SPEECH/08/

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European Commissioner for Competition Policy

Antitrust: preliminary report of sector inquiry into pharmaceuticals

Opening remarks at public hearing

Brussels, 28th November 2008

Ladies and gentlemen,

It's a great pleasure for me to welcome you to this public hearing on the preliminary findings of the pharmaceutical sector inquiry. Given our deep shared interest in this inquiry we can look forward to a day filled with interesting presentations and discussions.

It is very important that pharmaceutical markets function properly. Europe's citizens, including all of us here today, need access to safe, innovative and affordable medicines.

Much is at stake. There are tens of thousands of prescription and non-prescription medicines on the market, and more people are taking more medicines as our population ages. Medicines account for annual sales of over €214 billion at retail prices – approximately €430 per EU citizen in 2007.

Our sector inquiry was established because of indications that competition is not working in the sector as it should. We observed a decline in the launch of novel medicines and delays in the market entry for generic medicines, and it was clear we needed to make a contribution to the wider Commission effort to make the sector work better.

That work includes efforts to strengthen intellectual property rights – such as with a Community patent and the innovative medicines initiative. The sector inquiry fits well in these initiatives as it will provide ground-breaking information about bottlenecks that delay or block innovation or access to affordable medicines.

What have we found?

I must preface my remarks by saying we have much to thank the pharmaceutical sector for. We now live longer and conditions such as HIV/AIDS are more manageable in Europe because of this sector's contributions to our world. This would not have been possible without effective protection of intellectual property rights ensuring that companies reap the benefits of their innovation.

That said, today is also about looking at issues where we can do better. The preliminary report sets out a detailed description of the sector, rather than trying to identify wrongdoing by individual companies.

Let me go into some more detail on the report's content….

Looking first of all at **competition between so-called "originator" companies and "generic" companies**, it is clear that originator companies have changed their patent strategies in recent years, in ways that have caused us and others great concern.

What is at the heart of these strategies? Let me read you some extracts from a document we found during our inspections in January.

1. *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.*

2. *Process patents are not the biggest block but can put generics off if a superior chemistry job is done."*

This quote shows us not only how useful inspections are, but it is also a good example – and there are more examples in the report - that originator companies have designed and implemented strategies aimed at hindering their competitors, and thereby ensuring continued revenue streams for their medicines. The Preliminary Report refers to such strategies as a "tool-box". The successful implementation of these strategies contributes to the delaying or blocking of generic entry.

You may be surprised at how far originator companies will go to extend the breadth and duration of patent protection. EU-wide up to 1300 patents can be filed in relation to a single product – a practice called 'patent clustering', which creates a dense web of protection around products.

Some may tell me that the European Patent Office's opposition procedures are an effective tool for generic companies to challenge patents granted to originator companies. And indeed when generic companies opposed patents granted to originator companies before the European Patent Office, they prevailed in nearly 75% of cases. But when almost 80% of the opposition procedures take more than 2 years, then it is clear that the delays caused can have a high cost on Europe's healthcare systems.

We also observed nearly 700 cases of patent litigation between originator and generic companies concerning roughly 70 medicines that faced patent expiry during the period investigated. Whilst defending one's rights in court is of course legitimate, we cannot help but note that the generic companies win a clear majority of the cases. However litigation takes on average almost 3 years and is not cheap. We estimate the direct costs for the various parties to amount to at least €420 million. Lawyers are evidently getting rich, and generic entry is delayed, but the benefits to consumers are less clear.

Originator and generic companies also concluded more than 200 settlement agreements in the EU, to end ongoing litigation and disputes. Some of these settlements imposed limitations on market entry by generic medicines. More than €200 million were paid out by originator companies to generic companies - and we wonder whether some of these payments are made to keep generic companies off the market.

The speed of generic entry matters. We have found that one year following entry by generic medicines, prices are almost 20% lower, and 25% lower after two years. In a rare number of cases prices can drop as much as **80-90**% already in the first year**.** On a weighted average, on the basis of the sample we examined, it takes about seven months for generic medicines to enter the market once the relevant patent protection has expired. Can that speed be increased? We would like to know. Because if generic entry was immediate when medicines lose their exclusivity we believe prices would be lowered at least by an additional more than 5%.

That is in addition to the at least € 14 billion in savings we identified from a sample of generic medicines entering the market from 2000 to 2007 across 17 Member States. Imagine what could really be saved if the system worked optimally!

And for every day it does not work optimally it is every one of us who gets stuck paying the bill: both as taxpayers and patients. Let me however be clear about one thing: I am not saying that these delays are exclusively attributable to originator companies. They contribute however and this is a concern.

The report finds much more than a simple problem between originators and generics.

Our findings suggest that **originator companies have also developed strategies to block the development of new products by other originator companies**.

Let me give you an example of the strategy of an originator company as described in its internal patent strategy document. The company writes:

- *"We identify options to obtain or acquire patents for the **sole** purpose of limiting the freedom of operation of our competitors […]".*

Did you hear that? Acquiring patents “for the sole purpose” of limiting competitors' ability to compete.

Is this really what we want to achieve with intellectual property rights?

This document and other examples in the report show that 'defensive patenting' tactics are being used by originator companies to shield themselves against competition, rather than genuinely protect innovation.

In total, the samples investigated in our inquiry revealed at least 1,100 instances across EU Member States where the patents held by an originator company might, for example, be infringed by a medicine and/or an R&D programme of another originator company. This overlap means originator companies can find important research activities blocked, undermining the innovation process in the industry.

As I already said, we are also aware that the **regulatory framework** contributes towards some of the delays experienced in the sector.

It is therefore pleasing to confirm that originator and generic companies agree on the need for the creation of a Community patent and the need for a unified and specialised patent judiciary. Our findings in the sector inquiry fully support this call. Just recall the high number of court proceedings for our sample and that currently 11% of the final judgements have contradicting outcomes.

Comments were also received on rules governing marketing authorisations and the pricing and reimbursement status of medicines. Bottlenecks in the regulatory approval process have been identified, resulting for instance from a lack of sufficient resources in some Member State agencies and discrepancies in national assessment criteria**.**

Some initially grumbled about this inquiry, and I expect more will grumble about the findings. But for the most part we have received excellent cooperation. I would like to sincerely thank those who made themselves available to assist us in our work. This includes stakeholders, companies, associations and public bodies, who have provided us with a lot of information, data and feed-back. I am impressed with your cooperation – though I recognize that your contributions do not bind you to our findings. Let us keep this cooperation going.

I am particularly grateful to the European Patent Office which has provided us with technical assistance, enabling us to gain a better understanding of the specifics of the patent system, both in legal and in operational terms. It is wonderful to see that we can work together for Europe.

I am pleased that the existence of this inquiry has led to some hard thinking from all sides.

On the specific point of the Community Patent, I am aware that the French Presidency will present a progress report on the Community patent and the unified patent judiciary in the Competitiveness Council next week. I hope that Martin Power, the Head of Commissioner McCreevy's Cabinet, can give you an update on where we stand in the panel discussion later today.

In conclusion, let me say that the Pharma sector is taking on a more important role in family and government budgets, so we will not rest in doing what we can to make it work better for those buying medicines.

We now have a good overview of what is happening in the sector and why: the next step is to discuss our findings with the stakeholders and to draw the necessary conclusions. For this we launch today a public consultation on our report and I can only invite you to submit your comments and ideas to the Commission until the end of January 2009, when our consultation period ends. We will then prepare the final report for spring and draw the necessary conclusions.

It is early days, but you will not be surprised if I tell you that the Commission will not hesitate to initiate investigations where there are indications that the antitrust rules may have been breached.

Our preliminary report shows that we have picked up the trail of the scent, and now we are following the leads.