

## Pharmaceutical Sector Inquiry – Preliminary Report

### Fact Sheet "Originator-Generic competition"

Once a medicine marketed by the originator company is no longer protected by patents or other exclusive rights (data exclusivity), generic companies can enter the market with a medicine that is equivalent - in terms of efficacy, safety, and quality - to the original. This lowers prices and enhances access to affordable treatments.

#### **Tool-box of strategies used by originator companies**

The sector inquiry found that originator companies use a variety of strategies and instruments to maintain revenue streams from their medicines, in particular blockbusters, for as long as possible. These practices can delay generic entry and lead to healthcare systems and consumers paying more than they would otherwise have done for medicines. The instruments include:

1. strategic patenting
2. patent disputes and litigation
3. patent settlements
4. interventions before national regulatory authorities, and
5. life cycle strategies for follow-on products

#### **1) Strategic Patenting**

One common strategy is the creation of “patent clusters” by the filing of numerous additional patents for the same medicine. The following quotes, found in documents collected in the inspections of originator companies, confirm that one of the objectives of this strategy is to delay or block the market entry of generic medicines:

" [...]

*Inevitably there will be patents covering products on the market that can be, and will be challenged [...] The strategy today is to try and provide a solid protection for the substance (has a limited time though) and a portfolio protecting different aspects of product providing extended protection both in brea(d)th and time but inevitable less solid and robust."*

*"I suppose we have all had conversations around "how can we block generic manufacturers".*

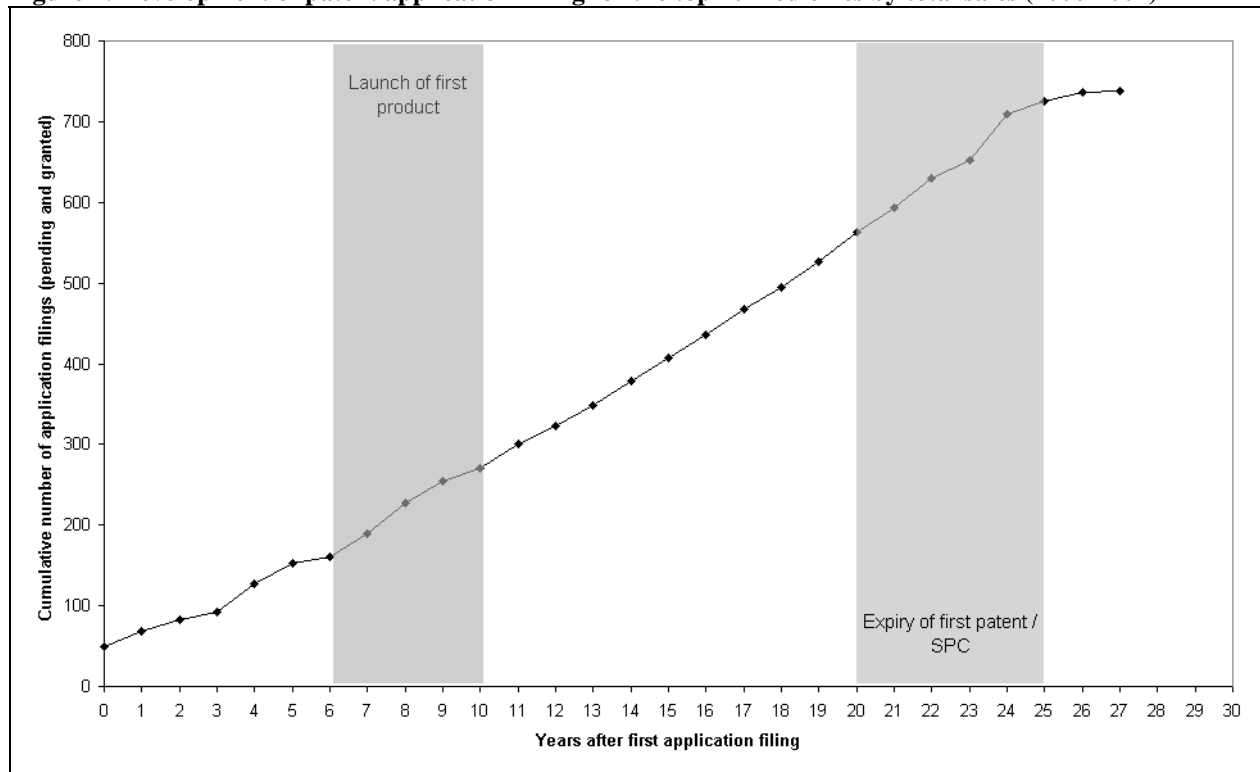
*[...] Don't play games in patenting new salt forms too late, the generics are starting earlier and earlier. Get claims on key intermediates that cover a number of routes. Process patents are not the biggest block but can put generics off if a superior chemistry job is done. [...]"*

*"Secondary patents will not stop generic competition indefinitely but may delay generics for a number of years, at best protecting the originator's revenue for a period of time."*

Individual blockbuster medicines are protected by up to nearly 100 product-specific patent families, which can lead to up to 1,300 patents and/or pending patent applications across the

Member States. A significant number of patent applications occur very late in the life cycle of a medicine, particularly for blockbuster medicines.

**Figure 1: Development of patent application filling for the top 20 medicines by total sales (2000-2007)**



Source: Pharmaceutical Sector Inquiry

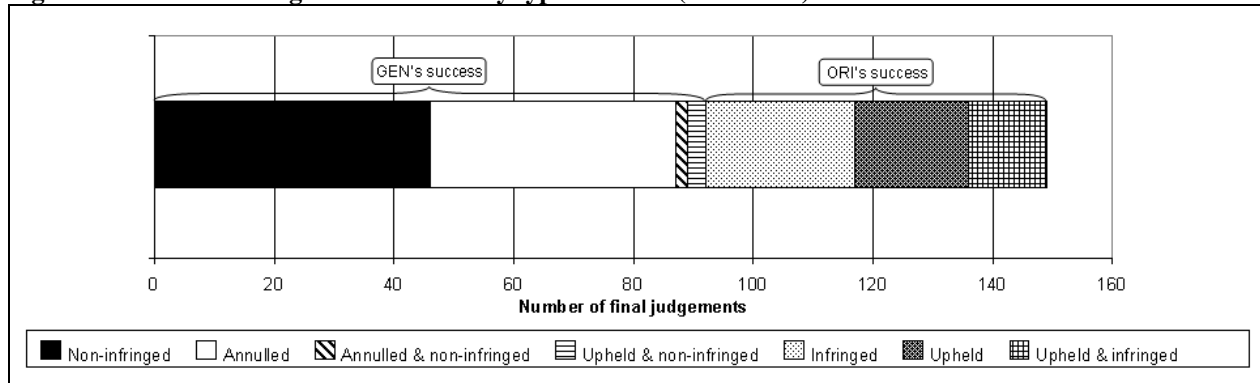
Patent clusters make it more difficult for generic competitors to see whether they can develop a generic version of the original medicine without infringing one of the many (new) patents of originator companies. In addition, certain originator companies admit internally that some of these new patents are not very strong.

## **2) Patent Litigation**

The number of patent litigation cases between originator and generic companies increased by a factor of four between 2000 and 2007. For this time period, the sector inquiry found close to 700 cases of patent litigation between originator companies and generic companies in relation to the medicines investigated. Out of these, 223 were reported as settled, 149 cases were reported as litigation in which a final judgment was reached by the court, the remaining are either pending or withdrawn. The duration of patent litigation varied considerably between Member States with an average duration of 2.8 years.

The majority of court cases were initiated by originator companies. However, generic companies won the majority of cases in which a final judgment was given (62%) (see Figure 2).

**Figure 2: Outcome of litigation in the EU by type of action (2000-2007)**



Source: Pharmaceutical Sector Inquiry

In 30% of the cases litigation was initiated between the same parties in more than one Member State with respect to the same medicine. In 11% of the final judgments reported, two or more different courts in different EU Member States gave conflicting final judgments on the same issue of patent validity or infringement.

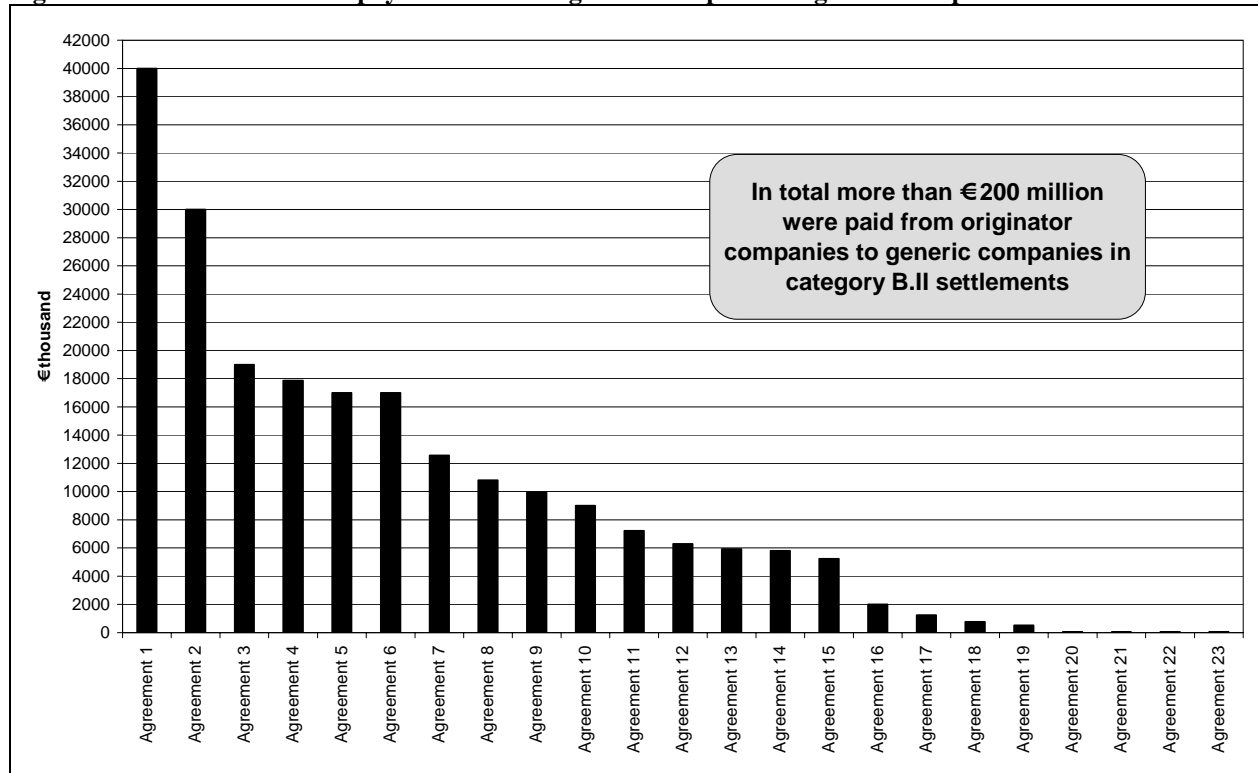
Moreover, originator companies asked for interim injunctions in 225 cases, obtaining them in 112 cases. The average duration of the interim injunctions granted was 18 months. In 46% of the cases in which injunctions were granted the subsequent court proceedings in the main case ended either with final judgments favourable to the generic company, or settlements which appear to be favourable to the generic company as they allowed early entry and/or foresaw a value transfer to the generic company.

### **3) Patent Settlements**

Originator and generic companies conclude settlement agreements to resolve patent disputes or opposition procedures. Between 2000 and June 2008, more than 200 settlement agreements were concluded covering some 49 medicines, of which 63% were best-selling medicines that lost exclusivity between 2000 and 2007.

In 48% of cases, the generic company's ability to market its medicine was restricted. A significant proportion of settlements contained – in addition to the restriction - a value transfer from the originator to the generic company in the form of a direct payment, a license, a distribution agreement or a "side-deal". Originator companies made direct payments to generic companies in more than 20 settlement agreements for a total amount exceeding €200 million (see Figure 3). It is this type of cases that has attracted antitrust scrutiny by the US competition authorities.

**Figure 3: Total value of direct payments from originator companies to generic companies**



Source: Pharmaceutical Sector Inquiry

#### **4) Interventions before National Regulatory Authorities**

Originator companies often made submissions before national authorities when generic companies applied for marketing authorisation and/or pricing and reimbursement status for their medicines. Originator companies claimed that generic medicines were less safe, less effective and of inferior quality compared to theirs. They also argued that marketing authorisations and pricing or reimbursement status could violate their patent rights. Claims relating to originator companies' exclusivity for marketing authorisation data were also raised. Interfering in administrative proceedings for generic medicines often leads to delays in generic market entry. When an originator company intervened, marketing authorisations procedures took on average 4 months longer. According to their internal documents, originator companies themselves believe that significant additional revenues result from such practices.

When lawsuits were lodged – mostly on originator companies' motion – generic companies won the vast majority of litigation cases.

#### **5) Life-Cycle Strategies for Follow-on Products**

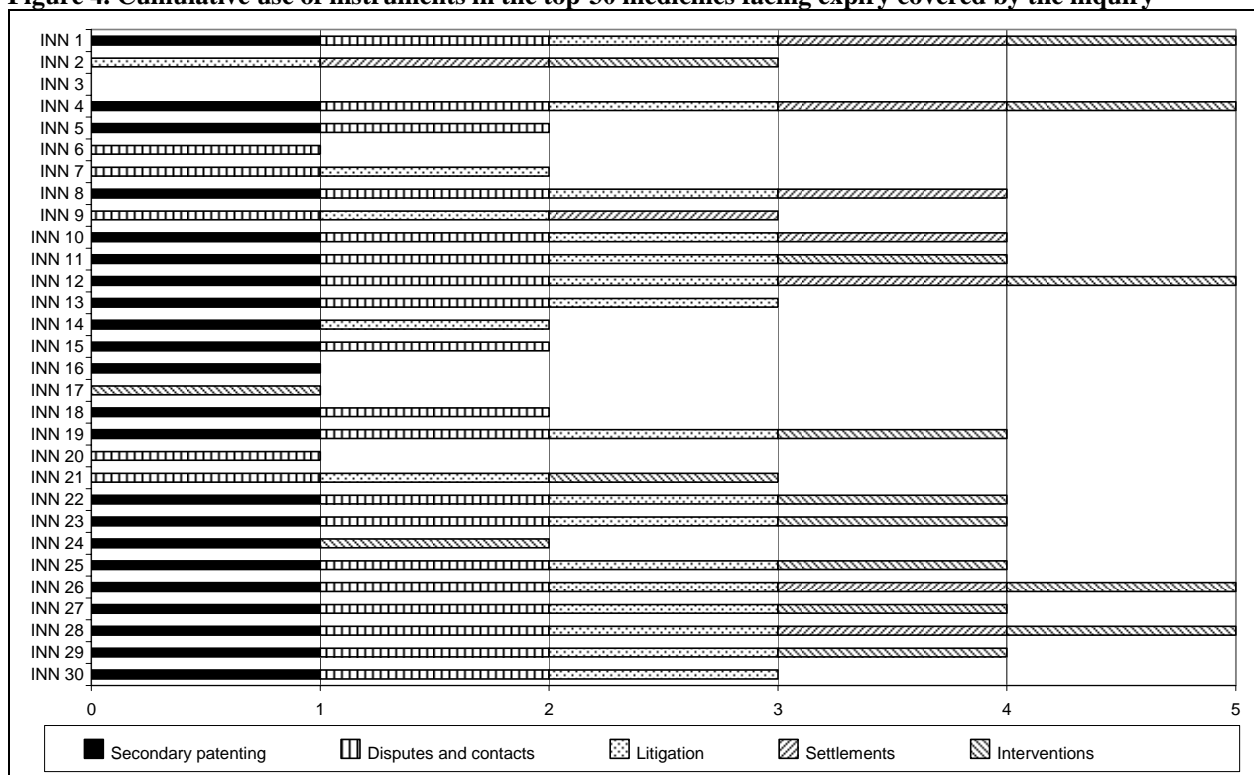
In a number of cases, originator companies tried to switch patients of their medicine facing imminent loss of exclusivity to a so-called second generation, or follow-on, medicine. The findings of the sector inquiry suggest that originator companies launched such follow-on

medicines in relation to 40% of the medicines in the sample selected for in-depth investigation, which had lost exclusivity between 2000 and 2007.

On average, the launch took place one year and five months before loss of exclusivity of the first generation medicine. In some cases, the first medicine was withdrawn from the market some months after the launch of the second generation medicine. If originator companies succeed in switching patients by that point, the probability that generic companies will be able to gain a significant share of the market decreases significantly. If, on the other hand, generic companies enter the market before the patients are switched, originator companies have difficulties in convincing doctors to prescribe their second generation medicine and/or obtain a high price for it.

In order to prolong the life cycle of their medicines, originator companies frequently combine two or more instruments from the "tool box" described above, plus secondary patenting (see Figure 4).

**Figure 4. Cumulative use of instruments in the top-30 medicines facing expiry covered by the inquiry**



Source: Pharmaceutical Sector Inquiry

For further information on the Pharmaceutical Sector Inquiry, please consult:  
<http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/index.html>