

The Pharma Sector Inquiry

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Opening of the Inquiry (January 2008)

On 15 January 2008 the European Commission launched an inquiry into competition in the pharmaceuticals sector.

The inquiry is a response to indications that competition in Europe's pharmaceuticals markets may not be working well: fewer new medicines are being brought to market, and the entry of generic medicines sometimes seems to be delayed. The inquiry will therefore look at the reasons for this.

In particular, the inquiry will examine whether agreements between pharmaceutical companies, such as **settlements** in patent disputes, have blocked or lead to delays in market entry. It will also look into whether companies may have created **artificial barriers** to entry (through the **misuse of patent rights, vexatious litigation or other means**). The sector inquiry does not aim to establish infringements of EC competition law by individual companies (Articles 81 and 82 EC).

The inquiry's findings will, if necessary, allow the Commission or national competition authorities to focus any future action on the most serious competition concerns, and to identify remedies to resolve the specific competition problems in individual cases.



"Individuals and governments want a strong pharmaceuticals sector that delivers better products and value for the money. But if innovative products are not being produced, and cheaper generic alternatives to existing products are being delayed, then we need to find out why, and, if necessary, take action."

Neelie Kroes, European Commissioner for Competition



EUROPEAN COMMISSION
Competition DG

Pharmaceutical Sector Inquiry

Preliminary Report

(DG Competition Staff Working Paper)

28 November 2008

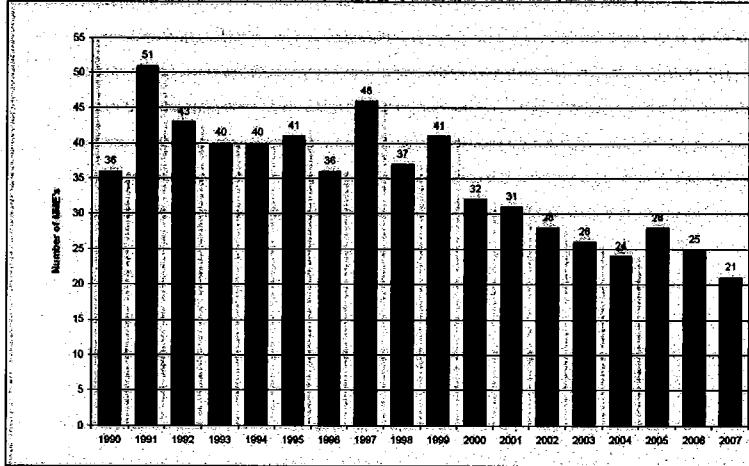
Preliminary Report

- The market for prescription and non-prescription medicines is worth over EUR 138 billion ex factory and EUR 214 billion at retail prices. This translated into a retail expenditure of approximately EUR 430 for each EU citizen in 2007.

Preliminary Report

- Patents are key in pharmaceutical sector, as they allow companies to recoup their often very considerable investments and to be rewarded for their innovative efforts.

Figure 8: Number of new molecular entities (NME) first launched worldwide (1990-2007)



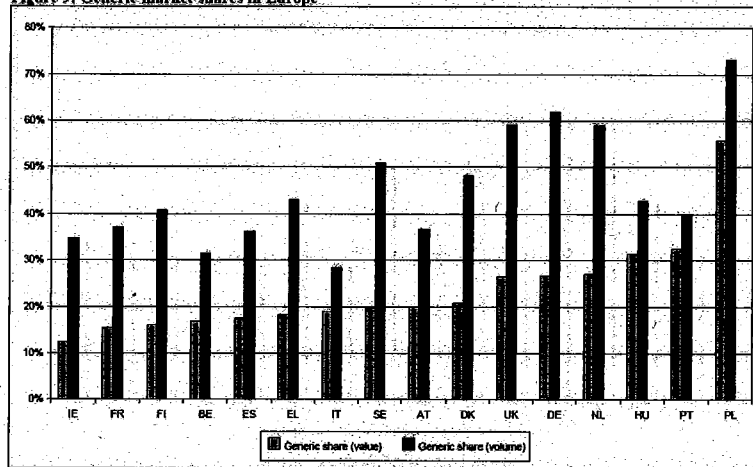
Source: EFPIA and CMR International (Thomson Reuter)

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Figure 9: Generic market shares in Europe



Source: Pharmaceutical Sector Inquiry (based on IMS data)⁵¹

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Preliminary Report

- Originator companies have designed and implemented strategies (a "tool-box" of instruments) aimed at ensuring continued revenue streams for their medicines. Although there may be other reasons for delays to generic entry, the successful implementation of these strategies may have the effect of delaying or blocking such entry.
- The strategies observed include filing for up to 1,300 patents EU-wide in relation to a single medicine (so-called "patent clusters"), engaging in disputes with generic companies leading to nearly 700 cases of reported patent litigation, concluding settlement agreements with generic companies which may delay generic entry and intervening in national procedures for the approval of generic medicines.

Preliminary Report

- The sector inquiry confirms that generic entry in many instances occur later than could be expected.
 - Seven months on a weighted average basis.
 - Price levels for medicines in the sample that faced loss of exclusivity in the period 2000 – 2007 decreased by almost 20% one year after the first generic entry.
 - Decreases in price levels were as high as 80-90% in rare cases.
 - Based on the sample of medicines under investigation that faced loss of exclusivity in the period 200 – 2007, representing an aggregate post-expiry expenditure of about EUR 50 billion over the period (in 17 Member States), the preliminary report estimates that this expenditure would have been about EUR 14 billion higher without generic entry.
- The savings from generic entry could have been about EUR 3 billion more, further reducing expenditure for these medicines by more than 5%, if generic entry had taken place without delay.

Preliminary Report - Main Findings

1. Products and Patents

- The pharmaceutical sector is one of the main users of the existing patent system. The number of pharmaceutical-related patent applications before the European Patent Office (EPO) nearly doubled between 2000 and 2007. Blockbuster medicines' patent portfolios show a steady rise in patent applications throughout the life cycle of a product.

Preliminary Report - Main Findings

2. Competition between Originator and generic Companies

- Originator companies use a variety of strategies to extend the commercial life of their medicines for as long as possible.
- Originator companies confirm that they aim to develop strategies to extend the breadth and duration of their patent protection
- One commonly applied strategy is filing numerous patents for the same medicine (forming so called "patent clusters" or "patent thickets")
- A second instrument used by originator companies appears to be filing "divisional patent" applications
- Enforcing patent rights in court is generally legitimate: it is a means of ensuring that patents are respected. The inquiry's preliminary finding is however that litigation can be an efficient means of creating obstacles in particular for smaller generic companies.

Preliminary Report - Main Findings

- Between 2000 and 2007, originator and generic companies engaged, out of court, in at least 1300 patent-related contacts and disputes concerning the launch of generic products.
- The number of patent litigation cases between originator and generic companies increased by a factor of four between 2000 and 2007. In total, close to 700 cases. 149 cases were reported as litigation in which a final judgment was reached.
- Generic companies won the majority of cases in which a final judgment was given (62%).
- 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.

Preliminary Report - Main Findings

- Total cost of patent litigation in the EU relating to the 68 medicines on which litigation was reported for the period 2000-2007, is estimated to exceed EUR 420 million.
- 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.
- Originator companies intervened when generic companies applied for marketing authorization and pricing/reimbursement status for their medicines.
- Intervention and litigation by originator companies interfering in administrative proceedings for generic medicines can lead to delays to generic market entry.

Preliminary Report – Main Findings

- The inquiry's preliminary finding is that originator companies spent on average 23% of their turnover on marketing and promotion activities for their products. As part of their commercial strategies, originator companies do not simply promote their own medicines to doctors and other healthcare professionals. There are also indications of practices seeking to put into question the quality of generic medicines.
- Indications that originator companies attempt to exercise influence over the distribution channel (wholesalers) and supply sources for the active pharmaceutical ingredients needed to produce the medicines in question.
- Launch of second generation products
- Patents relating to second generation products are sometimes criticized as weak by other stakeholders who argue that they show only a marginal (if any) improvement or additional benefit to the patients.

Preliminary Report - Public Consultation

- DG Comp solicited the views and comments of interested stakeholders by 31 January 2009.



Making Medicines Affordable

EGA Position Paper

"Patients must have immediate access to affordable generic medicines at day one after patent expiry"

EGA Position Paper

- In the opinion of the EGA, the following strategies are the most significant in creating hurdles to generic competition:
 - Interference in the grant (and/or activation) of marketing authorizations and pricing and reimbursement status;
 - Seeking weak or invalid patents, particularly second-generation patents – which may form part of a "patent thicket" or be used to block the entry of generic medicines in other ways;
 - Evergreening – e.g., switching patent demands by launching second-generation products with little or no added therapeutic value;
 - Information and marketing campaigns that question the quality, safety and efficacy of generic alternatives;
 - Vexatious litigation whose primary purpose is to delay the entry of generic medicines (e.g., by obtaining interim injunctions keeping generic companies off the market).

EGA Position Paper - Proposed Changes by the EGA

1. In Relation to Interference in Regulatory Procedures of Generic Medicines

- National authorities should not receive or take account of third party submissions when considering the grant of marketing authorizations or pricing and reimbursement status
- It is contrary to EU law to take account of the patent status of the originator's reference product in the context of applications for pricing and reimbursement status (patent linkage)
- Commission to modify existing EU legislation to include (a) an express mention of price and reimbursement procedures in the Bolar provision and (b) an equivalent provision (or provisions) in the Transparency directive.

EGA Position Paper - Proposed Changes by the EGA

2. In Relation to Applications for Weak or Invalid Patents

- Ensuring more rigorous assessment of existing patentability requirements – including in particular application of the inventive step requirement;
- Ensuring that applications for divisional patents do not cover essentially the same subject-matter as the parent application;
- Increasing the resources available to the EPO in order to allow more rigorous assessment;
- Imposing a "duty of candour" on patent applicants requiring them to disclose all information known to them which is material to the patentability of the invention; and
- Introduction of measures to reduce the length of opposition procedures and appeals to the Board of Appeals at the EPO, such as the introduction of strict timetables and measures to reduce delaying tactics.

EGA Position Paper - Proposed Changes by the EGA

3. In Relation to Evergreening Strategies

- The original version of the product is withdrawn from the market without objective justification as a means to facilitate the switching of patients to the follow-on product; and/or
- Misleading claims are made as to the added therapeutic value of the follow-on product in order to induce the switching of patient or prescribing intentions
- Second generation products with little or no added therapeutic value should be distinguished from incremental innovations which involve changes to existing products that bring proven added therapeutic value to patients. (e.g., through improved formulations or delivery mechanisms).

EGA Position Paper - Proposed Changes by the EGA

4. In Relation to Vexatious Litigation

- In all jurisdictions, patent cases to be handled by specialized patent judges with the necessary technical knowledge and expertise to decide cases quickly and correctly; and
- The current over-readiness of certain jurisdictions to grant interim injunctions excluding generic products from the market to be addressed (the introduction of suitably expert specialist judges would represent a major step forward in this regard).

EGA Position Paper - Proposed Changes by the EGA

5. Settlement Agreements

- *"For the reasons of law and policy articulated by the US Courts in particular, the EGA believes that settlement agreements which do not delay generic entry beyond the term (or scope) of patent exclusivity should not be considered to infringe EU competition law (absent exceptional circumstances)."*



THE EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATIONS

RESPONSE TO THE PRELIMINARY REPORT IN THE PHARMACEUTICAL SECTOR INQUIRY

30 January 2009

- *"If carried over to the Final Report, the tone and approach of the Preliminary Report risk causing considerable damage to the innovative sector. The threat of antitrust intervention in relation to many common legitimate practices will undermine what is already a limited commercial window of opportunity in the quest to deliver tangible improvements in public health."*

Strong Patent Protection is the Foundation of R&D: There is No Evidence that Patents Hinder Innovation

- Without strong system of intellectual property protection and an ability to enforce and defend patents, it would be even more difficult to fund high-risk pharmaceutical research.

Delays to Generic Entry are Over-Stated and Wrongly Attributed

- The toolbox approach casts doubts on the lawfulness of common commercial practices (patent portfolios, patent litigation, settlement agreements, regulatory inventions and the promotion of next generation improved products) in certain, but unidentified, circumstances.

The Potential for Savings from More Efficient Generic Markets is Largely Ignored

- It is paradoxical that Europe, as shown in the Preliminary Report, pays significantly more for generics but less for innovative drugs than the United States.

Policy Recommendations

- The Final Report should contain policy recommendations on how to reduce costs and increase legal and commercial certainty for all parties.
- It should address the most significant market entry barrier, namely the sheer complexity and diversity of the applicable national regulatory regimes.
- Whereas the Preliminary Report has focused on alleged practices designed to delay the access of generic medicines, the reality is that entry delays are much more significant for innovative medicines.
- Streamlining processes to provide faster access to therapeutic advances (including through the better enforcement of the Transparency Directive) improves the quality of life/longevity of patients and is in the broader public interest.

Policy Recommendations

- Stimulating price competition amongst generics and ensuring that those savings are in large part passed on to the ultimate payers should be a major focus of the Final Report.
- Adoption of the European Community Patent; the creation of a unified, specialized litigation system in Europe; a streamlining of the opposition procedure of the European Patent Office; and a mechanism to address patent disputes before generic launch.
- Intrusion into intellectual property rights can only be justified in the most "exceptional circumstances", and any attempt to expand this notion to challenge legitimate commercial practices will have a chilling effect on innovation.

Policy Recommendations

- The Commission's Final Report should take due account of the various parameters that shape competition and act as a stimulus to
 - (1) reduce regulatory barriers and strengthen intellectual property protection,
 - (2) generate efficiencies and savings for healthcare budgets, and
 - (3) promote Europe's health and competitiveness.

Comments from the EPO

- *"The EPO notes with satisfaction that European Commission's Preliminary Report supports the patent system and recognizes the importance of its function in promoting innovation by allowing the appropriation of inventions, which in turn, promotes healthy competition in the marketplace between pharmaceutical companies, in the interest of society at large."*
- *"The EPO welcomes the emphasis the report places on the need for the creation of a Community patent and a centralized, specialized European patent judiciary and wholeheartedly endorses the conclusions drawn by the Commission in this respect."*

**Comments from the EPO
The "Primary Patent" / "Secondary Patent" Distinction**

- *"The suggestion of generic companies that the EPO should subject so-called "secondary patent" applications to a higher level of scrutiny is incompatible with the principles of the EPC, the letter and spirit of which require the EPO to carry out its work in a neutral and predictable manner free of arbitrary considerations, and to subject all inventions to the same standards of patentability under the EPC."*

**Comments from the EPO
The "Primary Patent" / "Secondary Patent" Distinction**

- *"One of the express goals pursued by the patent system is to promote the creation of inventions built on other inventions, as demonstrated by the experimental use exception. Such early enablement of such further follow-on invention also constitutes one of the underpinnings of the mandatory publication of applications 18 months after the filing or earliest priority date. The filing of so-called 'secondary patents' is not the exclusive privilege of the holders of so-called 'primary patents'. Third parties may build upon such knowledge and file for follow-on inventions – in the pharmaceutical sector, both originator and generic companies do so."*

