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# Press Clipping

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**SUBJECT: SECTOR INQUIRY FINAL REPORT**

**DATE: 6-9 July 2009**

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1. Press Releases .....	1
1.1. European Commission .....	1
1.2. EGA .....	3
1.3. EFPIA .....	5
1.4. BEUC .....	6
1.5. Crowell & Moring .....	6
2. English Speaking Press .....	8
2.1. APM Health .....	8
2.2. Bloomberg .....	12
2.3. CNN .....	15
2.4. EuObserver .....	15
2.5. Euractiv .....	17
2.6. European Voice .....	20
2.7. Financial Times .....	22
2.8. International Herald Tribune .....	24
2.9. IP Watch .....	26
2.10. Irish Examiner .....	27
2.11. Pharma Times .....	28
2.12. Reuters .....	30
2.13. SCRIP .....	31
2.14. The Independent .....	33
3. French Speaking Press .....	35
3.1. Agence France Press .....	35
3.2. Agence Europe .....	36
3.3. Associated Press .....	38
3.4. My Pharma Editions .....	39
3.5. RTL info .....	41
3.6. Le Vif .....	42
4. Blogs .....	44

## **1. Press Releases**

### **1.1. European Commission**

Antitrust: shortcomings in pharmaceutical sector require further action

Market entry of generic drugs is delayed and there is a decline in the number of novel medicines reaching the market, according to the European Commission's final report on competition in the pharmaceutical sector. The sector inquiry suggests that company practices are among the causes, but does not exclude other factors such as shortcomings in the regulatory framework. As a follow up, the Commission intends to intensify its scrutiny of



the pharmaceutical sector under EC antitrust law, including continued monitoring of settlements between originator and generic drug companies. The first antitrust investigations are already under way. The report also calls on Member States to introduce legislation to facilitate the uptake of generic drugs. The report notes near universal support amongst stakeholders for a Community Patent and specialised patent litigation system in Europe.

Competition Commissioner Neelie Kroes said: "We must have more competition and less red tape in pharmaceuticals. The sector is too important to the health and finances of Europe's citizens and governments to accept anything less than the best. The inquiry has told us what is wrong with the sector, and now it is time to act. When it comes to generic entry, every week and month of delay costs money to patients and taxpayers. We will not hesitate to apply the antitrust rules where such delays result from anticompetitive practices. The first antitrust investigations are already under way, and regulatory adjustments are expected to follow dealing with a range of problems in the sector."

#### Main findings and policy conclusions

The inquiry has contributed significantly to the debate on European policy for pharmaceuticals, in particular for generic medicines.

On the basis of a sample of medicines that faced loss of exclusivity in the period 2000 to 2007 in 17 Member States, the inquiry found that citizens waited more than seven months after patent expiry for cheaper generic medicines, costing them 20% in extra spending.

Generic delays matter as generic products are on average 40% cheaper two years after market entry compared to the originator drugs. Competition by generic products thus results in substantially lower prices for consumers. The inquiry showed that originator companies use a variety of instruments to extend the commercial life of their products without generic entry for as long as possible.

The inquiry also confirms a decline of novel medicines reaching the market and points to certain company practices that might contribute to this phenomenon. Further market monitoring is ongoing to identify all the factors that contribute to this decline in innovation.

Reacting to the findings, the Commission will apply increased scrutiny under EC Treaty antitrust law to the sector and bring specific cases where appropriate. The use of specific instruments by originator companies in order to delay generic entry will be subject to competition scrutiny if used in an anti-competitive way, which may constitute an infringement under Article 81 or 82 of the EC Treaty. Defensive patenting strategies that mainly focus on excluding competitors without pursuing innovative efforts will remain under scrutiny. To reduce the risk that settlements between originator and generic companies are concluded at the expense of consumers, the Commission undertakes to carry out further focused monitoring of settlements that limit or delay the market entry of generic drugs. In the case of clear indications that a submission by a stakeholder intervening before a marketing authorisation body was primarily made to delay the market entry of a competitor, injured parties and stakeholders are invited to bring relevant evidence of practices to the attention of the relevant competition authorities.

On regulatory issues the inquiry finds that:

There is an urgent need for the establishment of a Community patent and a unified specialised patent litigation system in Europe to reduce administrative burdens and uncertainty for companies. A full 30% of patent court cases are conducted in parallel in several Member States, and in 11% of cases national courts reach conflicting judgements.

Recent initiatives of the European Patent Office (EPO) to ensure a high quality standard of patents granted and to accelerate procedures are welcome. This includes measures taken in



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March 2009 to limit the possibilities and time periods during which voluntary divisional patent applications can be filed (so called "raising the bar exercise")

The Commission is also urging Member States to:

ensure that third party submissions do not occur and in any event do not lead to delays for generic approvals

significantly accelerate approval procedures for generic medicines - for example, the Commission believes that generic products should automatically/immediately receive pricing and reimbursement status where the originator drug already benefits from such status, which would allow for a faster product launch in certain cases

take action if misleading information campaigns questioning the quality of generic medicines are detected in their territory

streamline trials that test the added value of novel medicines.

To assist Member States in delivering speedy generic uptake and improved price competition, the report contains an overview of national measures and their effects on generic uptake (volume, prices, number of entrants) and encourages Member States that want to benefit from generic savings to consider such measures. In this light the Commission will also examine existing EU rules in the area of pricing and reimbursement (Transparency Directive 89/105/EEC).

Background

The inquiry began in January 2008 (see [IP/08/49](#) and [MEMO/08/20](#)) to examine the reasons why fewer new medicines were brought to market and why generic entry seemed to be delayed in some cases. The goal is to find ways that help the market work better.

Preliminary results were published in November 2008. More than 70 submissions were received from stakeholders. Consumer associations, health insurers and the generics industry have welcomed the results arguing that they confirm their concerns. The originator industry and their advisors have supported the call for the creation of a Community Patent and a specialised litigation system, whilst arguing that generic delay and the decline in innovation is caused by regulatory shortcomings.

For further information, see also [MEMO/09/321](#)

The final report and more information on the pharmaceutical sector inquiry will be available at:

<http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/index.html>

## 1.2. EGA

EUROPEAN COMMISSION INQUIRY RECOMMENDS SYSTEMIC IMPROVEMENTS TO ENSURE IMMEDIATE ACCESS FOR PATIENTS TO AFFORDABLE GENERIC MEDICINES UPON PATENT EXPIRY

The EGA calls on European and national authorities for quick implementation of the conclusions and recommendations of the sector inquiry report.

The EGA welcomes the final report on the pharmaceutical sector inquiry launched today in Brussels. The final report takes the findings of the preliminary report of 28 November 2008 to the next level, concluding that substantial reforms in European and national legislation are required to ensure timely availability of generic medicines. The final report unfolds a number of key recommendations that should enhance generic competition in the European healthcare sector and generate significant cost savings to healthcare systems, patients and tax payers. A properly functioning pharmaceuticals market will encourage pharmaceutical



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companies to develop innovative medicines and improve the image of the pharmaceutical industry as a whole.

The EGA and its members worked closely with the Commission throughout the inquiry, recognising this initiative as an opportunity to address loopholes in the legislative framework. These loopholes give rise to incoherent generic medicines policies in member states and allow originator companies to behave anti-competitively, thereby blocking or delaying patient access to affordable generic medicines.

“Generic medicines have been facing severe delays in getting on the market for too long now. We welcome the importance given by the European Commission to the need of high quality patents and raising the bar for patent applications. The existence of certain dubious secondary patents has indeed created a block against competition and undermined confidence in real innovation”, commented Greg Perry, Director General of EGA, expressing his full support for the final report’s findings and recommendations. Reiterating the EGA’s longstanding plea for an urgent reform in the pharmaceutical sector, he added: “Tightening up Europe’s legislative framework in the four areas of patent law, pharmaceutical legislation, price and reimbursement rules and competition law will result in a properly functioning pharmaceutical market throughout Europe.”

In a press release issued this morning the European Commission also highlights that the inquiry showed that originator companies use a variety of instruments to extend the commercial life of their products without generic entry for as long as possible. Neelie Kroes, European Commissioner for Competition, said, “When it comes to generic entry, every week and month of delay costs money to patients and taxpayers. We will not hesitate to apply the antitrust rules where such delays result from anticompetitive practices. The first antitrust investigations are already under way, and regulatory adjustments are expected to follow dealing with a range of problems in the sector.”

The Commission states that it is also urging Member States to:

ensure that third party submissions do not occur and in any event do not lead to delays for generic approvals;

significantly accelerate approval procedures for generic medicines; for example, the Commission believes that generic products should automatically/immediately receive pricing and reimbursement status where the originator drug already benefits from such status, which would allow for a faster product launch in certain cases;

take action if misleading information campaigns questioning the quality of generic medicines are detected in their territory;

streamline trials that test the added value of novel medicines.

Companies represented within the EGA provide over 130,000 jobs in Europe. Today 50% of all medicines dispensed to patients in Europe are generic medicines but represent only 18% of pharmaceutical expenditure. Affordable generic medicines save EU patients and healthcare systems over €25 billion each year, helping to ensure patient access to essential medicines and providing urgently needed budget headroom for the purchase of new and innovative treatments.

The EGA and its members call upon the European and national authorities for quick implementation of the conclusions and recommendations of the sector inquiry report. From 2009 till 2020, a large number of pharmaceuticals are due to go off patent, representing nearly €90 billion. Immediate launch of generic alternatives for these products will bring massive savings for patients and will guarantee healthcare sustainability throughout Europe. But much of these savings will be lost if the Commission’s recommendations fail to be



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adopted.

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## ANNEX: Summary of EGA recommendations

### On the Patent System

- more rigorous assessment of patentability and specifically on inventive step
- more EPO resources for better assessment
- Duty of candour or Full Disclosure Statement
- No divisional patents covering same issue
- Strict timelines for oppositions

### On the Litigation System

- Strict timelines for litigation procedures
- Specialised/technical patent judges
- Addressing over-readiness of granting interim injunctions
- Community patent and unified patent court including EGA recommendations

### On Pharmaceutical Legislation

- Pharmaceutical legislation including provision prohibiting interventions or including a transparent intervention system with burden of proof on third party
- Express mention of all administrative procedures in Bolar provision
- Distinction between incremental innovation and no added therapeutic value
- Prohibition on negative information and marketing campaigns, including comparative adverts
- Quality criteria for all information and advertisement on medicines
- Misbehaviour effectively sanctioned by authorities

### On Price and Reimbursement Practices

- Proof of added therapeutic value for obtaining price and reimbursement
- Immediate/automatic price and reimbursement approval after marketing authorisation

## 1.3. EFPIA

Pharmaceutical Sector Inquiry - highlights regulatory shortcomings and need for a strong, effective patent system in Europe

Final report tones down earlier language, makes constructive policy recommendations:

Brussels, 8 July 2009: EFPIA, the voice of the pharmaceutical industry in Europe, acknowledged publication of today's final European Commission report into the pharmaceutical sector. It demonstrated a welcome shift away from the emotive language of the interim report, with a better balanced, more holistic view of the issues facing the sector. The final report identifies the numerous regulatory obstacles that need to be addressed to achieve more efficient innovative and off-patent pharmaceutical markets to the benefit of consumers and patients.

"We have stated consistently that complex and divergent regulatory barriers are the primary cause of market entry delay for both generic and innovative medicines. We are pleased that the final report recognises this reality;" said Arthur J. Higgins, CEO of Bayer Healthcare and President of EFPIA; "We welcome many of the policy recommendations, such as a more streamlined patent system that reduces costs and increases legal and commercial certainty.



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We commit to working constructively with the Internal Market Commissioner, Member States, and the European Patent Office to push reforms forward under the Swedish Presidency.”

The final report acknowledges the considerable variations in the speed and impact of generic market entry across Member States. Arthur Higgins added, “What is important is that the Commission uses this report to address the issue of competition in the off-patent market. This is an area that can generate savings which could be reinvested to fund innovative medicines.”

The Commission has recognised that while certain regulatory interventions incentivise rapid generic entry and drive prices lower, others (particularly price caps) can have the opposite effect. In 2008, a scheme in the Netherlands reduced generic prices by more than 80% by promoting price competition and challenging pharmacists’ incentives. This provided annual savings of approximately €25 per citizen, despite being limited to 33 products. By contrast, the potential €3 billion savings that immediate generic entry would have generated in the eight years of the Commission’s interim report represent an annual reduction of only €0.90 per citizen.

In its final version, the report failed to substantiate the initial allegation that patenting strategies dampened innovation<sup>1</sup> or delayed generic entry illegitimately. Importantly, the final report does recognize the importance of Europe’s innovative pharmaceutical sector and its very significant R&D efforts. The Commission correctly identifies that the protection of intellectual property rights is of fundamental importance for the pharmaceutical industry and paramount to maintaining Europe’s competitiveness.

#### 1.4. BEUC

Pharmaceutical Inquiry: Patients’ still getting a raw deal

The European Commission has today published its final report on competition in the pharmaceutical sector. The inquiry was launched in January 2008 and an interim report was published in November 2008. For BEUC, the European Consumers’ Organisation, many of the recommendations are well founded but some serious questions remain over the anti competitive practices employed by many pharmaceutical companies.

Monique Goyens, Director General of BEUC, said: “The sector inquiry clearly shows that the pharmaceutical market is not working properly and that vicious tactics are used to delay or prevent the entry of more affordable and innovative medicines into the market. Millions of euros are spent in promotional activities, in legal disputes and settlement agreements instead of in the development of new medicines to meet patients’ needs.

“Following the findings of this timely inquiry we encourage the European Commission and Member States to take concrete action and address unethical practices. Furthermore, we hope that the outcome of the inquiry will lead to a review of the regulatory framework to find a better balance between companies’ commercial interests and general public health interests, i.e. the interest of many patients who are still waiting for a new medicine to treat their disease and for new and effective medicines that can improve their quality of life.”

#### 1.5. Crowell & Moring

European Commission Publishes Final Report in Pharmaceutical Sector Inquiry and Opens Formal Proceedings against Patent Settlements



#### Antitrust Law Alert Jul.08.09

The European Commission today published the final report in its Pharmaceutical Sector Inquiry. The Commission's findings remain largely unchanged from those in the interim report published in November last year. However, the language of the final report is less overtly critical of originator companies and the Commission's focus appears to have shifted away from the pursuit of individual antitrust cases and towards changes to the regulatory framework governing pharmaceutical markets.

In the interim report, the Commission referred to what it called a "tool box" of strategies used by originators to delay generic entry, including:

the creation of patent clusters;

strategic use of litigation;

interventions in national regulatory processes for authorizing generic medicines;

lifecycle management ('evergreening'); and

pay-for-delay patent settlements.

The final report identifies the same strategies, but scales back the critical rhetoric: the term 'tool box' has disappeared, and a new section emphasizing the importance of innovation by originators has been inserted.

In terms of pursuing individual infringements, Competition Commissioner Neelie Kroes, introducing the final report, said only "We will not hesitate to apply the antitrust rules where such delays [in generic entry] result from anticompetitive practices" and "The first antitrust investigations are already underway". The focus for future action appears to be changes to the regulatory framework rather than individual cases and the Commissioner's quote on the final report finishes "regulatory changes are expected to follow dealing with a range of problems in the sector."

The formal opening of one set of infringement proceedings was also announced today, against the originator Servier and five generic companies. The proceedings concern both alleged abuse of dominance by Servier in respect of its patented cardiovascular medicine perindopril and settlement agreements entered into between Servier and the five generics. This will be an interesting case, particularly in relation to the line the Commission takes on settlement agreements. However, it may not herald widespread enforcement action. The Servier case was identified by commentators as a potential target for enforcement action some time ago (even before the publication of the interim report, [see here](#)) as the perindopril patent had been heavily criticized as a "try-on" and "the sort of patent which can give the patent system a bad name" by the UK Court of Appeal in 2008.

In terms of regulatory changes, the Commission highlighted an "urgent need" for the establishment of a unified specialized patent litigation system across the EU and an EU patent as well as the "relevance" of recent initiatives by the European Patent Office to improve its procedures. The Commission also called on Member States to take action to accelerate approval procedures for generic medicines - by reducing delays caused by originator interventions and granting automatic pricing and reimbursement status - and against misleading information campaigns by originators questioning the quality of generic medicines.

Overall, it seems likely that both sides of the pharmaceutical industry will take some comfort from the final report. Originators will be relieved that the Commission has stepped back from the rhetoric of the interim report and that the prospect of widespread antitrust enforcement against originators seems to have receded somewhat. At the same time, generics



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manufacturers will be pleased that the Commission is now pushing for a number of regulatory changes that facilitate the early entry of generic medicines onto the market.

The Head of the Commission's Sector Inquiry Task Force, Dr Dominik Schnichels, will be giving his first public presentation on the findings of the sector inquiry at the Brussels Offices of Crowell & Moring next Tuesday, 14 July 2009. [Click here for more information on the event.](#)

## **2. English Speaking Press**

### **2.1. APM Health**

Servier heads list of companies set for full EC investigation

LONDON, July 8 (APM) - The European Commission on Wednesday announced antitrust investigations into a number of pharma companies including Servier. In an announcement, which came shortly after publication of the pharma-sector inquiry (see early APM story), the commission said it was opening formal antitrust investigations against French pharmaceutical firm Servier and a number of generic companies for suspected breaches of EU rules on restrictive business practices and on abuse of a dominant market position. The generic companies concerned include: Krka, Lupin, Matrix (a subsidiary of Mylan since August 2006), Unichem Laboratory subsidiary Niche Generic, and Teva UK/Teva Pharmaceutical Incorporated. The investigation was regarding "a number of individual, possibly restrictive, agreements" between each of them and Servier. These agreements "may have the object or effect of hindering entry on to the market of generic perindopril, a cardiovascular medicine originally developed by Les Laboratoires Servier, on the EEA markets," the European Commission said.

#### **INSPECTIONS**

The commission said the opening of formal proceedings follows unannounced inspections carried out by the commission in November 2008 in several member states.

It also said this investigation does not form part of the sector inquiry, but that knowledge acquired during the sector inquiry has allowed the commission to draw conclusions on the areas where "action based on competition law could be appropriate and effective". The sector inquiry was kicked off in January 2008 with the commission making unprecedented dawn raids on company offices including: AstraZeneca, GlaxoSmithKline, Pfizer, Merck & Co and Sanofi-Aventis. At this stage it is not known if any bigger fish are to be individually investigated. Servier was not immediately available to comment.

EU already investigating individual companies over anti-competitive behaviour - sector inquiry report

by Peter O'Donnell BRUSSELS, July 8 (APM) - Closer scrutiny of settlements between originator and generic drug companies, action against individual companies accused of anti-competitive behaviour and an instruction to member states to increase use of generics are the key results from the European Commission's pharma investigation. Revealing the results of her 18-month inquiry into competition in the pharmaceutical sector, European Competition Commissioner Neelie Kroes announced on Wednesday morning the first antitrust investigations are already under way against individual companies - but declined to identify the companies being targeted. But the inquiry has also revealed that delays to market entry



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of generics and a decline in the number of novel medicines reaching the market is not uniquely due to company practices. Industry behavior is "among the causes" of the perceived problems, she said at a press conference in Brussels, but the inquiry "does not exclude other factors such as shortcomings in the regulatory framework". The Commission will also urge EU countries to introduce legislation to promote the uptake of generics. It says that approval procedures for generic medicines should be faster, and that generics should automatically and immediately be given a price and a reimbursement decision if the originator drug has already been through that procedure too. Competition Commissioner Neelie Kroes said: "We must have more competition and less red tape in pharmaceuticals. The sector is too important to the health and finances of Europe's citizens and governments to accept anything less than the best." The final report summarises the findings of the preliminary report, including the estimated 20% extra healthcare spending in 17 countries because of a seven-month delay in launching cheaper generics after patent expiry, and a decline in novel medicines reaching the market. "Further market monitoring is ongoing to identify all the factors that contribute to this decline in innovation," said Kroes. Defensive patenting strategies that mainly focus on excluding competitors without pursuing innovative efforts will remain under scrutiny, she said. The Commission warns that it will be applying increased scrutiny under EC Treaty antitrust law to the pharmaceutical sector, and will be bringing specific cases, where appropriate. "The use of specific instruments by originator companies in order to delay generic entry will be subject to competition scrutiny if used in an anti-competitive way," according to a Commission statement issued this morning. In particular, "defensive patenting strategies that mainly focus on excluding competitors without pursuing innovative efforts will remain under scrutiny". And to "reduce the risk that settlements between originator and generic companies are concluded at the expense of consumers, the Commission undertakes to carry out further focused monitoring of settlements that limit or delay the market entry of generic drugs". Member states are urged to ensure that generic approvals are not delayed by "third party submissions" - in other words, originator companies raising problems with the national regulatory authorities. And member states should take action "if misleading information campaigns questioning the quality of generic medicines are detected in their territory". Where an originator company intervenes with the national regulatory bodies with the primary aim of delaying the market entry of a competitor, "injured parties and stakeholders are invited to bring relevant evidence of practices to the attention of the relevant competition authorities". The Commission also backs the idea of a new Community patent system and a unified specialised patent litigation system in Europe. It points out that at present 30% of patent court cases are conducted in parallel in several member states, and in 11% of cases national courts reach conflicting judgements. The Commission says it started the inquiry because it was worried about the state of the EU pharmaceutical market, including a decline in novel medicines reaching the market (an average of 27 per year in the 2000s compared to 40 per year between 1995 and 1999) and the delays of generic market entry. It notes that medicines are a major expense in Europe, costing 214 billion euros per year - in retail prices, which is equivalent to 2% of GDP - and around 430 euros per year for every man, woman and child.

EFPIA claims "vindication" from sector inquiry

BRUSSELS, July 8 (APM) - Branded pharma companies are claiming a victory after the release on Wednesday morning of the European Commission's final report of its inquiry into competition in the sector. They say the milder tone now being adopted by the commission is



a vindication of their denials that they have obstructed generic access to the market. But generic firms say that the report's conclusions show the commission has not backed down. Meanwhile, some lawyers suggest that the commission has not, with this report, significantly clarified the grey area between competition and intellectual property rights. EFPIA's Brian Ager welcomed the support the final report showed for patents and intellectual property rights, and its recognition of their importance for innovation and competitiveness. He said he was "disappointed that the report still claims - erroneously - that industry practices in some way contribute to slowing generic entry". There is nothing to substantiate these claims, he maintained. But overall, he said, the report "demonstrated a welcome shift away from the emotive language of the interim report, with a better balanced, more holistic view of the issues facing the sector". EFPIA also noted that the final report identifies numerous regulatory obstacles that need to be addressed. Ager told a press conference in Brussels that the report "marks some progress" in the commission's understanding of the industry. Thomas Cueni, secretary general of Interpharma, and the leader of the EFPIA task force on the inquiry, told Brussels media that neither of the commission's principal allegations - that generic entry was delayed and innovation was declining - had been substantiated by the final report. He noted a "welcome change of tone" in the commission's report and its change of emphasis and balance. "We complained about the negative language in the preliminary report, and we are glad to see that this has changed," he added. Cueni listed favourable changes in the commission's attitude, including: the dropping of the "controversial" reference to a toolbox of blocking measures used by originators; the switch away from negative connotations of patent clusters and notion of defensive patents; the acceptance that regulation is an important factor that has to be included in the scope of the debate; and the new insistence that settlements must be judged case-by-case rather than on the assumption that they are all anti-competitive. Arthur Higgins, CEO of Bayer Healthcare and president of EFPIA, said: "We welcome many of the policy recommendations, such as a more streamlined patent system that reduces costs and increases legal and commercial certainty. We commit to working constructively with the Internal Market Commissioner, member states, and the European Patent Office to push reforms forward under the Swedish presidency."

#### NOT WATERED DOWN

Despite the branded industry's claims of the commission's softer tone, Greg Perry, director general of the generics industry association, EGA, told APM in a telephone press conference on Wednesday: "It has not been watered down." Perry said the final report had addressed "exactly the issues" that his members had wanted examining and was "great news". The interpretation given by EGA's Perry is that the inquiry's report "recommends systemic improvements to ensure immediate access for patients to affordable generic medicines upon patent expiry". He told APM that the final report endorses the criticisms of the preliminary report on delays to generic entry and the behaviour of originator companies. According to Perry, the commission has met the EGA demands to raise the quality of patents, to speed pricing and reimbursement decisions for generics, to act against misleading information about generics, and to promote speedy uptake of them. European parallel importers also welcomed the report. Heinz Kobelt, secretary general of the EAEPC, said: "The findings of the inquiry seem to justify this decision and would appear to have consequences for policy-making in the future." In Kobelt's view, the commission's analysis - "which suggests original manufacturers systematically undermine their competitors, including the generic market" - should now lead to action. But Suzanne Rab of the law firm Hogan & Hartson suggested that the commission has failed to grapple with the issues its inquiry was based on. She says the final report offers no detailed or definitive guidance on the legality of "patent thickets" or



"patent clusters" that delay generic entry. "The suggestion that the filing of additional patents is anti-competitive amounts, in effect, to 'second guessing' the patent system. A patent already granted must be presumed valid until a court has established that it is not. Any attempt to limit the absolute number of patents also gives rise to complexities as there is no obvious and principled methodology to decide how many patents are 'too many'."

Servier on offensive after EC opens formal investigation, generics companies confident

by Nick Smith LONDON, July 9 (APM) - Servier has broadly dismissed an intensification of the European Commission's investigation into its marketing practices. On Wednesday the commission announced a formal investigation into arrangements between Servier and companies with potential generic challengers to French group's perindopril. Although the European Commission's move takes the matter closer to legal action, in a statement Servier said: "The present communication indicates simply that the EC is treating the perindopril file as a priority without bringing any accusations to bear against Servier." The company was "waiting to hear what eventual grounds for complaint the EC might bring to bear and will reply to them in due course".

#### PHARMA INQUIRY

Noting that the announcement of the investigation into it came on the same day as the publication of the commission's pharma sector inquiry, Servier went on the offensive saying it would continue to defend its intellectual property. It quoted lines from the inquiry report which were positive for branded pharma. "Servier consider that the respect of intellectual property rights is a key condition for the research and development necessary to find new medicines, and will continue to defend their rights in this domain in accordance with the law."

#### CONFIDENT

Speaking to APM, most of the generics companies concerned said they were confident they would not ultimately be found to have acted in an anticompetitive manner. The full scope of the commission's investigation is not known at the moment but two of generic companies, Teva and Niche, confirmed it was the UK arms of their organisations that were under scrutiny. Spokespersons for Teva in Israel and the UK said they understood the investigation as far as they were concerned was UK only. A spokesman for Teva UK made clear the company's belief in its innocence. "Clearly we do not believe we have engaged in anti-competitive behaviour. We have been helping them (the commission) with their inquiry for some months." He added that the investigation into Teva UK had "not been a secret". He denied that after months of working with the commission the fact that the body had decided to publicly announce a formal inquiry should be regarded as negative or a failure to show innocence at an early stage.

NICHE Managing director of Unichem-owned Niche Generics, Gerard Cole also said it was the UK arm of the company which the commission was to investigate and it had been "totally compliant" with the commission's demands. He declined to say the company had acted in a proper manner but said "it comes down to how the commission interprets the data". However, he added: "We have provided all information the commission has asked for and the commission has stated just because there is the opening of a process does not mean there is proof (of guilt)."

KRKA PATENT PROTECTIONSlovenian company Krka denied any guilt in an email to APM saying intellectual protection meant it was not able to launch a generic competitor. "Krka has not done anything wrong; as long as the European patent office (EPO) has recognised patent for alfa form of perindopril, Krka could not sell the product. "Krka will no doubt defend



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itself to prove that any allegations are wrong and (it) cannot be held responsible that such patents are granted and upheld on opposition proceedings at (the) EPO."

LUPIN CHALLENGED PATENT In a reactive statement to APM, Lupin said it was confirming it was "assisting" the European Commission with its investigation in relation to the supply of perindopril in the EU. On further questioning, a spokesman for Lupin suggested its actions showed it has firmly challenged the Servier drug. "Lupin had earlier also additionally challenged the validity of Servier's alpha polymorph perindopril patent in the UK and EPO. It resulted in us obtaining the ability to enter the market when generic competition came up." In its written response Lupin noted that the commission had confirmed that the publication of its commission statement does not imply that it has proof of infringement of competition rules. "We feel confident about our position and are working with the European Commission to a resolution on the matter. Furthermore, we are in the midst of launching perindopril in several EU markets." MYLAN Mylan in the U.S., owner of Matrix, the final company named by the commission as under investigation, was not immediately available to respond for APM's requests for comment. ns/ak

## 2.2. Bloomberg

Teva, Servier Face EU Antitrust Probe for Drug Delays (Update3)

By Matthew Newman and Naomi Kresge

July 8 (Bloomberg) -- [Teva Pharmaceutical Industries Ltd.](#), France's Les Laboratoires Servier and other generic-drug makers face [European Union](#) antitrust probes of agreements that may have delayed the sale of a blood pressure medication.

The investigations, which also include [Krka Group d.d.](#), India's [Lupin Ltd.](#), [Mylan Inc.](#)'s Matrix Laboratories unit and [Unichem Laboratories Ltd.](#)'s Niche Generics unit, concern deals that may have hindered the market entry of a generic version of Servier's perindopril, the European Commission said today.

The probes come as antitrust regulators on both sides of the Atlantic focus on how settlements between brand-drug companies and generics might harm consumers. The U.S. Congress is considering legislation that would ban settlements that involve financial incentives given to generic-drug companies.

"Both brand and generic pharma companies will be keeping a careful eye on the next steps taken by regulators," said Suzanne Rab, a lawyer at Hogan & Hartson in London. The EU focus on patent settlements "mirrors to a certain extent developments in the U.S."

The commission said in a related [report](#) today that companies use a variety of techniques to delay the introduction of generics "for as long as possible." The commission, the EU's executive arm, said it will continue to probe whether the use of patents to delay generics violates antitrust rules.

Something 'Rotten'

"Overall, it's indeed a conclusion that there is something rotten in the state," European Competition Commissioner [Neelie Kroes](#) told journalists at a press conference in Brussels. "We will not hesitate to apply the antitrust rules where such delays result from anticompetitive practices."

The commission's final report follows an 18-month probe that began after raids at [GlaxoSmithKline Plc](#), [AstraZeneca Plc](#), [Sanofi-Aventis SA](#) and several competitors. The



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commission conducted additional raids in November at some of the companies that are the subject of today's heightened investigations.

Teva, based in Petah Tikva, Israel, said in a statement that it's "committed to competing strongly in a fair and open market" and will cooperate with the investigation.

Servier, a closely held company based in Neuilly-sur-Seine, France, said in a statement that it will "continue to defend its rights."

Simona Gorjup, a spokeswoman for Novo Mesto, Slovenia-based Krka, said the company never made arrangements with other drugmakers to delay generics.

"As soon as a patent situation enables it, Krka comes on the market with its own versions," Gorjup said in an e-mail.

'Sigh of Relief'

Spokesmen for Lupin and Unichem didn't immediately respond to requests for comment.

Gareth Williams, a partner at Marks & Clerk, said in a statement that the drug industry will be "breathing a sigh of relief" because the commission decided to probe individual cases "rather than using the blunt instrument of wholesale patent reform which would undermine innovation."

Companies may have received indirect payments via broader commercial transactions with Servier that effectively resulted in them being unable to launch generic versions of perindopril, said [Frances Cloud](#), a London-based independent analyst.

"The commission can reform the patent situation, and they can certainly directly ban out-and-out payments, which will presumably make originator companies a lot more cautious, but it's not totally going to get rid of the deals," Cloud said.

'Red Flag'

Makers of brand-name drugs face a decline in revenue starting in 2011 when products generating \$150 billion a year will have generic competition, analysts and investment advisers said last year. The EU spends [214 billion euros](#) on medicines a year, or 430 euros a person, the commission's preliminary report in November said.

While the investigation is a "red flag" for the industry, it's unlikely to pose a direct risk to Teva's business in Europe, said [Gilad Sarig](#), a Tel Aviv-based analyst for Bank Hapoalim. "Innovative companies are more the focus," Sarig said in an e-mail.

The European Federation of Pharmaceutical Industries and Associations, which represents brand name drug companies, said in a statement that the commission acknowledged that generic market drug delays are also caused by administrative and regulatory hurdles.

"We welcome the statement that there should be competition in the off-patent markets," said [Thomas Cueni](#), head of the industry group's task force on the probe.

The commission called for a "community" patent that would be valid in all of the EU's 27 member states. The current system is a patchwork of national patents that are enforced in national courts. The regulator said EU governments should "significantly accelerate" the approval procedures for generic drugs.

"Tightening up Europe's legislative framework in the four areas of patent law, pharmaceutical legislation, price and reimbursement rules and competition law will result in a properly functioning pharmaceutical market," Greg Perry, of the of the European Generic Medicines Association, said in a statement.

To contact the reporter on this story: [Matthew Newman](#) in Brussels at [Mnewman6@bloomberg.net](mailto:Mnewman6@bloomberg.net).

EU May Open Antitrust Cases in Drug Industry Probe (Update1)



Making Medicines Affordable

By Matthew Newman



July 7 (Bloomberg) -- [European Union](#) antitrust regulators may narrow the focus to a few companies in an industrywide probe of brand-name drugmakers' use of patents to keep would-be generic rivals from selling less expensive copies of medicines.

European Competition Commissioner [Neelie Kroes](#) will release a report on drug-industry competition tomorrow at 11:30 a.m. Following an 18-month investigation, the Brussels-based agency may say the probe now centers on a handful of specific companies, according to antitrust lawyers.

"The commission may be preparing individual antitrust cases," said [David Hull](#), a competition lawyer at Covington & Burling LLP in Brussels, in an interview. Hull represents brand-name drug companies in licensing and structuring of their distribution networks.

In its preliminary report, the agency accused drugmakers of costing consumers in 17 countries as much as 3 billion euros (\$4.2 billion) by using patent rules and lawsuit settlements to restrict sales of cheaper copies. Commission officials raided France's Les Laboratoires Servier, [Teva Pharmaceutical Industries Ltd.](#), the world's biggest generic-drug maker, and Slovenia's [Krka Group d.d.](#) in November, searching for evidence that patent settlements harm consumers.

The commission said in November that various tactics are used to delay or block the sale of generics, including filing large numbers of patents for the same drug, suing generic companies, settling patent disputes and intervening in national procedures for generic-drug approvals.

#### Generic Competition

Brand-name drug companies typically file patent suits against generic companies to prevent them from getting regulatory approval for copies. Settlements involve brand-name drugmakers paying generic companies to keep their products off the market.

The commission's final report follows a probe that began in January 2008 after raids at [GlaxoSmithKline Plc](#), [AstraZeneca](#), [Sanofi-Aventis SA](#) and several competitors. Makers of branded drugs face a decline in revenue starting in 2011 when products generating \$150 billion a year will have generic competition, analysts and investment advisers said last year. The EU spends [214 billion euros](#) on medicines a year, or 430 euros a person, the commission's preliminary report said.

The European Federation of Pharmaceutical Industries and Associations, which represents the brand-name companies, has said the commission doesn't recognize the highly regulated nature of the pharmaceutical market in Europe.

'Legitimate'

"No other sector is as highly regulated," [Thomas Cueni](#), head of the industry group's task force on the probe, said in an interview on June 17.



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The industry group said in its [response](#) to the initial report that the threat of antitrust action against “legitimate practices” will undermine a “limited commercial window” to develop new drugs.

AstraZeneca spokeswoman [Sarah Lindgreen](#) and Glaxo spokesman [Stephen Rea](#) declined to comment because neither company has seen the report.

“Reverse patent settlements are a possibility for an investigation,” said Thomas Graf, an antitrust lawyer at Cleary, Gottlieb, Steen & Hamilton LLP in Brussels. “It’s not clear what the legal theory for an investigation would be.”

The agreements are known as “reverse payment settlements” and were worth about 200 million euros, the commission said. The accords are known as reverse payment settlements because, in the typical patent case, it’s the accused infringer and not the patent owner, who pays.

#### Legal Uncertainty

The commission should issue guidelines on reverse payments and settlements rather than its “ad hoc” approach of using antitrust cases, said Hull.

“The probe has caused a lot of legal uncertainty,” Hull said. “They should give us some guidance on when these agreements comply with EU law.”

In the U.S., the Federal Trade Commission has investigated so-called pay for delay deals, where brand-name drugmakers pay rivals to keep generic alternatives off the market. U.S. courts have upheld such agreements as long as they don’t delay the entry of the generic drug beyond the terms of patents held by the brand companies.

To contact the reporter on this story: [Matthew Newman](#) in Brussels at [Mnewman6@bloomberg.net](mailto:Mnewman6@bloomberg.net).

### 2.3. CNN

#### Pfizer approached by EU's pharmaceuticals inquiry

US pharmaceuticals giant Pfizer Inc said it has received an official approach from the European Commission as part of that body's investigation into competition practices in the EU's pharmaceutical sector. A spokesperson for the company said: 'We can confirm that we have had a visit from commission officials regarding their sector inquiry into competition in the pharmaceutical sector. We understand the commission are contacting a number of companies and we are fully co-operating with them.' The UK's GlaxoSmithKline, AstraZeneca and France's Sanofi-Aventis (NYSE:SNY) have also confirmed that they have received approaches from the commission. Copyright Thomson Financial News Limited 2007. All rights reserved. The copying, republication or redistribution of Thomson Financial News Content, including by framing or similar means, is expressly prohibited without the prior written consent of Thomson Financial News.

### 2.4. EuObserver

Something 'rotten' in EU pharmaceutical sector, says Kroes

[ANDREW WILLIS](#)

08.07.2009 @ 14:00 CET



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EUOBSERVER / BRUSSELS – European competition commissioner Neelie Kroes turned to Shakespeare on Wednesday (8 July) to describe anti-competition practices being widely used by pharmaceutical companies throughout the European union.

"Overall it is indeed a conclusion that there is something rotten in the state," she said, paraphrasing comments made by the character Marcellus in Act I of the British playwright's famous work, Hamlet.



Ms Kroes made the statement following the publication of a final inquiry report on Europe's pharmaceutical sector – a document that points to widespread collusion between drug companies producing original products and others producing generic copies.

According to the report, a considerable number of generic drug producers have accepted payments to delay the release of medicines that are on average 40 percent cheaper than the original product two years after its initial release.

Sending a clear signal that it means to crack down on the practice that results in European citizens paying more for their medicines, the commission has opened a formal antitrust investigation against French company Les Laboratoires Servier and a number of generic drug producers suspected of collusion.

"When it comes to generic entry, every week and month of delay costs money to patients and taxpayers. We will not hesitate to apply the antitrust rules where such delays result from anticompetitive practices," said Ms Kroes.

The case, the first of its kind, surrounds the production of a generic form of perindopril, a cardiovascular medicine used to prevent heart disease and lower blood pressure originally developed by Servier.

The commission says it has evidence of a least a further 200 incidences of illegal agreements between European drug companies, all of which could lead to fines if sufficient evidence is found.

"We hoped to get out a case that is really damaging," said Ms Kroes when asked why the commission had concentrated its first case on Servier and not on other suspected companies, some of which are considerably bigger.

The debate over artificially inflated drug prices is particularly relevant at present as Europe's population grows older and the prospects for both private and public pensions look shakier due to the financial crisis.

"With the ageing population we are going to need more medicine," said Ms Kroes.

European citizens currently spend €214 billion per year on pharmaceuticals, equivalent to 2 percent of the bloc's total GDP or €430 per year per citizen.

The commission report also calls on member states to introduce legislation to facilitate the uptake of generic drugs and says a community patent and specialised patent litigation system in Europe is now more necessary than ever.



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At present 30 percent of patent court cases are conducted in parallel in several member states, and in 11 percent of cases national courts reach conflicting judgements.

## 2.5. Euractiv

Big pharma braced for EU probe closure[\[fr\]](#)[\[de\]](#)

Published: Wednesday 8 July 2009

The European Commission is today widely expected to confirm earlier allegations that big pharma groups are breaching EU competition rules by blocking the entry of cheaper generics onto the European market.

The 27-strong college of commissioners is meeting today (8 July) to conclude a year-long [investigation](#) into the pharmaceutical sector with a 600-page final report and 25-page summary for policymakers.

The Commission's inquiry was launched in dramatic fashion in January last year with a number of unannounced raids in the offices of top pharmaceutical companies, including the UK's GlaxoSmithKline and AstraZeneca, France's Sanofi-Aventis, US pharmaceuticals giant Pfizer and Swiss company Novartis AG ([EurActiv 17/01/08](#)).

A second series of raids were conducted in November, just days ahead of the publication of the Commission's interim report ([EurActiv 26/11/08](#)).

The aim of the EU executive's unprecedented intervention was to find out whether anti-competitive practices in the sector are hindering innovation and blocking the entry of cheap generics onto the European market.

The [preliminary report](#) also pointed to so-called 'patent cluster' strategies - whereby firms apply for multiple patents for the same medicine - and 'defensive patenting', both of which are primarily aimed at preventing competitors from developing new medicines ([EurActiv 28/11/08](#)).

"My forecast is not very optimistic because the Commission goes where the wind blows," said a Brussels lobbyist from a big pharma company, who preferred not to be named.

For the EU executive, "the priority goes to the generic medicines and to short-term savings for the member states in order to contain their health spending which have gone worse with the economic crisis," the source said.

Big pharma firms have long complained that their financial margins to conduct ever-more expensive R&D were being squeezed by rules allowing generic companies to copy key medicines a few years after they are placed on the market.

As a consequence, pharma groups have fewer years to yield a profit from their research which they claim has grown more expensive over time due to stricter regulations for placing medicines on the market.

"R&D is costing a lot, this is true, especially for intellectual property," added the pharma lobbyist, but it is "the only way forward to develop therapies".

"Without R&D, there will soon be no more products to copy."

Big pharma expresses relief over EU inquiry

Published: Thursday 9 July 2009



The European pharmaceutical industry has expressed satisfaction with the publication of a long-awaited investigation into alleged anti-competitive practices in the sector, saying the final report is softer than a preliminary version released in November 2008.

Background:

The European Union has spent more than a year investigating competition issues in the pharmaceutical sector. The investigation was launched in January 2008 in response to concerns that fewer new medicines were being brought to market, amid allegations that generic drugs were being delayed from reaching consumers.

Tensions have been high between the industry and the EU executive following a dramatic series of unannounced raids on the offices of top pharmaceutical companies in January and November 2008 ([EurActiv 17/1/08](#); [EurActiv 26/11/08](#)).

A damning preliminary report was published in November 2008, which alleged that anti-competitive practices in the sector are hampering innovation and blocking the entry of cheap generics onto the European market ([EurActiv 28/11/08](#)). According to the November report, big pharma firms were applying for multiple patents for the same medicine and seeking to prevent competitors from developing new drugs.

EFPIA, the trade group representing large pharmaceutical companies, highlighted a shift in tone in the EU executive's final report on the sector and welcomed the "constructive policy recommendations".

At a briefing yesterday (8 July), EU Competition Commissioner Neelie Kroes pressed for greater use of cheaper generic medicines in caring for an ageing population, and was critical of what she described as "rotten" agreements between some firms which hold up the release of new drugs.

However, the report puts considerable emphasis on the need for patent reforms and well-flagged plans for a single patent court system. This was welcomed by EFPIA, which said streamlining the European patent system would cut costs and reduce current legal uncertainties.

The pharma group also said the final report "failed to substantiate" earlier allegations that patenting strategies dampen innovation and illegitimately delay generic entry. It welcomed the acknowledgment in the report of the importance of Europe's research-based pharmaceutical industry.

Controversial deals

EFPIA board member Thomas Cueni said the EU has also accepted that not all "settlement agreements" between patent-holding pharma firms and generic manufacturers are necessarily improper.

The industry expressed concern that the push towards greater use of generics, coupled with the rising costs of conducting R&D in Europe, would damage the European pharmaceutical sector.

"The report demonstrates a welcome shift away from the emotive language of the interim report, with a better balanced, more holistic view of the issues facing the sector," EFPIA said.

However, Commissioner Kroes did have some harsh words for the industry, saying the report confirms that company practices are a significant factor behind "competition problems" in the pharma sector.

New competition case

She also announced a fresh antitrust investigation against a French pharmaceutical firm for suspected breaches of rules on restrictive businesses practices and on abuse of a dominant market position.



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The European Commission is to probe agreements between Les Laboratoires Servier and a number of generic companies over "possibly restrictive" practices which may have delayed the availability of a generic heart medication.

EU officials suggested further cases could follow, saying the new report would pave the way for increased regulatory scrutiny of settlement agreements in which brand-name companies pay generics manufacturers for not competing with them.

"It will look at this on a case-by-case basis to see if there is enough evidence that merits further scrutiny," an official said.

The generic medicines industry also welcomed the publication of the report and called for the swift implementation of its findings.

However, consumer groups were less impressed. BEUC, the European consumers organisation, said questions remain over anti-competitive practices in the pharma sector and patients are getting a raw deal.

Key findings of the pharmaceutical sector inquiry:

A Community patent and unified specialised patent litigation system in Europe would reduce administrative burdens and uncertainty for companies. A full 30% of patent court cases are conducted in parallel in several member states, and in 11% of cases national courts reach conflicting judgements.

Recent initiatives of the European Patent Office (EPO) to ensure a high quality standard of patents granted and to accelerate procedures are welcome. This includes measures taken in March 2009 to limit the possibilities and time periods during which voluntary divisional patent applications can be filed (so-called "raising the bar exercise").

The Commission is also urging member states to:

Ensure that third party submissions do not occur and in any event do not lead to delays for generic approvals, and;

Significantly accelerate approval procedures for generic medicines - for example, the Commission believes that generic products should automatically/immediately receive pricing and reimbursement status where the originator drug already benefits from such status, which would allow for a faster product launch in certain cases;

Take action if misleading information campaigns questioning the quality of generic medicines are detected in their territory, and;

Streamline trials that test the added value of novel medicines.

Positions:

EU Competition Commissioner Neelie Kroes said increasing competition and reducing red tape in pharmaceuticals is essential to the health and finances of Europe's citizens and governments.

"The inquiry has told us what is wrong with the sector, and now it is time to act. When it comes to generic entry, every week and month of delay costs money to patients and taxpayers. We will not hesitate to apply the antitrust rules where such delays result from anticompetitive practices. The first antitrust investigations are already under way, and regulatory adjustments are expected to follow dealing with a range of problems in the sector," she said.

In a statement, the Servier Research Group took note of the procedure launched against it and said it "will reply in due course", but was first "waiting to hear what eventual grounds for complaint the EC might bring to bear".

Noting that the Commission's objective in the inquiry was "to promote innovation" in the pharmaceutical sector, Servier underlined that 25% of its annual turnover was invested in research of new medicines and said it had launched three innovative medicines in the last



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four years, "each first in class in the cardiovascular, neuroscience and rheumatology domains".

"Servier considers that the respect of intellectual property rights is a key condition for the research and development necessary to find tomorrow's new medicines, and will continue to defend their rights in this domain in accordance with the law."

Arthur J. Higgins, CEO of Bayer Healthcare and president of EFPIA, welcomed the report and focused on streamlining intellectual property infrastructure.

"We have stated consistently that complex and divergent regulatory barriers are the primary cause of market entry delay for both generic and innovative medicines. We are pleased that the final report recognises this reality," he said.

"We welcome many of the policy recommendations, such as a more streamlined patent system that reduces costs and increases legal and commercial certainty. We commit to working constructively with the internal market commissioner, member states, and the European Patent Office to push reforms forward under the Swedish Presidency."

"What is important is that the Commission uses this report to address the issue of competition in the off-patent market. This is an area that can generate savings which could be reinvested to fund innovative medicines."

The European Generic Medicines Association (EGA) said generics have been facing severe delays in getting on the market for too long now.

"We welcome the importance given by the European Commission to the need of high quality patents and raising the bar for patent applications. The existence of certain dubious secondary patents has indeed created a block against competition and undermined confidence in real innovation," commented Greg Perry, director-general of EGA.

He reiterated the EGA's longstanding plea for an urgent reform in the pharmaceutical sector, calling for Europe's legislative framework to be tightened in the areas of patent law, pharmaceutical legislation, price and reimbursement rules and competition law.

Monique Goyens, director-general of European consumer organisation BEUC, said the sector inquiry shows the pharma industry is not working properly and that "vicious tactics" are used to delay or prevent the entry of more affordable and innovative medicines into the market.

"Millions of euros are spent in promotional activities, in legal disputes and settlement agreements instead of in the development of new medicines to meet patients' needs," Goyens said. She called for concrete actions at EU and member state level to address unethical practices.

"We hope the outcome of the inquiry will lead to a review of the regulatory framework to find a better balance between companies' commercial interests and general public health interests, i.e. the interest of many patients who are still waiting for a new medicine to treat their disease and for new and effective medicines that can improve their quality of life."

Next steps:

More cases: The European Commission has left the door open for additional inquiries into other pharmaceutical companies and will review around 200 agreements between companies over the coming months.

## 2.6. European Voice

Drug firms face anti-trust probe

By Jennifer Rankin



09.07.2009 / 04:03 CET

Six pharmaceutical firms under investigation; move follows 18-month inquiry into competition. The European Commission has opened an anti-trust investigation into six pharmaceutical companies and indicated that further action could follow, after an inquiry into the industry that found evidence of anti-competitive practices.

Neelie Kroes, the European commissioner for competition, announced yesterday (8 July) the start of an anti-trust investigation into Les Laboratoires Servier, a French company that manufactures new drugs, as well as five companies that make generic copies: Krka d.d., Lupin Limited, Matrix Laboratories Limited, Niche Generics Limited and Teva UK Limited. The Commission suspects that Servier and the generic companies have reached deals that hindered generic copies of a heart medicine developed by Servier from getting onto the market.

The Commission stressed that the investigation was not proof that the companies have broken the rules. Kroes confirmed that the Commission is looking at other companies, including the international giant GSK.

#### Delays

The announcement came at the end of an 18-month inquiry into competition in the pharmaceutical industry, launched in January 2008 with a number of dawn raids on some of Europe's biggest drug companies.

In the final report, published yesterday, the Commission concluded that market entry of generic drugs has been delayed as a result of company practices.

Consumers had to wait seven months after patents had expired until cheaper generic medicines came onto the market, according to a sample of medicines that the Commission studied in 17 member states. Consumers and taxpayers could have saved €3 billion between 2000 and 2007 if the medicines had come on the market immediately.

However, the Commission also said that shortcomings in the regulatory regime could not be excluded as part of the cause for delays.

Kroes called for more competition in the industry. "When it comes to generic entry, every week and month of delay costs money to patients and taxpayers. We will not hesitate to apply the anti-trust rules where such delays result from anti-competitive practices," she said. The commissioner said that the inquiry showed the need for a single community patent and patent litigation system. "The current lack of progress [on a community patent] is very damaging," she said, noting that 11% of patent cases in national courts reach conflicting judgements.

The European Federation of Pharmaceutical Industries and Associations (EFPIA), which represents originator companies, insisted that the Commission had failed to substantiate earlier allegations that patenting strategies dampened innovation and delayed generics illegally.

"We remain disappointed that the report still claims erroneously that industry practices in some way contribute to slowing generic entry," said Brian Ager, EFPIA's director-general. "There is nothing to substantiate these claims. On the contrary, the generic market operates as would be expected."

Greg Perry, director-general of the European Generic Medicines Association, welcomed the inquiry's conclusions. "The existence of certain dubious secondary patents has indeed created a block against competition and undermined confidence in real innovation," he said.

#### Community patent

All parts of the industry welcomed moves to speed up the creation of a community patent, a goal that the EU has struggled with for more than 20 years.



Suzanne Rab, a lawyer at Hogan and Hartson who has represented an originator company in the sector inquiry, said that the Commission's approach suggested it would pursue individual infringement cases, rather than draw up guidelines on competition law. She argued that "a consolidated statement of the legal framework" would be preferable to letting the law "develop ad hoc".

"Without such a holistic approach, originator and generic companies, as well as national authorities, are likely to find that there remains a degree of legal uncertainty as to the permissible conduct at the intersection of intellectual property law and competition law," she said.

## 2.7. Financial Times

### EU drug sector probe provokes concern

By Nikki Tait in Brussels

Published: July 8 2009 05:06 | Last updated: July 8 2009 05:06

Drug companies are nervously anticipating action by Europe's antitrust regulators in the wake of a final report into the way new medicines are developed and brought to market, due to be published on Wednesday.

The report, which is the result of an 18-month probe by EU competition officials, is not expected to accuse individual companies of wrongdoing, and will draw only general conclusions about the way in which pharmaceutical companies and generic drug manufacturers interact with patent system.

But lawyers say that the European Commission has collected a huge amount of data in the course of its investigation, and expect that individual investigations into suspected anticompetitive practices will inevitably follow.

"There will be enforcement actions, although I'm not sure this will be a direct follow-on to the report ... more a response to the vast amount of information the Commission has collected," said Christopher Thomas, partner at the Lovells law firm.

"They now have the richest set of data on any industry in Europe".

The commission's inquiry was triggered by concerns that fewer new medicines were coming to market and that the entry of cheaper generic drugs appeared to be delayed in some cases. The pharmaceutical industry maintains that there are fundamental reasons for these apparent trends that have nothing to do with anticompetitive behaviour – such as scientific challenges and increased regulatory burdens.

Nevertheless, the commission published a [highly critical interim report](#) in November and EU competition commissioner Neelie Kroes accused drugmakers of [blocking or delaying](#) the entry of cheaper generic medicines, adding billions to the cost of medicines.

Some observers think that when the final report is released on Wednesday morning some of the rhetoric may be toned down. But they expect the European Commission to maintain its concerns over behaviour in the industry, as well as to point out perceived flaws in the European patent system itself.

Consumer groups, meanwhile, are hopeful that there will be recommendations which could help speed up the entry of generic drugs into national health systems.

But if the commission does bring enforcement actions against individual companies, lawyers predict that legal fights may ensue.

"Cases are likely to be heavily defended by manufacturers involved," says Nicola Holmes at the Eversheds law firm. That, she predicts, could leave the industry in a quandary over what



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amounts to lawful behaviour: “The pharma industry could be left hanging for several years (as the cases are fought out),” she says.

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## EU regulator turns spotlight on drugs

By Nikki Tait in Brussels

Published: July 8 2009 05:06 | Last updated: July 8 2009 11:57

Europe’s top competition regulator is to turn the spotlight on individual drug companies after publishing a report on Wednesday which finds that the entry of generic drugs into the pharmaceutical market is being delayed and costs to consumers inflated.

The European Commission said that the first individual antitrust investigations stemming from an 18-month probe of the sector were already under way, and that its intensified scrutiny of practices in the sector would cover legal settlements between the “originator” companies that develop new medicines and generic manufacturers.

“When it comes to generic entry, every week and month of delay costs money to patients and taxpayers,” said EU competition commissioner Neelie Kroes as she unveiled the final report this morning.

“We will not hesitate to apply the antitrust rules where such delays result from anticompetitive practices. The first antitrust investigations are already under way and regulatory adjustments are expected to follow dealing with a range of problems in the sector”.

The commission’s final report finds that European citizens – who spend €214bn annually - waited more than seven months after patent expiry on original medicine for cheaper generic products, costing then 20 per cent in extra spending.

It claims that originator companies used a various means to extend the commercial life of their products without generic entry for as long as possible – including lengthy litigation, restrictive settlement agreements, the filing of large “patent clusters” for a single medicine.

But the report also suggests that, while company practices are among the causes of delayed market entry of generic drugs, others factors such as shortcomings in the regulatory framework may play a part.

It calls for an “urgent” overhaul of Europe’s patent system – with the establishment of a “Community patent”, a single intellectual property right that would apply across the EU, and a specialised European patent litigation system. At present, although companies can apply for a “European patent”, this is a basket of individual country patents, which have to be enforced in each state separately.

And the report urges member states to significantly accelerate approval processes for generic medicines so that they come on stream more quickly – a move which is strongly backed by consumer organisations. It says that the commission will also examine existing EU rules in the area of pricing and reimbursement.

## Brussels to probe drug patent abuses

By Nikki Tait in Brussels and Andrew Jack in London

Published: July 8 2009 17:54 | Last updated: July 8 2009 17:54

Europe’s top competition regulator on Wednesday opened its first probe into suspected marketing abuses by individual drug companies, as it concluded in a report that the entry of generic drugs into the EU’s pharmaceutical sector was being delayed and costs to consumers inflated.



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The European Commission's investigation will look into patent settlements around Servier's blood pressure medicine perindopril.

The private French company's patent expired in 2003, but it attempted to maintain its hold on the market through a series of secondary patents and also reached financial settlements with a number of generic drugs companies, which stopped others launching versions of its medicine.

The commission said it was looking, in particular, at Servier's agreements with [Krka](#) of Slovenia, India's [Lupin](#), Unichem's Niche Generics, [Matrix Laboratories](#), and [Teva](#) UK, part of the world's largest generic company. These "may have the object or effect of hindering entry on to the market of generic perindopril", it said.

Servier emphasised that the commission had not identified any "conclusive proof" and said it would "continue to defend [its] rights in this domain in accordance with the law". Teva said it would co-operate fully and was "committed to competing strongly in a fair and open market".

The opening of the investigation coincided with publication of the commission's final report following an 18-month investigation of the pharma sector, in which the watchdog concluded there was an EU-wide problem over the speed at which generics were coming on stream, as well as with the declining number of new medicines.

"When it comes to generic entry, every week and month of delay costs money to patients and taxpayers," said Neelie Kroes, EU competition commissioner.

The report found that company practices, including the ways they defended their patents, were among the causes of delayed market entry of generic drugs. But it also acknowledged that other factors – such as shortcomings in the regulatory framework – might play a part. It urged an overhaul of Europe's patent system, and suggested member states should significantly accelerate approval processes for generic medicines.

Drug companies welcomed the moderation in tone from last year's interim report, and EFPIA, the European pharmaceutical industry association, described Wednesday's document as "a better-balanced, more holistic view of the issues facing the sector".

But Ms Kroes still promised increased scrutiny of companies, suggesting that the Servier probe may be only the first of several enforcement actions.

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## 2.8. International Herald Tribune

### Europe Is Studying Delays in Access to Generic Drugs

By [JAMES KANTER](#)

Published: July 9, 2009

Europe's antitrust regulator took aim at drug companies in France, Israel, India and the United States on Wednesday after a lengthy inquiry into practices that it claimed kept low-cost medicines from reaching consumers quickly.

The [European Union](#) competition commissioner, Neelie Kroes, said the first case would focus on Les Laboratoires Servier, based in France, and on makers of generic drugs, including [Teva Pharmaceutical Industries](#) of Israel, and units of the United States company Mylan and the Indian group Unichem Laboratories.

Ms. Kroes said she suspected Servier and the other companies had reached agreements aimed at hindering the availability of a generic version of its cardiovascular medicine perindopril.



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“When it comes to generic entry, every week and month of delay costs money to patients and taxpayers,” Ms. Kroes said in announcing her findings. “We will not hesitate to apply the antitrust rules where such delays result from anticompetitive practices.”

Servier and Teva said in separate statements that they would cooperate with the investigation.

Brian Ager, the director general of the European Federation of Pharmaceutical Industries and Associations, said that drug companies “remain disappointed that the report still claims — erroneously — that industry practices in some way contribute to slowing generic entry.”

Mr. Ager said there was “nothing to substantiate these claims.”

European governments, which pay billions of euros for prescription medicines, are dealing with a financial crisis and [recession](#) that have severely strained their resources.

The European Union began investigating the pharmaceutical sector early last year after complaints that nonbranded drugs were slow in coming to the market and were often unavailable in Europe. Officials carried out surprise inspections at several companies, including [Pfizer](#) of the United States, [GlaxoSmithKline](#) of Britain and Teva.

A central concern of the European regulators is that dealings between brand-name companies and generic drug makers create unnecessarily long monopolies on prescription medicines.

The commission’s campaign could hurt sales of brand-name drugs, but it could also increase access by patients to cheaper medicines, particularly as patents worth tens of billions of euros are set to expire in the next few years.

Ms. Kroes said the inquiry found about 100 cases in which big pharmaceutical companies had reached settlements with generic companies that delayed cheaper medicines. Commission officials said that more than 10 percent of the settlement cases examined involved direct payments amounting to 200 million euros.

She also promised tough scrutiny of lobbying done by pharmaceutical companies at national agencies for patent extensions, as well as other practices like taking out unduly large numbers of patents and patenting new versions of older drugs — a practice known as evergreening — if the purpose of those strategies was to exclude competition.

Commission officials said that generic versions of drugs often were unavailable for at least seven months after the patent on the original version expired — a factor that drove costs up by at least 3 billion euros from 2000 to 2007 in 17 European Union countries.

Even so, Ms. Kroes took a softer approach to big pharmaceutical companies, which she had previously suggested bore most of the responsibility for skewing the market. On Wednesday, while criticizing their business practices, she underlined that factors beyond the control of those companies were also to blame.

“We must have more competition and less red tape in pharmaceuticals,” Ms. Kroes said. “The sector is too important to the health and finances of Europe’s citizens and governments to accept anything less than the best.”

In particular, Ms. Kroes urged governments to accelerate approval procedures for generic medicines and take steps to ensure that clinics and patients were reimbursed sooner.

She said the commission would propose reforms to existing European Union rules on the way governments should handle procedures for authorizing drugs and how they were priced.

She also called on governments to adopt a so-called Community Patent for all of the European Union, and to agree to reform ways in which patents are adjudicated to overcome conflicting national decisions and allow for earlier availability of generic drugs.

Drug companies have long been at odds with regulators in Europe, where countries have universal health systems and where governments negotiate the prices of medications.



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European pharmaceutical sales are worth 214 billion (\$299 billion) a year, representing 2 percent of the 27-member trade bloc's gross domestic product.

Ms. Kroes said the inquiry had been necessary to find out why the number of new drugs reaching the market had dropped to an average of 28 a year from 2000 to 2004, from 40 a year in 1995 through 1999

## 2.9. IP Watch

### EU Finds Anti-Competitive Abuse Of Pharmaceutical Patents, Launches Antitrust Action

By [Kaitlin Mara](#) @ 5:29 pm

Pharmaceutical companies are manipulating the intellectual property rights system and are “actively trying to delay the entry of generic medicines onto their markets,” a top EU official said of an EU inquiry into the pharmaceutical sector released Wednesday. As a result, there has been a decline in the number of innovative medicines getting to the market, it says.

Quotations from originator companies themselves illustrate the behaviour, according to a [fact sheet](#) [pdf] on the findings.

“We identify options to obtain or acquire patents for the sole purpose of limiting the freedom of operation of our competitors... rights covering competitive alternatives are maintained in major markets until risk of competing products appearing is minimal,” said one such quotation.

The final report of the inquiry will be [posted here](#) when it becomes available. An executive summary of the findings is available [here](#) [pdf].

In an immediate action related to the findings, European Commissioner for Competition Neelie Kroes [announced](#) that the first antitrust case resulting from the inquiry is now open. It alleges breaches of European rules on “restrictive business practices” and “abuse of a dominant market position,” and is against French company Les Laboratoires Servier and five generics with which it had made deals, according to a separate press release. Kroes was speaking at a press conference on 8 July.

“The sector is too important to the health and finances of Europe’s citizens and governments to accept anything less than the best. The inquiry has told us what is wrong with the sector, and now it is time to act,” she added in the press release.

The sector-wide inquiry was opened because the Commission suspected the slowdown in novel medicines entering the market - 27 annually since 2000 as compared to 40 annually between 1995 and 1999, [a press release said](#) - was a systemic problem, and they sought to find out what was causing it.

The European Generic Medicines Association (EGA) in a release emphasised the Commission’s finding showing “that originator companies use a variety of instruments to extend the commercial life of their products without generic entry for as long as possible.”

The EGA called for quick implementation of the recommendations. The organisation had itself made several, including more stringent patentability requirements (especially on inventive step), timelines for oppositions and litigation procedures, controls for medical advertisement, sanctions of misbehaviour, as well as community patents and a unified EU patent court.

#### Pharma Companies React

The European Federation of Pharmaceutical Industries and Associations (EFPIA) “acknowledged” the report, which it felt was toned down from what it called “the emotive



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language of the interim report.” This is because, the group’s [press release](#) says, there are more regulatory issues identified in this version.

The preliminary version released in late November sparked charges from the pharmaceutical industry ([IPW, Public Health, 5 December 2008](#)) that the numbers were “misleading,” and that the problem instead lay with problems in regulation. Intensive industry lobbying of EU officials followed in recent months, according to sources.

The final report says it should be viewed in the context of Commission regulatory activities on drug safety, transparency of pricing schemes, and protection of IP. However, it also says competition law enforcement “by itself will be an important component” for ameliorating current concerns, and the majority of the executive summary is dedicated to providing detail on company practices.

The EFPIA also said the final report “failed to substantiate the initial allegation that patenting strategies dampened innovation or delayed generic entry illegitimately,” and praised it for “recognis[ing] the importance of Europe’s innovative pharmaceutical sector” and the importance of IP to that sector.

EU Findings on Company Behaviour

The European Commission found that companies engaged in delaying strategies such as loading up a single medicine with up to 1,300 patents or engaging in litigation. These are won by generics about two-thirds of the time, the Commission said, but can last up to three years.

Meddling with regulators was also an issue, as the [Commission found](#) “originator companies intervened in national procedures for the approval of generic medicines in a significant number of cases, which on average led to four months of delay for the generic medicine.” Companies would release claims about the generic product’s safety and quality, the inquiry found.

The Commission also found “at least 200 settlement agreements between generic and originator companies,” many of which restrict generics, driving up prices for consumers, Kroes [said at a press conference](#) on 8 July.

Community Patent, Unified Litigation System “Needed Rapidly”

The “current lack of progress” on a community patent is “very damaging,” said Kroes. Further, nearly a third of national court cases on patents are happening in parallel in other jurisdictions, and in 11 percent of cases they “reach conflicting conclusions.”

“This is a waste of everyone’s time and money,” said Kroes.

All stakeholders, including originator companies also supported the idea of a community patent and a unified litigations system, the report says.

In case there were doubts, the Commission reports that it “will not be changing its tough approach to antitrust enforcement as a result of the [financial] crisis.”

Kaitlin Mara may be reached at [kmara@ip-watch.ch](mailto:kmara@ip-watch.ch).

## 2.10. Irish Examiner

Consumers hit by generic drug deals

By Ann Cahill, Europe Correspondent

Thursday, July 09, 2009

IRISH consumers are paying 20% more than they should for medicines because pharmaceutical companies are doing deals to prevent cheaper medicines coming on the market.



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IRISH consumers are paying 20% more than they should for medicines because pharmaceutical companies are doing deals to prevent cheaper medicines coming on the market.

Major companies that develop the drugs are buying off generic drug companies that normally produce the drugs at an average of 40% cheaper once the patent has lapsed. A study carried out by the European Commission found at least 200 such settlement agreements between companies that developed the drugs and the generic companies that make identical products. "This means high prices for consumers and for taxpayers, whereas if you have effective competition operating you get a decent product for a decent price and you have a proper stimulus for innovation", said Competition Commissioner Neelie Kroes. Once the patent runs out on a drug – usually 20 years after it was first invented – generic companies are entitled to produce it. But the commission's investigation found there was a seven-month delay in bringing to market generic versions of a sample of medicines whose patents ran out in the seven years to 2007 in 17 member states. This cost a minimum of €3 billion, or 20% in extra spending for the countries surveyed. Ms Kroes said if all off-patent drugs were included, including those that were not replicated by generics, then the true cost was much more. Ireland's medicines bill is around €2bn a year and the country is one of the few in the EU that does not allow pharmacists automatically to switch to generic versions once they are approved.

The Irish Pharmacy Union earlier this year said at least €30m could be saved by using generics. The Department of Health has resisted change, some believe because of the powerful pharmaceutical companies in the country. The commission said it will take companies found to be operating such practices to court and announced a case against Les Laboratoires Servier and five generic companies. The case will look at agreements between Servier and the generic companies that delayed the drug perindopril being produced cheaper by generics. The drug combats heart-disease and high blood pressure. Ms Kroes said the study found that national authorisation processes for drugs were being used to delay generic drugs being produced. There were also campaigns to smear generic drugs.

This story appeared in the printed version of the Irish Examiner Thursday, July 09, 2009

## 2.11. Pharma Times

EU "will act" against drugmakers over generic delays

09 July 2009 The European Commission says it will not hesitate to act against "anticompetitive practices" by drugmakers which delay the market entry of generics, but has also called on member states to do more to boost generic uptake. The entry of generics onto the European market is being delayed and there is also a decline in the number of novel medicines coming to market, the Commission concludes, in its final report on competition in the drug sector. EU officials are already investigating possible anticompetitive activities by drugmakers, but "regulatory adjustments" are also expected, said Competition Commissioner Neelie Kroes, announcing the investigation's findings yesterday.

"We must have more competition and less red tape in pharmaceuticals - the sector is too important to the health and finances of Europe's citizens and governments to accept anything less than the best," said Commissioner Kroes. "When it comes to generic entry, every week and month of delay costs money to patients and taxpayers. We will not hesitate



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to apply the antitrust rules where such delays result from anticompetitive practices,” she added.

Among the inquiry’s findings are that, during 2000-7, EU citizens waited on average more than seven months after patent expiry for generic versions to come to market, costing them 20% in extra spending, and that originator companies are using “a variety of instruments” to extend the commercial life of their products without generic competition for as long as possible.

Responding to these findings, the Commission says it will apply increased scrutiny to the sector under EU antitrust laws and bring specific cases where appropriate. Tactics to delay generic entry and defensive strategies “that mainly focus on excluding competitors without pursuing innovative efforts” will be monitored closely, as will “reverse payment” settlements that limit or delay generics’ market entry, it warns. However, it also sees an urgent need to establish both a Community patent and a unified specialised patent litigation system for Europe, in order to reduce administrative burdens and uncertainty for companies; at present, 30% of patent court cases are conducted in parallel in several member states, and in 11% of cases national courts reach conflicting judgements. The Commission says it welcomes the European Patent Office (EPO)’s recent initiatives aimed at ensuring a high quality standard of patents granted and accelerating procedures; these include moves to limit the possibilities and time periods during which voluntary divisional patent applications can be filed (the “raising the bar” exercise). Actions by the member states must include ensuring that third-party submissions do not occur, or that at least they do not lead to delays for generic approvals, the report goes on. They must also speed up their approval procedures and act against misleading information campaigns which question the quality of generics, it says, and recommends that generics should “automatically/immediately” receive pricing and reimbursement status where the originator drug already benefits from such status, as this would permit speedier launches in some cases. Responding to the inquiry’s report, spokesmen for the research-based industry have welcomed its shift away from the “emotive language” used to express its interim findings last November, and say the final report has failed to substantiate the Commission’s initial allegations that patenting strategies dampen innovation or delay generic entry illegitimately. “We have stated consistently that complex and divergent regulatory barriers are the primary cause of market entry delay for both generic and innovative medicines. We are pleased that the final report recognises this reality,” said Arthur J Higgins, president of the European Federation of Pharmaceutical Industries and Associations (EFPIA). “What is important is that the Commission uses this report to address the issue of competition in the off-patent market. This is an area that can generate savings which could be reinvested to fund innovative medicines,” added Mr Higgins, who is chief executive of Bayer Healthcare.

#### EGA thumbs up

The European Generic Medicines Association (EGA) applauded the report’s conclusions that substantial reforms to EU and national legislation are needed, pointing out that current loopholes in the legislative framework “give rise to incoherent generic medicines policies in member states and allow originator companies to behave anti-competitively.” “We welcome the importance given by the European Commission to the need for high-quality patents and raising the bar for patent applications. The existence of certain dubious secondary patents has indeed created a block against competition and undermined confidence in real



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innovation,” said the EGA’s director general Greg Perry. “Tightening up Europe’s legislative framework in the four areas of patent law, pharmaceutical legislation, price and reimbursement rules and competition law will result in a properly functioning pharmaceutical market throughout Europe,” he added. By Lynne Taylor

## 2.12. Reuters

### EU investigates drugmakers over antitrust practices

Wed Jul 8, 2009 5:33am EDT

By Foo Yun Chee

BRUSSELS, July 8 (Reuters) - EU regulators are investigating some drug companies over suspected antitrust practices that include deals with makers of cheap generics to delay medicines' market entry, the European Commission said on Wednesday.

In her final report of a probe into the pharmaceuticals sector, EU Competition Commissioner Neelie Kroes said delays in bringing cheaper generic medicines to the market had pushed up consumers' bills by 20 percent between 2000 and 2007. "We will not hesitate to apply the antitrust rules where such delays result from anti-competitive practices," Kroes, who is tasked with ensuring fair play in the 27-country European Union, said in a statement.

"The first antitrust investigations are already under way, and regulatory adjustments are expected to follow dealing with a range of problems in the sector," she said. The Commission statement did not identify any companies under investigation.

But separately, the EU's executive arm announced an antitrust investigation into privately owned French drugmaker Servier and generics firms Krka d.d, Lupin Limited, Matrix Laboratories Ltd ([MAXL.BO](#)), now a unit of Mylan Inc ([MYL.O](#)), Niche Generics Ltd, part of Unichem Laboratories Ltd, and Israel's Teva Pharmaceutical Industries Ltd ([TEVA.O](#)).

The Commission said its investigation concerned unilateral behaviour by Servier and agreements which may have blocked the entry of generic perindopril, a cardio-vascular medicine originally developed by Les Laboratoires Servier, into the European Economic Area.

Kroes launched her sector investigation in January 2008 with a series of raids on makers of brand-name drugs, including AstraZeneca ([AZN.L](#)), GlaxoSmithKline ([GSK.L](#)), Pfizer ([PFE.N](#)), Merck ([MRK.N](#)) and Sanofi-Aventis ([SASY.PA](#)).

There were also raids on generic drugmakers suspected of colluding to delay the entry of generics, sometimes in exchange for payments from originator companies.

Settlement deals have also come under fire in the United States, with the Federal Trade Commission last month estimating the cost to consumers at \$3.5 billion a year. [ID:nN233221] Legislation pending in the U.S. Congress would ban such deals.

Drugmakers blame most of the delays on regulatory and other bureaucratic issues, rather than deliberate action by companies.

The Commission said it would step up scrutiny of settlement deals to see if they comply with strict EU competition rules.

"To reduce the risk that settlements between originator and generic companies are concluded at the expense of consumers, the Commission undertakes to carry out further focused monitoring of settlements that limit or delay the market entry of generic drugs," it said.



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The EU executive said it would examine current EU rules on price and reimbursement, urged European countries to introduce legislation to facilitate the entry of generics and stress the need for a Europe-wide patent.

## 2.13. SCRIP

EU pharma sector inquiry report - the final countdown

06 July 2009 Ian Schofield

If it's not already in the diary, now's the time to pencil it in. On Wednesday July 8th, the European Commission's competition directorate is due to unveil its eagerly awaited final report on the inquiry into competition in the EU pharmaceutical sector.

What, exactly, will be in the report? Will anything have changed from the preliminary version released last year? No one is saying. It is thought that, as with the preliminary report, copies have been distributed in advance but industry lips are sealed, no doubt again at the behest of the commission.

The European Generic medicines Association issued a statement saying that it would not comment on the report until it was released. The commission hasn't yet said exactly what time it will be published, but when it is expect a flurry of press conferences by the EGA, the R&D industry body EFPIA and DG COMP itself.

Interest in the final outcome of the inquiry is intense. Launched as a result of concern that competition in the EU pharmaceuticals market might be restricted or distorted, it concluded that competition among originator companies and generics firms was not working as well as it should.

Deterring competition

The preliminary version of the inquiry report, released in November last year, controversially accused the European originator industry of using a "toolbox" of patenting and other strategies such as settlement agreements to delay or deter competition from generics and other originator companies. It claimed patenting strategies were a factor in the decline in pharmaceutical innovation, and that some patents were "good" while others were "bad."

Its suggestion that originator companies were engaging in widespread anticompetitive activity was roundly condemned by the R&D industry, which claimed the report was "sensationalist" and had failed to address the real issues facing the sector, such as the effects of national policies and practices in hindering generics' access to market.

Many lawyers stepped forward to say that DG COMP had showed poor understanding of European patent rules, that competition law should not be used to address patent issues, and that the report had failed to take "market complexities" fully into account. Some claimed there was nothing really new in the report, although it has to be said that it did contain some very interesting admissions from internal company memos that otherwise would not have seen the light of day.

Generics companies naturally drew more comfort from the commission's findings that their products' market access was being held up by originator tactics. The EGA said the report had identified some "key problems" in the EU system that needed addressing, such as interfering with generic regulatory procedures.

Any changes?

While DG COMP is keeping the final report tightly under wraps, it is possible that the volley of criticism that greeted the preliminary version will have led it to tone the report down in



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some respects, particularly its focus on R&D companies as the main reason for generic market delays.

Certainly the critics' arguments carry a lot of weight. Those finding fault with the commission's approach include not only the originator industry and many firms specialising in competition and patent law, but other august interveners too, such as Lord Justice Jacob of the Court of Appeal of England and Wales and the European Patent Office – which was particularly irked by the idea that it had granted both "good" and "bad" patents.

So, will these criticisms have pierced the competition directorate's armour? While not offering any particular prognosis on the outcome, EFPIA told Scrip it hoped the final version would be "more balanced" and that it would take on board industry's claims that such delays could be attributed more to national practices and off-patent market inefficiencies than to the behaviour of originator companies.

It said that it had maintained "constructive engagement" with the commission over the inquiry and believed it had "put its point across", notably on issues such as national regulatory policies and the need to streamline litigation processes. "Fingers crossed that the report will reflect this."

Improving the patent system

Whether or not the final report does take a more nuanced approach, it should at least have something constructive to say in terms of improving the European patent litigation system in general. The inquiry revealed that there had been a number of contradictory judgments in European patent litigation cases and that the direct costs associated with litigation amounted to €420 million.

DG COMP said at the time that inefficiencies in the system could be overcome by establishing the planned unified patent judiciary and single Community patent – a conclusion supported by both originator and generics firms.

Further action possible

The commission has described the inquiry as a "comprehensive stocktaking exercise" that is not intended to identify any individual cases of wrongdoing or provide guidance on the compatibility of certain behaviour with EU competition law.

However, it does say that the results of the inquiry will allow it to determine whether further action needs to be taken under antitrust rules to improve competition in the pharmaceutical sector. Just what that action might be is not yet clear.

But remember that the inquiry kicked off with unannounced inspections of certain pharmaceutical companies, which resulted in reams of confidential documents being seized. And after it published the preliminary report, the commission noted that the inquiry was "upstream of any antitrust proceedings in specific cases, which may or may not follow". So will there be more raids? We will have to wait and see.

EC opens antitrust case against Servier and generics

08 July 2009

Ian Schofield

The European Commission has opened its first antitrust case following the inquiry into competition in the pharmaceutical sector. The case involves a settlement agreement between the French firm Servier and a number of generic companies.

The announcement was made by Neelie Kroes, the competition commissioner, during her presentation of the final report on the inquiry on July 8th. She said that the agreement, which



involved generics firms including Krka, Lupin and Teva, concerned suspected breaches of the EU treaty rules on restrictive business practices and abuse of a dominant position.

According to Ms Kroes, the deal "affected the entry of generic competitors to [Servier's] perindopril, a leading drug for heart disease and high blood pressure".

She noted that the commission was aware of some 200 other settlement deals between originators and generics firms that had caused drug prices to remain "substantially higher than if competition had existed". She also warned that more antitrust actions would be on the way and that one outcome could be financial penalties.

"Where delays to generics results from anticompetitive activities, the commission will not hesitate to apply the antitrust rules," she declared. "I would like to underline that the commission's job is to put an end to the economic damage done by anticompetitive actions, and if that requires fines so be it. If companies give an undertaking to end these problems, then that is obviously better."

The final report on the inquiry, which has just been published, "unfortunately confirms that there are competition problems in the pharmaceutical sector, and that company practices are a significant factor behind them," Ms Kroes announced. "In particular it concludes that originator companies are actively trying to delay the entry of generic medicines."

She stressed that cheaper generics were vital to tackling the problems of an ageing populations and constraints on national healthcare budgets. Generics were, she said, on average 40% cheaper than the originator drug two years after market entry. However, on the basis of a sample of drugs that lost patent protection during 2000-2007, the report found that in 17 member states customers waited more than seven months after patent expiry for cheaper generic to arrive.

She also noted that the final report confirmed that originators were misusing marketing authorisation processes to delay generic entry and conducting "misleading campaigns to discredit generic drugs", and called on member states to address this problem within their national health systems.

The commission, she concluded, with the help of insights from the report, will step up enforcement and work with the member states to improve the regulatory framework and the procedures for pricing and reimbursement and marketing authorisation.

The final inquiry report also addresses various patenting and litigation issues. More coverage on the report itself and reactions from industry and other parties will follow on scripnews.com.

## 2.14. The Independent

EU promises crackdown on pharma industry

[By Alistair Dawber](#)

Thursday, 9 July 2009 EU anti-competition authorities yesterday said they would act against pharmaceuticals groups that were suspected of delaying the launch of new medicines, adding that a lack of competition was harming patients and taxpayers.

However, the report was seen by many in the industry as a watered down version of interim findings published last November.

Neelie Kroes, the EU's competition commissioner said: "we must have more competition and less red tape in pharmaceuticals. The sector is too important to the health and finances of Europe's citizens and governments to accept anything less than the best."



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Industry insiders were quick to jump on the differences between November's findings and the final draft, published yesterday, which found that regulatory aspects the drugs industry in Europe was also responsible for hampering competition, as well as the actions taken by the pharmaceutical giants.

"We have stated consistently that complex and divergent regulatory barriers are the primary cause of market entry delay for both generic and innovative medicines. We are pleased that the final report recognises this reality," said Arthur J. Higgins, the chief executive of Bayer Healthcare and President of EFPIA, the body that represents the interests of big pharmaceutical companies in Europe.

The interim report squarely laid the blame for anti-competitive practices in the sector with the big groups, saying that the industry's aggressive use of patents and legal action has cost patients across Europe €3bn in extra medicine costs since the start of the decade.

Industry sources claimed that the report was a vindication of its stance that the use of patents was a vital and legitimate way of protecting revenues. Diana Sternfeld, head of patent litigation at Rouse, an intellectual property consultancy, said the report "recognises that intellectual property is key to innovation in the pharmaceutical sector."

However, the report did confirm that the commission is concerned that big pharmaceutical companies have relied on the patent system to extend the life of money-spinning medicines, at the costs of getting new drugs to market.

"The findings of the inquiry suggest that in recent years originator companies have changed their patent strategies. In particular, strategy documents of originator companies confirm that some of them aimed at developing strategies to extend the breadth and duration of their patent protection." Documents gathered in the course of the inquiry confirm that an important objective of this approach is to delay or block the market entry of generic medicines."

This confirmed parts of the interim report, which accused Europe's big pharmaceutical companies, including the FTSE 100 listed GlaxoSmithKline and AstraZeneca, of deliberately acted to stunt the growth of the generics drug market. The interim findings highlighted cases in which drugs have had more than 1300 patents filed against them: "the number of pharmaceutical-related patent applications before the European Patent Office nearly doubled between 2000 and 2007. Contrary to what might be assumed blockbuster [defined as treatments generating \$1bn of revenue] medicines' patent portfolios show a steady rise in patent applications throughout the life cycle of a product."

The companies yesterday pointed out, however, that the commission has now also accepted other reasons for the delay in getting cheaper medicines to market, especially the decentralised and highly complex nature of the various regulatory regimes across the EU.

The commission also pointed to pharmaceutical firms' reliance on litigation as a means to acting anti-competitively: "In certain instances originator companies may consider litigation not so much on its merits, but rather as a signal to deter generic entrants." The report pointed out that, "the number of patent litigation cases between originator and generic companies increased by a factor of four between 2000 and 2007."

Lawyers representing companies in the industry pointed to the report's focus on litigation as odd, however. "It is accepted that litigation is not an anti-trust issue," said Tony Woodgate, a competition partner in the life sciences group at law firm Simmons & Simmons.

The Commission said it was already investigating privately owned French drugmaker Servier, and several generics groups, over suspicions that they may have blocked generic cardio-vascular treatments from entering the market.



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### 3. French Speaking Press

#### 3.1. Agence France Press

##### Bruxelles enquête sur les fabricants de médicaments génériques

La Commission européenne a annoncé mercredi qu'elle enquêtait sur le secteur pharmaceutique, qu'elle soupçonne de freiner l'accès au marché européen des médicaments génériques, notamment par des pratiques d'entente avec les fabricants de ces médicaments moins chers.

Dans un rapport qui tire les conclusions d'une grande enquête sectorielle sur la pharmacie lancée mi-janvier, la Commission européenne met en évidence des "retards dans l'introduction" sur le marché des produits génériques, qui ont renchéri de 20% les dépenses de santé des citoyens européens entre 2000 et 2007.

"Les pratiques des entreprises sont en partie à l'origine de cette situation", souligne la Commission, dont l'enquête montre que les laboratoires "utilisent divers instruments pour étendre la durée de vie commerciale de leurs produits afin d'empêcher aussi longtemps que possible l'entrée des génériques sur le marché".

"La Commission entend intensifier son contrôle sur les arrangements qui limitent ou retardent l'entrée sur le marché des médicaments génériques", poursuit-elle.

"Les premières enquêtes antitrust sont déjà en cours et des ajustements réglementaires sont attendus pour régler une série de problèmes dans le secteur", a indiqué la commissaire européenne à la Concurrence Neelie Kroes.

La Commission européenne a annoncé dans le même temps l'ouverture d'une enquête sur le groupe pharmaceutique français Servier et plusieurs fabricants de génériques, dont le numéro un mondial, l'israélien Teva, qu'elle soupçonne d'ententes.

##### Bruxelles veut doper les médicaments génériques

BRUXELLES (AFP) - 08/07/2009 16h33

Des échantillons de médicaments génériques. La Commission européenne veut promouvoir les médicaments génériques moins chers en s'attaquant aux pratiques anticoncurrentielles du secteur pharmaceutique qui freinent leur développement via des procès interminables ou des ententes entre laboratoires.

Dans un rapport qui tire les conclusions d'une enquête sur le secteur de la pharmacie lancée mi-janvier, la Commission européenne met en évidence des "retards dans l'introduction" des génériques sur le marché.

Ils ont renchéri selon elle de 20% les dépenses de santé des citoyens européens entre 2000 et 2007.

Les génériques, copies de médicaments dont les brevets ont expiré, sont commercialisées en moyenne 40% moins chers que les marque originales deux ans après leur entrée sur le marché, un argument de poids face aux déficits de beaucoup de systèmes d'assurance maladie européens.

En cause pour les retards: des lacunes du cadre réglementaire, mais surtout les pratiques des laboratoires, qui "utilisent divers instruments pour étendre la durée de vie commerciale de leurs produits afin d'empêcher aussi longtemps que possible l'entrée des génériques sur le marché", souligne-t-elle.

La Commission pointe notamment les innombrables procès opposant les laboratoires aux fabricants de génériques sur les questions de brevets, avec près de 700 litiges répertoriés.



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Egalement visées, les interventions des laboratoires lors des procédures nationales d'autorisation de mise sur le marché, qui retardent l'arrivée des génériques.

Ou encore les nombreux accords à l'amiable --plus de 200 répertoriés dans l'UE-- passés entre laboratoires et fabricants de génériques pour mettre fin à des litiges, qui ont entraîné dans 50% des cas une restriction de l'accès au marché pour les copies moins chères, selon Bruxelles.

La Commission, qui a décidé d'accroître son contrôle sur ces arrangements, a indiqué qu'elle "intensifiera ses contrôles du secteur" et "étudiera certains cas particuliers lorsque cela lui semblera adéquat".

Elle a également annoncé l'ouverture d'enquêtes contre plusieurs groupes, dont le laboratoire français Servier et le premier fabricant mondial de génériques, l'israélien Teva, à la suite de perquisitions menées en novembre 2008.

Les autres groupes concernés sont des spécialistes des génériques, parmi lesquels Krka, Lupin, Matrix Laboratories, et Niche Generics.

La Commission leur reproche "plusieurs accords, potentiellement restrictifs, conclus entre chacun d'eux et Servier", qui auraient eu pour effet "d'entraver l'entrée sur les marchés" du générique d'un médicament cardiovasculaire mis au point à l'origine par Servier.

"Servier attend de savoir quels sont les éventuels motifs de contestation que la Commission européenne pourrait porter à sa connaissance et y répondra le moment venu", a réagi le laboratoire français dans un communiqué, ajoutant qu'il "continuera de défendre ses droits dans le domaine de la propriété intellectuelle selon les règles juridiques établies".

Dans son rapport, Bruxelles souligne par ailleurs la nécessité de prendre des mesures sur le plan réglementaire, notamment la mise en place d'un brevet communautaire et d'un système de règlement des litiges spécialisé en matière de brevets en Europe.

"Nombre des recommandations" de la Commission "sont justifiées", a estimé le Bureau Européen des Unions de Consommateurs (BEUC), pour qui "l'enquête sectorielle démontre clairement que le marché pharmaceutique fonctionne mal".

L'association européenne des médicaments génériques (EGA) a appelé de son côté "les autorités nationales et européennes à mettre en place rapidement les conclusions et recommandations du rapport".

### 3.2. Agence Europe

Bruxelles, 08/07/2009 (Agence Europe) - La commissaire européenne à la Concurrence a présenté, mercredi 8 juillet, le rapport final de la Commission sur la concurrence dans le secteur pharmaceutique. Neelie Kroes a expliqué que l'enquête de la Commission avait montré que l'entrée sur le marché des médicaments génériques prend du retard. Tout en soulignant à plusieurs reprises la nécessité d'encourager l'innovation, elle a déploré un déclin du nombre de nouveaux médicaments mis sur le marché. La Commission entend intensifier son examen du secteur pharmaceutique au regard de la législation communautaire en matière d'ententes, notamment en continuant à surveiller les accords conclus entre les laboratoires produisant des médicaments princeps et les fabricants de génériques. Les premières enquêtes sont déjà en cours, a dit Mme Kroes en évoquant en particulier une entente entre le laboratoire Servier et les fabricants de génériques Krka, Lupin, Matrix, Niche Generics Limited et Teva, concernant un antihypertenseur, le perindopril. Interrogée sur les suites que la Commission entendait donner à un autre cas suspect impliquant le laboratoire GSK, la Commissaire a réaffirmé que toutes les enquêtes seront menées à leur terme et conduiront, lorsque les violations du droit de la concurrence



sont avérées, aux amendes appropriées. Le cas Servier est « un avertissement à l'industrie pharmaceutique que nous n'accepterons aucun abus ni aucune mauvaise pratique dans le secteur », a-t-elle ajouté.

Sur la base d'un échantillon de médicaments dont les droits d'exclusivité ont expiré dans 17 États membres entre 2000 et 2007, l'enquête montre que les citoyens ont dû attendre plus de sept mois après l'expiration du brevet pour obtenir des médicaments génériques moins chers, ce qui a renchéri de 20 % leurs dépenses de santé. Neelie Kroes a fait état d'un surcoût global de 3 milliards d'euros. Durant sa conférence de presse, elle a longuement insisté sur « l'importance du secteur pharmaceutique pour la santé et le budget des consommateurs et des contributeurs » ainsi que pour les finances publiques, en particulier dans le contexte de l'augmentation de la consommation de médicaments liée au vieillissement de la population européenne. Les retards à l'introduction des produits génériques sur le marché sont problématiques car, après deux ans de présence sur le marché, ces derniers sont en moyenne 40 % moins chers que les médicaments princeps. La concurrence des produits génériques engendre donc une baisse substantielle des prix pour les consommateurs. L'enquête montre que les laboratoires produisant des médicaments princeps utilisent divers instruments pour étendre la durée de vie commerciale de leurs produits afin d'empêcher aussi longtemps que possible l'entrée des génériques sur le marché. L'enquête confirme également un déclin du nombre de nouveaux médicaments mis sur le marché et met en évidence certaines pratiques des entreprises qui pourraient contribuer à ce phénomène. Un suivi complémentaire du marché est en cours afin de cerner tous les facteurs qui contribuent à ce déclin de l'innovation.

La Commission entend intensifier ses contrôles du secteur dans le cadre des dispositions du traité CE en matière d'ententes et étudiera certains cas particuliers lorsque cela lui semblera adéquat. L'utilisation d'instruments visant à retarder l'entrée des produits génériques sur le marché fera l'objet d'un examen au regard du droit de la concurrence si elle a des fins anticoncurrentielles, ce qui est susceptible de constituer une infraction à l'article 81 ou à l'article 82 du traité CE. Les stratégies défensives en matière de brevet visant principalement à évincer les concurrents sans traduire des efforts d'innovation continueront de faire l'objet d'un examen attentif. Afin de réduire le risque que des accords soient conclus au détriment des consommateurs entre les laboratoires innovants et les fabricants de génériques, la Commission entend intensifier son contrôle sur les arrangements qui limitent ou retardent l'entrée sur le marché des médicaments génériques. S'il apparaît clairement que l'intervention d'un acteur du marché auprès d'un organisme d'autorisation de mise sur le marché visait essentiellement à retarder l'arrivée d'un concurrent, les parties lésées sont invitées à porter à la connaissance des autorités compétentes en matière de concurrence des preuves pertinentes de ces pratiques.

Sur le plan réglementaire, l'enquête montre que la création d'un brevet communautaire et la mise en place, en Europe, d'un système de règlement des litiges unifié et spécialisé dans les brevets revêtent un caractère urgent afin de réduire la charge administrative et l'incertitude pesant sur les entreprises. Le brevet communautaire serait « une bénédiction », a dit la Commissaire en affirmant que la Commission doit absolument faire avancer ce dossier. Au moins 30 % des recours en justice portant sur des brevets sont examinés en parallèle dans plusieurs États membres et, dans 11 % des cas, les tribunaux nationaux rendent des jugements contradictoires. Pour Mme Kroes, « c'est un gaspillage d'argent et de temps pour tout le monde ». La Commission estime aussi que les initiatives récentes de l'Office européen des brevets (OEB) pour garantir des normes de qualité élevée pour les brevets accordés et accélérer les procédures sont bienvenues. Il s'agit notamment des mesures



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prises en mars 2009 pour limiter les possibilités et la durée pendant laquelle les demandes volontaires de brevets divisionnaires peuvent être déposées (mesures visant à «élever le niveau»).

La Commission incite également les États membres à: (1) prévenir les interventions de tiers et, en tout état de cause, à ce qu'elles n'entraînent pas de retard dans l'approbation des médicaments génériques ; (2) accélérer de façon significative les procédures d'autorisation pour les médicaments génériques. La Commission considère notamment que les produits génériques devraient bénéficier automatiquement et immédiatement d'un statut de prix et de remboursement lorsque le médicament princeps est déjà doté d'un tel statut, ce qui permettrait dans certains cas un lancement plus rapide du produit ; (3) prendre des mesures si des campagnes d'information trompeuses remettant en question la qualité des médicaments génériques sont constatées sur leur territoire ; (4) rationaliser les essais qui testent la valeur ajoutée des nouveaux médicaments.

Afin d'aider les États membres à favoriser l'utilisation de produits génériques et à améliorer la concurrence par les prix, le rapport présente un aperçu des mesures nationales et de leurs effets sur l'utilisation des génériques (volume, prix, nombre d'entrants) et encourage les États membres qui veulent bénéficier des économies engendrées par les génériques à envisager de telles mesures. Dans cette optique, la Commission examinera également les règles de l'UE en vigueur en matière de fixation des prix et du niveau de remboursement (directive 89/105/CEE concernant la transparence).

Les résultats préliminaires de cette enquête avaient été présentés par Mme Kroes en novembre 2008 (EUROPE n° 9793). Le rapport final et des informations complémentaires sur l'enquête sectorielle dans l'industrie pharmaceutique seront disponibles à l'adresse suivante:

<http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/index.html> (O.J.)

### 3.3. Associated Press

The Associated Press - 08/07/2009 Ã 13:18 - 135 mots

Retard sur les génériques: Bruxelles met en garde les laboratoires pharmaceutiques

L'Union européenne a ouvert des enquêtes sur de grands groupes pharmaceutiques européens, dont un laboratoire français, soupçonnés de retarder l'arrivée de médicaments novateurs ou de génériques moins chers. Des inspections sont menées dans les locaux des laboratoires, a prévenu mercredi Bruxelles.

"La commission européenne a lancé une enquête sectorielle sur la concurrence dans l'industrie pharmaceutique et procède à des inspections dans les locaux d'un certain nombre de sociétés spécialisées dans les produits pharmaceutiques novateurs ou génériques", précise-t-elle dans un communiqué.

Une enquête a commencé mercredi sur le Laboratoire Servier en France, soupçonné de retarder le lancement de versions génériques de l'un de leurs médicaments contre les maladies cardiaques. Les enquêteurs tentent d'établir si le laboratoire a conclu une entente avec des concurrents pour retarder la mise sur le marché de versions moins chères de ce médicament. AP

The Associated Press - 08/07/2009 Ã 19:29 - 387 mots

Retard des génériques: Bruxelles met en garde les laboratoires



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Bruxelles a mis en garde mercredi les groupes pharmaceutiques contre les retards de mises sur le marché de génériques ou la réduction du nombre de nouveaux médicaments. La commission européenne promet de surveiller étroitement le secteur et a déjà ouvert une enquête sur les laboratoires Servier en France.

Le rapport final de la Commission européenne sur la concurrence dans le secteur pharmaceutique note que l'entrée sur le marché de médicaments génériques, des médicaments meilleur marché fabriqués à partir de molécules tombées dans le domaine public, prend du retard" et que le nombre de nouveaux médicaments mis sur le marché décline.

Sans exclure d'autres facteurs, l'enquête sectorielle menée par Bruxelles juge que les pratiques des entreprises sont "en partie à l'origine de cette situation".

"Il est temps d'agir", a déclaré la commissaire européenne chargée de la concurrence Neelie Kroes. "En ce qui concerne l'entrée sur le marché des médicaments génériques, toute semaine ou tout mois de retard génère des coûts pour les patients et les contribuables".

"Nous n'hésiterons pas à appliquer les règles antitrust lors que ces retards résultent de pratiques anticoncurrentielles", a-t-elle averti. "Les premières enquêtes antitrust sont déjà en cours et des ajustements réglementaires sont attendus pour régler une série de problème dans le secteur".

La Commission promet notamment de surveiller attentivement les accords conclus entre les laboratoires et les fabricants de génériques.

D'ores et déjà, Bruxelles a annoncé mercredi avoir décidé d'ouvrir une "procédure formelle d'examen" contre les Laboratoires Servier en France, une décision qui concerne également plusieurs fabricants de génériques qui avaient conclu des accords avec le groupe français. Cette enquête fait suite à des inspections menées en novembre 2008 dans plusieurs Etats de l'Union européenne. Elle vise à établir si une entente a eu lieu visant à retarder le lancement de versions génériques d'un médicament cardio-vasculaires des laboratoires Servier.

D'après Bruxelles, les médicaments génériques sont en moyenne 40% moins chers que les marques déposées originales deux ans après leur lancement et ils jouent un rôle crucial dans la réduction des coûts de la santé en Europe.

Brian Ager, un représentant de l'EFPIA, la Fédération européenne des associations et industries pharmaceutiques, a contesté les conclusions du rapport de l'UE estimant qu'il "prétend à tort que les pratiques de l'industrie contribuent d'une certaine façon à ralentir l'entrée sur le marché des génériques. Il n'y a rien pour étayer ces affirmations", a-t-il assuré.  
AP

### 3.4. My Pharma Editions

Médicaments génériques: Bruxelles va intensifier son examen du secteur pharmaceutique  
Publié le 8 juillet 2009



Dans un rapport final issu de son enquête sur la concurrence dans le secteur pharmaceutique lancée mi-janvier, la Commission européenne met en exergue des "retards dans l'introduction" sur le marché des médicaments génériques et constate un "déclin du nombre de nouveaux médicaments mis sur le marché". Si l'enquête considère que



les pratiques des laboratoires « sont en partie à l'origine de cette situation, elle n'exclut pas d'autres facteurs tels que des lacunes dans le cadre réglementaire. »

« Les citoyens ont dû attendre plus de sept mois après l'expiration du brevet pour obtenir des médicaments génériques moins chers, ce qui a renchéri de 20 % leurs dépenses de santé », avance la commission sur la base de son enquête (réalisée sur un échantillon de médicaments qui ont perdu leur exclusivité dans 17 États membres entre 2000 et 2007). Selon elle, « après deux ans de présence sur le marché, ces derniers sont en moyenne 40 % moins chers que les médicaments princeps. La concurrence des produits génériques engendre donc une baisse substantielle des prix pour les consommateurs. »

Ainsi, l'enquête sectorielle de la Commission montre que « les laboratoires de princeps utilisent divers instruments pour étendre la durée de vie commerciale de leurs produits afin d'empêcher aussi longtemps que possible l'entrée des génériques sur le marché. » Elle confirme également « un déclin du nombre de nouveaux médicaments mis sur le marché et met en évidence certaines pratiques des entreprises qui pourraient contribuer à ce phénomène ».

Bruxelles pour « une concurrence renforcée »

Pour donner suite à ces conclusions, la Commission européenne entend ainsi intensifier son examen du secteur pharmaceutique au regard de la législation communautaire en matière d'ententes, notamment en continuant à surveiller les accords conclus entre les laboratoires de princeps et les fabricants de génériques. « Nous devons renforcer la concurrence et réduire la bureaucratie dans le domaine pharmaceutique. Ce secteur est trop important pour la santé et les finances des citoyens et des gouvernements européens pour que nous acceptions autre chose que ce qu'il y a de mieux. Cette enquête nous a montré ce qui ne fonctionnait pas dans ce secteur. Maintenant, il est temps d'agir » a déclaré à cette occasion Neelie Kroes, membre de la Commission chargé de la concurrence.

La Commission européenne a ainsi annoncé dans le même temps l'ouverture d'une enquête sur le groupe pharmaceutique français Servier et plusieurs fabricants de génériques, dont le numéro un mondial, l'israélien Teva, qu'elle soupçonne d'ententes. L'enquête a trait « à plusieurs accords, potentiellement restrictifs, conclus entre chacun d'eux et Servier », qui auraient eu pour effet « d'entraver l'entrée sur les marchés » du perindopril générique, un médicament cardiovasculaire mis au point par les laboratoires Servier.

Bruxelles appelle à des mesures nationales en faveur des génériques. Sur les conclusions de son enquête, la Commission incite les États membres à « prévenir les interventions de tiers et, en tout état de cause, à ce qu'elles n'entraînent pas de retard dans l'approbation des médicaments génériques; accélérer de façon significative les procédures d'autorisation pour les médicaments génériques. » La Commission considère notamment que les produits génériques devraient bénéficier automatiquement et immédiatement d'un statut de prix et de remboursement lorsque le médicament princeps est déjà doté d'un tel statut, ce qui permettrait dans certains cas un lancement plus rapide du produit. Elle appelle également les États à « prendre des mesures si des campagnes d'information trompeuses remettant en question la qualité des médicaments génériques sont constatées sur leur territoire; et enfin rationaliser les essais qui testent la valeur ajoutée des nouveaux médicaments. »

Enfin, sur le plan réglementaire, l'enquête de la commission prône « la création d'un brevet communautaire et la mise en place, en Europe, d'un système de règlement des litiges unifié et spécialisé dans les brevets revêtent un caractère urgent afin de réduire la charge administrative et l'incertitude pesant sur les entreprises ». Selon le rapport, « au moins 30 % des recours en justice portant sur des brevets sont menés en parallèle dans plusieurs États



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membres et, dans 11 % des cas, les tribunaux nationaux rendent des jugements contradictoires ».

Le rapport final et des informations complémentaires sur l'enquête sectorielle dans l'industrie pharmaceutique seront disponibles à l'adresse suivante: <http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/index.htm>

### 3.5. RTL info

Les entreprises pharmaceutiques freinent l'arrivée de médicaments moins chers

Ce sont les conclusions de l'enquête de la Commission européenne sur la concurrence au sein du marché pharmaceutique qui a été publiée hier mercredi. Elle prouverait que les grandes entreprises pharmaceutiques freinent l'accès au marché européen des médicaments génériques, notamment par des pratiques d'entente avec les fabricants de ces médicaments moins chers.

Servier, l'exemple concret

La Commission européenne a annoncé, en même temps que les conclusions du rapport, l'ouverture d'une enquête sur le groupe pharmaceutique français Servier et plusieurs fabricants de génériques, dont le numéro un mondial, l'israélien Teva, qu'elle soupçonne d'ententes. L'enquête concerne aussi les fabricants de génériques Krka d.d., Lupin Limited, Matrix Laboratories Limited (filiale du laboratoire de génériques américain Mylan) et Niche Generics Limited (filiale du groupe Unichem), a précisé la Commission.

L'enquête a trait "à plusieurs accords, potentiellement restrictifs, conclus entre chacun d'eux et Servier", qui auraient eu pour effet "d'entraver l'entrée sur les marchés" du perindopril générique, un médicament cardiovasculaire mis au point par les laboratoires Servier. Cette enquête fait suite à des perquisitions menées en novembre 2008 par les services européens de la concurrence dans le secteur pharmaceutique, notamment chez Teva et Servier.

"L'enquête sectorielle démontre clairement que le marché pharmaceutique fonctionne mal et que des pratiques malhonnêtes sont utilisées pour retarder voire empêcher la mise sur le marché de médicaments plus abordables et plus innovants. Des millions d'euros sont dépensés à des fins promotionnelles, en litiges ou dans des règlements amiables avec l'industrie générique pour éviter la mise sur le marché de médicaments concurrents et ce, au lieu d'investir cet argent pour l'élaboration de nouveaux médicaments répondant mieux aux besoins des patients", rapporte Monique Goyens, Directeur Général du Bureau Européen des Unions de Consommateurs (BEUC).

Coût de ces pratiques pour nous : 20% de dépenses de santé en plus

Très concrètement, la Commission européenne met en évidence des "retards dans l'introduction" sur le marché des produits génériques, qui ont renchéri de 20% les dépenses de santé des citoyens européens entre 2000 et 2007. "Les pratiques des entreprises sont en partie à l'origine de cette situation", souligne la Commission, dont l'enquête montre que les laboratoires "utilisent divers instruments pour étendre la durée de vie commerciale de leurs produits afin d'empêcher aussi longtemps que possible l'entrée des génériques sur le marché". L'enquête sur la concurrence au sein du marché pharmaceutique a débuté en janvier 2008 et un rapport intermédiaire a été publié en novembre 2008.

La Commission européenne va sévir



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Le Bureau Européen des Unions de Consommateurs encourage la Commission européenne et les Etats membres à prendre des mesures concrètes et à s'attaquer aux pratiques contraires à l'éthique. De plus, le BEUC espère que les résultats de cette enquête permettront de réviser la législation dans le but d'établir un meilleur équilibre entre les intérêts commerciaux des entreprises et l'intérêt général en matière de santé publique. "La Commission entend intensifier son contrôle sur les arrangements qui limitent ou retardent l'entrée sur le marché des médicaments génériques", a répondu la Commission. "Les premières enquêtes antitrust sont déjà en cours et des ajustements réglementaires sont attendus pour régler une série de problèmes dans le secteur", a indiqué la commissaire européenne à la Concurrence Neelie Kroes.

### 3.6. Le Vif

«Oui, les grands labos étouffent les médicaments génériques...»

«... Mais ils ne sont pas seuls en cause», estime la Commission européenne. Neelie Kroes, commissaire à la Concurrence, admet ainsi des «lacunes dans le cadre réglementaire». La guerrière antitrust a d'ores et déjà menacé : «Les premières enquêtes antitrust sont déjà en cours et des ajustements réglementaires sont attendus pour régler une série de problèmes dans le secteur.»

L'entrée sur le marché des médicaments génériques prend du retard, dénonce le [rapport final](#) de la Commission européenne sur la concurrence dans le secteur pharmaceutique. Neelie Kroes, commissaire à la Concurrence, constate par ailleurs un déclin du nombre de nouveaux médicaments mis sur le marché.

Quant aux causes, si les grands laboratoires et leurs conseillers «motivent le retard dans la mise sur le marché des médicaments génériques et le déclin de l'innovation par des lacunes dans le cadre réglementaire», l'enquête sectorielle de la Commission considère que les pratiques de ces mêmes entreprises «sont en partie à l'origine de cette situation», même si elle «n'exclut pas d'autres facteurs».

Kroes à Big Pharma : «Cette enquête nous a montré ce qui ne fonctionnait pas dans ce secteur : maintenant, il est temps d'agir !»

«Cette enquête nous a montré ce qui ne fonctionnait pas dans ce secteur : maintenant, il est temps d'agir !», a d'ores et déjà annoncé Neelie Kroes dans le communiqué : «Nous devons renforcer la concurrence et réduire la bureaucratie dans le domaine pharmaceutique. Ce secteur est trop important pour la santé et les finances des citoyens et des gouvernements européens pour que nous acceptions autre chose que ce qu'il y a de mieux. En ce qui concerne l'entrée sur le marché des médicaments génériques, toute semaine ou tout mois de retard génère des coûts pour les patients et les contribuables.»

Et de menacer : «Nous n'hésiterons pas à appliquer les règles antitrust lorsque ces retards résultent de pratiques anticoncurrentielles. Les premières enquêtes antitrust sont déjà en cours et des ajustements réglementaires sont attendus pour régler une série de problèmes dans le secteur.»

7 mois entre l'expiration d'un brevet et l'arrivée d'un médicament générique, cela augmente de 20 % les dépenses de santé

Dans le détail, sur la base d'un échantillon de médicaments qui ont perdu leur exclusivité dans 17 Etats membres entre 2000 et 2007, «l'enquête démontre que les citoyens ont dû attendre plus de sept mois après l'expiration du brevet pour obtenir des médicaments génériques moins chers, ce qui a renchéri de 20 % leurs dépenses de santé», écrit encore la



Commission. Les retards à l'introduction des produits génériques sur le marché sont particulièrement importants parce que, «après deux ans de présence sur le marché, ces derniers sont en moyenne 40 % moins chers que les médicaments princeps ».

Problème : «L'enquête montre que les laboratoires de princeps utilisent divers instruments pour étendre la durée de vie commerciale de leurs produits afin d'empêcher aussi longtemps que possible l'entrée des génériques sur le marché.» Plus encore, «l'enquête confirme également un déclin du nombre de nouveaux médicaments mis sur le marché et met en évidence certaines pratiques des entreprises qui pourraient contribuer à ce phénomène. Un suivi complémentaire du marché est en cours afin de cerner tous les facteurs qui contribuent à ce déclin de l'innovation.»

Des mesures seront prises en cas de «campagnes d'information trompeuses remettant en question la qualité des médicaments génériques»

Plusieurs actions sont envisagées par Neelie Kroes, qui intensifiera ses contrôles du secteur pharmaceutique.

- L'utilisation d'«instruments spécifiques» par les Big Pharma pour retarder l'entrée des produits génériques sur le marché sera scrutée afin d'en déterminer l'aspect anticoncurrentiel.

- Les «stratégies défensives en matière de brevet», visant principalement à «évincer les concurrents sans traduire des efforts d'innovation», continueront de faire l'objet d'un examen attentif.

- Afin de réduire le risque que des accords soient conclus au détriment des consommateurs entre les grands labos et les génériqueurs, la Commission «entend intensifier son contrôle sur les arrangements qui limitent ou retardent l'entrée sur le marché des médicaments génériques».

- L'idée est également d'accélérer directement la mise sur le marché de médicaments génériques, notamment en faisant bénéficier «automatiquement et immédiatement» d'un statut de prix et de remboursement aux génériques «lorsque le médicament princeps est déjà doté d'un tel statut».

- Une attention particulière, enfin, sera accordée au marketing des médicaments non génériques. Des mesures seront prises «si des campagnes d'information trompeuses remettant en question la qualité des médicaments génériques sont constatées sur leur territoire».

Beuc : cette enquête démontre «que des pratiques malhonnêtes sont utilisées pour retarder voire empêcher la mise sur le marché de médicaments plus abordables»

Pour le Bureau européen des unions de consommateurs, sis à Bruxelles, nombre de ces recommandations sont justifiées mais de nombreuses questions restent en suspens concernant les pratiques anticoncurrentielles auxquelles ont recours les entreprises pharmaceutiques, indique le Beuc dans un [communiqué](#).

«L'enquête sectorielle démontre clairement que le marché pharmaceutique fonctionne mal et que des pratiques malhonnêtes sont utilisées pour retarder voire empêcher la mise sur le marché de médicaments plus abordables et plus innovants, résume Monique Goyens, directrice générale du Beuc. Des millions d'euros sont dépensés à des fins promotionnelles, en litiges ou dans des règlements amiables avec l'industrie générique pour éviter la mise sur le marché de médicaments concurrents, et ce, au lieu d'investir cet argent pour l'élaboration de nouveaux médicaments répondant mieux aux besoins des patients.»

Outre les mesures à prendre pour «s'attaquer aux pratiques contraires à l'éthique», la directrice générale du Beuc espère «que les résultats de cette enquête permettront de réviser la législation dans le but d'établir un meilleur équilibre entre les intérêts



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commerciaux des entreprises et l'intérêt général en matière de santé publique, c'est-à-dire les intérêts de nombreux patients en attente d'un nouveau médicament permettant de soigner leur maladie ou de la mise sur le marché de médicaments plus efficaces permettant d'améliorer leur qualité de vie».

#### 4. Blogs

##### [EU Commission Publishes Final Report On Competition Inquiry into the Pharmaceutical Sector](#)

Wednesday, July 8, 2009



Ms Neelie Kroes, European Commissioner for Competition

Today, on July 08, 2009 the European Commission [has adopted](#) the Final Report on its competition inquiry into the pharmaceutical sector, pursuant to Article 17 of Regulation 1/2003 EC. In my [earlier posting](#) I had reported that the [preliminary report](#) as published in november last year was not too friendly towards the patent system.

At the end of the inquiry process the EU Commission stresses that where appropriate it will make full use of its powers under antitrust rules (Articles 81, 82 and 86 of the EC Treaty), merger control ([Regulation \(EC\) No 139/2004](#)) and State aid control (Articles 87 and 88 of the EC Treaty). The EU Commission, in close cooperation with the National Competition Authorities, announced to pursue any antitrust infringement in the sector, wherever required by the Community interest. According to the final report, action can also be taken at national level and in areas which were not the primary focus of the inquiry or are outside its scope.

With regard to Intellectual Property, the main findings of the EU Commission are now as follows:

'[...] Promotion of innovation and driving economic growth are common goals of industrial property law and competition law. Innovation constitutes an essential and dynamic component of an open and competitive market economy. Intellectual property rights promote dynamic competition by encouraging undertakings to invest in developing new or improved products and processes. So does competition by putting pressure on undertakings to innovate. Therefore, both intellectual property rights and competition are necessary to promote innovation and ensure a competitive exploitation thereof. If the existence and exercise of an industrial property right are not of themselves incompatible with competition law, they are not immune from competition law intervention. However, certain practices can only be an infringement in exceptional circumstances

[...]

With regard to competition between originator companies in particular, defensive patenting strategies that mainly focus on excluding competitors without pursuing innovative efforts and/or the refusal to grant a license on unused patents will remain under scrutiny in particular in situations where innovation was effectively blocked.



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As regards competition between originator companies and generic companies, delays to generic market entry are a particular point of concern. The possible use of specific instruments by originator companies in order to delay generic entry will be subject to competition scrutiny if used in an anti-competitive way, which may constitute an infringement under Article 81 or 82 of the EC Treaty. In the case of clear indications that a submission by a stakeholder intervening before a marketing authorisation body was primarily made to delay the market entry of a competitor/applicant, injured parties and stakeholders are invited to bring relevant evidence of practices to the attention of the relevant competition authorities.

[...]

All stakeholders expressed strong support for the urgent creation of a single Community patent and a unified and specialised patent litigation system in Europe which are currently under discussion. Rulings by the unified litigation system should be swift, of high quality and cost-effective. The results of the inquiry confirm that the Community patent and unified litigation system would create significant cost and efficiency improvements, in particular by reducing the costs associated with multiple filings, by eliminating essentially parallel court cases between the same parties in different Member States and by enhancing legal certainty through the avoidance of conflicting rulings. The Commission continues to make all efforts leading to the rapid adoption of these instruments.

Stakeholders agree on the importance that European - and in the future Community - patents granted by the EPO should respond to a high quality standard. Strong support was further received by all stakeholders that the EPO should be enabled to accelerate procedures whenever possible. Based on its findings of the sector inquiry, the Commission supports the recent initiatives by the EPO to "raise the bar". In this respect the Commission welcomes the recent decision to limit the time period during which the voluntary divisional patent applications can be filed. The Commission also supports the EPO in its efforts to shorten the opposition and appeal procedures.'

Ok, all this sounds a bit like some sabre rattling with potential actions plotted to play out competition law against patent law. EU Community Patent and UPLS - both not yet revolutionary proposals, as well as 'raising the bar'.

Wednesday, 8 July 2009

[The pharma sector in Europe: what will become of it?](#)

STOP PRESS: the full report can now be downloaded from the DG Competition website [here](#).



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Eight months after the publication of its 426-page [preliminary report](#), DG Competition of the European Commission has at last unveiled its controversial Final Report on the Pharmaceutical Sector (see earlier IPKat posts [here](#), [here](#), [here](#), [here](#), [here](#) and [here](#)). This report, some 600 pages, long, will take a lot of reading. Meanwhile, here's the thrust of the report as described in this morning's [press release](#): "Antitrust: shortcomings in pharmaceutical sector require further action

Market entry of generic drugs is delayed and there is a decline in the number of novel medicines reaching the market ... The sector inquiry suggests that company practices are among the causes, but does not exclude other factors such as shortcomings in the regulatory framework. As a follow up, the Commission intends to intensify its scrutiny of the pharmaceutical sector under EC antitrust law, including continued monitoring of settlements between originator and generic drug companies. The first antitrust investigations are already under way. The report also calls on Member States to introduce legislation to facilitate the uptake of generic drugs. The report notes near universal support amongst stakeholders for a Community Patent [it has taken about two decades to win this battle...] and specialised patent litigation system [... and rather less time to win this one ...] in Europe [... but this is a much wider issue than pharma alone].

Competition Commissioner Neelie Kroes said: "We must have more competition and less red tape in pharmaceuticals [That's no surprise]. The sector is too important to the health and finances of Europe's citizens and governments to accept anything less than the best. The inquiry has told us what is wrong with the sector, and now it is time to act. When it comes to generic entry, every week and month of delay costs money to patients and taxpayers. We will not hesitate to apply the antitrust rules where such delays result from anticompetitive practices. The first antitrust investigations are already under way, and regulatory adjustments are expected to follow dealing with a range of problems in the sector."

#### Main findings and policy conclusions

The inquiry has contributed significantly to the debate on European policy for



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pharmaceuticals, in particular for generic medicines.

On the basis of a sample of medicines that faced loss of exclusivity in the period 2000 to 2007 in 17 Member States, the inquiry found that citizens waited more than seven months after patent expiry for cheaper generic medicines, costing them 20% in extra spending [the Kat bets these figures will come in for some conflicting explanations, along with others in the report].

Generic delays matter as generic products are on average 40% cheaper two years after market entry compared to the originator drugs. Competition by generic products thus results in substantially lower prices for consumers. The inquiry showed that originator companies use a variety of instruments to extend the commercial life of their products without generic entry for as long as possible [this applies in all patent-driven industries to some extent; if it's an evil to be cured here, does that cast light on DG competition's view of patents in other sectors?].

The inquiry also confirms a decline of novel medicines reaching the market and points to certain company practices that might contribute to this phenomenon. Further market monitoring is ongoing to identify all the factors that contribute to this decline in innovation [the IPKat has said this before and he'll say it again: if he had £100 million to invest, every penny of it would go into the generics sector -- he wouldn't waste a penny on original research nowadays, unless he was thinking of becoming a philanthropist].



Left: Moggins burrows into a box of debranded, repackaged cat-nip pills in search of an English translation of the contra-indications

Reacting to the findings, the Commission will apply increased scrutiny under EC Treaty antitrust law to the sector and bring specific cases where appropriate. The use of specific instruments by originator companies in order to delay generic entry will be subject to competition scrutiny if used in an anti-competitive way, which may constitute an infringement under Article 81 or 82 of the EC Treaty. Defensive patenting strategies that mainly focus on



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excluding competitors without pursuing innovative efforts will remain under scrutiny. To reduce the risk that settlements between originator and generic companies are concluded at the expense of consumers, the Commission undertakes to carry out further focused monitoring of settlements that limit or delay the market entry of generic drugs [this is an interesting phenomenon: it would be great to get some current data and to take a look at how these settlement payments affect pharma in the US]. In the case of clear indications that a submission by a stakeholder intervening before a marketing authorisation body was primarily made to delay the market entry of a competitor, injured parties and stakeholders are invited to bring relevant evidence of practices to the attention of the relevant competition authorities.

On regulatory issues the inquiry finds that:

There is an urgent need for the establishment of a Community patent and a unified specialised patent litigation system in Europe to reduce administrative burdens and uncertainty for companies. A full 30% of patent court cases are conducted in parallel in several Member States, and in 11% of cases national courts reach conflicting judgements [so 89% don't. Let's look at positives and see how we can push that figure up while we await a systemic overhaul].

Recent initiatives of the European Patent Office (EPO) to ensure a high quality standard of patents granted and to accelerate procedures are welcome. This includes measures taken in March 2009 to limit the possibilities and time periods during which voluntary divisional patent applications can be filed (so called "raising the bar exercise")

The Commission is also urging Member States to:

ensure that third party submissions do not occur and in any event do not lead to delays for generic approvals

significantly accelerate approval procedures for generic medicines - for example, the Commission believes that generic products should automatically/immediately receive pricing and reimbursement status where the originator drug already benefits from such status, which would allow for a faster product launch in certain cases [the IPKat suspects that, if the approval system were devised now, it would be a lot simpler than the current one anyway]

take action if misleading information campaigns questioning the quality of generic medicines are detected in their territory [presumably misleading campaigns of this nature are already unlawful, so what the Commission wants looks like specific state intervention rather than leaving it to generics to protect their own interest]

streamline trials that test the added value of novel medicines.

To assist Member States in delivering speedy generic uptake and improved price competition, the report contains an overview of national measures and their effects on generic uptake (volume, prices, number of entrants) and encourages Member States that want to benefit from generic savings to consider such measures. In this light the Commission will also examine existing EU rules in the area of pricing and reimbursement (Transparency Directive 89/105/EEC)".



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The IPKat will have to do a lot of reading before he reaches proper positions. Meanwhile, readers are welcomed and encouraged to post their comments below.