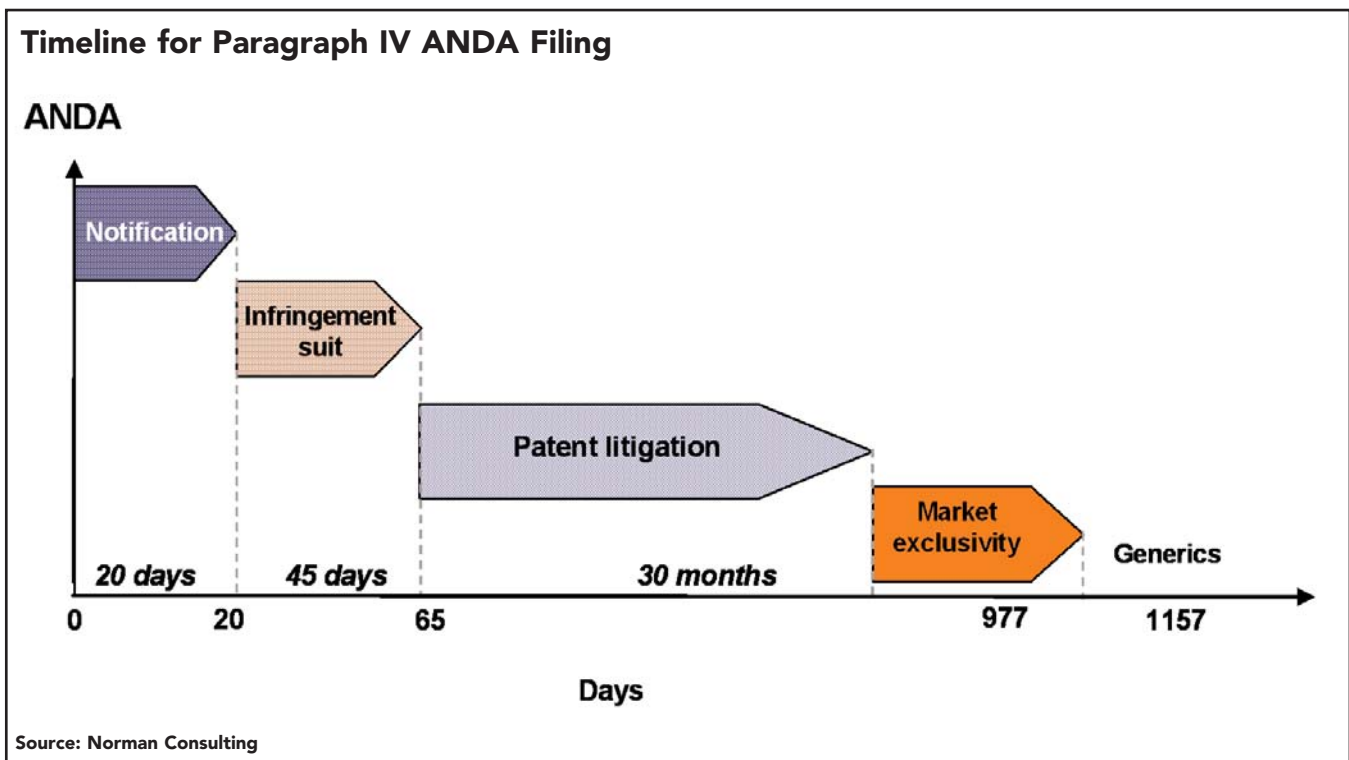


# Patent Protection Strategies

Maximising Product Revenues



**This NEW report provides detailed insights into the efficacies and applications of patent protection, helping you to optimise and sustain your strategies to maximise product revenues...**

## Business Intelligence for the Pharmaceutical Industry

**Business Insights'** portfolio of healthcare management reports are designed to help you make well informed and timely business decisions. We understand the problems facing today's pharmaceutical and healthcare executives when trying to drive your business forward, and appreciate the importance of accurate, up-to-date, incisive product, market and company analysis. We help you to crystallize your business decisions.

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### Some key findings from this report...



"The decline in revenues once patent protection expires is now expected to be precipitous, as illustrated by the more recent example of Merck & Co.'s Zocor. Merck's US market exclusivity for this product expired on 23 June 2006, after the patent lifetime had been extended for an extra six months for pediatric exclusivity. Quarterly sales of the branded drug sharply declined, from \$3.1 billion in 2005 to \$1.9 billion in 2006, while sales of the generic simvastatin in the same period reached \$1.4 billion..."

- **ANDA reviews are most effectively delayed by pursuing litigation for patent infringement.**
- **A recently established US Supreme Court ruling will extensively influence future patenting strategies**, having been formed in the April 2007 US Supreme Court ruling on patentability involving KSR International Co -v- Teleflex Inc.
- **Contingency plans can effectively counter failed or defective patent strategies**, as shown in the Claritin and Prozac case studies.
- **Successful patent protection strategies can vastly enhance the sustainability of product franchise revenues**, significantly exceeding the lifetimes of basic patents. Prominent examples include AstraZeneca's Losec and Nexium, and Amgen's epoetin alfa.
- **Holistic investigation of a firm's 'Freedom to Operate' is necessary prior to resource committal** in product development or commercialization.

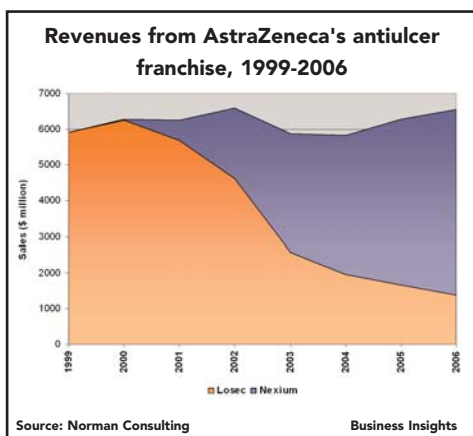
## Patent Protection Strategies

As new drug developments continue to necessitate increasingly high investments, successfully protecting revenue sustainability from the threat of low cost substitutes is reliant upon fully harnessing the efficacies of the patent system. In a market environment where competition from generics companies is becoming increasingly aggressive and the patenting of therapeutics is continually subject to impending legislative change, understanding how to effectively reassess, develop and exploit patent protection strategies is essential in facilitating enhanced market exclusivity and revenue returns over the lifecycles of new drugs.

**Patent Protection Strategies: Maximising product revenues** is a new report published by Business Insights, examining the need for optimising and sustaining the patent protection of novel products. The report explores the best methods of exploiting legislation to maximise revenue generation and protecting the considerable investments associated with innovations. It will also examine the both the offensive and defensive tactics that can develop product lifecycle strategies, through the refinery of organisational patent protection in tandem to encumbering the market entry of generic substitutes.

**Use this report to understand how to successfully develop and apply patent protection strategies, exploit legislation effectively and secure the lifecycles of your innovations to maximise revenue returns...**

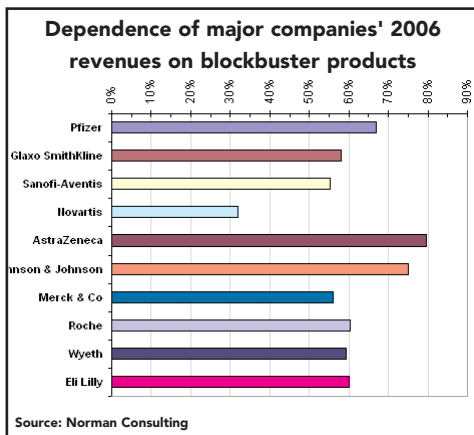
## Top five reasons to order your copy today



"AstraZeneca's protection of its high value ulcer franchise is probably the most successful such example to date of sustaining revenues from a high value franchise after patent expiration. The financial success of this strategy is clearly illustrated in the above chart, note how the value of this combined franchise has barely changed throughout the period 2000 to 2006..."

- **Strengthen product protection by tailoring patent options** to the individual specifications of your products more effectively.
- **Create a multi-strategy approach to defend your products and their revenues**, as detailed within this report.
- **Enhance the efficacy of your patenting policy and opportunity management** with explicit insights into the impending legislative changes concerning biosimilars and pediatric exclusivity, in addition to fallout analysis from the April 2007 Supreme Court ruling.
- **Integrate your patent protection and product lifecycle strategies with greater fluency**, and reap the long term revenue benefits that improved synchronicity will afford.
- **Improve your current patenting practises by benchmarking case histories**, and augment your organisation's approach to achieve effective and successful strategy application.

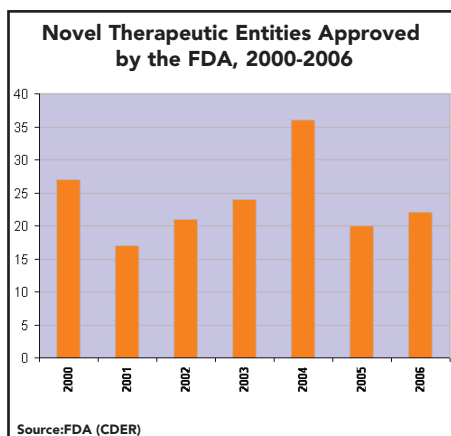
## Key issues examined in this report...



"The dependence of major companies' revenues on the sales of blockbuster products is a recent development and one that serves to focus attention on sustaining revenues from these products, highlighting which patent portfolios are of greatest importance. It is also critical for them to identify new emerging products which have blockbuster potential, to ensure that adequate patent coverage is obtained..."

- **Recouping drug development costs.** The acute importance of sustainable market exclusivity for new drugs, through the use of patents and other legislative methods, in relation to recovering development costs and optimising revenue returns.
- **US Supreme Court ruling.** The scope of product patentability and patent protection strategies in general are widely expected to experience drastic changes as a result of the April 2007 ruling.
- **Growing market prevalence of authorised generics.** An industry-wide debate has been evoked over the increasing use of authorised generics, based upon concerns over validity and consumer benefit.
- **Biosimilar legislation.** In June 2007, American Congress established a legal framework concerning the market admission of biosimilar products.
- **Implications of declining NCE's.** Diminishing NCE's highlight the importance of maximising patent protection for new drug entrants.

## Your questions answered...



"The number of NCE's approved by the FDA in 2006 was eighteen, four of which had 'Orphan Drug' status. Four Biological License Applications (BLAs) were also approved in 2006. This continued the (historically) low level annual of new therapeutic entity approvals, as shown above. When contrasted to the levels of R&D expenditure it is evident that so few approvals will struggle to generate a return on investment..."

- How can the nominal 20 year period of patent protection be most effectively extended?
- What frameworks can be applied to formulate a holistic market strategy incorporating patent and product lifecycle considerations?
- How can the market entry of generic substitutes be delayed?
- Do significant differences exist between the patenting methods practised across the major markets?
- How may legislative changes impact upon future patent strategies and what areas of new legislation are currently under discussion?
- What are the most effective patenting techniques and how can they be applied to maximise the sustainability of product revenues?

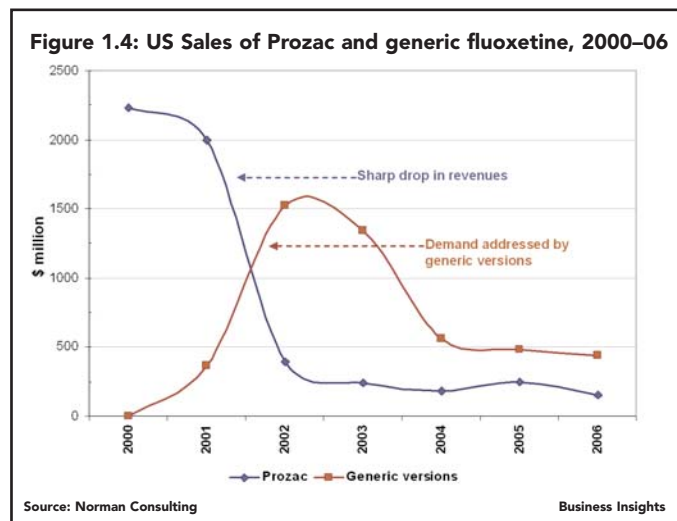
## Sample Information: 'Patent Protection Strategies'

### Chapter 1: The need for patent protection

#### The impact of generics

The need for an effective defense of a company's patents is highlighted by the rapid loss of revenues that results when cheaper generic substitutes become available. Although this has always been a problem for the suppliers of branded pharmaceutical products, it has become a more critical issue with the emergence of blockbuster products.

The consequent revenue losses can be disastrous for a company's cash flow and, if a company is over reliant on a single product, could even prove catastrophic.



The first clear example of how this could impact upon revenues is provided by the example of Eli Lilly's Prozac (fluoxetine). In 2000 global sales of Prozac were \$2.6 billion of which \$2.2 billion was generated in the US. Eli Lilly believed that it had patent protection for Prozac, in the US, until 2004, thereby preventing the availability of cheaper generic substitutes until that time. And Lilly's strategy for defending this franchise was based upon that assumption.

However, the validity of this patent was challenged by Barr Laboratories and, following a series of court rulings in Barr's favor it was determined that Lilly's market exclusivity for fluoxetine would end on 2 August 2001. Barr had anticipated that it would win the case and had stockpiled fluoxetine enabling it to flood distribution channels rapidly, in order to take full advantage of the 180 day exclusivity granted to the first generic product. This led to a much sharper erosion of Prozac sales than anticipated by either Eli Lilly or by market analysts. Prozac revenues declined by 66% in the final quarter of 2001, continued to fall through 2002, as shown in Figure 1.4, and then more slowly thereafter.

Revenues from generic fluoxetine products also declined as various suppliers battled for cost leadership of this segment. The failure of Eli Lilly's patent strategy cost the company around \$6 billion in lost revenues. The decline in revenues once patent protection expires is now expected to be precipitous as illustrated by the more recent example of Merck & Co.'s Zocor (simvastatin). Merck's US market exclusivity for this product expired on 23 June 2006 after the patent lifetime had been extended for an extra six months for pediatric exclusivity.

Order this report today to find out more...

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