

2023 trends in competition for Pharma companies

The future of healthcare and life sciences

Webinar
Tuesday 6 December



The next abusive practices in the spotlight

Mark Jephcott



The rise and fall of pay for delay



2009

Pharma sector inquiry

Catalyst for EU (and NCA) enforcement activity

2013

Citalopram

Settlement agreements delaying generic entry of Citalopram

2013

Fentanyl

Co-promotion agreement delaying generic entry of Fentanyl

2014

Perindopril

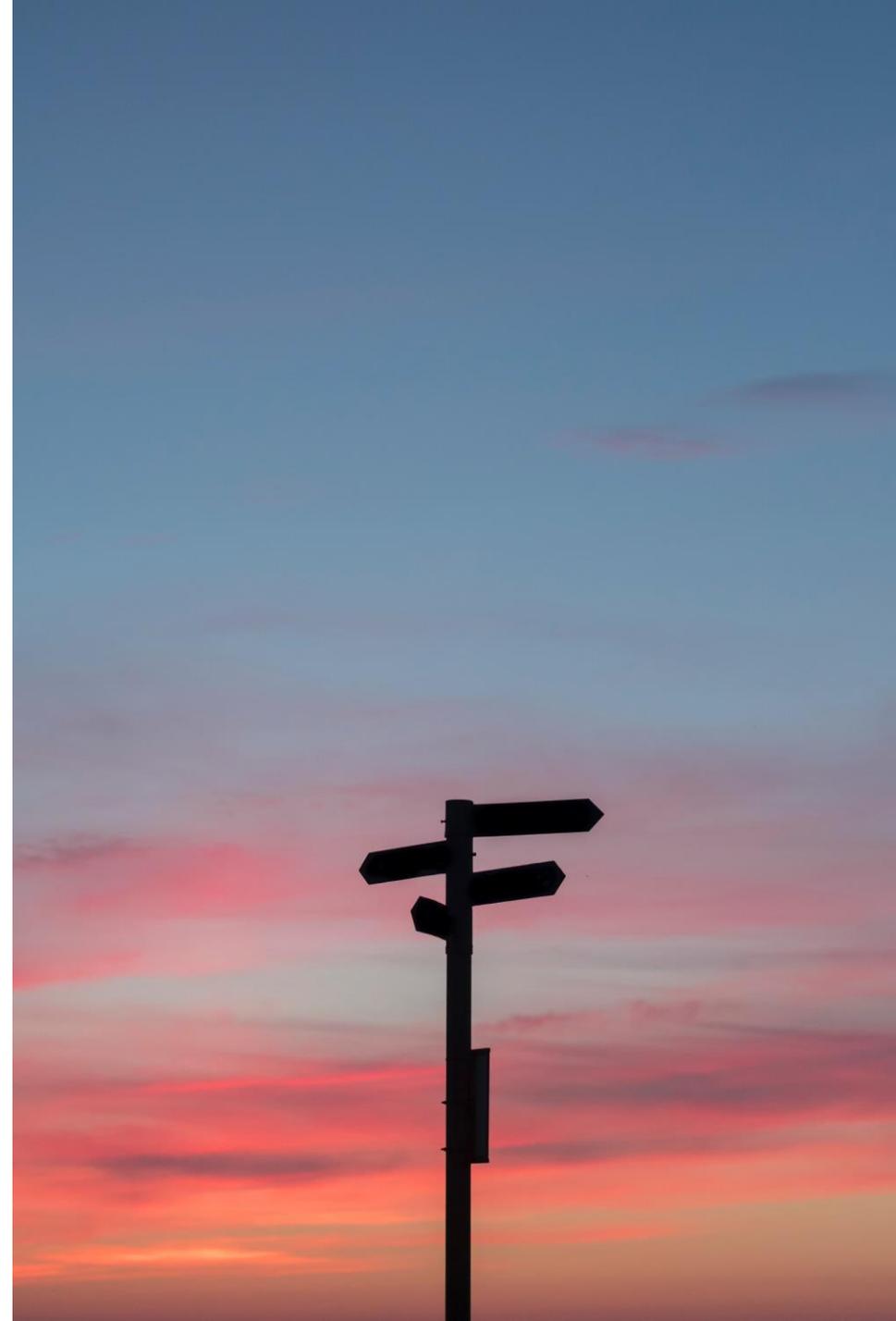
Settlement agreements delaying generic entry of Perindopril

EC identifies **3 categories of settlement agreements:**

No restriction on the market

A restriction on the market but without any reverse payment system

Both a restriction on the market and a reverse payment from originator to generic (a by object infringement)



Pay for delay: now settled law



Paroxetine, Citalopram and Perindopril: offering up a coherent **analytical framework** for assessing “by object” pay for delay?

3 key criteria

- whether the originator and generic are **potential competitors**
- whether the agreement contains a reverse payment (or **value transfer**)
- whether the generic in exchange **agrees to refrain from entering the market**

Potential competition

Whether there is a “**real and concrete**” possibility of market entry by the generic at the relevant time

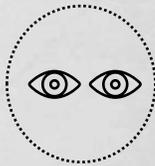
Characterisation as “by object”

Must be adopted when it is “plain from the examination of the settlement agreement concerned that the **transfers of value** provided for by it **cannot have any explanation other than** the commercial interest of both the holder of the patent at issue and the party allegedly infringing the patent **not to engage in competition on the merits**”

Abuse of patent process (back) in the spotlight?



Teva II



Investigation opened in 2021 following dawn raids



Oct issue of SO: preliminary view that Teva **misused patent procedures** to artificially extend basic patent protection for Copaxone and delay generic entry



So called **divisionals game**: filing and withdrawing secondary patent applications, forcing competitors to file new challenges each time



Abuse of patent process (back) in the spotlight?

Consentyx (Switzerland and EU):

- Investigation opened in Sep following dawn raid.
- Allegations concern acquisition of patents to initiate litigation to shield Consentyx from competition – so called **blocking patents**

MSD (Spain):

CNMC fine on MSD in Oct for engaging in **unjustified litigation** (**withholding information** to gain an injunction), delaying generic entry of competing contraceptive

Abuse of patent process: where next?



Teva II at an early stage.

Looking back to **AstraZeneca** for framework within which EC investigation proceeds?

- **CJEU upheld two separate abuses:**
 - (i) misleading representations before MS patent offices and
 - (ii) deregistration of marketing authorisations in MS
- Clear that each case decided on its facts: no “bright line” test **BUT**
 - **Misleading representations** can constitute an abuse where overriding purpose is exclusion of generic entry AND
 - **Entirely lawful use of regulatory systems** can also constitute an abuse where anti-competitive intention to exclude

EC focus on biosimilars as a vital source of price competition in pharma markets:

- *EC White Paper*: originators defending themselves with second generation products, reformulations, dosing improvements, supporting devices and/or competing on price
- The next frontier for abuse of dominance enforcement?

Key considerations when negotiating prices with health authorities

Riccardo Pennisi



Is there a competition law relevance?

Competition authorities are not
regulators...

Nonetheless...

Excessive pricing has been considered, under certain conditions, as **an abuse**.

This is why, **an economic analysis is crucial**.

United Brands test, having two limbs:

- Is the price excessive?
- If the answer is in the affirmative, is the price unfair?

Concept of “**unfairness**” is vague, unfair in itself or when compared to competing products



Different approach in the US: one of the criticisms is that it is **too difficult to assess** whether a price is excessive.

Recent cases of excessive prices in the pharmaceutical sector



Phenytoin
(2016→2022, UK)

Syntocinon
(2018, Denmark)

Chenodeoxycholic Acid
(2021, Netherlands; 2022, Italy; 2022, Spain)

Hydrocortisone tablets
(2021, UK)

Anticancer drugs
(2016, Italy; 2021, EU; 2022, UK)



To keep in mind when negotiating prices with health authorities

1 Prudent assessment of the **relevant market** 

2 Prices should be **justifiable** (cf. the *United Brands Test*) 

3 Relevance of **“intent”** 

4 Needless to say: **no exchanges of information** with competitors... 

Communications with health authorities

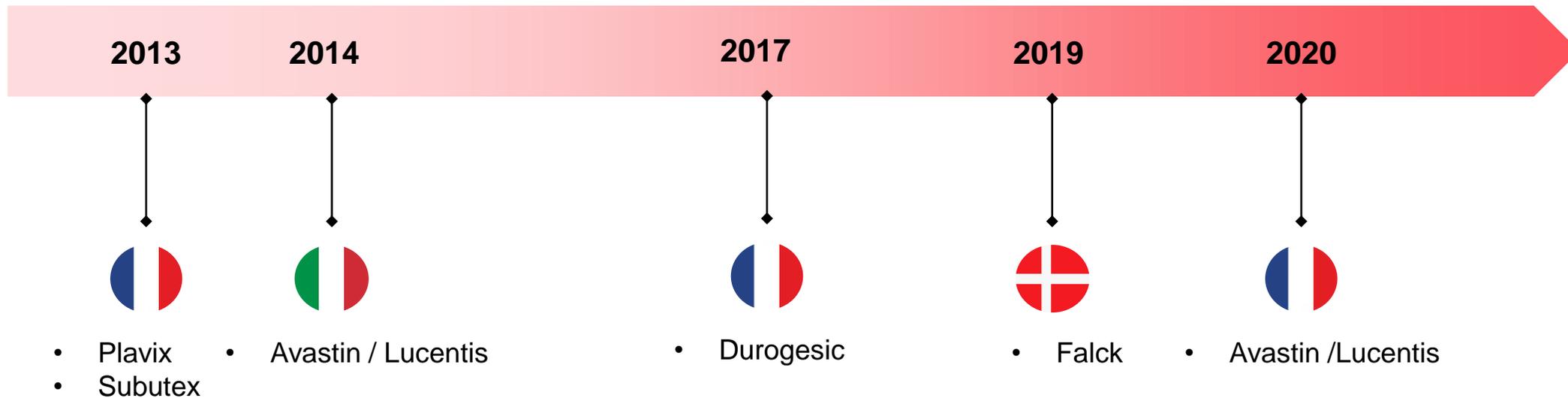
Internal documentation

Disparagement under the EU Commission's scrutiny

Omblin Ancelin



Case-law on denigration driven (so far) by national competition authorities



With different approaches at national level?



Qualification: abuse and/or anticompetitive agreement

Different standards of proof ?



From unfair competition/unfair commercial practices to antitrust issue



Is veracity of the denigrating information important?



Is the sector/context in which the denigration is implemented important?



Is it limited to princeps/generics competition?

Towards a more consistent and consolidated approach in the EU?

2021



4 March 2021

Investigation against Teva's alleged disparagement of product competing with Copaxone.

2022



20 June 2022

EU Commission opened an investigation related to Vifor's alleged disparagement campaign of iron medicine



October 2022

SO sent to Teva.

Clear signal of willingness to challenge:

- broader categories of abuses cases
- the growing importance of non-price related competition parameters

What is the role of state aid rules?

Cees Dekker



Reshoring manufacturing capacity




MINISTÈRE
DE L'ÉCONOMIE,
DES FINANCES
ET DE LA RELANCE
*Liberté
Égalité
Fraternité*



the globe. One way to
Industry reports econom
argued that the

certain manufacturing capacity in
dependencies. Participants
as very much

Do state aid rules stand in the way or do they facilitate reshoring production capacity?

EU efforts to 'reshore' drug production trip over subsidy rules

EU regulations restrict government handouts to support drug production.

Paris, 3 March 2022

IPCEI/Serious disturbance

Article 107(3)(b)

Projects of common EU interest

- Single project
- At least 4 member states involved
- Important co-financing by beneficiaries
- Cross border initiatives
- Balancing positive and negative effects

Serious disturbance in the economy (especially in crises such as Covid).



€5.4 billion
aid for
hydrogen
technology
value chain

12 member states



€2.9 billion
research and
innovation
project along
the battery
value chain

15 member states

41 projects

**35 participating
companies**



SA.59021

Aid in favour of
InnoGenerics-NL

Development of certain economic areas

Art. 107(3)(c) TFEU



Aid to **facilitate the development of certain economic activities** or of certain **economic areas**, where such aid does not adversely affect trading conditions to an extent contrary to the common interest.



Balancing of positive and negative effects



Several decisions of the EC on capacity remuneration mechanisms:

- to ensure that there is sufficient capacity for the production of electricity to meet the expected demand of electricity.
- Beneficiaries are remunerated for their availability (mostly selected through a competitive bidding process).

Service of General Economic Interest



Compensation for 'extra costs'



Obligation to provide a service

- e.g. to keep in stock a certain range of products/volumes
- to keep in place a certain production capacity



Extra costs may be funded

What extra costs?



Cost efficiency



The Ferring-case

Obligation to:

- keep in stock a range of medicines comprising at least nine tenths of all forms of medicines currently sold in France;
- to satisfy at all times the needs of its regular customers for a period of at least two weeks;
- to deliver any medicine in its range within 24 hours of receipt of the relevant order;
- to deliver any medicine (as defined) that is sold in France to any pharmacy requesting it.