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Insight

Newsflash

The European Commission publishes its Final Report in the Pharmaceutical Sector Inquiry

Introduction

On 15 January 2008, DG Competition ('DG COMP') opened a sector inquiry into the European pharmaceuticals industry by way of unannounced inspections on several companies. This was the first time that dawn raids had been used to open a sector inquiry. At that time, DG COMP said it had started this inquiry to examine the reasons behind fewer new pharmaceuticals being brought to market and delays to generic entry in the EU.

DG COMP issued its Preliminary Report on 28 November 2008 – see [Preliminary Report](#) and its Final Report on 8 July 2009 - see [Final Report](#).

DG COMP also announced on 8 July 2009 that it has opened proceedings against Servier and five generics manufacturers (Krka, Lupin, Matrix Laboratories Limited, Niche Generics and Teva) on suspicion of conduct in relation to perindopril contrary to both Articles 81 and 82 of the EC Treaty.

In general, the Final Report presents a more balanced view than the Preliminary Report. In particular, DG COMP paints a fairer picture of the real world in which the European pharmaceutical industry operates.

This client alert will summarise the main findings of the Final Report.

I. A welcome recognition of the reality of the world in which the European pharmaceutical industry operates

A. The role of innovation and of IP rights

The Final Report recognises that innovation is of fundamental importance to the pharmaceutical sector and that IP rights in the pharmaceutical sector are a particularly important element in the promotion of such innovation:

"The pharmaceutical sector in the EU indeed has one of the highest investments in R&D in Europe and relies significantly on intellectual property rights to protect innovation. The exclusivity periods granted through patent law and other mechanisms (SPC, data exclusivity) provide incentives to originator companies to continue innovating."

The Final Report also acknowledges the link between IP rights and innovation, stating that the pharmaceutical sector is one of the highest investors in R&D and is heavily reliant on strong IP protection to protect the fruits of that R&D investment.



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B. The European pharmaceutical sector displays certain unique features

The Final Report notes that there are certain unique features which set the pharmaceutical sector apart from all other sectors.

First, not only do public authorities in each Member State set pharmaceutical prices directly or indirectly but they are also the ultimate economic purchasers of pharmaceuticals:

“prices are most often the result of a regulated decision-making process, involving nevertheless negotiations between stakeholders. Where this is not the case, i.e. in countries with so-called free pricing, prices are dependent on the regulated reimbursement decisions.”

Second, the ultimate consumers of prescription medicines, i.e. the patients, do not decide which products to buy. Rather, such decisions are generally taken by doctors, and in certain Member States, by pharmacists.

Finally, the conduct of patients and doctors are relatively unaffected by the cost of specific pharmaceutical products as most or all of such costs are normally borne by national health insurance schemes.

II. Findings as to the alleged effect on competition of the conduct of pharmaceutical companies in the EU

A. Competition between originator and generic companies in the EU

The headline figure of EUR 3 billion that DG COMP stated in the Preliminary Report could be saved if generic entry had happened faster is maintained. This number is based on the assumption that generic entry would happen immediately i.e. on day one after patent expiry in 2000-2007 in the EU Member States for essentially all the medicines that went off patent in that period.

However, the Final Report also acknowledges that delays to generic entry in the EU are caused by a number of factors, not least regulatory delays and country-by-country differences in promoting generic uptake. The conduct of originator companies highlighted in the Final Report is therefore only one of a number of relevant factors.

Moreover, the Final Report argues that the reference in the Preliminary Report to a so-called “toolbox” of practices employed by originator companies in order to delay the entry of generic medicines onto the market in the EU does not have a pejorative meaning but rather is the term commonly used by originator companies themselves. Nevertheless, the Final Report now refers to the elements in the “toolbox” as “life cycle management strategies”. Similarly, the Final Report explains that the use of terms such as “secondary

patents” is not intended to portray such patents in a negative light but rather to merely reflect the fact that they follow the primary patent from a time perspective.

The Final Report also recognises that the use of several life cycle management strategies that are individually legitimate does not necessarily render their combination contrary to the EC competition rules.

1. Patent clusters – the Final Report notes that certain medicines are protected by up to nearly 100 product-specific patent families, which can lead to up to 1300 patents and/or pending patent applications across the Member States.

The Final Report also states that the average number of patents and patent applications for the top selling medicines is 140% higher (i.e. 237) than the average of the overall sample (98.5), although it is difficult to understand why such a finding is so revealing.

2. Secondary patents: litigation and opposition procedure – although stating that the right to enforce patents is a fundamental right, DG COMP concludes that certain litigation may be problematic where it serves as a “signal to deter generic entrants.”

Notwithstanding the above, and in contrast to the Preliminary Report, the focus of the Final Report is less on potential delays, but rather on the costs associated with such litigation. The total cost of patent litigation between 2000 and 2007 is said to have been over EUR 420 million, of which a significant proportion DG COMP claims could be avoided if a unified EU-wide patent litigation system were created.

DG COMP also looked at opposition procedures before the EPO, where it is said that generics had a 60% success rate in cases that went to final judgment or decision. This caused delay in DG COMP’s view (about 2 years).

3. Settlements and other agreements – as in the Preliminary Report, DG COMP states that based on the data it collected, it found 208 settlement agreements concluded between 2000 and June 2008, of which 63% were related to best-selling medicines that came off-patent between 2000 and 2007 (this is perhaps not surprising given that the sample of products covered by the sector inquiry was chosen with a view to including most of the medicines that went off-patent in the 2000-2007 period).

Moreover, according to the data collected by DG COMP, some of the main considerations taken into account by a majority of both originator companies and generic companies when entering into settlements include: 1) the strength of their positions in the patent litigation; 2) the inherent uncertainty of such litigation; and 3) the high costs of patent litigation.

However, as to whether certain types of settlement agreements are incompatible with EC competition law, the Final Report states that “*such an assessment would require an in-depth analysis of the individual agreement, taking into account the factual, economic and legal background*”, which is beyond the scope of the sector inquiry. This absence of guidance is disappointing – it would have been better for all actors in the pharmaceutical industry had DG COMP been able to set forth its views as to which settlements are – or are not – problematic.

4. Interventions before national authorities - the Final Report focuses on instances where originators asked pricing and reimbursement bodies not to give a price for generics and asked marketing authorisation bodies not to authorise a generic for safety issues.

According to DG COMP, originators only won 2% of cases against marketing authorisation bodies on patent-related issues and only 19% of cases on data exclusivity. Such interventions result in an average delay of 4 months for generic entry.

5. Follow-on or second-generation products - the Final Report recognises the value of follow-on products, stating that such incremental innovation “*can lead to significant improvements of existing products.*”

However, DG COMP’s Final Report continues to question whether the timing of the switch to second generation products may be a strategy by originators to delay generic entry. In that regard, based on the data it collected, DG COMP notes that the average time a second generation product is launched by an originator ahead of loss of exclusivity of the first product is around one year and five months.

Again though, the compatibility of such practices with EC competition law is said to be beyond the scope of the sector inquiry as such an assessment would require an in-depth analysis of the factual, economic and legal backdrop against which each practice takes place.

B. Competition between originator companies in the EU

1. Defensive Patents - the Final Report states that the Commission will scrutinise defensive patents “*where the originator company maintains and uses patents to block the development of a new, competing product rather than for protecting an invention of its own*” or where such patents “*mainly focus on excluding competitors without pursuing innovative efforts and/or the refusal to grant a license on unused patents (...) in particular in situations where innovation was effectively blocked.*”

The Final Report’s definition of what constitutes a “defensive patent” is thus narrower than the Preliminary Report’s which said that defensive patents were questionable where they are used for the sole purpose of excluding competitors.

2. Patent-related exchanges – the Final Report also looked at patent-related exchanges in the EU between originators and found 1100 cases where they were overlaps between originators’ R&D poles, which DG COMP says may have potentially detrimental effects on innovation.

However, as the Final Report shows, requests for licenses were only refused in 20% of these cases. Moreover, DG COMP found that only 40% of originator companies in the inquiry were involved in patent litigation during the 8 year period of investigation (which does not seem particularly high).

The Final Report also states that there were 1450 agreements between originator companies concerning the 219 medicines under investigation (which accounted for about half of the total pharmaceutical market).

III. Findings as to the regulatory framework in the EU

This section is the part which has most changed since the Preliminary Report. DG COMP says that this is because of the significant number of comments it received about these matters during the public consultation following the publication of the Preliminary Report, including from [White & Case](#).

A. Patent law and the enforcement system in the EU

1. The Community patent and a unified patent litigation system – the Final Report continues to push for the adoption of the Community patent and a unified patent litigation system, saying that the comments DG COMP received during the course of the public consultation confirm that generic and originator companies support this. This may therefore herald a renewed political push to get the Community patent proposal adopted.

2. Quality of patents - the Final Report welcomes the fact that the EPO is reflecting on how to further increase the quality of patents and how to make filings of third party observations easier and more attractive.

3. Launch at risk - the Final Report notes the suggestion put forward by EFPIA that where a generic company is considering launching “at risk”, it should be under an obligation to challenge the patent’s validity prior to launch. While not ruling out this idea, the Final Report does not consider that such a mechanism would create any added value at this stage due to significant discrepancies between national legal systems regarding the duration of court proceedings and the conditions for obtaining interim injunctions.

B. The marketing authorisation system in the EU

1. Enforcing the existing acquis - the Final Report does not set out any immediate steps to be taken in relation to marketing authorisation bottlenecks. Rather,

the Commission will seek to ensure that national implementation of the 2004 EU regulatory framework is effectively enforced.

The Final Report also states that the Commission will act against Member States who have not fully or correctly implemented the data exclusivity rules introduced in Community legislation in 2004.

2. Freeing up capacity – in the Final Report, the Commission gives its support to the EMEA and national medicines agencies to assess how resources and capacity problems may be solved within the network of national authorities.

The Final Report also indicates that the Commission has invited Member States to actively speed up and streamline administrative procedures.

3. Patent linkage – the Final Report says that the Commission will act against patent linkage, in particular where there are clear indications that a submission by a stakeholder was primarily made to delay market entry.

C. The pricing and reimbursement system in the EU

1. Enforcement of the Transparency Directive - the Final Report urges all stakeholders to ensure that the time-limits established by the Transparency Directive are respected.

The Commission will also continue to investigate all complaints which suggest an incorrect transposition or systematic disrespect of the Transparency Directive.

2. Pricing and reimbursement bodies should not take into account patent status or bio-equivalence – the Final Report states that pricing and reimbursement bodies should refuse to consider claims by originator companies that generic products are infringing a patent or are not bio-equivalent.

In that regard, the Commission refers to EFPIA's response to the public consultation and states that applications by generic companies for pricing and reimbursement status do not amount to a violation of patent law.

3. Cross-border reference pricing - the Final Report accepts that cross-border reference pricing can lead to delays in market entry. However, the Commission does not propose to take any action on this issue as this is a Member State competence.

4. Automatic grant of pricing and reimbursement status to generics - the Final Report invites Member States to consider policies which would facilitate the rapid access of generic products to market.

In particular, the Final Report suggests that generic products should automatically be granted pricing and reimbursement status where the corresponding originator product already benefits from reimbursement.

D. Next steps

Many of the regulatory problems highlighted by the Final Report fall outside of the EC's competence and it is unclear how far the Member States will act upon the Commission's recommendations.

As for competition law enforcement, the Final Report indicates that a number of areas will be the subject of increased focus by DG COMP:

- defensive patenting strategies that mainly focus on excluding competitors without pursuing innovative efforts and/or the refusal to grant a license on unused patents;
- patent settlement agreements that limit generic entry and include a value transfer from an originator company in particular where the motive of the agreement is the sharing of profits via payments from originator to generic companies to the detriment of patients and public health budgets;
- clear indications that a submission by a stakeholder intervening before a marketing authorisation body was primarily made to delay market entry

This may result in further investigations into potential infringements of Articles 81 or 82 of the EC Treaty being opened or pursued over the coming months. DG COMP observes that *“the sector inquiry has identified a number of issues that warrant further scrutiny under the competition rules. The Commission in cooperation with the national authorities will not hesitate to make use of its enforcement powers under competition law, where there are indications of practices that have the potential to restrict or distort competition in the market.”*

DG Comp also extends an invitation to any company that considers that itself a victim of such practices to step forward and inform the competition authorities, which may spell a more turbulent period for companies in this sector going forward.

Finally, DG COMP has stated that it is considering further *“focused monitoring”* of the pharmaceuticals sector, in particular of settlement agreements that limit generic entry and include a value transfer from an originator company to a generic company.