The Swiss-Liechtenstein Issue – Implications for SPCs in Europe

Dr. Christoph T. Feddersen

Brussels, January 21, 2004

The Problem – a (not so) hypothetical example

- Blockbuster drug Generica
  - EP on Jan. 1, 1990 – expiration on Dec. 31, 2009
  - Swiss marketing authorization on Jan. 1, 1997
  - EU marketing authorization on Jan. 1, 1999
- SPC under Regulation 1768/92
  - Based on first marketing authorization
  - Swiss authorization – SPCs expires on Dec. 31, 2011
  - EU authorization – SPCs expires on Dec. 31, 2013

Which marketing authorization governs the SPC life?

- Different outcome across the EEA
  - UK, Luxembourg, Germany (substantially reduced SPC protection, based on Swiss marketing authorization)
  - NL, Iceland, Liechtenstein ("extended" SPC protection, based on the first marketing authorization within the EEA, not considering a Swiss marketing authorization)
- Commission position
  - Swiss marketing authorization governs the duration of an EU SPC

Who cares?

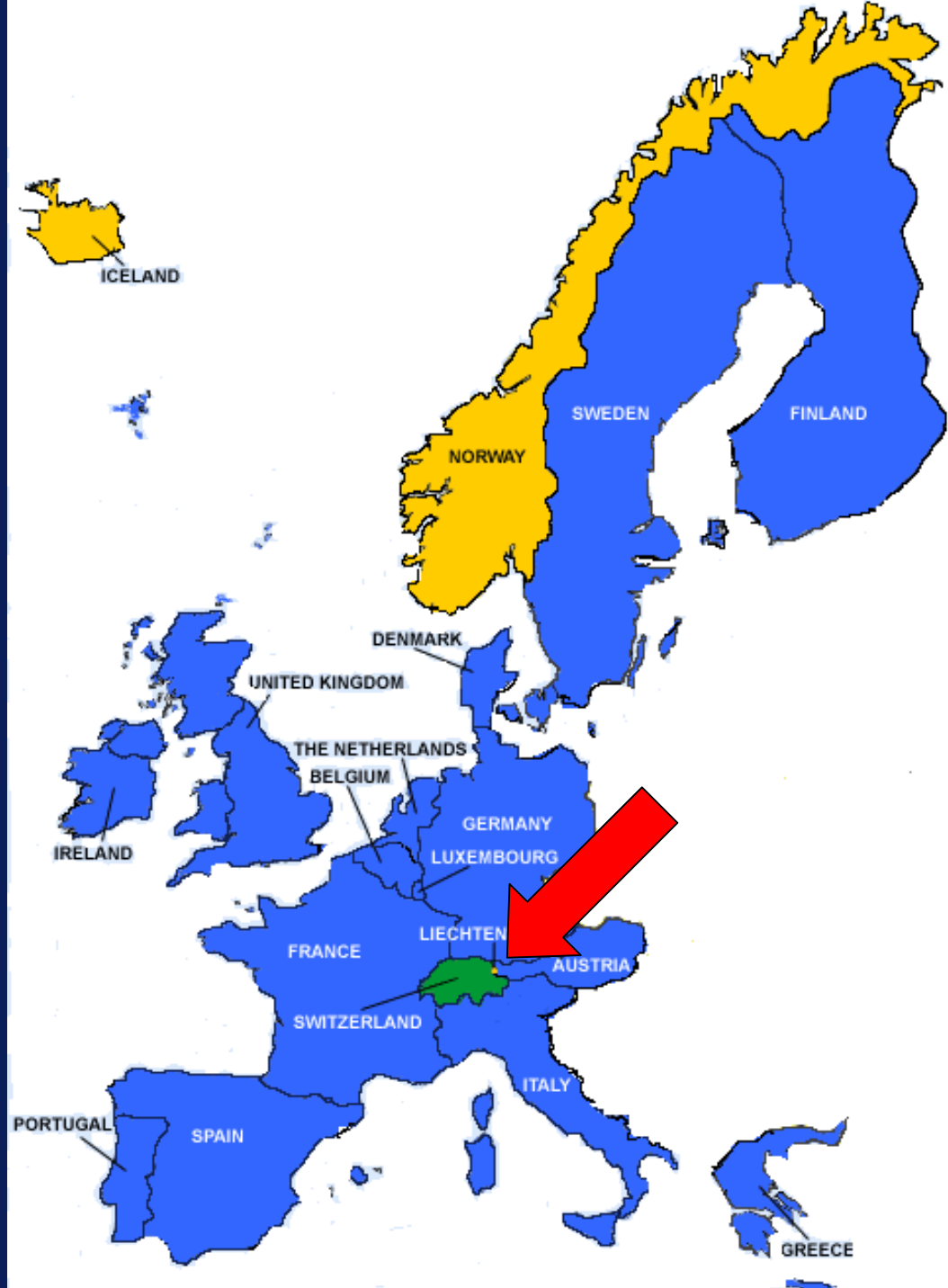
- Two cases pending before the ECJ
  - Novartis (C-207/03) and Millennium (C-252/03)
- Substantial reduction in SPC protection
  - At a time when sales are usually at the highest level
- Over 46 products affected (www.patent.gov.uk)
  - The Wellcome Foundation Ltd., Novartis AG, FMC Corporation, Pfizer Inc., Vertex Pharmaceuticals Inc., Sanofi-Synthelabo SA, Alcon Labs. Inc, G.D.Searle & Co, Protein Design Labs, Merck & Co. Inc., Hoechst AG, IMMUNEX Corp., BASF AG, Du Pont., Hoffmann-La Roche AG, Eli Lilly, Novo Nordisk, Biochem Pharma Inc, Boehringer Ingelheim, Dow AgroSciences, Bayer AG, SmithKline Beecham, Wyeth, Teijin Limited, Genentech, Inc.

The European Economic Area

- Uniting the 15 (25) Member States and the three EEA EFTA States (Iceland, Liechtenstein, Norway)
  - NOT Switzerland
- Internal market
  - Governed by the same rules (goods, services, capital and persons)
  - EEA is a free trade area ➔ rules of origin are important
- What it is NOT
  - CAP, customs union, common trade policy, CFSP, EMU

EU-EEA-EFTA

- EU = 15 (25)
- EEA = 15 (25) + 3
  - Iceland, Liechtenstein, Norway (NOT Switzerland)
- EFTA = 3 (or 4)
  - Iceland, Liechtenstein, Norway
  - (and Switzerland)



CLEARY GOTTLIEB

The EEA – Extension of the acquis

- The EEA – extending the EU-essentials
  - Extension of *acquis communautaire* and implementation of rules which are essentially those of Community law (EEA [2002] ECR I-3493)
- "Mirror" legislation and time-lag
  - "Dynamic" aspect and continuous update of the EEA rules by adding new EU legislation
- EFTA Surveillance Authority and EFTA Court
  - Performing the role of the EU Commission and the ECJ for the EEA

The Principality of Liechtenstein

- 33,145 inhabitants
- GDP: $825 million
- Labor force: 29,000
  - 19,000 foreigners
  - 13,000 commuting from Austria, Germany, Switzerland
- 75,000 letter box companies
- Accession to EEA in 5/95

CLEARY GOTTLIEB

Liechtenstein's relations with Switzerland

- Customs union (1924)
  - Liechtenstein as integral part of Swiss customs territory (essentially "another" Swiss canton)
  - No custom border between Liechtenstein and Switzerland
- Patent union (1980)
  - Uniform patent, uniform SPC, centrally administered by Swiss authorities
- Marketing of medicinal products
  - Automatic recognition of Swiss IKS marketing authorization (IKS responsible for authorization in the different Swiss cantons)
  - IKS authorization results in LIE marketing authorization

Modifications following LIE's EEA Accession

- Swiss referendum in 1992 – rejection of EEA
- Successfully squaring the circle?
  - Close relations with Switzerland vs. common market
- Goods
  - Concept of "parallel marketability" (Swiss and EEA product marketable at the same time without transpiring into the other territory)
- Medicinal products
  - Mirroring of "parallel marketability"
  - Exhaustion of EU-SPCs only applies to Liechtenstein

SPCs for patented pharmaceuticals

- Regulation 1768/92 – effective Jan 2, 1993
- Compensation for loss in patent term granted by national patent offices
  - "basic patent" and "valid authorization to place the product on the market" in accordance with Directive 65/65/EEC or Directive 81/851/EEC
- Critical for recouping R&D
  - Sales of patented pharmaceuticals generally highest just before the patent's expiry
- Cf. Regulation 1610/96

Uniform duration of up to five years

- Uniform duration throughout the Community
  - To avoid "*[t]he introduction of a different period of protection for medicinal products in each of the Member States of the Community [which] would create obstacles to their free movement within the internal market and distort the conditions of competition*" (COM(90)101 final)
  - *Spain v Council* [1995] ECR I-1985; *Biogen* [1997] ECR I-357; *Yamanouchi* [1997] ECR I-3251
  - Article 13 of Regulation 1610/96
- Max. five years protection (Article 13(2))

When does it start (and end) – Article 13

- Expiration of basic patent ("extension")
- Duration – period between dates of patent filing and market authorization, reduced by five years
  - The certificate "*shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community reduced by a period of five years*"
- [Filing within six months of market authorization]

SPCs – in the EU 15 and EEA 18

- Uniform SPCs in the EU 15 and EEA 18
- Regulation 1768/92 – effective 1.5.95 in the EEA
  - EEA Joint Committee Decision 7/94 (transposing Regulation 1768/92 in "EEA law")
  - EEA Council Decision 1/95 ("A number of adjustments need to be made to the EEA as a consequence of its entry into force for Liechtenstein")
- Amended Article 3(b) – Article 13 unchanged
  - "An authorization granted in accordance with the national legislation of the EFTA State shall be treated as an authorization granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC"

The EEA-irrelevance of Swiss authorizations (I)

- No Harmonization/mutual recognition of marketing authorizations between Switzerland and the EU
  - Segregation of Swiss and Community markets
  - The EU/Swiss bilateral agreements exclude this issue
  - Swiss marketing authorization is irrelevant for the product's marketability in the EEA (in fact, Swiss procedure used to be much shorter)
  - *Polydor v Harlequin* case-law on exhaustion also applies to Switzerland and the EEA ([1982] ECR 329)

The EEA-irrelevance of Swiss authorizations (II)

- Free movement of medicinal products and recognition of authorizations only between LIE and Switzerland
  - Liechtenstein must recognize Swiss authorizations to avoid undermining the customs union
  - Only products originating in the EEA can move freely in the EEA (Swiss products do not originate in the EEA)
  - Concept of parallel marketability proves duality of systems

The EEA-irrelevance of Swiss authorizations (III)

- 1998 Liechtenstein law on marketing authorizations shows irrelevance under Liechtenstein law
  - 1998 Arzneimittelgesetz as implementation of Liechtenstein's EEA-obligations
  - Provides for marketing authorizations in accordance with Directive 65/65/EEC or Directive 81/851/EEC

The EEA-irrelevance of Swiss authorizations (IV)

- Amendment of Article 3(b) of Regulation 1768/92 for EEA purposes does not provide for permanent derogation
  - "An authorization granted in accordance with the national legislation of the EFTA State shall be treated as an authorization granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC"
  - Mere transitional arrangement to ensure that pre-EEA-accession authorizations could be basis for SPC (Austria, Finland, Iceland, Norway, Sweden, Liechtenstein)

The EEA-irrelevance of Swiss authorizations (V)

- An absurd example – blockbuster Generica
  - On the same day – authorized in S, prohibited in EEA
  - (Article 12(2) Regulation 2309/93 -- Commission refusal to issue centralized authorization "shall constitute a prohibition" to market the product }
  - No SPC available throughout the EEA – but effect of Swiss authorization for EEA-SPC?
  - What if, on appeal against the Commission decision (about 40 months later), Commission authorizes product – must the SPC be based on the Swiss authorization?

Possible strategies for pharmaceutical companies (I)

- Delayed filings?
  - Undesirabe for both patients and companies
- SPC Application
  - Provide only EEA marketing authorization
  - UK, Germany, Luxembourg
  - Proviso – pending ECJ litigation
- Review current SPC status
  - Based on which marketing authorization?

Possible strategies for pharmaceutical companies (II)

- Re-starting the clock?
  - Pre-ECJ ruling:
    - Remedies against national SPCs are subject to national law
    - Article 234 EC – reference proceeding
  - Post-ECJ ruling:
    - Filing for correction of erroneously calculated SPC duration
    - Remedies under national law and Article 234 EC
    - Complaint to the Commission