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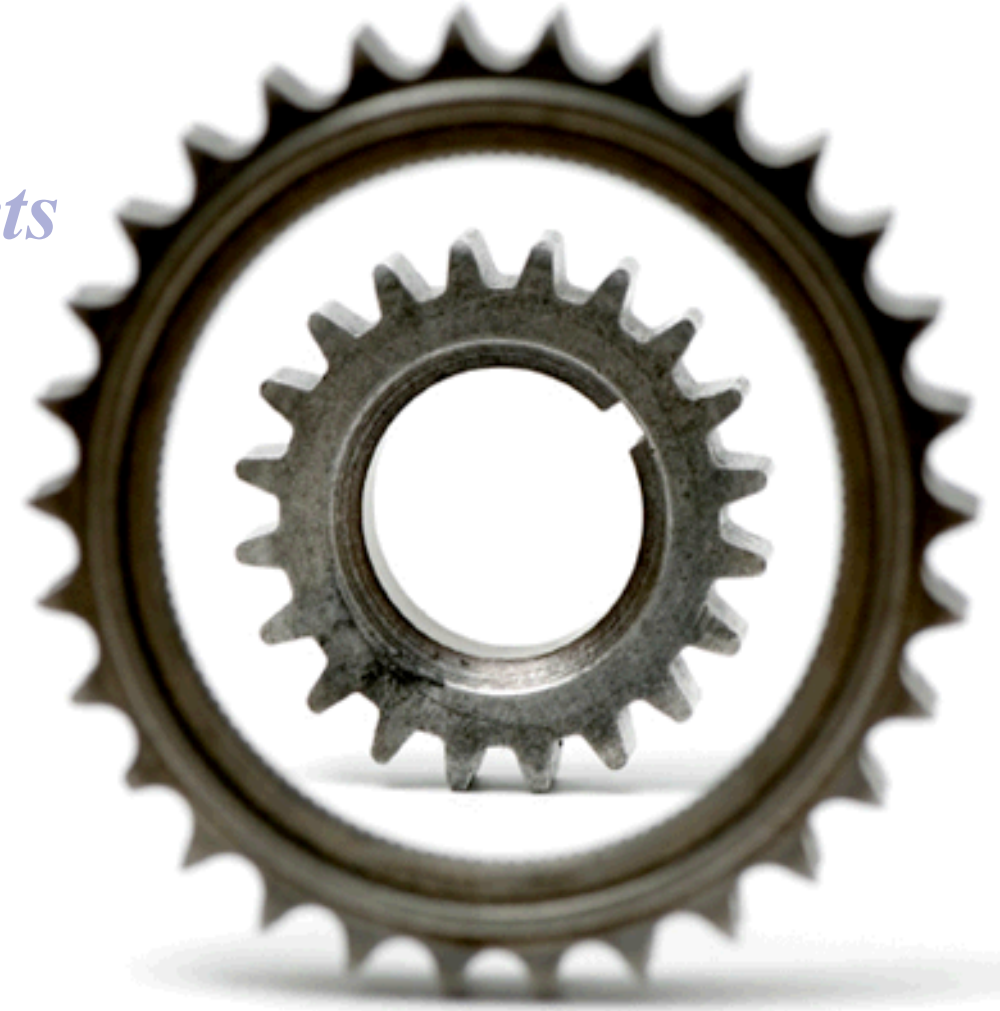
Marketing your products within the EU:

how to deal (or not …) with parallel trade



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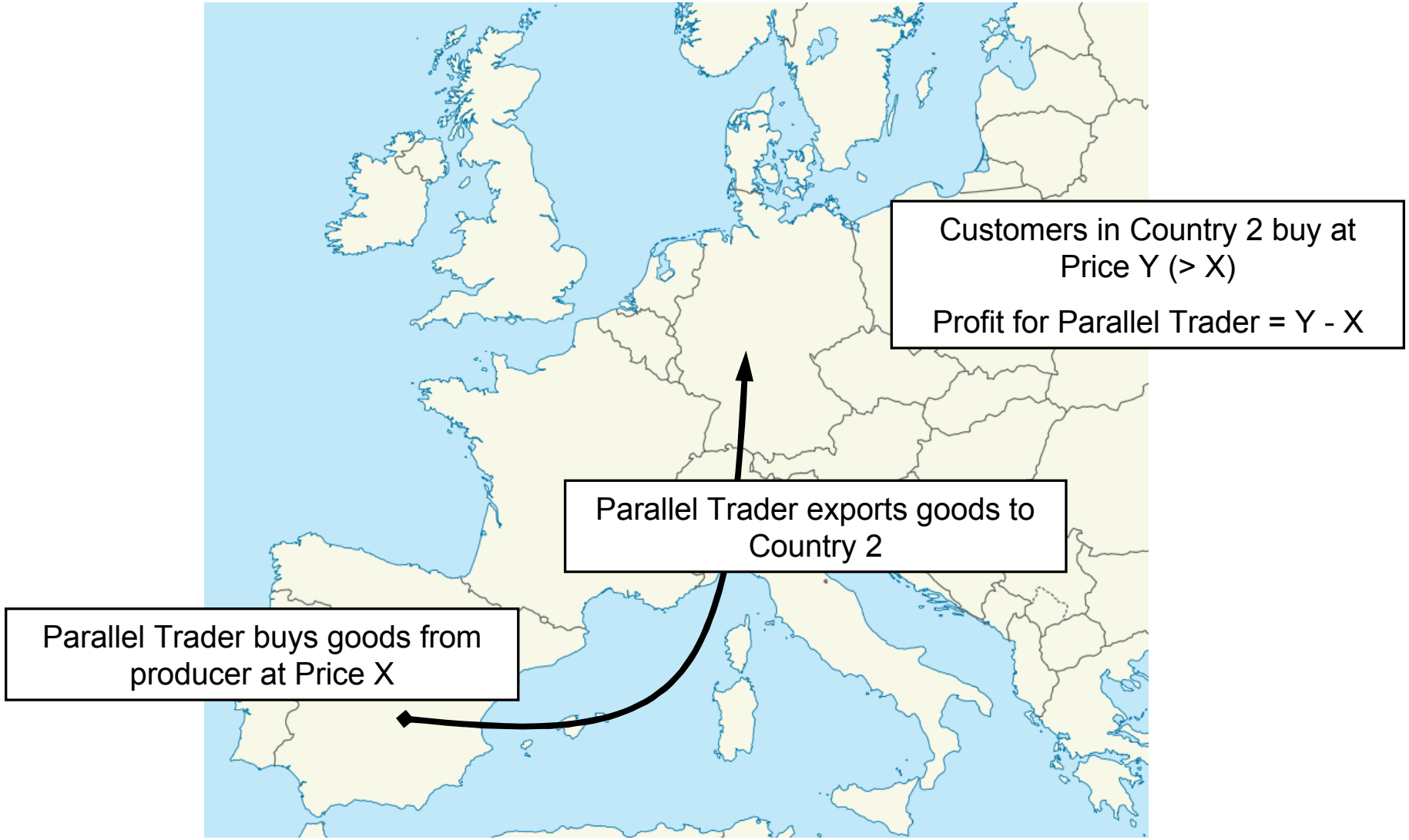
What is Parallel Trade?



Introduction: Why Should You Care About Parallel Trade?

- Parallel trade is lawful within the European Union and is the natural consequence of the free movement of goods within the unified market

  → Condition: the good must have been legally placed on the market (i.e.: owner must have "exhausted" his exclusive rights over the goods)

Outline of the Presentation

1. Why is it hard to attack parallel trade? EU policies …

2. Intellectual Property Rights and the Exhaustion of Rights Doctrine

3. Competition law: from "*No No!*" to "*Why not?*"

Why is it hard to attack parallel trade?

– Parallel Trade is considered as “desirable” at EU level

– Member States cannot restrict free movement of goods

– Neither can Companies

Intellectual Property Law and Exhaustion of Rights (1/3)

Can Intellectual Property (IP) rights be used to stop parallel trade?

- **YES, IF** the goods imported were placed in the market without the owner's consent

- **NO, IF** the goods have been placed legally in the market, ie. If the IP rights are exhausted

- Exhaustion of rights doctrine **applies to all industrial property rights**

- **Burden of proof of exhaustion** lies on whoever seeks its benefit (*Zino Davidoff* , C-C-414/99 to C-461/99)

  → **except** in certain circumstances (notably selective distribution systems) where proof of <u>where</u> the goods were first placed can lie on the supplier

Intellectual Property Law and Exhaustion of Rights (2/3)

4 conditions for IP rights to be "exhausted": products must have been:

(i) **effectively marketed**

→**no exhaustion** for products which:

- Were just offered for sale
- Were marked as "sample" or "not for sale"

(ii) **within the EEA**

(EU + Norway + Iceland + Liechtenstein)

→**no "universal" exhaustion of rights**

- international exhaustion is contrary to EU law

→**no exhaustion** when

- products are marketed outside the EEA
- products are manufactured within the EEA for exportation outside the EEA

Intellectual Property Law and Exhaustion of Rights (3/3)

4 conditions for IP rights to be "exhausted": products must have been:

(iii) **by the owner of with its consent**

→consent can be **express or implied**, but must be certain

→**no exhaustion** if intention is absent or equivocal

→consent is **only requested for the initial placing**/marketing of goods

(iv) **consent for each item/ batch of items**

→no exhaustion for a "type of goods"

Intellectual Property Law and NON exhaustion of Rights (1/2)

– The exhaustion of rights doctrine is **not absolute** and an IP right owner can object to the circulation of goods where this **affects the specific subject-matter of the IP right**

– "Specific subject matter" is defined for each IP right:

- **Trade mark**: exclusivity, guarantee of origin, quality control
- **Patent**: rewarding inventive efforts by granting an exclusive right to manufacture and be the first to place in the
- **Copy rights**: protection of moral and economic rights of the authors

Intellectual Property Law and NON exhaustion of Rights (2/2)

- **Exception**: in certain areas repackaging may be **necessary** for parallel imports
  - Ie: parallel importer cannot penetrate the market without modifying the presentation of the product
- The owner of a trademark **cannot** oppose the repackaging of its products **when this repackaging is necessary and satisfies a number of conditions**
- This is particularly true in sectors like the pharma sector, but also for luxury goods

Competition Law: How to Tackle The Issue ?

– If a product has been placed in the market and the IP owner's right is exhausted: it must circulate freely within the EEA

– Companies try to avoid parallel trade of their product through a number of measures

– Some measures are prohibited *per se, c*onditionally possible, and some even a *priori* lawful (to date …)

– Practices can be apprehended from two angles: unlawful agreements and abuse of dominant position

– In any event:
  - Competition law can only prohibit restrictions to **lawful** parallel trade
  - But competition law will ensure that IP rights are not used to trade mark owner to partition national markets

Competition Law: How NOT to Tackle the Issue: Contractual *Yes* & *No*

– Constant case law opposed to **export prohibition clauses**

> "***By its very nature, a clause prohibiting exports constitutes a restriction on competition***, *whether it is adopted at the instigation of the supplier or of the customer since the agreed purpose of the contracting parties is the endeavour to isolate a part of the market*" (*Miller International Schallplatten*, Case 19/77, § . 7)

– No clause can "*(b) the restriction of the territory into which, or of the customers to whom, a buyer party to the agreement, may sell the contract goods or services*"

– **Except : it IS** possible to restrict (within a territory or cross borders):
  - **Active sales**
  - **Sales to end users** by a buyer operating at the wholesale level
  - Sales by the members of a selective distribution system to **unauthorised distributors**

– But no restrictions of passive sales to end user: includes no restrictions on **Internet sale**

Competition Law: How NOT to Tackle the Issue: Tacite/Passive Agreements

– No need for express consent: there can be an “unlawful agreement” a result of the **mere acquiescence** by a distributor to a supplier’s policy or if can be deducted from its behavior

– **Must still prove this acquiescence/intention**

– Notion of “consent/acquiescence”: requires proof of a concurrence of wills in the absence of direct documentary evidence that passive sales were to be restricted

– Standard of proof can, however, appear relatively low

Competition Law: Abuse of Dominant Position issues? Refusal to Supply and Quota Policies…

- Issue raised by – and since – the Bayer case: do unilateral measures which, in effect, restrict parallel trade, constitute an abuse of dominant position?

- GSK Greek case
  - Complete refusal to supply a distributor which exports can constitute an abuse of dominant position unless the requests are "out of the ordinary"', compared to
    - national market needs
    - previous purchases from distributor
  - Limitations to amounts supplied can be lawful under specific conditions

  (ECJ, C-468/06 to C-478/06, 16 September 2008, *Lélos Kai Sia EE vs. GSK AEVE)*

- The French examples

Competition Law: Abuse of Dominant Position issues? Dual Pricing

- What is dual-pricing and how can it solve the parallel trade issue?

- Is it lawful? GSK case – implemented when Spanish law allowed dual pricing

  - ECJ upheld the Commission against CFI: “per se restriction”
  - ECJ upheld the CFI against the Commission: exemptions possible under 101(3) TFUE

- What are the conditions to benefit from an individual exemption?

- Could it depend on the sector at stake? Regulated/non regulated? CLEARLY an important factor ..

Parallel imports and Regulatory hurdles

- Pharmaceutical products may only be marketed if they have been granted a marketing authorisation

- Is the parallel importer entitled to rely on the original marketing authorisation in the country of importation? (*Smith & Nephew*, 12 November 1996) Yes, if:
  - The imported product benefits from a marketing authorisation in the Member States from which it is exported
  - The imported product although not identical in all respects, has at least been manufactured according to the same formulation, using the same active ingredient as the product already available in the Member State of import, and has the same therapeutic effect
  - The two products have a common origin – still applicable (*Kohlpharma*, 1 April 2004)
  - Unless there are countervailing considerations relating to the effective protection of the life and health of humans

- The withdrawal of the original marketing authorisation in the Member State of import does not affect the parallel imported products UNLESS there is a risk for human health (*Paranova Oy,* 8 May 2003)

The Bulgarian case

– What is wrong with this decision?

Questions?

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