

3 December 2008

Insight

The Commission's Preliminary Conclusions from the Pharmaceutical Sector Inquiry

Introduction

On 15 January 2008, the European Commission opened a sector inquiry into the pharmaceutical 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, the Commission said it had started this inquiry to examine the reasons behind fewer new pharmaceuticals being brought to market and delays to generic entry. The Commission's Preliminary Report was issued on 28 November 2008 – see [Preliminary Report](#).

There was also a public hearing to launch the report, a summary of which is described below.

Preliminary factual findings in the Report (as described at today's hearing)

The Commission looked at three issues: measures to hinder generic entry, competition between originator companies and the regulatory framework.

Commissioner Kroes opened the hearing by giving a headline figure of at least EUR 3 billion that the Commission calculated could have been saved during 2000-2007 if generic entry had happened faster. Savings of EUR 14 billion already occurred due to generic entry, but the Commission found that if entry had happened faster, additional savings would have been made. The Commission acknowledged that delay was caused by a number of factors. The delay was not caused exclusively by the originators – there are a number of other factors, not least regulatory delays and country-by-country differences – but the Commission felt that the originators had “contributed” to the delays. See [Kroes' remarks](#).

After the Commissioner's presentation, the sector inquiry team gave more details on these matters. They did not present any conclusions – as this is just the preliminary report.

A. Hindering Generic Entry

The Commission gave a presentation which claimed there was a “toolbox” to delay generic entry comprising five factors.



Protecting the interests of the pharmaceutical industry

We advise leading pharmaceutical multinationals and the major US and EU industry associations on EU and national law and policy affecting the pharmaceuticals sector. Our work covers competition law, including licensing and distribution issues, regulatory matters, intellectual property, data protection, and national implementation of EU measures, notably on pricing and reimbursement.

White & Case LLP
 Avocats-Advocaten
 62 rue de la Loi Wetstraat 62
 B-1040 Brussels
 Belgium
 T +32 2 239 26 20
 F +32 2 219 16 26
www.whitecase.com

This document is prepared for the general information of our clients and other interested persons. It is not, and does not attempt to be, comprehensive in nature. Due to the general nature of its content, it should not be regarded as legal advice.

We believe this information will be of interest to you. However, if you do not wish to receive further similar information about events or legal issues from White & Case, then please e-mail unsubscribe@whitecase.com.

1. Patent clusters – the fact that there were many patents (over 1300 in one case, apparently) around the original product. One reason why this number is so high is presumably because the Commission counts the same EPO patent 27 times – once for each national patent in each of the 27 Member States. Nonetheless, the Commission wants to put the patent thickets under the microscope.

2. Weak secondary patents – litigation and opposition procedure. The Commission said they felt that too many weak secondary patents were being filed and sought to support this finding by looking at litigation and opposition procedures at the EPO, where they said generics had a greater than 60% success rate (75% for opposition procedures) in cases that went to final judgment or decision. This caused delay in the Commission's view (about 2 years) and suggested that secondary patents were weaker.

Patent settlement agreements. The Commission found more than 200 settlement agreements concluded between 2000 and 2007 of which 63% were best-selling medicines. For 45 of the agreements, there was a value transfer from the originator to the generic. There were 22 instances where generics received a direct transfer of money. This seems a relatively small number given the number of companies involved and the 7 year period of investigation. However, it will be a clear focus of further enquiry, either by the Commission or by national competition authorities. At the hearing, the Commission made specific reference to the FTC's enforcement activities in this area (but failed to mention its lack of success before the courts).

3. Interventions before national authorities. The Commission focused 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. Originators won only 2% of cases against marketing authorisation bodies on patent-related issues and only 19% of cases on data exclusivity. Such interventions meant delay of 4 months on average for generic entry. The implication of this is that the Commission may find that certain actions by dominant undertakings to be "vexatious", since they know that they have little chance of success (although each case will be inherently fact-specific).

4. Follow-on or second-generation products. The Commission focused on the timing of originators' move to second generation products – and when they try to switch patients to the second-generation product. They found 40% of the products that they had sampled were second-generation products. A

switch was successful when it took place during the time when the original product was on patent (it took place on average just over a year before the expiry of the patent on the first generation product). This may be a future area of focus – but it is unclear how bringing out an improved second-generation product would be a competition violation.

The Commission also said that many companies used more than one of these tactics. It was important to review the cumulative effect of the "toolbox."

B. Practices between originator companies

The Commission also spoke about defensive patents, which they said were questionable where they are used for the **sole** purpose of excluding competitors. The Commission then looked at patent-related exchanges between originators and said it found 1100 cases where they were overlaps between originators' R&D poles; however, requests for licenses were only refused in 20% of these cases. The Commission found that 40% of the originator companies in the inquiry were involved in patent litigation during the 7 year period of investigation (which does not seem particularly high).

There were 1450 agreements between originator companies concerning the 219 medicines under investigation (which accounted for about half of the total pharmaceutical market).

The Commission also expressed an interest in further reviewing agreements between originators in Germany, Italy, Spain and Portugal.

C. Regulatory framework

The Commission pushed for the adoption of the Community patent, saying that both generic and originator companies supported this. The Commission was also worried by the fact that 11% of final judgments in national patent litigations had contradicting outcomes in patent cases. (One might comment that 11% shows a fair degree of consistency.)

This may herald a renewed political push by the Commission to get the Community patent proposal adopted. This has been blocked for many years, notably due to the need for the 27 Member States to agree on the language to be used (something that raises strong national and cultural feelings). It seems unlikely that the sector inquiry would be able to resolve political objections of this nature, but with this report, the Commission has expressed a willingness to have another run at this.

Marketing authorisation bottlenecks were also mentioned as relevant, as were pricing and

reimbursement delays. But there was limited discussion of them at the public hearing.

Comments by Lord Justice Jacob on the Report

After the presentation of the preliminary findings by DG Competition, a number of other stakeholders presented their views. Of particular interest were the views expressed by Lord Justice Jacob, one of the most senior patent judges in the UK.

Lord Justice Jacob started his intervention by pointing out that the most important statistic in the entire report was 17% (being the percentage of turnover spent on R&D), a figure unrivalled by any other industry. He warned the Commission that it would create difficulties for everyone if it were to endanger this 17%. He felt that the Commission's attempt to contrast this 17% of R&D spending with 23% of turnover spent on marketing was misleading, as the 23% was not spent on advertisements and publicity campaigns but on training and educating doctors to improve their knowledge of the pharmaceuticals that are available and to encourage them to be less conservative in their practice.

Lord Justice Jacob emphasised that the number of important medicines going off-patent in the near future was prodigious and would not be counterbalanced by the arrival of new medicines. This would create a problem for the industry (in terms of loss of sales) and thus for R&D, as today's R&D is paid from today's sales to fund tomorrow's medicines. He suggested that "those who want to blame the industry should come around with suggestions for improvements".

Lord Justice Jacob then outlined some "fundamental truths" about the pharmaceutical industry:

- R&D expenditure is based on current sales, i.e. today's sales are funding today's R&D;
- Without patent protection, there is no innovation (as the example of the Soviet Russia demonstrates);
- The risk involved is "colossal", as most R&D is unsuccessful and the few winners have to pay for the losers;
- The patent lifetime is limited to 10-11 years during which period all future R&D has to be funded – in the opinion of Lord Justice Jacob this period is "too short" and the SPC system should be reviewed;
- Prices are mostly negotiated with governments which are much bigger than the seller, leading to different prices across the EU – something that should no longer exist in Europe;
- Generic companies do not have to bear R&D costs and do not undertake any risks as the only products they sell are the ones that have already proved successful. He wondered whether – given the cost of manufacturing the majority of pharmaceuticals is low - generic prices should now be a lot lower than

the 20% below the originator price (the number stated in the report).

Lord Justice Jacob then presented his views on the patent system. He pointed out that pharmaceutical patents only represent a minor percentage of all patent applications and that other sectors use patents to protect their products "at a scale that put pharma to shame" (he gave the example of telecoms). He admitted that patent offices can only serve as a filter and will never catch all unfounded applications as this would often require chemical experiments. Therefore the only remedy would be an efficient and competent European patent court, possibly coupled with the creation of a Community patent. Lord Justice Jacob admitted that the EPO's opposition procedure was a failure, not just for the pharmaceutical sector, and that the EPO should improve this system.

Lord Justice Jacob said he could have no sympathy for generic companies who complained of being enjoined when launching despite an existing patent. If they thought the patent was invalid, they should get it invalidated prior to launch – if they did not do so then they were likely to be enjoined in the UK (based on a judgment that Lord Justice Jacob had himself written). Lord Justice Jacob also expressed surprise that governments stand aside when generic companies are enjoined – why do government not also go to court and seek to receive a cross-undertaking in damages, so that they will receive compensation if the generic launch is wrongly delayed.

Based on his view of the pharmaceutical industry and the patent system, Lord Justice Jacob reflected on the role of a competition authority. He agreed that if a patent owner knew that his patent was not good, yet it sought to exclude others based on this patent, then there could be a role for a competition authority – however in his professional life, Lord Justice Jacob had only seen one such case.

Comments by other Stakeholders on the Report

A number of other stakeholders gave their views on the report. Mr. Higgins, President of EFPIA, stated that not only had the report "not reached any conclusions that the industry's activities have impeded competition" but that it was rife with "myths and mischaracterisations" (see [Higgins Speech](#)). Mr. Higgins argued that the report misunderstands the dynamics of the R&D industry. That industry remains as innovative as it has always been and it is simply "not meaningful" for the Commission to argue that innovation is in decline simply because the number of new molecules launched may be falling – in fact the "approval of new active substances in the EU has actually increased between 2005 and 2007 from 28 to 40 according to the EMEA". Rather, "what is needed is a more holistic approach to measure and

understand innovation, including the value of incremental innovation.” In particular, the report fails to sufficiently focus on the increased challenges in and costs associated with developing new medicines, due to high attrition rates, regulatory hurdles and national pricing and reimbursement policies.

Mr. Higgins also rejected the report’s claim that the industry uses a “toolbox” of measures to delay generic entry. He highlighted the irony that, at the same time the report acknowledges that patents are key to pharmaceutical innovation it seeks to prevent the industry from legitimately enforcing these rights.

He further also stated that the report overstates the level as well as the reasons for delays in generic market access. Instead of focusing on the duration between patent expiry and generic entry, the report should have considered ways to ensure greater price competition between generics: “The key question is why US citizens pay so much less for generics than Europeans”, not why generic entry may take so much time.

Finally, Mr. Higgins dismissed the implied criticism contained in the report that pharmaceutical companies are “more interested in marketing than R&D”. What the Commission incorrectly refers to as “marketing” is in fact the process by which pharmaceutical companies provide healthcare professionals with vital information to ensure that “patients receive the right medicines”. Moreover, and in any case, the cost of “marketing” does not in any way affect the level of expenditure (17% of sales) which the industry annually spends on R&D, a ratio which “has no equal in any industry.”

Mr. O’Riordan, Vice-President of EGA, complained about ‘evergreening’ strategies, admitting however that some new formulations can be valuable. He said that the ex-factory price achieved by generic manufacturers is not terribly high – if this is true it would suggest that the high price of generics noted by Lord Justice Jacob are due to other inefficiencies (or excessive profits being taken by players) further down

the distribution chain. Interestingly, he also stated that delays by reimbursement bodies are significant, sometimes up to 13 months (the report states that on average generic entry occurs only 7 months after patent expiry and only 4 months for the most valuable medicines).

Mr. Velzel, CEO of UVIT (a Dutch health insurance company) explained how his company had generated savings through generic competition. In a first attempt, pharmacists had been obliged to dispense a generic whenever its price was lower than the originator’s version; this, however, only led to minimal price decreases by generic companies of 3-5%. A much larger price decrease was then achieved through tenders and incentives for pharmacists to dispense generics.

In the question period, Mr. Higgins seemed to accept a US-style pre-notification system for patent settlement agreements. “Transparency”, he said, “is our friend.” This is an initiative that the Commission will no doubt consider further.

Next steps and analysis

There is now a two-month consultation period to respond to the report. The deadline for comments is **January 31, 2009**. The Commission encouraged interested parties to read the report over the holiday period and respond.

Separately, the Commission will assess whether it needs to open specific investigations into potential infringements of Articles 81 or 82. Indeed, on 24 November 2008, the Commission made unannounced inspections on several pharmaceutical companies (press reports say the companies involved include France’s Servier, Israel’s Teva and the smaller generic, Krka).

The Commission’s final report on the Sector Inquiry is expected in Spring 2009.