RECONCILING COMPETITION AND IP LAW: PATENTED PHARMACEUTICALS AND DOMINANCE ABUSE

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CIPIL conference “Is IP good for our health?” Cambridge 7 March 2020
Pharma growing share of annual healthcare costs
9% share of €72 Bn total healthcare budget; 1/3 pharma intramural with 7-9% annual growth
Strains overall cap hospital care decreasing from 0.8 (2019) to 0.0 (2022)

Pricing problem areas
Repurposing of existing drugs with limited new research and price hikes
Extremely priced new patented and orphan drugs
High volume expensive drugs

Regulation/government intervention
Generic price cap based on external reference pricing ineffective
Only limited centralised price negotiations

Other solutions tried so far
Extramural/outpatients: selective purchasing
Intramural/inpatients
☐ Add-on pricing
☐ Promote collective purchasing
☐ Pursue a more active competition policy

To what extent is the latter compatible with IP rights?
Patented pharmaceuticals
Protecting innovation and property
- IP rights as an absolute bar to antitrust?
- Cautious approach by EU antitrust authorities

Proposed approach
IP and competition rules apply in parallel
- A patent is not always a relevant market
- Coexistence of IP and competition principles

Case law on exclusion
- Cases 56/64 & 58/64 Consten (1966): IP not to frustrate cartel prohibition
- Case 24/67 Parke, Davis (1968): IP right existence ≠ dominance per se
- Case 15/74 Centrafarm (1974): IP right exercise may constitute abuse
- Case C-457/10 AstraZeneca (2012): abuse of patent system as abuse

“As [the General Court] pointed out, the illegality of abusive conduct under Article 82 EC is unrelated to its compliance or non-compliance with other legal rules and, in the majority of cases, abuses of dominant positions consist of behaviour which is otherwise lawful under branches of law other than competition law.” (AstraZeneca, para 132)

Pay for delay cases
- Case T-472/13 Lundbeck (2016): restrictive agreement possible within scope patent
- Case T-169/14 Servier (2018): generics are potential competitors even within scope
- Case C-307/187 Generics (2020): idem + balancing of proven co-competitive effects
**Competition law preference for enforcing prohibition on exclusion**
Stay out of price regulation; let markets fix themselves; what is an unfair price?

**Yet recently move from pay for delay cases to excessive prices**
Prosecution of exploitative abuse off-patent drugs
- Aspen (Italy); Pfizer/Flynn (UK); CD Pharma (DK); Aspen (COMP)

**Now from off-patent to IP protected and orphan drugs?**
Fair price: taking incentives to innovate into account
Including in cost-plus context (step 1)
- Investments in innovation
- Probability of success
- Life cycle approach
- Portfolio effects

**Market definition and dominance**
Role of IP regulation
Countervailing market power?
Off-label; pharmacy preparation as substitutes?
How to avoid overinvestment in social welfare terms?
Role of HTA and Qaly/ICER:
- Price cap
- Willingness to pay
- Comparator across products?

Public (price) intervention
External reference pricing (price cap) ppp based
Managed entry agreements
Horizon scanning

Promote competition for the market
Tendering
Preferential sourcing
Joint purchasing initiatives
- At national scale
- At international/EU scale
- Effective switching v volume
Adjust regulation
Close regulatory loopholes/gaps
❑ Revision of orphan regime
❑ HTA (method) at EU level

Open regulatory loopholes
❑ Promote pharmacy preparation
❑ Compulsory licensing – also as competition remedy

More effective competition enforcement
Develop a framework to take innovation into account
Win or lose: at least try enforcing the rules
Develop experience and track record

Academic contribution: shed more light on
❑ Balance between innovation, access and affordability
❑ IP rights and competition principles
❑ Competition versus regulation
❑ Alternative funding models
COMPULSORY LICENSING IN PHARMA

Based on Article 31 TRIPS agreement
Use Without Authorization of the Right Holder
- Requirement of prior negotiations on reasonable terms
- Adequate remuneration based on economic value
- Judicial recourse

Exceptions
- Remedy for anti-competitive practices
- Interim measures
Pharma specific issues
- Fair value, access to data, public health

As a competition law remedy
Voluntarily as part of a settlement and/or commitment
Enforced as any proportional effective behavioural or structural remedy
- Including access to data
- Parallel to TRIPS implementation, as part of it, or direct effect?