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Review

EU, Competition and Trade

Final report on pharmaceutical sector inquiry: Self-assessment is the best medicine

The European Commission has released the Final Report on its inquiry into the pharmaceutical sector, confirming many of the concerns identified in its Preliminary Findings last November, but softening the harshest criticism of the industry.

The Commission believes that pharmaceutical companies are harming the market by blocking innovation and delaying the entry of new drugs, ultimately threatening European citizens' well-being. The Authority is tightening its scrutiny of the way both originator and generic pharmaceutical manufacturers manage intellectual property rights, and will take action against behaviour it deems anticompetitive.

Market players will need to carefully self-assess their judicial, regulatory, IP and commercial practices, on new terms.

THE COMMISSION'S FINDINGS

The Report sets out the conclusions of an 18-month inquiry:

- Entry of generic drugs onto the market remains slow and too few novel medicines are developed.
- These market failures are largely blamed on originator pharmaceutical companies and their conduct towards rivals and generic manufacturers.
- Under the spotlight are vexatious litigation, patent "clustering", settlement agreements, interventions in regulatory procedure, and the launch of follow-on products.

"THE INQUIRY HAS TOLD US WHAT IS WRONG … IT IS TIME TO ACT."

Commissioner Nellie Kroes' team has toned down its approach since the Preliminary Findings but, make no mistake, steps will be taken following the Final Report. The Commission launched its inquiry in January 2008 with dawn raids on several companies (both originators and generics), and yesterday's release of the Final Report was accompanied by the launch of Formal Investigations into a number of market players. The Commission seems determined to show that it can bite, and it is already doing so.

The Commission will keep a closer eye on the behaviour of all companies in the sector, actively monitoring their conduct on the lookout for breaches of Articles 81 and 82 EC (anticompetitive agreements and abuse of dominance). Enforcement action will be pursued on a case-by-case basis where generics entry is delayed or innovation restricted.

> "We will not hesitate to apply the antitrust rules where (delays to generics) result from anticompetitive practices."
>
> *Neelie Kroes, European Commissioner for Competition*

The Commission has asked for help from Member States, urging governments to:

- Pursue appropriate enforcement action.
- Ensure that third party submissions do not delay generic entry.
- Speed up the testing of new medicines and approval of generics.
- Prevent originators from misleading the public as to the quality of generics.

The Commission has also called for reform of the patent system, including the introduction of a single patent court to streamline proceedings.

WHAT HAPPENS NEXT?

The Report states that future action in this sector should create a competitive environment based on access to innovative, safe and affordable medicines without delay. The Commission will approach this objective from many angles, targeting particular types of conduct but retaining a global perspective.

Settlement agreements

In particular, settlement agreements concluded between manufacturers at the expense of consumers will be the subject of intense monitoring. The Commission lays much of the blame for market failure on these agreements, highlighting that *"more than 200 settlement agreements with generic companies were concluded by originator companies in the EU … and in approximately 50% generic entry was restricted".*

To the satisfaction of many in the industry, the Commission has stopped short of introducing a system of compulsory notification for settlements. This approach was adopted in the US, but the Commission will limit its remit to monitoring agreements and taking action on a case-by-case basis as appropriate.

Defensive patenting

Defensive patenting strategies which focus on excluding competitors without pursuing innovation are also under attack. Victims of defensive patenting are encouraged to inform the Commission or National Competition Authorities and likewise, Member States have been urged to actively pursue appropriate enforcement action.

The world view

Given the nature of the pharmaceutical market (and the global reach of its key players) the Commission will not look at Europe in isolation. It is highly likely that the Commission will increase its interaction with Competition Authorities overseas, such as in Turkey – where an independent sector inquiry was launched earlier this year – and the US – where the Department of Justice ushered in by the Obama administration is set to take a tougher stance than its predecessors.

Incidentally, the Commission did emphasise in the Final Report that it will not relax its strict antitrust approach to the pharmaceuticals sector on account of the financial crisis.

THE IMPACT ON INDUSTRY

By not introducing settlement notification rules, and by choosing not to follow the US Department of Justice's recently expressed presumption of illegality for reverse payments, the Commission will have eased the worst fears of businesses in the sector. Nevertheless, there is no doubt that the Final Report will usher in a new, tougher antitrust and IP regime that companies at all levels of the market must adapt to quickly.

Self-assessment: prevention is better than cure

It will be vital for originator and generic manufacturers to conduct full and detailed self-assessment of their practices with regard to IP rights. Companies must determine whether they are likely to fall foul of the Commission's scrutiny in order to be prepared for the possibility of investigation, enforcement actions, or private litigation.

"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."

BEUC, European Consumer Organisation

A key area for self-assessment will be settlement agreements, both past and future. Companies should consider whether a settlement solves a genuine IP issue, and whether it is likely to lead to any restriction of innovation or delay of generic entry at the expense of consumers. If so, the Commission may conclude that the parties' conduct is anticompetitive and breaches European competition laws.

Regulatory proceedings and litigation

Originators will need to exercise caution when intervening before a regulatory authority, for example if a generic company is seeking authorisation to market its products. The Commission is alive to the possibility that intervention can be abused as a delaying tactic. Equally, care should be exercised where a company intends to bring patent litigation – the Commission will take a dim view of litigation that is vexatious or brought with the sole intention of impinging on other companies' innovation, or slowing down the entry of generics.

Patent strategies

Manufacturers will also need to give some thought to their patent strategy. Practices such as patent "clustering" (filing multiple patents for the same medicine) and "divisional" applications (splitting an initial patent application into multiple parts) are legitimate under patent law, but can breach competition law. The Commission will take a particularly hard line on companies that block the market by developing non-genuine patent portfolios.

Administering the poison pill

As much as the Final Report may pose threats to the pharmaceutical industry, it also presents opportunities for some parties to take action and protect their own interests. The Commission will welcome complaints from victims of anticompetitive behaviour, whether they are manufacturers, downstream suppliers or even consumers. In addition, the conclusions of the Final Report and – perhaps more importantly – the outcome of the Commission's ongoing Formal Investigations, will provide a roadmap for parties to bring private enforcement actions on legal and business grounds that have already been endorsed at European level.

"We welcome the importance given … to the need for high quality patents and raising the bar for patent applications."

European Generic Medicines Association

CONCLUSION

- The Commission believes that certain conduct of manufacturers in the pharmaceutical sector may well hinder innovation, delay the entry of cheaper generic drugs, and ultimately harm consumers.
- Closer attention than ever will be paid to intellectual property to ensure that rights are not abused to the detriment of competition.
- The Commission may have stepped back slightly from its harsh Preliminary Findings, but its zeal is evident in the dawn raids and Formal Investigations it has already launched.
- Prudent companies should consider carefully what the Final Report may mean for them.

FURTHER INFORMATION

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