Competition Matters

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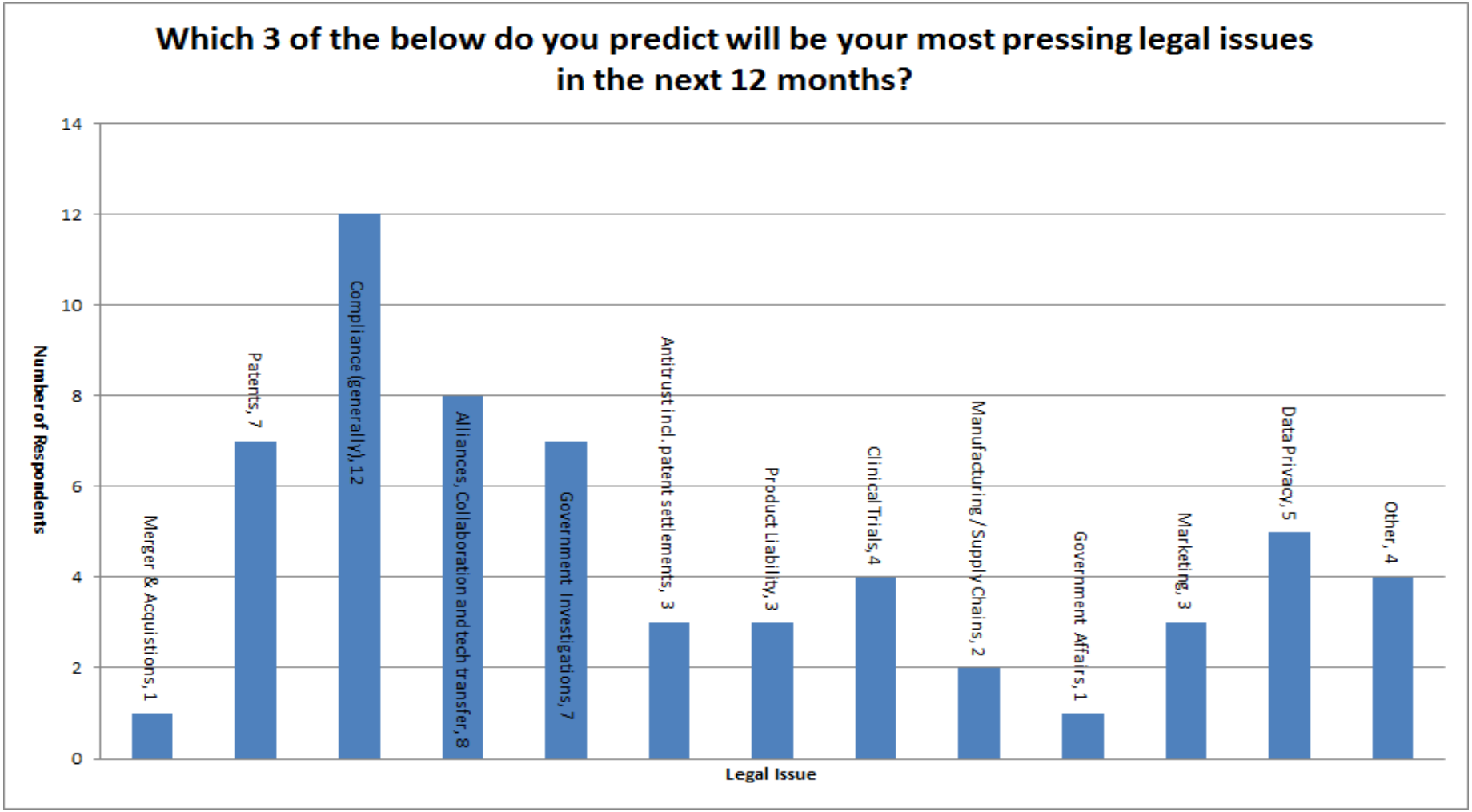
Crystal Ball Gazing – We Asked the In-house Community…

Life Sciences Survey : Most pressing legal issues in the next 12 months?



'Other' Included the following – (i) Pharma issue – pricing and reimbursement; (ii) tenders, regulatory issue, incl. appeal of pricing decisions etc.; (iii) Regulatory; (iv) Clinical data transparency

Agenda

- Parallel trade – still a hot topic
- Competition law aspects covered by recent jurisprudence at national level
- Changes of distribution models throughout Europe

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Parallel trade – interventions by public authorities

Principles for limiting exports of certain drugs

- Free movement of goods is fundamental principle of EU law
- Art. 34-35 TFEU prohibit quantitative restrictions on intra-community trade and “all measures having equivalent effect”
- Art. 36 TFEU allows for exceptions:
  - Where justified on the basis of public health protection
  - Restrictions do NOT constitute a means of arbitrary discrimination or disguised restriction on parallel trade
  - Test: any public health justifications advanced by MS must be:

- genuine (designed to achieve a real/stated public health objective):

- proportionate (measures must be ‘appropriate’ and ‘not more restrictive than is necessary’ to achieve legitimate objective) :

National regulations limiting exports of certain drugs (1)

France – Draft Decree (2012) including measures aimed at avoiding medicines supply shortages on the French market

- possibility of wholesalers to export medicines subject to the following conditions:
  - wholesalers could export medicines once they had fulfilled their public service obligations in terms of a regular supply to the national market (i.e. surplus products) and
  - the medicines which could be exported should not have been on the list of products which have suffered supply shortages on at least one occasion.
- Opinion of the French Competition Authority (July 2012)
  - a restriction on the market and on competition must be justified by objective reasons relating to public health protection, for example, the security of supply of sensitive medicines.
  - a provision aimed a priori at limiting parallel export in order to prevent supply shortages on the market and to protect public health may be justified and proportionate as they pursue the objective of public health.
  - the FCA considered that actually the Draft Decree provided an export ban for virtually all medicines for which a shortage has been observed at least once and was recorded on the dedicated list.
- The Decree published on 28 Sept 2012 however did not make any reference to the ability of authorities to ban exports of medicines

National regulations limiting exports of certain drugs (2)

Slovak Republic - new legislation (January 2013) brought changes to the system of monitoring and the restrictions on exports of drugs

- WS reporting obligation to State Institute for Drug Control (SIDC) on “intended” exports 30 days before
- SIDC right to object for each batch within 30 days of notification
- the SIDC is entitled to ban the export only on the grounds that the drug is in short supply in Slovakia and its export would jeopardize the availability and provision of health care in Slovakia.
- if SIDC does not ban the exports, it can be done only within the period of three months as of notification of SIDC .

Bulgaria - on 16 January 2014, the Bulgarian Parliament adopted amendments to the Bulgarian Medicinal Products in Human Medicine Act;

- prior notification procedure before the Bulgarian Drug Agency in case of export of prescription medicines reimbursed by the State, empowering the Bulgarian Drug Agency to ban exports in case of drug shortages.
- end January 2014: the Bulgarian President has imposed a veto on the amendments to the Medicinal Products in Human Medicine Act

National regulations limiting exports of certain drugs (3)

Hungary - new legislation came into force in July 2013;

- MAH's obligation to supply all WS if "specifically indicated" for local market needs; these purchases shall not be exported
- MAH obligation to ensure, continuously, defined stock level for all WS for certain products as defined in MOH decree
- The amended Medicines Act allows the competent authority (GYEMSZI) to prohibit the export of a particular medicine if there is a risk to patient supply in Hungary.
- The export ban will last as long as there is a real risk to security of supply subject to a maximum period of 12 months.

National regulations limiting exports of certain drugs (4)

Czech Republic

- Two specific cases – the Czech law does not explicitly regulate this sensitive issue
- Legal provision put forward: Section 11(h) of Act No. 378/2007 Coll. on Pharmaceuticals authorises the Ministry of Health to adopt measures to ensure access to medicinal products which are important for the provision of healthcare, and to support research, development and access to medicinal products for rare diseases

Romania – new legislation came into force in April 2013

- Based on Article 850 of Law no. 95/2006 on the reform in healthcare "*at the proposal of the Ministry of Health, the Government may limit or prohibit for a certain periods the export of certain medicines, on grounds related to public health interest*".
- **The distribution outside Romania of specific INNs indicated in the order is suspended until 31 December 2013.**
- **the measure was prolonged** until 30 June 2014

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Important competition law aspects covered by recent jurisprudence

Focus of the competition authorities

- **Increased focus** of competition authorities on pharmaceutical sector:
  1) **sector inquiries**;
  2) **targeted investigations on potential**
     - **anti-competitive practices**;
     - **abuse of dominance** cases.

Sector inquiries at national level (1)

France – sector inquiry opened in **February 2013**

19 December 2013: French Competition Authority's report published

- The inquiry was focused on the competitive structure and practices at each level of the distribution chain of pharmaceutical producers, wholesalers and pharmacists.

- Aspects analyzed:

✓ <u>From the point of view of pharmaceutical producers</u>

- The pricing policy operated by producers;
- The penetration of generic medicines

✓ <u>From the point of view of wholesale distributors</u>

- distributors' pricing and trade relations with pharmaceutical producers and pharmacies.
- the direct sales from the producers to the pharmacies
- the competitive pressure that the wholesale distributors may exert, as importers or exporters of medicines, on the distribution of medicinal products.

✓ <u>From the point of view of pharmacies</u>

- The role of pharmacies in the supply of medicinal products
- Online sale of medicinal products

Sector inquiries at national level (2)

Turkey: pharmaceutical market research conducted by Turkish Competition Authority (TCA) – **report published on 19.04.2013**

- focus of the sector inquiry: analysis of the structure and operation of the market at the supplier level.
- In addition, suppliers' activities at the retail pharmacy market and their relations with pharmaceutical wholesalers have been scrutinized.

Romania - new sector inquiry opened in March 2013 – still on-going

- in-depth analysis of the current level of generic medicine penetration;
- change of medicines distribution system.

The RCC recommended to all companies involved in the distribution of pharmaceutical products in Romania not to make changes in the actual structure and distribution system until the competition authority finalizes the sector inquiry.

Targeted investigations

- **EC and national level**
  - IPR-related abuse of dominance cases
  - anticompetitive agreements – pay-for delay
    - patent settlement
    - co-promotion agreements
- **National level**
  - abuse of dominance cases
    - defamation against generics
    - refusal to supply

At national level – antitrust investigations (1)

UK - on-going pay-for-delay case before the OFT

- On 19 April 2013, the OFT issued a SoO related to the the UK supply of paroxetine, a prominent antidepressant medicine.
- The OFT alleges GlaxoSmithKline might have concluded agreements which infringed competition law with generic companies, over the supply of paroxetine in the UK.
- The generic companies were each attempting to supply a generic paroxetine product in competition to GSK's branded paroxetine product, Seroxat. However, in each case, GSK challenged the generic companies with allegations that their products would infringe GSK's patents. To resolve these disputes, each of the generic companies concluded one or more agreements with GSK.
- The OFT's provisional view is that these agreements included substantial payments from GSK to the generic companies in return for their commitment to delay their plans to supply paroxetine independently.
- The OFT also alleges GSK's conduct could amount to an abuse of a dominant position in the same market.
- The OFT considers that if companies act to delay the potential emergence of generic competition the NHS may be denied significant cost savings
- OFT final decision expected to be issued in October 2014

At national level – antitrust investigations (2)

Italy – Xalatan case

- In 2012, the Italian Competition Authority **("ICA")** found that Pfizer abused its dominant position by adopting a strategy aimed at blocking or delaying the entry of Xalatan competing generics on the market.
- Pfizer's strategy:
  - adopting a strategy to illegitimately extend patent protection for Xalatan, including obtaining a divisional patent and a supplementary protection certificate for the patent;
  - conducting an aggressive enforcement campaign against generic competitors wishing to enter the market following the expiry of Xalatan's original patent.
- On appeal, the Lazio Administrative Court overturned the ruling on the grounds that Pfizer lawfully defended its intellectual property from exploitation.
- On 12 February 2014, **Italy's Council of State upheld the 10.6 mil. euros fine levied by the ICA** arguing that:
  - Pfizer's strategy was exclusively aimed at preventing the entrance into the market of competing generic versions; and
  - it was not relevant whether the divisional patent and supplementary protection certificate were legitimately obtained

At national level – antitrust investigations (3)

Spain – Xalatan case

- In 2012 the Spanish Competition Authority ("CNC") opened an investigation to ascertain whether Pfizer allegedly prolonged the patent protection for Xalatan by strategies to obstruct or delay the introduction of generic drugs competing with Xalatan.

- The investigation was opened following the findings of the Italian Competition Authority in the Xalatan case in Italy.

- In February 2014, the CNC established that Pfizer **did not abuse its dominant position** when extending the patent protection for Xalatan on the grounds that Pfizer lawfully made us of its intellectual property rights.

At national level – antitrust investigations (4)

Italy – recent cases

- Italian competition authority **("ICA")** fines Roche and Novartis
  - ICA opened an investigation against Roche, Genetech and Novartis for the involvement into an illicit agreement with the view to excluding in Italy the ophthalmic use of Avastin.
    - Avastin (marketed by Roche) is registered for usage in cancer therapies and Lucentis (patented by Genetech/ Roche and marketed by Novartis) is used for the treatment of ophthalmic pathologies;
    - Several studies showed no difference between Avastin and Lucentis in the treatment of ophthalmic pathologies; Lucentis is more expensive than Avastin.
  - ICA established that Roche and Novartis colluded with a view to ensure Novartis high sales of Lucentis, while Roche preferred collecting royalties paid by Novartis for the distribution of Lucentis
  - **Fines: Novartis – 92 mil. euros; Roche – 90,5 mil. euros**
- On **29 January 2014**, ICA opens investigation against Novartis and Italfarmaco – pending case
  - The ICA investigates into bid rigging practices allegedly carried out with regard to the competitive procedures organized by some regional health authorities for the supply of octreotid (a medicine produced only by the companies).
  - Allegedly, the agreement included price-fixing and market sharing arrangements.

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Denigration against generic competitors

Main risks faced by originator companies

1. **unfair competition** – risk of being sued before the **ordinary courts** of law for unfair competition practices through defamation against generic versions of the innovative product aimed at

- limiting the entry of competing generics on the market; OR
- favoring own generic products

Example: **Merck vs. Teva litigation** in the Netherlands

Teva sued Merck before the Dutch courts regarding defamatory conduct by sending letters to wholesalers, pharmacists and physicians claiming the consequences for them in using/dealing with Teva's alleged infringing product

Merck claimed that Teva's generic Alendronate was of inferior quality and posed a health and safety risk to public

2. **abuse of dominance** – if a link between the dominant position of the innovative producer and denigration may be established

Decisions of the French Competition Agency – the Plavix case (14 May 2013) (1)

- **Background of the case**
- Sanofi-Aventis implemented a **denigration strategy** with a goal
  - to limit the entry of **Plavix** competing generics in the market and
  - to favor Sanofi-Aventis' own products, the originator Plavix medicine and its generic version marketed by Sanofi-Aventis, **Clopidogrel Winthrop**
  - Although the patent protecting Plavix expired in July 2008, Sanofi filed complementary patents to extend the initial protection
  - These complementary patents do not however call into question the bioequivalence of the clopidogrel generics, which allowed them to be listed in the directory of generic medicines
  - **Complaint** from the **Teva Sante** company against Sanofi's strategy
  - Sanofi's strategy was aimed **to stop the generic substitution process:**
    - **at the prescription stage** – by convincing doctors to insert the indication "non substitutable" to the prescriptions, so as to limit the substitution of Plavix by a generic medicine
    - **at the substitution stage** – by encouraging pharmacists to substitute Plavix by its own generic medicine, Clopidogrel Winthrop, to the detriment of generic competitors

The Plavix case (14 May 2013) (2)

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❑ **Decision** of the French Competition Authority

- **narrow definition of the relevant market**: ATC 5 level - Clopidogrel = separate market
- Sanofi-Aventis **abused its dominant position** in the French market of clopidogrel prescribed by ambulatory care

=> Fine level: <u>EUR 40.6 million</u>

❑ **Lessons from the Plavix case**

- Implying that the variations in salts and therapeutic indications of Plavix generic competitors could have consequences on health and legal liability <u>when the French authorities had already granted marketing authorizations</u> and <u>had confirmed by letter to Sanofi the bioequivalence of these generic products</u> constituted an **abuse of dominant position.**
- An originator's statements concerning the quality of a generic competitor's products vis-à-vis physicians and pharmacists can constitute an abuse of a dominant position if:

✓ the **statements** are **inaccurate**

✓ create an **illegitimate doubt on the efficacy and safety** of the competing generics and

✓ have the effect of **maintaining or strengthening a dominant position**!

The Schering Plough case (1)

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- **Background**
  - **Arrow Génériques** company filed a **complaint** for practices implemented by **Schering Plough** laboratory, at the launching of the generic product **Subutex®** on the market
- **Decision ordering interim measures (11 December 2007)**
  - **relevant market**: high dosage buprenorphine, comprising Subutex and its generics, constitutes a relevant market, distinct from the methadone relevant market.
  - The Competition Authority **ordered** Schering Plough to publish at his own costs a text reminding:
    - the bioequivalence of generic drugs which have been permitted on the market and
    - the possible substitution by pharmacists as soon as they are listed as generic drugs.

The Schering Plough case (2)

- **Decision on the merits** issued on 19.12.2013
- Schering Plough's conduct had unfairly hindered the launching of the generic drug for Subutex® through **two major practices**:
  - **defamation** against Arrow's generic drug among pharmacists, even before its entry on the market, and
  - a significant **change in Subutex® business conditions in pharmacies** when the generic drug entered the market (stock saturation, extension of payment terms, discounts).
- By influencing both doctors and pharmacists, Schering-Plough hindered competition at two key stages of the generic substitution:
  - at the **prescription stage** by significantly increasing the number of "non-substitutable" references (67% of prescriptions contained this reference), which limited the level of Subutex® generics;
  - and at the **dispensing stage** of this medicinal product, by providing pharmacists with incentives not to substitute Subutex® when the prescription did not contain the "non-substitutable" reference.
- **Sanctions** applied:
  - 15.3 million euro fine to Schering-Plough for disparagement and unwarranted discounts granted to pharmacists; its parent company Merck & Co was also fined

Decisions of the French Competition Agency – the Subutex case (19 December 2013)

- **Sanctions** applied:
  - **15.3 million euro fine** to Schering-Plough for disparagement and unwarranted discounts granted to pharmacists; its parent company Merck & Co was also fined 414,000 euros for participating in the anticompetitive agreement.
- **Compliance commitments** submitted by Schering-Plough
  - Schering-Plough undertook to monitor the planned marketing strategy prior to the arrival of generics, and to train salespeople on the unlawfulness of disparagement.
  - The penalties imposed on Schering-Plough have therefore been reduced.

Decisions of the French Competition Agency – the Subutex case (19 December 2013)

- **Arrow Génériques** company filed a **complaint** for practices implemented by **Schering Plough** laboratory, at the launching of the generic product **Subutex®** on the market
- Decision: by influencing both doctors and pharmacists, Schering-Plough hindered competition at two key stages of the generic substitution:

➢ at the **prescription stage** by significantly increasing the number of "non-substitutable" references (67% of prescriptions contained this reference), which limited the level of Subutex® generics;

➢ and at the **dispensing stage** of this medicinal product, by providing pharmacists with incentives not to substitute Subutex® when the prescription did not contain the "non-substitutable" reference.

=> Fine level: **EUR 15.3 million** fine to Schering-Plough for disparagement and unwarranted discounts granted to pharmacists; its parent company Merck & Co was also fined 414,000 euros for participating in the anticompetitive agreement.

- **Compliance commitments** submitted by Schering-Plough

➢ It undertook to monitor the planned marketing strategy prior to the arrival of generics, and to train salespeople on the unlawfulness of disparagement.

➢ .The penalties imposed on Schering-Plough have therefore been reduced.

Legitimate vs. illegitimate behavior

❑ **Key principle:**

"*It is not the task of a dominant undertaking to take steps on its own initiative to exclude products which it regards, rightly or wrongly, as dangerous or inferior to its own product*."

(Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings)

✓ **It is legitimate** for a pharmaceutical producer/laboratory to put forward before HCPs the **objective qualities** of its **own innovative** products within information/promotion campaigns

Golden rules

- promotion/information campaigns need to be limited to a **neutral** description of the **objective** characteristics of **own products**
- information campaigns should not be accompanied by direct/indirect incentives for physicians/ not to prescribe competing generics;
- the same applies for promotion campaigns aimed at pharmacies
- any difference between the innovative and generics needs to be **substantiated** based on **clear and precise data**, as well as the effects/consequences of such differences on the safety and efficiency of generics
- any allegations regarding the lack of safety of the generics need to be based on **scientifically proven** data and need to be **documented** as such

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Refusal to supply cases

Partial fulfillment of orders placed by distributors The Roche/Relad case in Romania (1)

- Investigation against Roche was closed without sanctions
  - Relad challenged the decision in court
  - challenge was rejected in first instance in March 2014 by the Bucharest Court of Appeal ➔ potential appeal before the High Court of Romania
- Analysis of the RCC similar to the EC approach under GSK Greece case
  - ordinary orders assessed by reference to (i) the historical commercial relationship between Roche and all its distributors and (ii) market growth
- The RCC also factored parallel trade into its analysis
  - regulated prices in Romania (lowest level in the EU) make products attractive for parallel trade
  - RCC found that 6 of 8 Roche distributors had exported Roche products in 2010 and in fact such exports were higher in 2010 relative to 2009

Partial fulfillment of orders placed by distributors The Roche/Relad case in Romania (2)

- Roche/Relad decision comprises no specific reference to quota management systems
- Assessment of implications resulting from partial confirmations by Roche of orders received from distributors
- RCC accepted Roche's argument that the reductions in deliveries was justified by stock shortages resulting from an intra-group country allocation system
- Claim made by Roche was verified by the RCC by reference to the availability of Roche monthly stocks in Romania during 2008-2010

The UK approach – Abbvie v. Chemistree (1)

- Chemistree claimed that Abbvie held a dominant position with respect to Kaletra – an HIV patented medicine

  - Kaletra was supplied by Abbvie to Chemistree for its homecare service
  - Abbvie supplied Kaletra directly to hospitals
  - Abbvie's policy was not to supply Kaletra to wholesalers in mainland UK (Abbvie operated a separate supply chain for that part of its business)
- Chemistree's demand for Kaletra increased continuously
  - Abbvie identified a supply shortage in the market and requested information from Chemistree to verify that UK patient needs were met
  - only 15% of the quantities of Kaletra ordered by Chemistree ➔ homecare
  - remaining 85% ➔ wholesale activities (including exports to Lithuania).
- Abbvie subsequently reduced its deliveries to Chemistree to the level of homecare supply and refused to supply Chemistree in relation to the remaining quantities

The UK approach – Abbvie v. Chemistree (2)

- Chemistree applied for interim relief aimed at forcing supply on grounds of alleged abusive conduct on the part of Abbvie ➔ UK High Court denied the request

- UK Court of Appeal upheld the decision of the High Court and held that <u>a patented pharmaceutical product should not be regarded as a distinct relevant market</u>
  - Court of Appeal acknowledged that for some patients Kaletra is a must-have medicine (e.g. patients who had previously been prescribed Kaletra)
  - However, new patients have access to the whole range of substitutes
  - Without any evidence regarding Kaletra's market share (which Chemistree did not provide) ➔ no reason to narrow the relevant product market to encompass only Kaletra

Conclusions of the Abbvie case
Findings of the UK High Court

- Article 102 TFEU has never been held to oblige a supplier to adopt a particular manner of distribution of its own products (para. 40)
- If an undertaking supplies a customer on the basis that the supply is for retail sale and has a policy of not supplying wholesalers, the fact that, unknown to the supplier, its customer is reselling some of those products on the wholesale market does not mean that the customer's orders for the purpose of wholesale constitute "ordinary orders" (para. 43)
- The fact that some or perhaps all of the claimant's wholesale requirements were for parallel export trade cannot convert what would otherwise not be an abuse into abusive conduct (para. 44)
- Even for a supplier that actively supplies wholesalers it may not be an abuse to refuse suppliers which are out of proportion to those quantities previously sold to those wholesalers to meet domestic requirements. Therefore, in the particular context of pharmaceutical medicines it may indeed be legitimate to restrict supplies in such a way that parallel exports would be restricted (para. 47)

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Changes of distribution models throughout Europe

Current trends in medicines distribution
The Commission's Report

- Paper submitted by the Commission to the 2014 OECD Global Forum on Competition

- Price competition between pharmacies is limited
  - pharmacies typically charge the maximum regulated prices ➔ prices are largely homogeneous across pharmacies within the same country

- Consolidation of the distribution chain in the pharmaceutical sector:
  - mergers (where allowed by regulatory framework)
  - joint procurement at retail level
  - vertical integration (mainly wholesaler-retailer)

DTP distribution
Report on the Pharmaceutical Distribution Chain

- EMINET report in March 2011 – *The Pharmaceutical Distribution Chain in the European Union: Structure and Impact on Pharmaceutical Prices*
- DTP distribution is on the rise in the EU
  - DTP accounts for more than 20% of pharmacy sales in the Czech Republic, France and Italy
- Alternative schemes for DTP
  - <u>Distribution performed by the manufacturer</u>
    - manufacturers perform their own wholesaling by developing their own distribution network or by acquiring existing wholesalers
  - <u>Sole Agency</u>
    - typical DTP option
    - manufacturers sell directly to customers via an exclusive wholesaler acting as an agent or logistics services provider (LSP)
    - the LSP does not own stock and does not offer discounts
  - <u>Reduced Wholesaler Model (RWM) used to supply pharmacies</u>
    - manufacturers use a small number of wholesalers (typically 1-3)
    - otherwise traditional/standard model of distribution
    - the UK ➔ RWM schemes cover approx. 20% of the market