

Lifecycle Management and EU Competition Law

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- **Legal Framework**
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 - Denigrating Competitors
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LEGAL FRAMEWORK

- EC and Member States have identified life cycle management strategies as competition law violations on different grounds.
- Article 101 TFEU prohibits agreements between undertakings that restrict competition.
- Article 102 TFEU prohibits certain abusive practices by companies holding a dominant position.
 - What constitutes a dominant position?
 - » Relevant pharmaceutical markets
 - » Market share
 - » Highly specific to the pharmaceutical industry and actual conduct involved.

AstraZeneca (EU)

- AZ made misrepresentations vis-à-vis national patent offices and national courts which led to the grant of SPCs for Losec.
- The General Court ruled (1/7/2010):
 - Misrepresentations by a dominant company before public authorities that lead to the grant of an exclusive right to which an undertaking is not entitled, or to which it is entitled for a shorter period, may constitute an abuse within the meaning of Article 102 TFEU.
- AZ's dominant position was assessed on national markets for oral formulations of prescription proton pump inhibitors.
- This ruling has been upheld by the ECJ (6/12/2012).

Boehringer Ingelheim (EU)

- In July 2011, the European Commission closed its investigation into allegations that BI applied for unmeritous patents, following a settlement between the parties removing BI's potential blocking position.

MISLEADING REGULATORY AUTHORITY (CONT'D)

Pfizer (Italy)

- On 17 January 2012 the Italian competition authority imposed a fine on Pfizer for abusing its dominant position by:
 - artificially extending the duration of the Italian patent protection through divisional applications and an SPC;
 - exploiting the state of legal uncertainty to delay generic entry;
 - starting an aggressive legal campaign to enforce its exclusive rights against companies preparing the launch of generics (legal warnings and threatening with civil and administrative actions).
- The authority concluded that Pfizer had a dominant position on the market for commercializing glaucoma medicines based on the active ingredient latanoprost.
- The authority's fine has been upheld by the Italian Council of State (20/1/2014), after it was annulled in first instance.

Pfizer (Spain)

- On 19 December 2012, the Spanish competition authority announced that it had opened formal proceedings against Pfizer over concerns that the company may have unjustifiably delayed the market entry of generic medicines through artificial patent prolongation in Spain.
- However, on 13 February 2014 the authority closed the investigation after concluding that the Pfizer's patent prolongation did not amount to an infringement of Article 102 TFEU.
 - The authority applied the AstraZeneca ruling, but concluded that these conditions were not met.

DENIGRATING COMPETITORS

Sanofi-Aventis (France)

- On 14 May 2013, the French competition authority fined S-A for implementing a practice of driving out competition by disparaging generic versions of its Plavix product to healthcare professionals in order to favor sales of the original product and S-A's own generic version.
 - The authority found that S-A had implemented a global and structured communication strategy in order to squeeze generic suppliers competing with Plavix out of the market in two stages:
 - by discouraging doctors at the prescription stage from substituting Plavix with generic medicines by instilling doubts as to their quality and safety in terms of bioequivalence, without any substantiated evidence based on verified fact;
 - by strongly urging pharmacists to sell its own generic substitute.
 - S-A was deemed to hold a dominant position in the French market for clopidogrel supplied outside hospitals.
 - This decision is subject to appeal.
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DENIGRATING COMPETITORS (CONT'D)

Schering-Plough (France)

- On 19 December 2013, S-P was fined by the French competition authority for disparaging Arrows' generic product and for offering pharmacists discounts to stock its Subutex product.
- S-P organized seminars and telephone meetings and prepared sales pitch templates for its medical and pharmaceutical representatives so that they could disseminate an alarmist message to doctors and pharmacists on the risks of prescribing or dispensing the Arrow generic, even though it did not have access to any specific medical study to justify such a position.
- S-P was deemed to have a dominant position on the French market for high-dosage buprénorphine sold outside hospitals.
- This decision is subject to appeal.

DEREGISTERING TO DELAY ENTRY

AstraZeneca (EU)

- AZ deregistered marketing authorizations for the Losec capsule in various Member States in combination with the withdrawal from the market of the Losec capsules and the introduction of Losec MUPS tablets.
 - Pursuant to EU law in force at the time of the decision, a market authorization for a generic product could be granted pursuant to a simplified procedure only if the original reference product was still registered. AZ practices thus delayed and made more difficult the marketing of generic products competing with Losec.
- The General Court ruled (1/7/2010):
 - A dominant company cannot use regulatory procedures in such a way as to prevent or make more difficult the entry of competitors on the market, in the absence of legitimate reasons to defend its commercial interests or another objective justification, and this is the case irrespective of "its compliance or non-compliance with other legal rules."
- This ruling has been upheld by the ECJ (6/12/2012).

DEREGISTERING TO DELAY ENTRY (CONT'D)

Reckitt Benckiser (UK)

- On 15 October 2010, the UK OFT (now CMA) reached an early resolution agreement with RB whereby the company admitted an infringement of Article 102 TFEU.
- RB was deemed to hold a dominant position in the market for the supply of heartburn medication to the National Health Service (NHS).
- RB had withdrawn and de-listed its Gaviscon Original Liquid product from the NHS prescription channel, after the product's patent had expired but before the publication of a generic name for it. This meant that more prescriptions would be offered for its alternative patent-protected product, Gaviscon Advance Liquid.
 - Where a medicine's patent has expired and a generic name has been assigned to it, doctors can use their prescribing software to search for the brand and then provide their patients with an open prescription that lists its generic name. The pharmacy that dispenses the medicine can then choose whether to dispense the branded medicine or a cheaper generic medicine.

PREDATORY PRICING

Napp Pharmaceutical (UK)

- On 30 March 2001, the OFT (now CMA) found that Napp had abused its dominant position in the supply of its MST sustained release morphine tablets and capsules in the UK.
 - The OFT concluded that virtually the only viable means of gaining entry to the “community segment” (i.e. GP’s) of the market was through the “strategic gateway” of sales to hospitals.
 - By matching the prices offered by competitors with discounts in excess of 90% off its list prices, Napp effectively foreclosed the hospital segment of the market. Napp’s prices in the hospital segment were below average direct cost.
 - By charging to the community segment prices that were on average well over 10 times higher than its price in the hospital segment, Napp abused its position. Napp’s prices and margins were significantly higher than on its other products and significantly above those of its competitors.
 - The OFT imposed directions that regulated the prices for MST.
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PREDATORY PRICING

GlaxoSmithKline (France)

- On 14 May 2007, the French competition authority held that GSK was guilty of predatory pricing in the market for cefuroxime — a market in which it did not hold a dominant position — in order to protect its dominance in the market for injectable acyclovir (Zovirax) and prevent generics from entering the hospital medicines market.
- GSK's strategy was allegedly to build a reputation of predator in a small non dominated market
- The decision of the authority was overruled by the Court of Appeal which found that the links between the dominated market and the market where the abuse took place were not sufficiently strong. This judgment has been confirmed by the French Supreme Court.

EXCLUSIONARY REBATES

Schering-Plough (France)

- On 18 December 2013, S-P was fined by the French competition authority for, amongst other things, offering pharmacists discounts to stock its Subutex product.
- In anticipation of the generic entry, S-P saturated pharmacy aisles by offering discounts and easy payment options, with the effect that pharmacists had enough Subutex in stock to last several months.
- This decision is subject to appeal.

In 2005, also the Finnish competition authority expressed concerns over a rebate arrangement between pharmaceutical companies and pharmacies.

REFUSAL TO LICENSE

Merck (Italy)

- Merck found to be dominant in the market for the production of the carbapenem active ingredient, essential for the production of carbapenem antibiotics.
- Merck's patent rights valid in Italy but patent right expired in most other EU countries.
- Refusal to license Italian manufacturer Dobfar who requested license to produce the active ingredient for export deemed abusive.

Glaxo (Italy)

- Glaxo found to be dominant in the market for migraine drugs based on patent on intermediate product.
- Refusal to license Italian manufacturer to produce product for sale in Spain deemed abusive.

Sandoz (France)

- On 24 July 2003, the French competition authority imposed a fine on Sandoz for granting university hospitals discounts on the purchase price of two cyclosporin products on condition that the hospital also purchased other Sandoz products.
- The authority found that Sandoz abused its dominant position in the market for cyclosporin to foreclose competitors – which included generic competitors for its products - in the markets for other pharmaceutical products.

ANTI-COMPETITIVE AGREEMENTS

Novartis-Roche (Italy)

- On 27 February 2014, the Italian competition authority found that Roche and Novartis infringed Article 101 TFEU by taking part in an anti-competitive agreement in the market for ophthalmic drugs.
- The authority analyzed the agreement under the by-object and the by-effect standard.
- The authority concluded that Roche and Novartis created an artificial product differentiation between Avastin (Roche) and Lucentis (jointly marketed by Roche and Novartis).
- Lucentis and Avastin work in similar ways though Avastin was developed and approved as a cancer drug. Because of the similarities, some doctors prescribe Avastin for eye disease because it is significantly less expensive.

- The authority alleged that Roche and Novartis claimed that Avastin is more dangerous than Lucentis, in order to influence prescriptions by doctors and health services.
- Novartis holds a more than 30% of the shares in Roche and was therefore deemed to benefit both directly and indirectly from the alleged collusion.
- Both parties have appealed the decision.

- No consistent approach to market definition.
- Market definition varies by authority and products concerned.
 - ATC 3 or ATC 4 class
 - Condition treated
 - Molecule
 - Channels (pharmacies v hospitals)

CONCLUSIONS: ENFORCEMENT BASED ON ANTICOMPETITIVE AGREEMENT

- The Novartis-Roche case was based on a by-object and by-effect standard
 - On 11 September 2014, the ECJ raised the standard for by-object infringements in Case C-67/13 P *Groupement des cartes bancaires*:
 - “in order to determine whether an agreement (...) reveals a sufficient degree of harm to competition that it may be considered a restriction of competition ‘by object’ (...), regard must be had to the content of its provisions, its objectives and the economic and legal context of which it forms a part.”
 - “The concept of restriction of competition ‘by object’ can be applied only to certain types of coordination between undertakings which reveal a sufficient degree of harm to competition that it may be found that there is no need to examine their effects” (para. 58).
 - Limitation for competition authorities to apply by-object approach and forego establishment of competitive harm (See also Glaxo/Spanish Pricing).
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EducationLL.M., The University of Chicago Law School,
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Ms. Vandenborre's practice focuses on EU and international merger control and competition law enforcement.

Her enforcement work in the pharmaceutical sector includes the representation of GUK, a Mylan, Inc. affiliate in the first reverse payment patent settlement investigation by the European Commission. She is currently representing the company in the appeal before the EU General Court against the Commission's decision. Ms. Vandenborre previously was involved in the representation of a pharmaceutical company in relation to an Article 102 action initiated by an EU Member State competition authority based on life cycle management issues. She also assisted in the successful appeals before the EU General Court, and subsequently the EU Court of Justice leading to the annulment of a Commission decision finding that GlaxoSmithKline's pricing policy violated Article 101 by restricting parallel imports between EU Member States.

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