

Workshop on

Recent Challenges in Competition and IP in Pharmaceutical Markets



26 February 2019 9:30 – 18:00





Paris, OECD Conference Centre - Room CC9 or distant participation by WEBEX



Registration by email to: Sofia.pavlidou@oecd.org and Rebecca.lambert@oecd.org



Documentation: oe.cd/2tD

AGENDA

Affordable access to many drugs is made difficult by high prices. At the same time, serious questions are being asked about the degree of innovation and value offered by increasingly costly treatments.

On 26 February 2019, the OECD will hold a one-day workshop in Paris to study the interaction between competition and IP rights in pharmaceutical markets, which will be moderated by Pedro Caro de Sousa (OECD).

Particular focus will be given to:

- the role of competition in protecting innovation, and :
- patent strategies that seek to deter or delay the entry of generic medicines into the market, such as pay-for-delay, producthopping, abuse of Intellectual Property ('IP') processes, ever-greening or patent clustering, among others.

The workshop offers an opportunity to investigate the impact and role that IP rights play in the pharmaceutical sector while sharing experiences on how to address anticompetitive practices. We will also discuss the challenges of investigating and sanctioning such practices, and to identify potential best practices.

9:30 - 9:45

Welcome and opening remarks from Antonio Gomes, Acting Deputy Director DAF

ANTITRUST AND IP

The first part of the workshop will describe the main features of the interaction between antitrust and IP, and how tensions between them play out in the pharmaceutical sector. This section will also provide an overview of the main anticompetitive practices in the pharmaceutical sector, and discuss how IP affects antitrust enforcement in this sector.

Keynote	speakers

Professor Duncan Matthews (Queen Mary University of London)

Professor Michael Carrier (Rutgers University)

9:45 - 11:00

Presentation by the keynote speakers

- Relevance of IP in pharmaceutical sector, and how it impacts competition enforcement
- Discussion of anticompetitive practices in the pharmaceutical sector where IP rights have an impact on enforcement.

10:45 - 11:00

Intervention by BIAC

11:00 - 11:15

Coffee break

AGENCY CASE STUDIES – Reverse Patent Settlements

This session will look at pay-for-delay agreements - i.e. those agreements between an originator and a generics manufacturer where the former pays the latter to settle a patent injunction and agrees conditions to delay generic entry into the market. Settling the dispute eliminates the potential for competition and allows the parties to share profits that would otherwise be eroded by lower prices. The session will look at the challenges raised by these cases, including how to identify anticompetitive patent settlements and the identification of potential competition.

11:15 – 12:00	Case study by the European Commission
12:00 – 12:30	Reaction by keynote speakers / Comment by competition agencies
	[Including interventions by Portugal, Turkey and the UK]
	Q&A and discussion from the floor

12:30 - 14:00 **Lunch break**

AGENCY CASE STUDIES - Anticompetitive abuses of IP and Regulatory Mechanisms

This session will discuss conduct that, while prima facie legal, uses existing regulatory mechanisms to prevent or delay market entry by competitors. Such conduct includes providing misleading information to IP and health regulators; sham litigation; abuse of regulatory processes such as Risk Evaluation and Mitigation Strategies (REMS) and refusal to provide samples to potential competitors; etc.

14:00 – 14:45	Case study by the French Competition Authority
14:45 – 15:15	Reaction by keynote speakers / Comment by competition agencies
14.40 10.10	[Including interventions by Italy and Canada]
	Q&A on the case study
15:15 – 15:30	Coffee break

AGENCY CASE STUDIES - Other Anticompetitive Practices with an IP Element

This session proposes to address anticompetitive practices where IP rights are a relevant consideration, even if they are not explicitly directed at manipulating the IP system. Examples include product hopping, denigration of competitors, anticompetitive licensing, rebates, bundling and other agreements that seek to delay generic entry

16:30 – 16:45	Coffee Break
	Q&A on the case study
16:00 – 16:30	[Including interventions by Romania and the UK]
	Comment by competition agencies
15:30 – 16:00	Case study by the Italian Competition Authority

CONCLUSIONS AND CLOSING REMARKS

CONCESSIONS AND CESSING NEW ARRIVANCE		
16:45 – 17:30	Conclusion by the Keynote Speakers and Moderator	
	Key takeaways from agency experience	
	 Practical enforcement challenges in addressing anticompetitive practices involving IP in pharmaceutical sector 	
	Avenues for future work and inter-agency cooperation	
17:30 – 17:45	Closing remarks by Antonio Capobianco, Acting Head of the Competition Division	