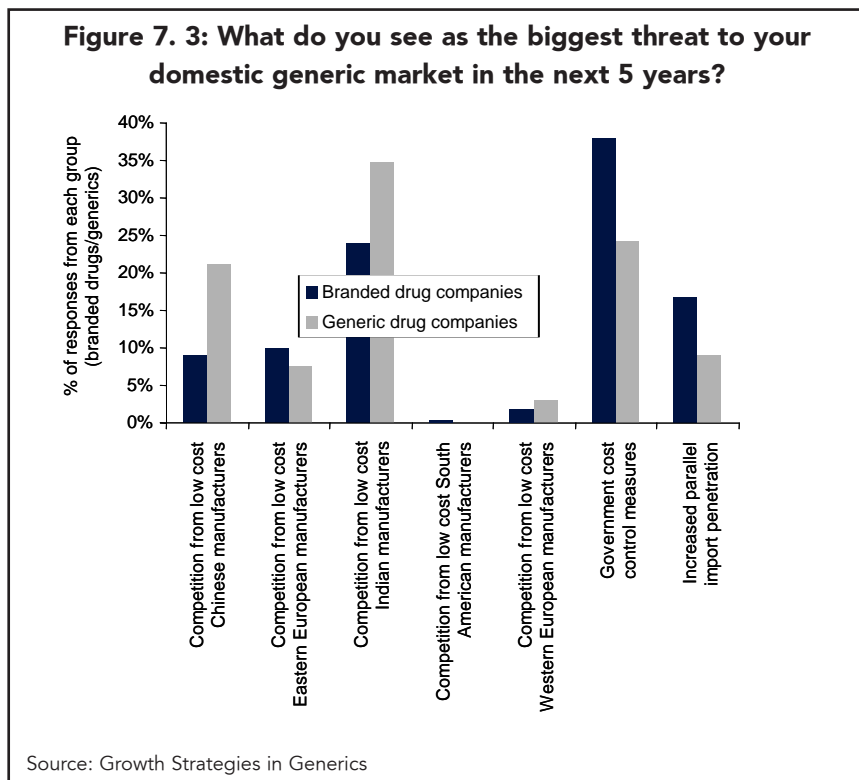


Growth Strategies in Generics

Innovative and aggressive strategies and their impact on branded pharmaceuticals



“In June 2004, a Business Insights Survey of 287 pharmaceutical executives in Europe, the US and Asia found that respondents from both generic and branded drug companies see Indian manufacturers as a major threat in the next five years...”

Strengthen your competitive position by understanding the growth strategies of generic drug companies and the impact that this will have on both the generic and the branded pharmaceutical sector in the future, with the help of our latest management report...

Growth Strategies in Generics

Innovative and aggressive strategies and their impact on branded pharmaceuticals

Figure 1.4: Examples of differences between US & Europe

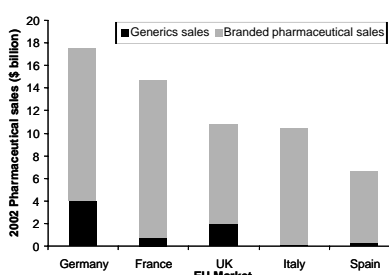
Aspect	USA	Europe
Generic Market Size	US \$15bn	US \$6.5bn
Development pre-patent expiry	Allowed by Hatch-Waxman	Forbidden – constitutes patent infringement
Registration	Valid all states	Valid in individual states only
First to file generic application	Obtains 180 day exclusivity	No advantage relative to other applicants
Litigation by originator against generic applicant	Blocks regulatory process	No effect on regulatory process

Source: Growth Strategies in Generics

“One key question is whether the new Bolar clause will have any significant impact on the rate at which generic copies are launched in Europe post patent expiry or the speed to market of new copies. Those companies that are intent on being in the market on day one have already developed relationships with developers in countries not affected by product patent legislation either in the EU or outside it, e.g India and Iceland...”

Key findings in this report

Figure 1.2: Generic penetration in Europe



Source: Growth Strategies in Generics

“The southern European generics markets of Italy, Spain and France exhibited strong growth in 2002, but still contributed less than 3.6% to global generics sales.

According to a statement from the French generic industry association GEMME in September 2003 this situation had improved and generics accounted for 5% by value and 10% by volume – this clearly still leaves plenty of room for expansion...”

‘Growth Strategies in Generics: Innovative and aggressive strategies and their impact on branded pharmaceuticals’

is a report which assesses the growth prospects of generic drugs in Europe and the US. The report gives a detailed analysis of the impact of new legislation, the strategies of the key players and market pressures on the generic and branded drug sectors.

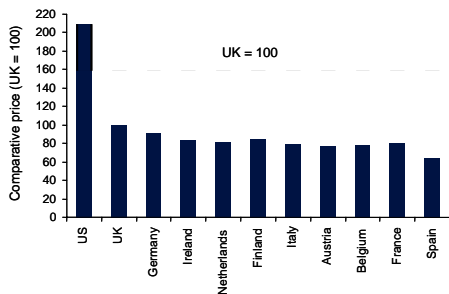
The generics market in both Europe and the US is highly dynamic. **Growth is high, and forecast to continue strongly in the next five years as penetration of generics in pharmaceutical sales is still comparatively low in key markets such as the UK and France.** At the same time, the distinctions between some generics companies and traditional, R&D-led pharmaceutical companies are blurring as generics companies move up-stream and invest in R&D while pharmaceutical companies such as Novartis, Sanofi and Merck retain successful generic subsidiaries.

However, market saturation threatens to erode profit margins for generics companies as prices are forced lower, while manufacturers outside Europe and the US take an increasing market share. Identify the key trends in manufacturing, marketing, competitive structure, profit margins and intellectual property in Europe and the US with the help of our latest report.

- **Indian manufacturers represent the greatest threat to the existing generics market**, and will force both mainstream pharmaceutical companies and established generics companies to explore alliances and acquisitions there.
- **Generic drug sales are forecast by the majority of branded drug and generic drug company executives to be above 5%.** One third of all executives forecast growth above 10%.
- **On balance, new legislation in both the EU and the US has been more beneficial to generics companies**, lowering barriers to entry and speeding up the approvals process.
- **The distinction between established generics companies and mainstream pharmaceutical companies is blurring** as companies such as Teva and Ranbaxy increase their investment in R&D in a bid to push their product portfolios upstream.
- **Biogenerics will reach Europe before the US due to recent legislative changes.** Lower regulatory barriers have meant that Eastern Europe is an area of expertise for biogenerics.

The answers to your questions...

Figure 3.3: Comparison of different national pharmaceutical price levels



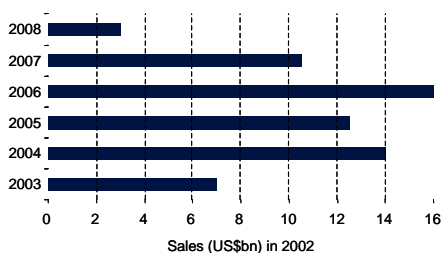
Source: Growth Strategies in Generics

"A brand in Germany losing its patent protection will present a far more attractive target to copiers than its lower priced equivalent in Spain. This raises the interesting question of whether governments could promote generic growth and lower drug bills in the long term by placing fewer restrictions on brand pricing at the time of launch..."

- What will be the impact of Indian and Chinese manufacturers on established generic drug manufacturers?
- How will each new piece of legislation in Europe and the US affect the growth strategies of generic and branded pharmaceutical companies?
- How are generics companies seeking to diversify and develop in the future?
- What are the key trends that will drive generics growth in Europe and the US?
- What successful strategies are generics companies using and how are these evolving in the face of increasing market pressures?
- Which country markets will see the highest growth and what are the most attractive therapy areas for generics companies to target?

Top reasons to order your copy today...

figure 6.2: Value of major US patent expiries to 2008



Source: Growth Strategies in Generics

"A review of the portfolios of the top 40 pharmaceutical companies shows that products with total sales of \$137 billion in 2002 will have lost primary US patent protection by 2008. This represents over 50% of the \$235 billion in total product sales generated by these 40 companies in 2002. Looking ahead, 2006 could present a key opportunity for generics companies to profit from patent expiries, as blockbuster drugs with 2002 sales of over \$16 billion face expiry of their US patent protection..."

- **Understand the growth strategies of generics companies**, the decisions driving their expansion and the challenges they face.
- **Assess how generics companies are adapting to competitive pressures** and blurring the distinctions with mainstream pharmaceutical companies.
- **Learn how pricing of generics will change in the next five years** and the impact this will have on the market.
- **Benchmark your opinions on how the generics market will develop against senior executives** from both generic and mainstream pharmaceutical companies.
- **Identify the risk posed by fast growth new entrant manufacturers** in China, India, Eastern Europe and Latin America.

Sample information from the report

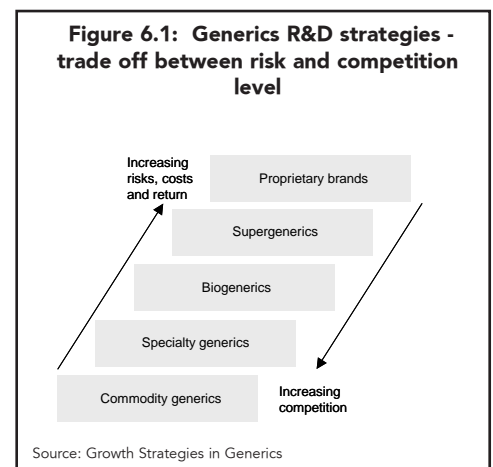
CHAPTER 6: US BARRIERS TO GENERICS GROWTH

Company strategies

Investment in original R&D

This is perhaps one of the riskiest and most resource intensive steps that generic firms can take. There are five major R&D strategies open to players in the generics market. Starting from the most difficult and expensive R&D targets, the core strategies are:

- Proprietary drugs-development of new chemical entities
- Supergenerics development of value-added reformulations of off-patent drugs that require new drug application (NDA) submissions
- Biogenerics develop bioequivalent or clinically equivalent versions of biological products
- Specialty generics development of bioequivalent versions of barrier-to-entry products
- Commodity generics-development of simple-to-manufacture, multi-source products following patent expiry



Teva is a good example of a generic firm that has pursued an R&D strategy in tandem with its generics business. Apart from its Copaxone MS therapy, it has established Teva Oncology Europe. The company is number three in oncology generics in France, and in the top three in Germany and Italy. Likewise, IVAX's Indian R&D operations and the Institute for Drug Research in Hungary demonstrate its view of its future growth areas. This approach does of course sometimes backfire - the failure of some of the products in Barr's R&D pipeline have left Barr dependent upon the outcome of its pipeline paragraph IV filings to provide revenues. Ranbaxy too sees R&D as an important part of its future and carrying it out at home gives it even more of an advantage since R&D costs there are around 1/20th of those in the US. The diagram above clearly illustrates the trade-off between increasing risks and reducing levels of competition.

Acquisitions can also be used to save time and accelerate growth or ease a move into another commercial area. The example was mentioned earlier of generic companies wishing to expand in the branded arena, acquiring a small, targeted sales and marketing operation, which can help them to hit the ground running. Specific instances include IVAX, who prepared for the launch of its branded respiratory line through the acquisition of Wakefield Pharmaceuticals, an operation focused on detailing drugs to respiratory specialists and Andrx who acquired CTEX which had its own marketed product line and, most importantly for Andrx, 100 sales representatives.

Order this report to find out more...

Table of contents

Growth Strategies in Generics: Innovative and aggressive strategies and their impact on branded pharmaceuticals

CHAPTER 1: OVERVIEW OF THE GENERICS MARKET

- US vs Europe - differences and contradictions
- Global opportunities - forthcoming patent expiries
- Underdeveloped markets
- Expand or stay at home?
- Multinational companies' involvement in generics

CHAPTER 2: SUCCESSFUL US STRATEGIES

- Overview of the US generics market
- Leading US generics companies
- The road to success
 - Distribution of commodity generics
 - Manufacture and distribution of commodity generics
 - Acquisition
 - Patent challenges
 - Specialty generics
 - Proprietary drugs
 - Biogenerics

CHAPTER 3: SUCCESSFUL EUROPEAN STRATEGIES

- Overview of European generics market
 - Pricing
 - Intellectual property
 - Generic prescribing levels
- Leading European generics
- The road to success
 - Distribution of commodity generics
 - Manufacture and distribution of commodity generics
 - Patent challenges
 - First to launch
 - Acquisition
 - Specialty generics
 - Proprietary drugs
 - Biogenerics

CHAPTER 4: US LEGISLATION AND ITS IMPACT

- Overview of US generics legislation
- Hatch-Waxman amendments
 - Benefits to R&D pharmaceutical companies
 - Benefits to generics companies
 - Disadvantages of the legislation
- Mc-Cain-Schumer legislation
- Gregg-Schumer Act
- The impact of new legislation

CHAPTER 5: EUROPEAN LEGISLATION AND ITS IMPACT

- Overview of European generics legislation
- Directive 2001/83
- Directive 2004/83/EC
 - Benefits to R&D pharmaceutical & generics companies
- The impact of new legislation and other IP issues

CHAPTER 6: US BARRIERS TO GENERICS GROWTH

- Threats to the generics industry
 - Market saturation and overseas competitors
 - Increasing wholesaler consolidation
 - Gaps in patent expiries
 - Reference prices and parallel imports
- Company strategies
 - Movement away from normal release oral commodity generics
 - Adjustment of product portfolios
 - Investment in original R&D
- The role of trade associations

CHAPTER 7: EUROPEAN BARRIERS TO GENERICS GROWTH

- Threats to the generics industry
 - Market saturation
 - Increasing wholesaler consolidation
 - Overseas competitors
 - Reference prices and parallel imports
- Company strategies
 - Adjustment of product portfolios
 - Expansion into overseas markets
 - Challenging patents
 - Alliances with multinationals
- The role of trade associations

CHAPTER 8: FUTURE PROSPECTS AND SURVEY RESULTS

- Trends in manufacturing
- Trends in marketing
- The future of generics in the US
 - Profit margins and legislation
- The future of generics in Europe
 - Pan-European generics and legislation
 - Intellectual property
- The generics competitive landscape
- Growth prospects for generics

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