Bird&Bird TEUL CENTRE FOR A DIGITAL SOCIETY

Competition Law & Sector Regulation in the Telecom & Pharmaceutical Sectors

Brussels

22 March 2023



Welcome



Hein Hobbelen Partner

Bird & Bird



Marco Botta

Scientific Coordinator

European University Institute



Brussels seminar

Competition Law and Sector Regulation in the Telecom and Pharmaceutical Sectors

Prof. Marco Botta 22.3.2023

Centre for a Digital Society (CDS)

Areas





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Marco Botta Scientific Coordinator



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Marsida Nence Administrative Assistant



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Roberta Carlini Research Associate



Maria Alessandra Rossi Advisor

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Paolo Boldi University of Milan



Erik Bohlin **Chalmers University**



Irina Brass UCL



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CDS – next executive training courses

5 June – 7 June 2023, online: Regulating Digital Platforms: Competition Policy v. Ex-Ante Regulation >> REGISTRATIONS OPEN!

➢ 21-22 September 2023 (tbc), Brussels, DG CNECT: 6th Seminar for national judges on Electronic Communications.

➢ 4-6 October 2023, EU Court of Justice (Luxembourg): final workshop ENTraNCE for Judges 2023.

➢Hybrid courses (EUI campus + Zoom) >> 16 - 20 October 2023:

- 1) Florence Patent Licensing Academy.
- 2) Florence Competition Autumn School.



CDS – Policy Events in Planning

- 19 April 2023, webinar: 'Re-shuffling the Connectivity Ecosystem'.
- 24-26 May 2023, Gdańsk: 31st Postal Delivery and Economics Conference.
- 22-23 June 2023, EUI campus: Summer Digitalization Conference (co-organized with OECD),
 'Global Data Governance' ➤ REGISTRATIONS OPEN!
- 20 October 2023, EUI campus: Autumn Competition Conference.
- 6 December 2023 (tbc), EUI campus: scientific seminar, 'Regulation and Regulators in the Digital Age'.

Today's event

> Fourth seminar jointly organized by EUI and Bird & Bird.

Book launch: PARCU, MONTI, BOTTA (eds.) The Interaction of Competition Law & Sector Regulation, (Edward Elgar Publishing, 2022).

> Objective of the seminar: interaction of competition law and regulation in specific sectors:

- 1) Net neutrality and fair sharing in telecom.
- 2) Exessive prices in pharma.

> Key-note speech: Paul Csiszár, Director, DG Competition – European Commission



Today's event – practical information

• Broadcasting:

- 1) Conference broadcasted via LinkedIn + Zoom.
- 2) Zoom participants can ask questions to the panelists via the chat box ➤ NO microphone and camera.

• Hastag 🔰 🛅 : #BrusselsSeminar2023

• Video recordings: available on the event webpage after the conference.



Edited by Pier Luigi Parcu, Giorgio Monti and Marco Botta



THE INTERACTION OF COMPETITION LAW AND SECTOR REGULATION Emerging Trends at the National and EU Level



ENTraNCE books

ENTraNCE for Judges: training programme for national judges in EU competition law, organized by EUI and co-funded by DG Competition since 2011.

ENTraNCE books:

- 1) Published at the end of every edition of ENTraNCE for Judges.
- 2) Contributions from invited speakers and participant judges.
- 3) Edited by Parcu, Monti and Botta.
- 4) Objective: analysis of 'emerging trends at the national and EU level' in EU competition law.

> ENTraNCE books published by Edward Elgar:

- 1) Abuse of Dominance in EU Competition Law (2016).
- 2) Private Enforcement of EU Competition Law. The Role of the Damages Directive (2018).
- 3) EU State Aid Law (2020).
- 4) Economic Analysis in EU Competition Law (2021)
- **5)** Interaction of Competition Law and Sector Regulation (2022).

Objectives of the volume

> Objective: analysis of emerging trends in the interaction between competition law and regulation in the telecom, energy and pharmaceutical sectors.

> Interdisciplinary approach: contributions from lawyers and economists.

> Main topics discussed in the book:

- Co-investment agreements in building Very High Capacity Networks (VHCNs): overlap 1) between competition law and sector regulation.
- Failure to provide information by the energy operator as abusive conduct. 2)
- Excessive prices of drugs: overalp of competition law with IP/pharma regulation. 3)



Chapters in the volume

- **1) PARCU**, MONTI, **BOTTA**, Introduction to the volume.
- 2) CAVE, Liberalizing network utilities: economic principles and European regulatory experience.
- 3) CROCIONI, SILOS RIBAS, Could ex-ante regulation create incentives for anti-competitive behaviour?
- **4) VAN DUIJVENVOORDE**, *Regulating connectivity: linking the EU telecommunications framework to the digital future.*
- **5) PARCU**, ROSSI, Technology and the shifting boundaries of regulation and competition in the EU telecom sector.
- 6) COELHO, Competition law as an instrument for re-assigning radio spectrum and energi resources.
- 7) SIRAGUSA, SETARI, Recent EU and Italian trends in the energi sector: failure to provide information as abusive conduct.
- 8) PITRUZZELLA, Recent CJEU case law on excessive pricing cases.
- 9) **SCOTT**, The saga of a century old pharmaceutical remedy, phenytoin sodium sold in capsules.
- **10)** COLANGELO, Excessive pricing in pharmaceutical markets: recent cases in Italy and in the EU.
- **11) AKKER**, SAUTER, *Excessive pricing of pharmaceuticals in EU law: balancing competition, innovation and regulation.*



Thank you for your attention!

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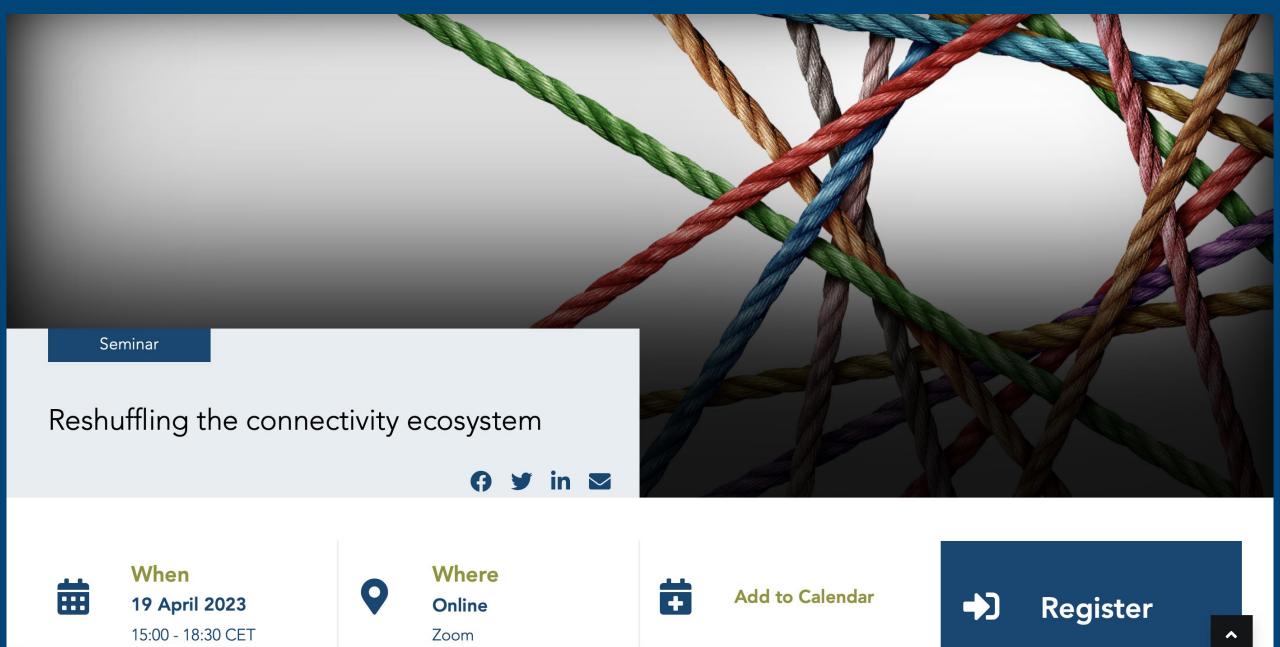




Net neutrality and fair sharing in the telecom sector

Dr. Anna Renata Pisarkiewicz Bird & Bird Brussels, 22 March



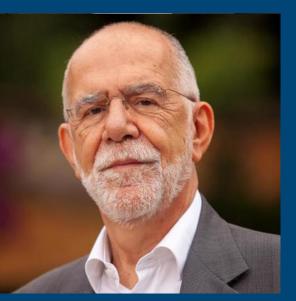


Panelists

Martin Cave Imperial College Business School



Pier Luigi Parcu European University Institute



Gera van Duijvenvoorde Leiden University & KPN



Peter Alexiadis King's College London



Exploratory Consultation: The future of the electronic communications sector and its infrastructure

Period: 23 February - 19 May 2023

1	TECHNOLOGICAL AND MARKET DEVELOPMENTS: IMPACTS ON FUTURE NETWORKS AND BUSINESS MODELS FOR ELECTRONIC COMMUNICATIONS	Q1 – Q20
2	Fairness for Consumers	Q21 – Q31
3	Barriers to the Single Market	Q32 – Q39
4	Fair Contribution by All Digital Players	Q40 – Q62



Political Commitment:

European Declaration on Digital Rights and Principles for the Digital Decade Joint Declaration of the European Parliament, the Council and the Commission 26 January 2022

Commitment to:

- developing adequate frameworks so that all market actors benefiting from the digital transformation assume their social responsibilities and make a fair and proportionate contribution to the costs of public goods, services and infrastructures, for the benefit of all Europeans.
- ensuring access to excellent connectivity for everyone, wherever they live and whatever their income
- protecting a neutral and open Internet where content, services, and applications are not unjustifiably blocked or degraded.



Political Commitment: EU's Digital Targets

Decision (EU) 2022/2481establishing the Digital Decade Policy Programme 2030



ICT Specialists: 20 million + gender convergence

Skills:

Basic Digital Skills: min 80% of population



Digital Transformation of Businesses **Tech up-take:** 75% of EU companies using Cloud/AI/Big Data

Innovators: grow scale-ups & finance to double EU Unicorns

Late adopters: more than 90% of SMEs reach at least a basic level of digital intensity



Secure and

sustainable

infrastructures

digital

Cutting edge Semiconductors: double EU share in global production

Connectivity: Gigabit for everyone

Data - Edge & Cloud: 10,000 climate-neutral highly secure edge nodes

Computing: first computer with quantum acceleration



Key Public Services: 100% online

e-Health: 100% of citizens have access to medical records online

Digitalisation of public services

Digital Identity: 80% of citizens have access to digital ID



Political Commitment:

Decision (EU) 2022/2481 of the European Parliament and of the Council establishing the Digital Decade Policy Programme 2030 14 December 2022

By 2030, networks with gigabit speeds should become available to those who need or wish to have such capacity. All Union end-users should be able to use gigabit services provided by networks at a fixed location deployed up to the network termination point. Moreover, all populated areas should be covered by a next-generation wireless high-speed network with performance at least equivalent to that of 5G. All market actors benefiting from the digital transformation should assume their social responsibilities and make **a fair and proportionate contribution** to the public goods, services and infrastructures, for the benefit of all citizens in the Union (Recital 13).



The future of the connectivity infrastructure: the problem and its roots

The issue: How do get from where we are today to the 2030 digital targets?

The problem:

- an investment gap of €65 billion per year, amounting overall to €250 billion to meet the European Gigabit Society interim targets by 2025.
- Hence, the investments need to reach the 2030 Digital Decade targets will need to be significantly higher.

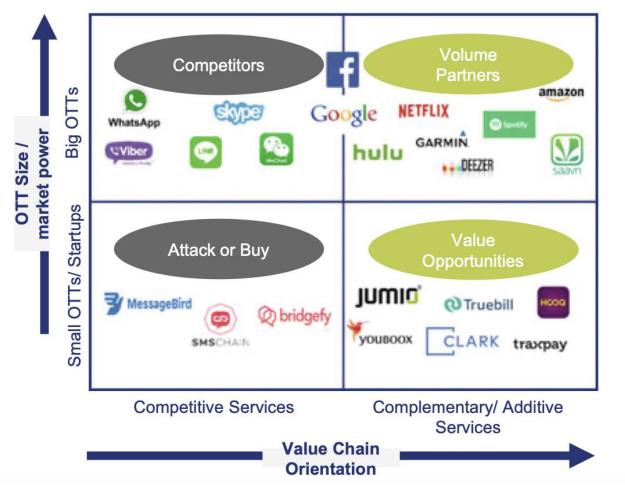
Potential causes behind the sub-optimal investment:

- Fragmented EU markets: barriers to in-country and lack of incentives for cross-border consolidation
- Intense competition and low ARPU (decreasing in mobile), despite increasing quality of broadband (higher speeds)
- Overly restrictive, too interventionist regulation, focused on static rather than dynamic welfare effects
- Strong net neutrality rules
- High but also very heterogenous spectrum fees across the EU MS
- Uncertain business case, low willingness to pay
- Overall performance of the telecom sector and difficulty to attract investment (investment cycles and returns)

Context: telecommunications market in which previous telco business models are under attack both on the retail and wholesale level.

Telcos v OTTs / CAPs





OTT-Player Types

Type "Competitor"

- Global Reach / high market strength
- Competitive Voice / Data offering to telcos

Type "Small offender"

- Limited market strength/ Startup type
- Threat to telco voice / data services

Type "Potential volume partner"

- Global Reach/high market power
- Services Complementary with telco

Type "Small OTT Service provider"

- Limited market strength/ Startup type
- Services complementary with telco

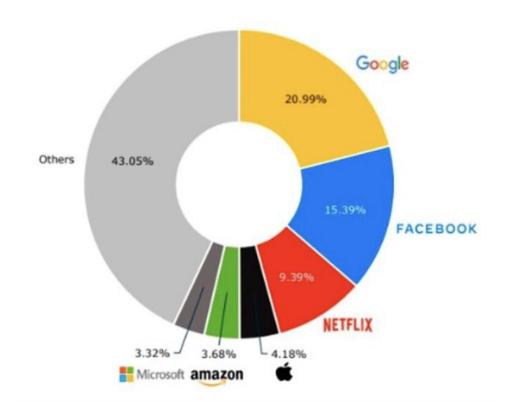
Source: Kramer and Jalajel (2018), OTT Partnering with Telcos: On the Rise

Large Traffic Generators:

Does data growth imposes costs that are unfair and unsustainable?

	Brand	2021	2022
1	Google	20.99%	13.85%
2	Netflix	9.39%	13.74%
3	Facebook	15.11%	6.45%
4	Microsoft	3.32%	5.11%
5	Apple	4.18%	4.59%
6	Amazon	3.36%	4.24%
TOTAL 56.35% 47.98%			47.98%

Source: Sandvine (2023), <u>The Global Internet</u> <u>Phenomena Report.</u>



Source: Source: Axon Partners Group (May 2022). Europe's internet ecosystem: socio-economic benefits of a fairer balance between tech giants and telecom operators.

Studies and reports on the topic



The future of the connectivity infrastructure: Main issues

Data traffic growth and its impact on costs and investment

- Does data growth imposes costs that are unfair and unsustainable?
- Is there any difference in the impact of data growth on costs in mobile and fixed networks?

Asymmetric bargaining power between major OTTs/CAPs and telecom network operators

- in relation to IP traffic? According to BEREC (2022): not an issue
- in the capillary, access network?

Telecommunications markets: in search for the right theory

- One-sided, two-sided markets or rather a connectivity ecosystem?
- Market vs ecosystem failures

Fair share and net neutrality

- Can these two co-exist?
- Unlevel playing field: traffic versus content prioritization

If there is an investment gap, and fair share/cost recovery from CAPs will not solve the problem or would in parallel raise disproportionate regulatory and transaction costs, what could be an effective way to close the investment gap?



Questions for debate: Round 1



- What has changed in comparison to the situation 10 years ago, when in response to telcos' complaints about the impact of the OTTs, Neelie Kroes unapologetically told the telecom operators to 'adapt or die'?
- What is the underlying problem/market failure that this consultation seeks to address? Is it sub-optimal investment? Can a contribution from traffic generators can be the right solution?
- Do you agree with framing the VHCN/broadband market as a two-sided market?
- How do connectivity goals, in your view, fit into the fair share debate?
- Could the EECC offer a legal basis for fair share? If additional investment were to be obtained from large traffic generators, who precisely should pay and to whom? Considering that the US FCC wants to address the connectivity problem by brining tech companies into universal service, could such an approach work in the EU instead of a very controversial direct compensation?
- One of the main concerns is that additional revenues obtained from CAPs might not necessarily be used for investment at all, or not for the right investment. Do you envision that it would be necessary to introduce a clear mechanism that would mandate how this money would have to be spent?

Questions for debate: Round 2



- Would you agree that we would not have a problem of under-investment today if we did not have strict rules on net neutrality as introduced by the Open Internet Regulation? What do know today about the impact of net neutrality rules on investment and economic welfare effects in general?
- Would it make sense to differentiate between weak and strong net neutrality?
- Do you see the Open Internet Regulation as the source of the problem or maybe the solution?
- Recently Meta has stopped paying to DT fees for data traffic, and the case which has gone to court will apparently be transferred from a court in Bonn to a specialised court in Cologne with expertise in competition issues. While according to BEREC preliminary assessment concerning the remuneration paid by large CAPs to ISPs from 2022 there are no problems that would require regulatory intervention, this case, as well as a case brought by SK Broadband (Korea) against Netflix show that existing agreements may nonetheless be problematic. How do such agreements fit into the Open Internet Regulation, and considering the German case, do you think we can expect more litigation between the telecoms operators and CAPs?





Thank you for your attention!

anna.pisarkiewicz@eui.eu











Competition Law and Sector Regulation in the Telecom and Pharmaceutical Sectors

Coffee break Back at 17.15



Excessive pricing in the pharmaceutical sector

Prof. Marco Botta

Brussels seminar, Bird & Bird 22 March 2023

 $\square \square \square$

Excessive pricing – legal test



- Art. 102(a) TFEU: dominant firm shall not 'impose directly or indirectly unfair purchase or selling prices' ≻ excessive pricing.
- United Brands test :
- 1) **Excessive limb**: the difference between price and costs is 'excessive'.
- 2) Unfair limb: the price is 'unfair in itself' OR 'unfair when compared to competing products'.
- Alternative test ➤ benchmarking approach:
- 1) NCA compares excessive price with a 'benchmark' price (e.g. competitors; different geographic areas):
- 2) *AKKA-LAA*: difference between excessive and benchmark price has to be 'appreciabily high', 'significant' and 'persistent'.
- 3) *Pfizer-Flynn*: NCA should verify its findings under multiple tests.
- 4) Dominant firm may put forward objective justifications.



Enforcement dilemma

• Authors AGAINST enforcement:

- 1) What is 'excessive'? What is 'unfair'? ➤ if some customers are ready to pay, the price is NOT excessive.
- 2) High prices attract new entrants ➤ markets self-adjust in the long term.
- 3) Sanctioning excessive pricing harms dominant firm's incentives to invest in its infrastructure and to innovate.
- 4) High burden of proof for the NCA; legal test is unclear.

• Authors PRO enforcement:

- Some products are 'indispensable': consumers have high 'willingness to pay' even in the presence of excessive pricing ➤ demand is NOT elastic.
- 2) Legal and *de facto* monopoly ➤ new entry is NOT possible.
- 3) Dominant firm may engage in rent-seeking behaviors, rather than innovating.
- 4) Burden of proof is high, BUT legal test has been clarified by CJEU case law.



Peculiarities of the pharmaceutical sector

- Demand of drugs is NOT elastic:
- 1) Some drugs are 'indispensable' for our health ➤ consumers have high willingness to pay.
- 2) Information asymmetry ➤ consumers buy a drug because of a therapy/prescription.

R&D investments and patents:

- 1) Drugs are released on the market after years of testing and receiving State authorization.
- Patents: temporary monopoly right to compensate past R&D investment by pharmaceutical firm ➤ 20 years + supplementary protection certificate (SPC) + orphan drugs.
- 3) High R&D investments + patent rights \succ entry barriers.
- State intervention: retail price cap + reimbursement by health care fund ➤ consequences:
- 1) Consumers demand is NOT elastic.
- 2) Price and availability of drugs changes in every EU Member State.



Main decisions sanctioning excessive pricing cases in pharma

• Pfizer-Flynn (UK):

- 1) In 2016, CMA sanctioned excessive price of phenytoin sodium capsules ➤ off patent drug against epilepsy.
- 2) Decision quashed by CAT in 2018, and by the Court of Appeal in 2020.
- 3) July 2022: new CMA decision ➤ CAT second ruling is pending.

• Aspen (IT):

- 1) In 2016, AGCM sanctioned excessive price of Cosmos (i.e. anti-cancer drug) ≻ similar to *Pfizer-Flynn*.
- 2) Decision fully upheld by *TAR Lazio* and *Consiglio di Stato*.
- Aspen (EU):
- 1) 2021 EU Commission commitment decision ≻ price cap.
- 2) Same infringement of AGCM decision, BUT Italy NOT assessed by EU Commission.
- Leadiant (NL):
- 1) In 2021, ACM sanctioned excessive price of Leadiant ≻ orphan drug against rare methabolic desease.

Autoriteit

Consument & Markt

2) Same case investigated by NCAs in IT, BE, ES.









Common features among the 4 NCAs decisions

- Drugs peculiarities:
- 1) Drugs target 'rare' diseases ➤ consumers' demand NOT elastic.
- 2) Limited demand ➤ NO new market entry after patent expiration.

• Off-patent drugs

- 1) Off-patent drugs: when patent expires, the price should decrease ➤ price increase unfair.
- 2) NO patent rights \succ NO innovation justification.
- 3) Exception: *Leadiant* case \succ orphan drug.

• Evidence of abuse:

- 1) Re-branding + sudden price increase without changing the product features ≻ price increase unfair.
- 2) Excessive price: price increase over 1000%.
- 3) Aspen: aggressive negotiation strategy with health care authority ➤ threat to withdraw the products from the market.
- Legal test:
- 1) United Brands test \succ price increase is 'unfair in itself'; difficult to identify 'competing products'.
- 2) Limited reliance on benchmarking approach \succ difference in price regulation among EU MS.



Questions for the debate



- 1) Should NCAs investigate excessive pricing cases in pharma? Would it be better for the State to intervene directly via price regulation?
- 2) What is the role of an 'exploitative strategy' by the dominant firm in the assessment of an excessive pricing case (e.g. Aspen aggressive negotiation strategy with health care authority) ?
- 3) Should NCAs enforcement against excessive pricing be limited to off-patent drugs, or include drugs covered by patent rights (e.g. orphan drugs)?
- 4) Can a price be considered as 'unfair in itself' under *United Brands* test? What type of evidence should the NCA put forward in the case?
- 5) What is the role of the 'benchmarking approach' in the assessment of excessive pricing of drugs?
- 6) Incentive effect of commitment v. infringement decisions in an excessive pricing case? www.eui.eu

Panelists

Baptist Vleeshouwers Bird & Bird **Ilan Akker** Dutch Authority for Consumers and Markets Margherita Colangelo University Roma Tre







Adam Scott UK Competition Appeal Tribunal





COMPETITION APPEAL TRIBUNAL

Introduction

- Pfizer and Flynn have both appealed the CMA's retaken Decision on *Phenytoin sodium*
- I can summarise the grounds but, as it is sub judice, I can't discuss the merits
- And what I say today should not be taken as a policy or prediction of a position after due evidence and argument

Adam Scott

Costs, comparables and fairness

- United Brands led to a search for unfair in itself or by comparison
- Napp [2002] CAT 1 [90] variety of methods based on costs and comparables
- *Napp* approved by the AG in *Latvian Copyright*
- How are competition authorities let alone courts to handle the volume of evidence that economists can generate ?
- Fair and unfair are qualitative terms and hard to define
- Judges have to assess procedural fairness and substantive unfairness

Pfizer – summary of grounds

- 1. Real world indicators of value ignored
- 2. Narrow focus on cost-plus analysis contrasted with QALY analysis like NICE and value for money
- 3. Excluding alternative methods and especially demand-side factors
- 4. Procedural unfairness
- 5. Penalty appeal

Flynn – summarised grounds

- 1. Findings tainted
- 2. Returns consistent with comparators
- 3. Pricing in line with comparators or not out of all proportion
- 4. Pricing not high enough to be abusive
- 5. Flynn's risks not captured
- 6. Not recognising economic value beyond cost-plus nor Flynn's role in assuring security of supply

What is the context for fairness ?

- Pfizer mention QALY and NICE
 - NICE is the UK's National Institute for Clinical Excellence and
 - QALY is
- Generically national health services or systems of social security with reimbursement have to work out what treatments are worth supporting financially
- They are in a weak position when a treatment seems essential to continue or to endorse for introduction
- BUT treating one patient may mean denying treatment to others

What is the overall context in Pharma?

We want

- A healthy pharmaceutical industry
- Risks managed through regulated distribution
- Innovation to continue
- Security of supply

We have

• Complexity in partial regulation, market authorisation, prescribing practices and patients accustomed to particular formulations

What is the context of an old but seemingly essential drug?

- Patients and medical practitioners are relying on such drugs
- Manufacturers and distributors if alone or otherwise dominant therefore have leverage
- Manufacturers and distributors may have their power reinforced by structural factors and behavioural patterns
- Those responsible for procurement or for reimbursement are therefore generally weak in market terms

Questions for the debate



- 1) Should NCAs investigate excessive pricing cases in pharma? Would it be better for the State to intervene directly via price regulation?
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- 5) What is the role of the 'benchmarking approch' in the assessment of excessive pricing of drugs?
- 6) Incentive effect of commitment v. infringement decisions in an excessive pricing case? 22 March 2023 Dr Adam Scott

The task for me

Adam concludes the first round of interventions as the only one to discuss the last question concerning infringement v. commitment decisions in excessive pricing cases.

The task for authorities and for courts

- Investigations are heavy on effort and cost
- Excessive pricing has not proved easy to prove
- There is great capacity for appeals
- There is considerable risk if a finding is upheld
 - Of substantial fines and
 - Even more substantial claims for damages

So what of commitments

- EVP Vestager on Aspen: a strong signal not to engage in abusive pricing
- Aspen's commitments offered a fast, comprehensive and lasting solution
 - Price reductions
 - Continued supply
- Breach of commitments could lead to significant fines
 - Without any finding of infringement
- Commitments don't exclude national private actions for damages
 - EUCJ Case C-547/16 Gasorba v Repsol



ROBERT SCHUMAN CENTRE

Thank you for your attention!

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