Parallel Trade and EU Competition Law
A survey of practice in the EU Member States

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Parallel Trade

- National price regulation for pharmaceutical products – significant price differences across Europe.
- Leads to arbitrage opportunities between "low price" countries (Greece, Spain, France, new Member States?) and "high price" countries (e.g. UK, Germany, Scandinavia).
- Loss of profit for pharma companies – gain for parallel traders – but where is the benefit to the consumer? Loss of profit for pharma companies may mean less R&D.
  - But see ECJ in *Sot Lélos* - the EU’s highest court is sceptical.
- For data: OFT market studies (2007); see also Kanavos/Holmes, Pharmaceutical Parallel Trade in the UK, 2005.
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Typical business practices

• Prohibition to resell or export in supply agreement;
• Dual pricing policies (for home use/ for export);
• Limitation of supply (Stock Allocation Schemes);
• Rearrangement of distribution systems;
• Direct to pharmacy sales;
• Measures that make import effectively more difficult (packaging, labeling, etc.).
EU Competition Law in the EU Member States
Legal Background (1)

- **Article 81 (1) EC prohibits**
  - Agreements or concerted practices (*cf.* Bayer/Adalat);
  - Between undertakings or associations of undertakings;
  - Which have as their object or effect the prevention, restriction or distortion of competition, and
  - Which may affect trade between Member States;
- **Unless the conditions of Article 81 (3) EC are met (*cf.* GSK-Spain)**
  - Agreement contributes to improving the production or distribution of goods, or promotes technical or economic progress,
  - While allowing the consumer a fair share of the resulting benefit,
  - Is indispensible to achieve objective, and
  - Does not eliminate competition in respect of a substantial part of the products in question.
- **Article 82 EC prohibits**
  - Any abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it.
**Article 3 Regulation 1/2003:**

- If a measure may affect trade between Member States, Article 81 EC and Article 82 EC are directly applicable in the EU Member States and take precedent;
  - Business measures which do not violate Article 81 EC cannot be prohibited based on the national Article 81 EC equivalent;
  - But: Stricter national provisions relating to the abuse of a dominant market position are possible, even where Article 82 EC is directly applicable.
- National law alone applies where there is no effect on trade between Member States (unlikely in parallel trade cases);
- Member States may of course regulate business conduct based on other policy objectives (but need to be consistent with the EU Treaty, e.g. Article 28 EC, Article 86 EC etc.).
**EU Competition Law in the Member States**

**Procedural Framework**

- **Actions by parallel traders against business practices of pharmaceutical companies (typically in low price countries).**
  - Complaints to NCA;
  - Action in a national court (performance, and/or damages).

- **Actions by pharmaceutical companies against business practices of parallel traders (typically in high price countries)**
  - Usually IP, trademark, repackaging issues (court actions);
  - Competition law aspects possible, usually secondary;
  - Risk of “abuse of process” argument?

- **Any national court can refer, the highest Court must refer question to the ECJ, if divergence from EU rules (Article 234 EC)**
  - Syfait (C-53/03) - Competition authority not a „court“.
  - Sot Lélos (C-468/06 et al) – national court to assess „ordinary supplies“
France

- Two sets of decisions relating to supply quotas – first concerning exporters; second concerning wholesalers.

- Public service obligation of wholesalers in France:
  - Satisfy the orders of all pharmacies located on their claimed geographic sector;
  - Offer at least 90 per cent of the medical products existing in France;
  - Hold a permanent stock representing two weeks’ worth of supply;
  - Deliver any medical product in it’s stock within 24 hours.
France – The Exporter Case

• French NCA, decision of 20 December 2005 – Pharma-Lab (not appealed, final)
  • Rejects complaint by exporters, Pharma-Lab and others against major pharmaceutical manufacturers because of reduction of supply quotas;
  • NCA finds some parallel conduct, but no agreement/ concurrence of wills has been proved between either manufacturers, or manufacturers and wholesalers.
  • NCA finds no abuse of a dominant market position
    • Specific regulatory and economic context; a quota system for exporters or wholesalers would be economically unjustified and create barriers to entry;
    • Demise of exporters would not abolish parallel trade as national wholesalers remain in the market;
    • No distortion of competition, as exporters are free to become wholesalers (with the public service obligations).
France – The Wholesaler Case

• French NCA, three decisions of 5 July 2007 and 13 December 2007, CSRP/Phoenix Pharma.
  • Complaints by Chambre syndicale de la repartition pharmaceutique ("CSRP") and Phoenix Pharma;
  • Manufacturers apply supply quotas to individual wholesalers;
  • Manufacturers offered commitments to amend supply system to increase fluidity, flexibility and transparency, primarily:
    • Periodic adjustment of quotas in line with demand;
    • Improve information to wholesale distributors;
    • New entrants obtain distribution quotas to start their business activities.
  • NCA found commitments satisfactory.
• Paris Court of Appeals annulled for procedural reasons (access to file) with Judgment of 26 November 2008.
Greece – The Syfait, Sot Lélos saga (1)

Once upon a time …

- **November 2000** GSK stops supply to certain Greek wholesalers, because of shortages, and starts to distribute to Greek hospitals and pharmacies through Farmacenter;
- GSK applies for negative clearance to Greek NCA (withdrawn/ then re-filed later), wholesalers file complaints;
- **February 2001** GSK restarts supplies to wholesalers;
- **August 2001** Greek NCA orders interim measures, GSK applies for injunction and annulment (dismissed);
- **November 2001** National Organisation for Medicines publishes circular requiring delivery of medicines equivalent to prescription requirements plus 25%;
- **December 2001** on insistence of NCA, GSK agrees to deliver quantities of medicines equivalent to national consumption plus 18%.
Greece – The Syfait, Sot Lélos saga (2)

… Luxemburg refused to deal with the Greek NCA …

- 2003 - Greek NCA asks ECJ for a preliminary ruling (Syfait, C-53/03),
- 2005 - ECJ rejects referral request, because NCA is not a „court“
- 2006 - Greek NCA decision (appealed)
  - GSK dominant in relation to Lamictal (epilepsy);
  - No violation of Article 82 EC;
    - But note: The ECJ says of Article 2 that it „essentially corresponds to Article 82 EC“ (C-468/06, para. 6);
    - What’s going on? Is this a case of a national provision that is broader than Article 82 EC in the sense of Article 3 VO 1/2003?
• **2001/2002** - Wholesalers bring actions against GSK to order supplies, and damages in Athens court (dismissed and appealed).

• **2006** - Athens Court of Appeals refers questions relating to the interpretation of Article 82 EC to ECJ for a preliminary ruling (not in one case – in 11 cases!).
  - Sot Lélos et al, C-468/06 to C-478/06.
Greece – The Syfaiot, Sot Lélos saga (4)

... received a response from Luxemburg!

- **ECJ, Judgment of 16 September 2008**
  - Refusal to supply wholesaler can be an abuse of a dominant position also in the pharma sector;
  - Unconvinced by arguments that there is no or limited benefit to consumers because of price regulation in the pharma sector and that a loss of profit will lead to less pharmaceutical R&D;
  - Manufactures must meet requests for „ordinary supplies“;
  - National court to determine what are „ordinary supplies“.
- **See for additional discussion also the opinions of AG Jacobs (C-53/03) and AG Ruiz-Jarabo Colomer (C-468/06).**
Greece – The Syfait, Sot Lélos saga (5)

But what does it mean?

• The Athens Court of Appeals case continues, so it will have to address the question;
• The NCA has completed the investigation – appeal pending - need to reopen?
• What are „ordinary supplies“?
  • Historic supply levels? Plus increase if demand increases?
  • Are increased exports “out of the ordinary”?
  • Prescription demand plus 18%?
  • Prescription demand plus 25%?
• It seems fair to say, the saga continues …

→ More detailed discussion of EU analysis by Hector Armengod in panel tomorrow morning!
Netherlands – Stock Allocation Scheme

• NCA Decision of 2002, Merck Sharp & Dohme/Euromedica (upheld on appeal);
• NCA investigated a stock allocation scheme
• Applied the reasoning developed in Bayer/Adalat and found no agreement, apparently also no dominance;
• Stock allocation scheme did not violate the relevant national provision because it was enforced unilaterally without having to rely on the co-operation of clients.
Spain – Direct to pharmacies sales

  - Pfizer and Pharmacia refused to supply wholesalers and supplied pharmacies directly;
  - The Court points out that according to the Spanish legislation on pharmaceuticals, the laboratories have an obligation to supply continuously their products into the market
    - Manufacturers may rely on the wholesalers as intermediaries; but
    - Manufacturers are free to choose to supply directly to pharmacies.

- Comparatively long line of case-law in Spain (NCA and courts) supporting dual pricing and/or direct to pharmacies or other alternative distribution schemes.
Spain – Cases before the NCA

• 25 September 2008 – Laboratorios farmaceuticos
  • Spanish NCA rejects complaint by SEDIFA and GRUFARMA (wholesalers) against five pharmaceutical companies.
  • Pharmaceutical companies terminated their contracts with all wholesalers, concluded new contracts with some of them but not with complainants;
  • NCA finds no collusion, the decisions to terminate the contracts with the distributors were based on objective criteria (territorial coverage, capacity to react to emergencies, logistics, etc.);
  • According to the NCA, the termination of the contracts with the wholesalers could have been the result of the entry into force of the new Spanish Medicines Law (Law 29/2006)
Spain – Spanish Medicines Law (1)

- Article 90 of the new Spanish Medicines Law (Law 29/2006) entitles the Government to fix the prices of the prescription medicines reimbursed by the National Health System, and allows the pharmaceutical companies to fix the prices for medicines that are not reimbursed by the State.

- According to the NCA, this provision requires pharmaceutical companies to know where their products have been supplied in order to determine their price. Relations with a large number of wholesalers makes the obtainment of this data more complicated, and this could be another objective justification for the decision of the pharmaceutical companies to terminate their contracts with some of these wholesalers.

- Finally, Article 68 of the new Medicines Law entitles pharmaceutical companies to distribute directly their products to pharmacies.
Spain – Spanish Medicines Law (2)

• 2007 – Spanish Civil Court of First Instance
  • Not a competition law case;
  • Case on the legality of the Spanish Medicines Law;
  • Court found that the Spanish Medicines Law does not impose any obligation to supply as required by a wholesaler on pharmaceutical companies.
Spain – Dual Pricing

- **Pending** - Complaint filed on 17 October 2007 by European parallel traders’ association EAEPC to Spanish NCA against dual pricing practices of pharmaceutical companies in Spain;

- **ECJ – GSK-Spain – Dual pricing (Appeal pending)**
  - EU Commission Decision of 8 May 2001 (partially annulled)
  - CFI, Case T-168/01, Judgment of 27 September 2006 (appealed)
United Kingdom

- **Market Studies**
  - OFT - Pharmaceutical Price Regulation Scheme (2007)
  - OFT - Distribution and Medicines in the UK (2007)
  - See also: Pharmaceutical Parallel Trade in the UK (2005)

- **Parallel trade issues arise mostly in disputes between manufacturers and re-importers about labeling, repackaging.**
  - Manufacturers would need to show an objective justification for restrictions on specific types of repackaging (the “5 BMS Conditions”), e.g., recently Boehringer Ingelheim case (2008).
  - In extreme cases, as regards dominant companies, litigation against parallel importers may carry a risk of “abuse of process” argument.

- **Direct-to-pharmacies sales model legal**
  - Pfizer announced exclusive distribution deal with UniChem
  - Wholesalers applied for injunction (rejected 2 March 2007).
What about the new EU Member States?

- Scarce case law, if any
  - Nascent competition regimes in new Member States;
  - Distribution networks well adapted to parallel trade issues or parallel trade generally not (yet) well developed?
  - Possibly acceptance problem of PIs from new Member States?
- One example reported for Poland may shed some light, but it is not a parallel trade case:
  - Polish competition authority fined Johnson & Johnson Poland and its distributor Hurtofarma for price fixing and customer sharing (re EPO). (There were at least two similar decisions in 2004)
  - Polish Court annulled this decision because it disagreed with the analysis as a horizontal agreement and required analysis as a vertical agreement.
  - Status to date: Appealed, apparently still pending.
  → Note: Polish Government intervened pro parallel trade in the Sot Lélos case
Switzerland

- Switzerland is of course not an EU Member State;
- Consultation on Swiss law on exhaustion of patents;
  - Swiss Supreme Court (1999) favored national exhaustion principle, which would hinder parallel trade;
  - Swiss Competition Commission in favor of international exhaustion of patents principle, favoring parallel trade;
- An abuse/ „fraudulent use“ of a patent position may still be captured by competition law, however exercise of IP rights in and of itself not captured.
Other recent NCA activity in the pharma sector
Examples (1)

- National Health Service not „undertaking“ (Ireland);
- Anticompetitive agreements between
  - manufacturers relating to supply of hospitals (Czech Republic, Italy);
  - pharmaceutical manufacturers (Portugal, Romania)
  - manufacturer and distributors (Poland, Romania)
  - wholesalers (Germany);
- Exclusive distribution agreement exempted (Turkey);
- Pharmacy opening hours/ limits on advertisement (no fine but change required – Belgium, Hungary);
- Resale price maintenance (OTC) (Germany);
- Prohibition of internet sales violates Art. 81 EC (France);
Other recent NCA activity in the pharma sector
Examples (2)

- Compulsory licensing of generic manufacturers (Italy);
- Predatory pricing by dominant manufacturer (France);
- Excessive prices (UK);
- Margin squeeze (UK);
- Rebates may be abusive (Finland);
- Wholesalers refusal to supply retail pharmacists (Italy).

Note also:
- Patent settlements (USA);
- EU Sector Inquiry.
Thank you!

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