



ACM Decision 24 september 2014
AstraZeneca (Nexium)

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Overview

- Introduction and remarks
- Introduction of the case
- Construction of the case and theory of harm in SO
- PPI's
- Hospital Market vs. Community Market; spill over effect
- Abuse: exclusionary strategy
- Evidence of dominant position: a market for locked-in users of Nexium?
- Final remarks

Introduction

- Clear harmful conduct
- Strategy considerations
- 102 TFEU (24 DCA) appropriate route
- Innovative market definition
- Proving dominance: evidentiary limits
- No dominance, no fine
- Published decision

remarks

- Importance of factual evidence
- 102 TFEU in a legal, economic and medical/pharmaceutical playing field
- Is ACM acting as a IPR legislator? Effects on innovation by enforcement
- A non-confidential version English version will be available on acm.nl

Introduction of the case

- ACM Case AstraZeneca (*Nexium*) shows difficulties with enforcement of Article 24 CA, 102 TFEU
- Complexity of pharmaceutical sector: IP rights, regulation; prescription, use, payment in different hands
- Consumer harm: Possibly the introduction of generic drugs was hampered
- No infringement: dominance doubtful
- Ingenious (novel) theory of harm, vulnerable in court

Proton Pump Inhibitors

- Dutch market for PPIs: heartburn, gastroesophageal reflux disease, gastric ulcers
- First PPI: Losec (omeprazol)
- After expiry of patent, in 2002 entry of generic omeprazol
- New patented PPIs also enter the market: brand names Prezal, Pantozol, Pariet and Nexium (by AstraZeneca)
- Active ingredients almost similar to Losec
- (Contested) statement of objections (SO) stipulates virtually full therapeutic interchangeability of PPIs

Hospital Market vs. Community Market I

- (Small) hospital market:
 - Purchase by hospitals
 - Budget restrictions
 - Take into account both price and quality/therapeutic value
 - Negotiated prices
 - Prescriptions by specialist limited to the hospital ‘formulary’
- (Large) community market:
 - Purchase by community pharmacies
 - Price set by AstraZeneca, subject to regulated price cap
 - Prescriptions by specialist and general practitioners on the basis of active ingredient (molecule structure)
 - Pharmacy must deliver according to prescription; full reimbursement by insurance companies

Hospital Market vs. Community Market II

- Hospital market:
 - All PPIs compete with each other
 - High discounts/low prices for Nexium (and other branded PPIs)
 - One market for all PPIs
- Community market:
 - Policy of insurance companies: pharmacy receives generic price
 - Stimulates competition between drugs with the same active ingredient (Losec and omeprazol generics)
 - Patented drugs are not subject to this policy → much higher prices
 - One market or more?

Spill over effect I

- Prescriptions in hospitals lead to follow-on prescriptions in community market
- Plus ‘endorsement effect’
- Statistical relationship: no mechanical relationship, no causal link
- Positive correlation: general practitioners “tend to follow” hospital prescriptions

Spill over effect II

- Two functions in theory of harm:
 - Creates '*locked-in*' users of Nexium → dominant in separate market
 - Through spill over effect more hospital sales result in more community sales → element of abuse
 - Quantity of spill over effect:
 - SO: calculation of spill over effect not necessary; proof of its existence and use by AstraZeneca suffices;
 - AstraZeneca: spill over effect is not appreciable
- ACM effort to estimate the follow-on effect based on data in the file

Abuse according to SO I

- Price-costs investigation revealed: hospital price Nexium below Average Avoidable Costs
- Not possible to match by suppliers of generic omeprazol
→ foreclosure of the hospital market
- Through spill over effect AstraZeneca can artificially enhance its sales of Nexium on the community market at much higher prices
- Profitable strategy of AstraZeneca at the expense of users on the community market: equally well-off with generic omeprazol → consumer harm

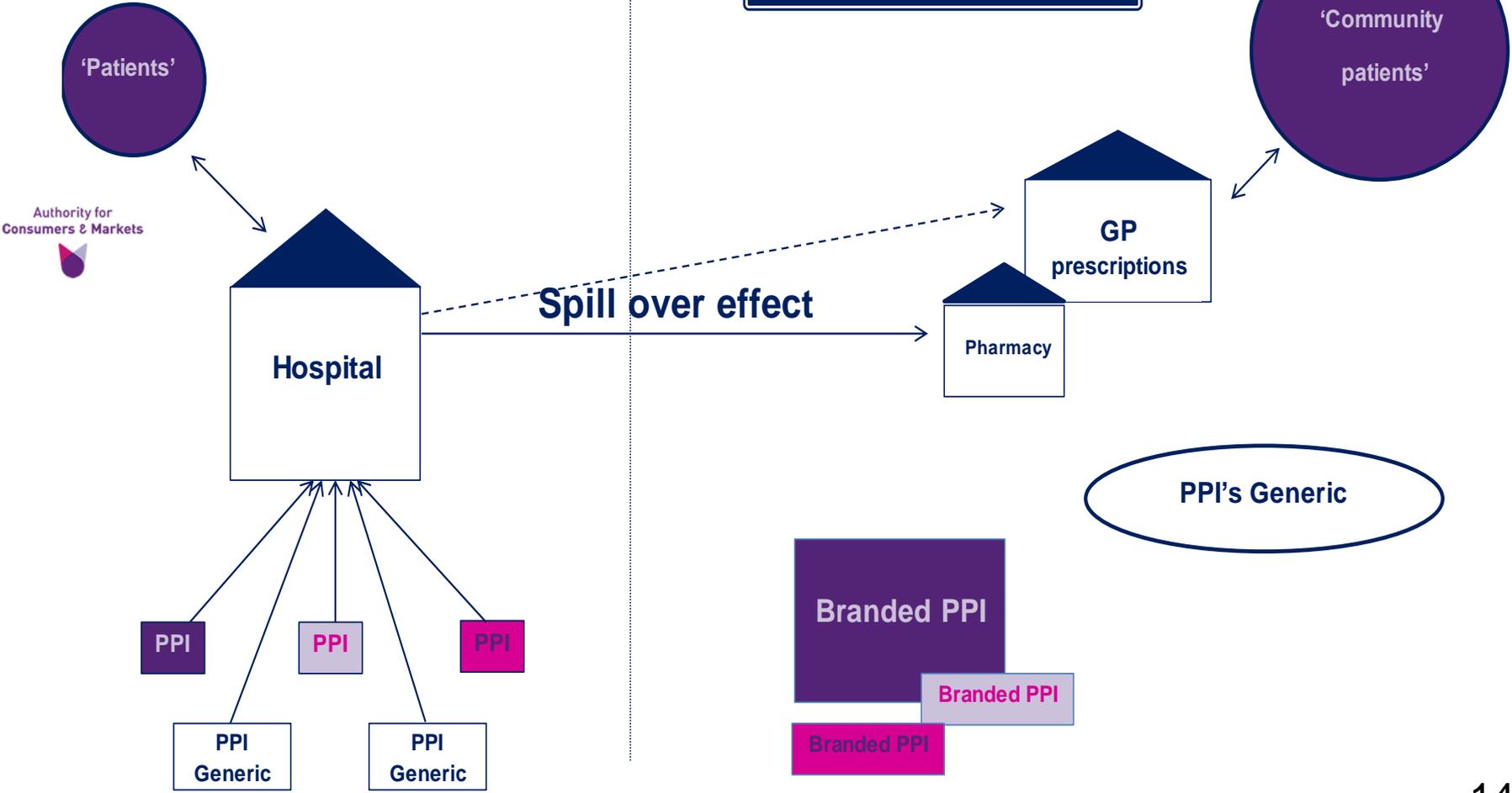
Abuse according to SO II

- Abuse
 - No accusation of discriminatory pricing
 - No accusation of excessively high community prices
 - No accusation of ‘evergreening’ (Losec not withdrawn from the market)
 - But: pricing practice causing foreclosure on hospital market and harm on the community market

Abuse – discussion (not in Decision)

- SO: “there is no other reasonable explanation for incurring losses on the hospital market”
- AstraZeneca’s counterarguments:
 - A clever and profitable marketing strategy is not an abuse in the sense of the competition rules
 - Meeting competition of branded PPI’s.
 - Suppliers of generic drugs are not “as efficient competitors” because they have a totally different business model; they are not interested in the hospital market anyhow

- Patent vs. generics
- Reimbursement system
- Preferred supplier policy
- Spill over effect



Relevant market en dominant position I

- SO: a separate community market consisting of users who, due to the spill over effect, were bound to Nexium
- For this group by definition 100% market share
- Interesting: the locked-in 'group' is identified only in a statistical sense → limited factual prescription data
- AstraZeneca: reasoning of SO lacks logic: dominance implied in the supposed abuse

Relevant market & dominant position II

- AstraZeneca's other counterarguments:
 - Separate market comes into being from day One and the market could in theory consist of just one bound user - that doesn't make sense
 - Users are not 'bound': spill over effect is too weak
 - GP's free to choose at all times
 - Countervailing power exercised by insurance companies

Construction of the case and theory of harm questioned

- Unprecedented: dominance on separate part of community market; abuse on hospital market
- Extra profits on the community market enabled high discounts on the hospital market: regular “investment”?
- Community market: extra sales of Nexium at the expense of generic PPIs: but not on the same market with each other?
- Really a competition problem or a matter of making use of particular circumstances, e.g. the Dutch system of health care insurance?
- Medical discussion: other PPIs as effective from a therapeutical point of view as Nexium?

Final remarks

- No determination of dominance
- No infringement, no fine
- Importance of factual evidence
- 102 TFEU in a legal, economic and medical/pharmaceutical playing field
- Is ACM acting as a IPR legislator? Effects on innovation by enforcement
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