Parallel Trade in Post-Accession Europe

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The Ten New Member States

- 74.9 million inhabitants
- € 784.9 billion GDP (*i.e.*, € 11,790 per capita)

Source: European Commission 2002

Cyprus
Malta
Hungary
Poland
Slovakia

Estonia
Lithuania
Czech Republic
Slovenia
Latvia

EU Enlargement And Economic Realities

- Overall difference in GDP
  - Ten new Members account for 8.5% of GDP of EU 15
- Difference in GDP per capita as between CEC 8
  - Slovenia: 50% above average, Latvia: 50% below average
- Overall difference in Health Spend
  - 2000 Health spend per capita – EU 15: $1780, CEC 8: $312

➔Scope for arbitrage gains and parallel trade

Exhaustion Of IP Rights In The EU (I)

The owner of an IP right protected by the legislation of a Member State cannot rely on that legislation to prevent the importation or marketing of a product which has been lawfully marketed in another Member State by the owner of the right himself, with his consent, or by a person economically or legally dependent on him

- Established case law of the Court of Justice, also applies to trademarks and copyrights
  (Case C-10/89 *CNL-SUCAL v HAG* [1990] ECR I-3711; Case C-9/93 *IHT v Ideal Standard* [1994] ECR I-2789)
- Article 7 of the Trademark Directive (Directive 89/104/EEC)

Exhaustion Of IP Rights In The EU (II)

- Derogations from the principle of free movement of goods must be strictly interpreted
  (Case C-191/90 *Generics and Harris Pharmaceuticals* [1992] ECR I-5335)
- Compulsory licenses do not exhaust patent rights
  (Case 19/84 *Pharmon BV v Hoechst* [1985] ECR 2281)
- Community exhaustion, not international or global exhaustion
  (Case C-355/96 *Silhouette* [1998] ECR I-4799; Case C-173/98 *Sebago* [1999] ECR I-4103; Cases C-414 to 416/99 *Davidoff* [2001] ECR I-8691)
- 2003 Commission Staff Working Paper
  - "It follows that the Commission, as a result of the investigations carried out in the preparation of this report, has not found any deficiencies in current legal provision relating to possible abuses of trade marks within the EU."

The Specific Mechanism (I)

(1) With regard to the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia or Slovakia, the holder, or his beneficiary, of a patent or SPC for a pharmaceutical product filed in a Member State at a time when such protection could not be obtained in one of the abovementioned new Member States for that product, may rely on the rights granted by that patent or supplementary protection certificate in order to prevent the import and marketing of that product in the Member State or States where the product in question enjoys patent protection or supplementary protection, even if the product was put on the market in that new Member State for the first time by him or with his consent.

The Specific Mechanism (II)

(2) Any person intending to import or market a pharmaceutical product covered by the above paragraph in a Member State where the product enjoys patent or supplementary protection shall demonstrate to the competent authorities in the application regarding that import that one month's prior notification has been given to the holder or beneficiary of such protection.

The Spanish Precedent (I)

The holder, or his beneficiary, of a patent for a pharmaceutical product, filed in a Member State at a time when a product patent could not be obtained in Spain for that product may rely upon the rights granted by that patent in order to prevent the import and marketing of that product in the present Member State(s) where that product enjoys patent protection even if that product was put on the market in Spain for the first time by him or with his consent.

This right may be invoked for the products referred to in paragraph 1 until the end of the third year after Spain has made these products patentable.

The Spanish Precedent (II)

- Merck v Primecrown (ECJ [1996] ECR I-6285)
  - The "derogation from the principle of free movement of goods [introduced by the Act of Accession]" has to "be interpreted strictly"
  - "The provisions in question must therefore be interpreted in a way that the transitional periods expire on the date which ensures the earliest application, in the field concerned, of the principle of free movement of goods in Spain and Portugal"
  - ["To permit an inventor to invoke a patent held by him in one Member State to prevent the importation of the product freely marketed by him in another Member State where that product was not patentable would cause a partitioning of national markets"]

A Pro-Competitive Tool – In CEC 8

- Differential Pricing
  - Allows companies to partition the common market?
- Increased competition
  - Equal footing for foreign companies in CEC 8?
- Not Intended To "Increase Parallel Trade within EU 25"
  - Parallel trade in certain pharmaceuticals between CEC 8 and EU 15(+2) unwanted

The Core Issues

- "Patent or SPC for a pharmaceutical product"
- "Filed in a Member State at a time when such protection could not be obtained"
- Parallel Trader "shall demonstrate that one month's prior notification has been given"

"Patent or SPC for a pharmaceutical product"

- Does not apply to products:
  - Put into circulation before May 1, 2004 (exhaustion does not apply retroactively)
  - Which are "off-patent" (or "off-SPC") on May 1, 2004
  - Which enjoy "full" patent protection under CEC 8 patent laws (registered after patent protection became available)
- Applies to:
  - Imports from CEC 8 and intra-CEC 8 trade
  - Imports into EU 15(+2) and EEA 3
  - Intra-EU 15 re-imports, if originating in CEC 8

"Filed in a Member State at a time when such protection could not be obtained"

- Availability of patent/SPC protection
  - Relative equivalence to pre-existing protection in EU 15
  - In CEC 8: Between 1991 and 1994 (expiration 2016-2019)
  - NOT: Pipeline protection (afforded as "transitional" or "bilateral" (i.e., with US) concession)
  - NOT: Protection contingent on local content or working requirements
  - NOT: Liechtenstein SPCs pre-1997

Parallel Trader "shall demonstrate that one month's prior notification has been given"

- New Concept
  - Re-packaging cases (15 working days)
  - In context of accession – new (and untested) concept
- Advance notice
  - Which right holder receives notice and which entity?
  - Authority must verify?
  - What needs to be notified?
  - Sanctions?

Advance Notice (I)

- Notification by parallel trader
  - Not 3rd party – bears burden of proof
- Of right-holder
  - MA holder or patent proprietor?
- Of "right" right-holder
  - Preemptive information of parallel trader and internal training
  - Adaptation of license agreements

Advance Notice (II)

- Obligation on national authorities
  - No license unless trader proves notification
  - Trader's application must include evidence that "right" entity was notified
  - Revocation of license if no/false notification
  - Administrative fines to incentivize accurate notifications
- (Minimum) contents of notification
  - Relevant product, pack size, dosage strength, date when and location where product was obtained and is intended to be marketed

Implementation

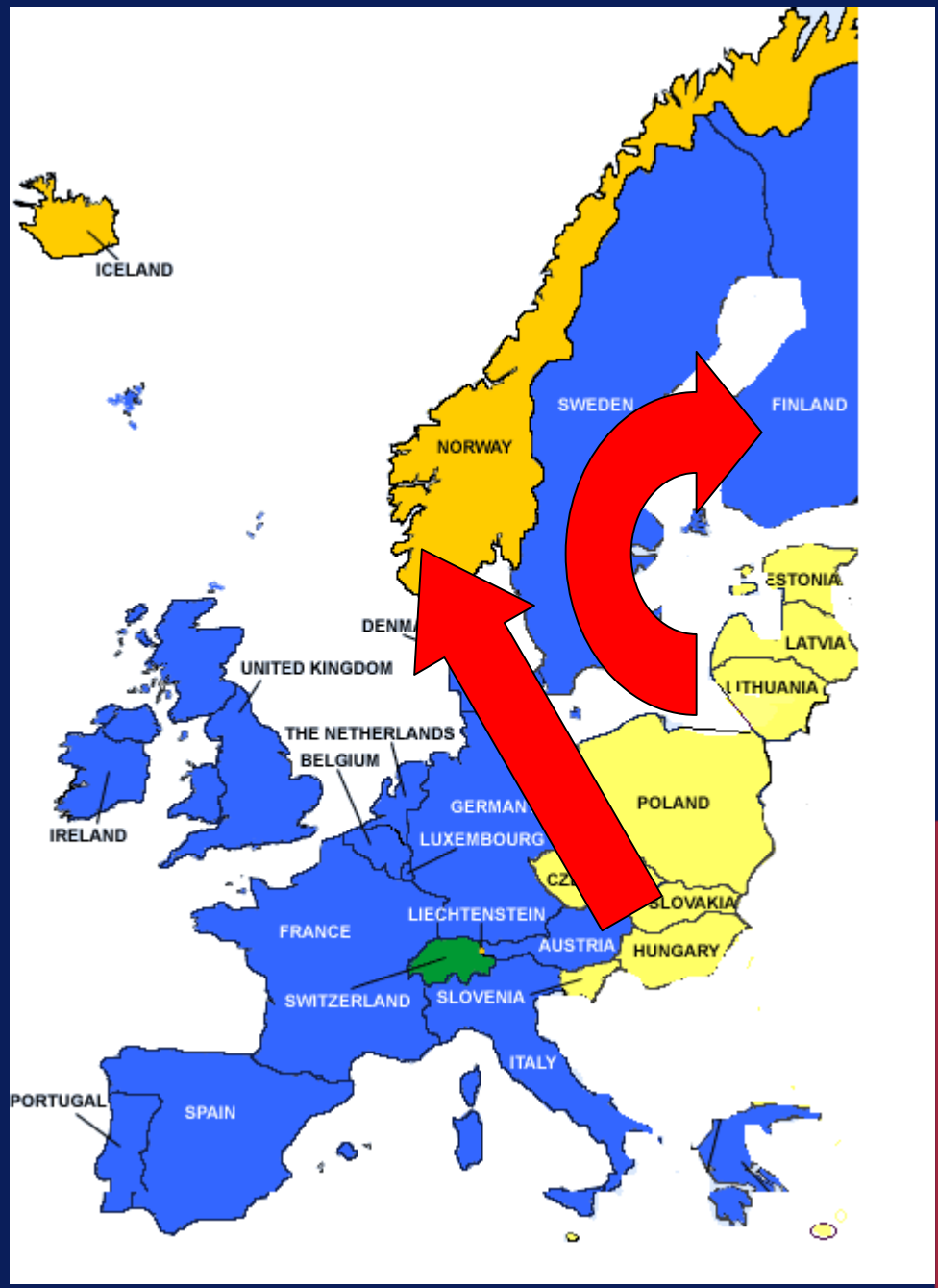
- Directly Applicable in Member States
- Implementation required
  - No European Commission guidance – significant risk of divergent implementation
  - Efforts ongoing in EU 15 and EEA 3 (not Portugal due to the lack of parallel import procedures)
  - In CEC 8 – (half-hearted) efforts
- Damage claims for lack of implementation

Divergent Implementation In EU 15/EEA 3

- Proof of notification
  - Required: B, DK, F, FI, G, NL,
  - Not required: S, UK
- Notification
  - Of MA holder: ES, S
  - Of "other" entity: G, NL, UK
- "Traceability" (country of origin)
  - Apparently not foreseen in the UK

Traceability – A Real Problem

- Finland (and Iceland)
  - Jan. 1, 1995
  - (June 1, 1996)
- Norway
  - Jan. 1, 1992
  - Czech Rep. & Slovakia only



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