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Cleary's Pharma Bites Disparagement

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July 2021

Disparagement – Background

— Pharmaceutical regulatory compliance rules generally prohibit disparagement of rival products. However, financial or liability exposure for companies violating these rules is limited.

— National competition authorities (notably in France and Italy) have begun considering disparagement as an antitrust theory of harm. This development is noteworthy:

- These antitrust precedents have so far applied a low bar for what is deemed disparaging, essentially encompassing any statement about a competitor's product that is false or ought reasonably to have been known to be misleading.
- Antitrust fines imposed for disparagement have been significant *e.g.*, Roche and Novartis together received fines of €183 million in Italy and €444 million in France (other fines have been in the range of €15 - 40 million).

— The European Commission is actively exploring creating an EU antitrust disparagement precedent of its own (as exemplified by the ongoing investigation of Teva), which could lead to additional disparagement investigations, particularly if fueled by complaints.

Disparagement – Potential Violation of Article 101/102

Disparagement can be considered a form of abuse by dominant companies under Article 102 TFEU or a concerted anti-competitive practice under Article 101 TFEU

Abuse (Article 102)

— "**The disclosure of information likely to discredit a competitor constitutes** [abusive] **denigration**, regardless of whether the information is accurate **unless the information in question relates to a topic of general interest and is based on a sufficient factual basis**, and provided it is expressed with some measure."

French Court of Appeal, *Janssen-Cilag*, (2019)

Anti-competitive practice (Article 101)

— "**Dissemination**, in a context of scientific uncertainty, to the EMA, healthcare professionals and the general public **of misleading information relating to adverse reactions** resulting from the use of one of those products for the treatment of diseases not covered by the MA for that product, **with a view to reducing the competitive pressure** resulting from such use on the use of the other medicinal product, **constitutes a restriction of competition 'by object'.**"

Court Of Justice of the EU, *Hoffmann-La Roche* (2018)

National Precedents: Examples Of Disparagement As Abusive Conduct Under Article 102

Questioning regulatory rulings	Suggesting to HCPs that generics might not meet the conditions required for MA, even though these issues had already been ruled on favorably by the regulator (FCA, *Janssen-Cilag*)
Misinterpreting regulatory warnings	Incorrect reporting of regulatory warnings to HCPs to discourage their switching from originators to generics (FCA, *Janssen-Cilag*)
Misleading regulators	Disseminating misleading and biased information to regulators to discourage off-label use of a competing product (FCA, *Roche-Novartis*)
Instilling doubts among HCPs	Raising unsubstantiated safety concerns about generics in interactions with HCPs (FCA, *Schering-Plough; Sanofi-Aventis*)

EU Teva Investigation – Potential Disparagement Concerns

— The European Commission – in its ongoing *Teva* investigation – is actively exploring establishing a disparagement precedent at EU level.

> *The Commission has indications that **Teva's campaign**, primarily directed at healthcare institutions and professionals, **may have targeted competing products to create a false perception of health risks associated with their use**, even following the approval of these medicines by competent public health authorities.*

Teva, European Commission Press Release, March 4, 2021

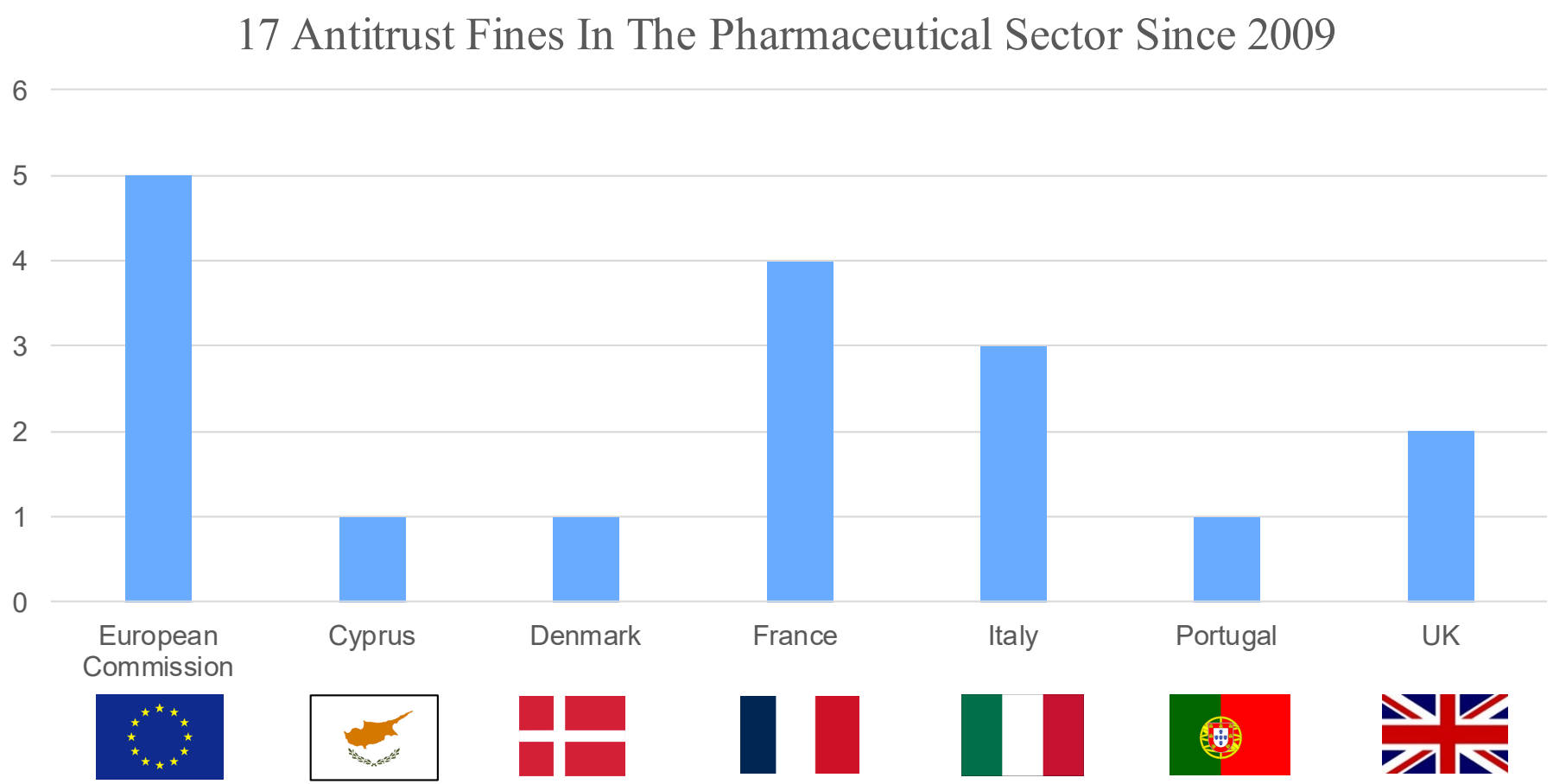
— Teva's practices allegedly seeking to prevent substitution of its originator product with follow-ons are also subject to review by the U.S. House of Representatives.

Practical Implications

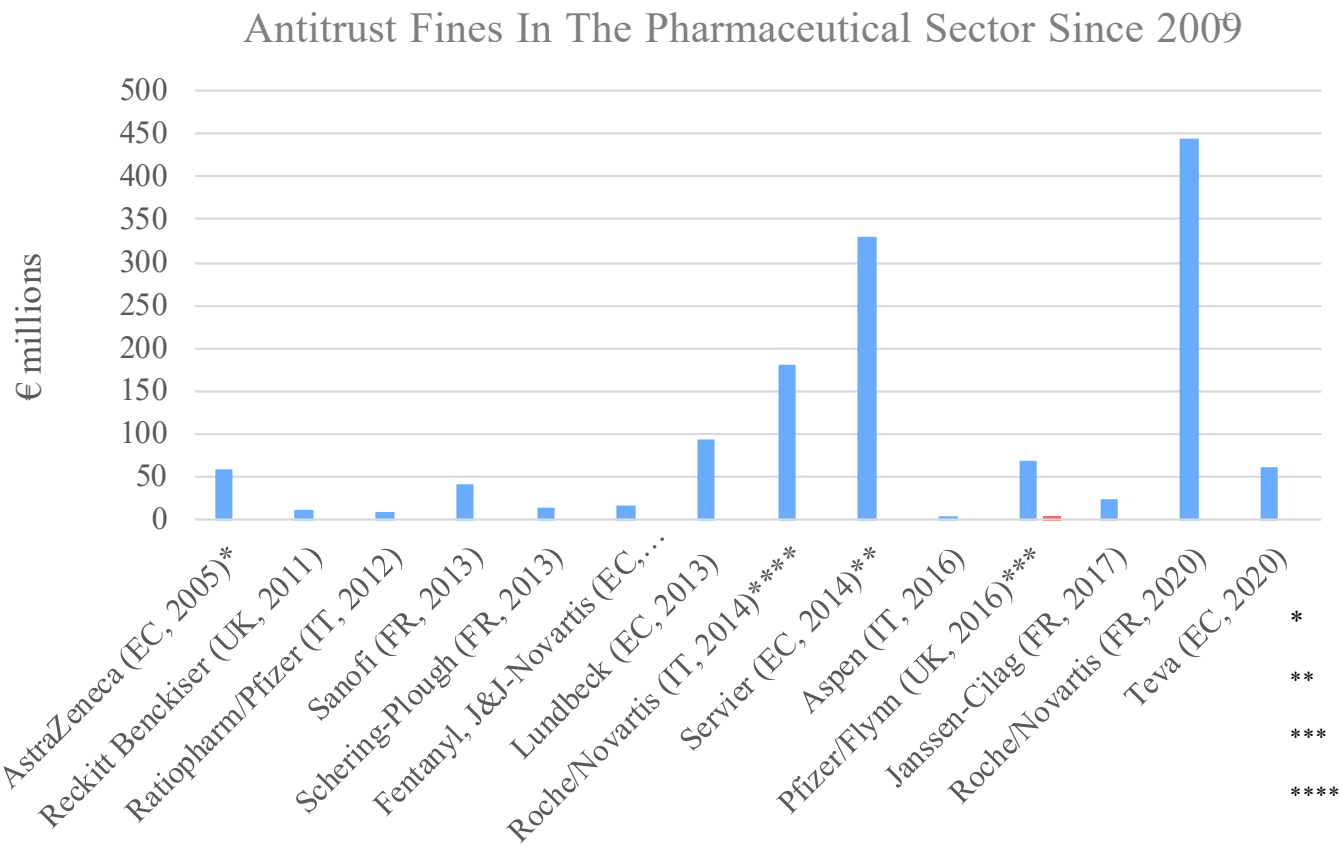
1. Risk that antitrust regulators define product markets at narrow, originator level, finding originator dominant. Places messaging by originators into spotlight as potential disparagement.
2. Precedents suggest low bar for conduct that might be deemed disparagement – any statement about a competitor's product that is false or ought reasonably to have been known to be misleading.
3. Given precedents, companies should be cautious in making statements about competitors:
   - To the extent previous regulatory findings are questioned in communications, messaging should be based on new objective, comprehensive, and peer-reviewed evidence.
   - Regulatory warnings (in particular in relation to switching between an originator and a follow-on) should be quoted *verbatim*.
   - Communications on efficacy or safety should be based on the content of SmPCs and, if needed, supplemented with objective, comprehensive, and peer-reviewed evidence.
   - Any differences between competing products should be communicated in a fulsome, dispassionate, and neutral manner, and reflect precise findings and limitations of peer-reviewed evidence.
   - No concerted messaging with competitors on competitive products.

Annex

EU Enforcement In The Pharma Sector (1)



EU Enforcement In The Pharma Sector (2)



\+ Chart excludes cases where fines <€1 million, *i.e.*, Cyprus (Pfizer), Denmark (Aspen), Portugal (Roche).

* Reduced to €52.5 million by the ECJ (2012)

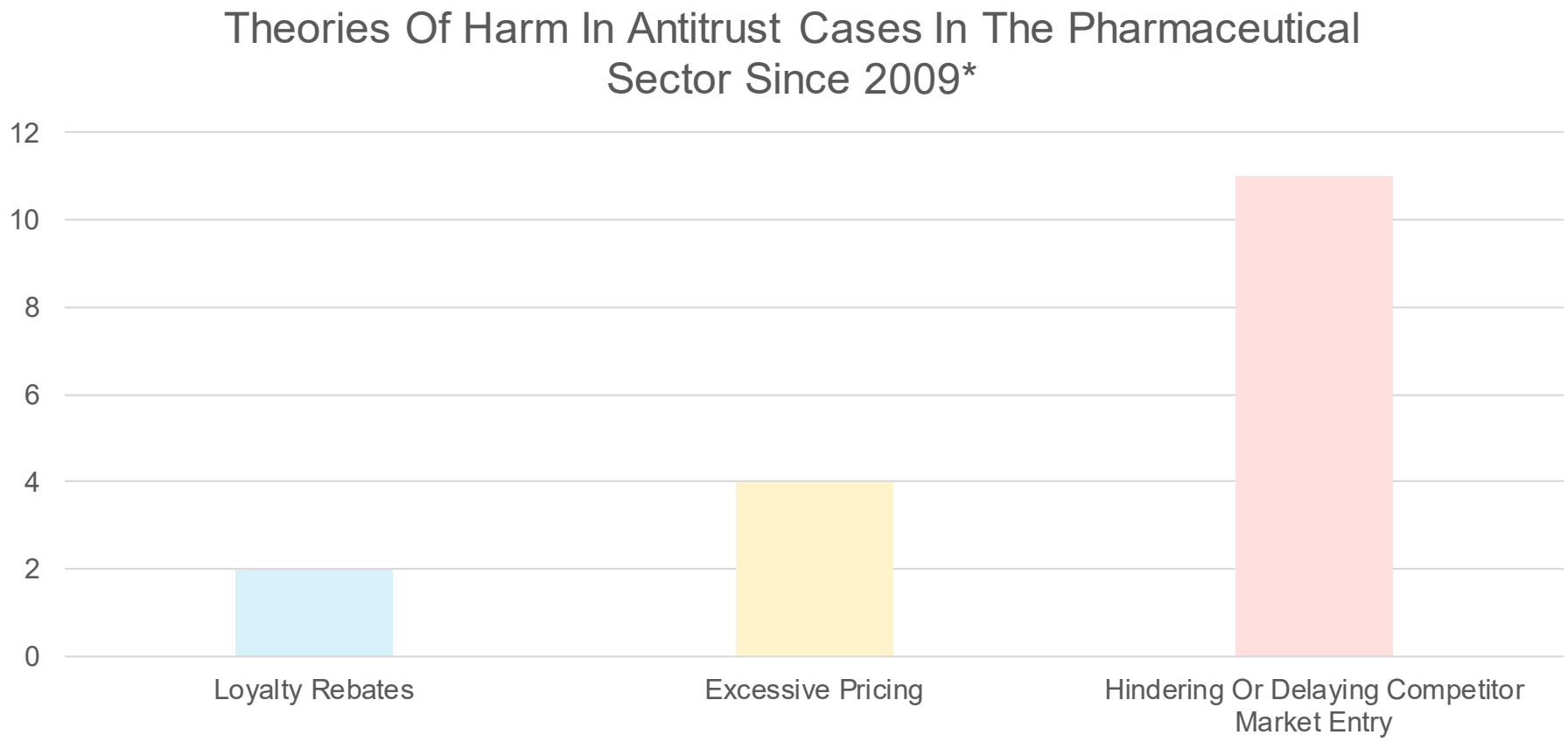
** Partially overturned by GC; pending appeal to ECJ

*** Partially overturned by CAT; remitted back to CMA

**** On appeal at Paris Court of Appeal

EC fining practice has increased exponentially in recent years; there is a high probability that future EC pharma cases would attract higher fines.

EU Enforcement In The Pharma Sector (3)



* This chart only includes cases where the EC/NCA issued a fine.