

“Bolar” exception to patent rights: Some economic implications

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Outline of presentation

- Rationale of “Bolar”-type exception to patent rights
- Some facts about patented and generic medicines drawn from studies of the US and EU markets
- Article 30 of the TRIPS Agreement
- The EU-Canada Bolar dispute in brief
- Economic arguments made by both sides
- Concluding remarks

Rationale of “Bolar” exception

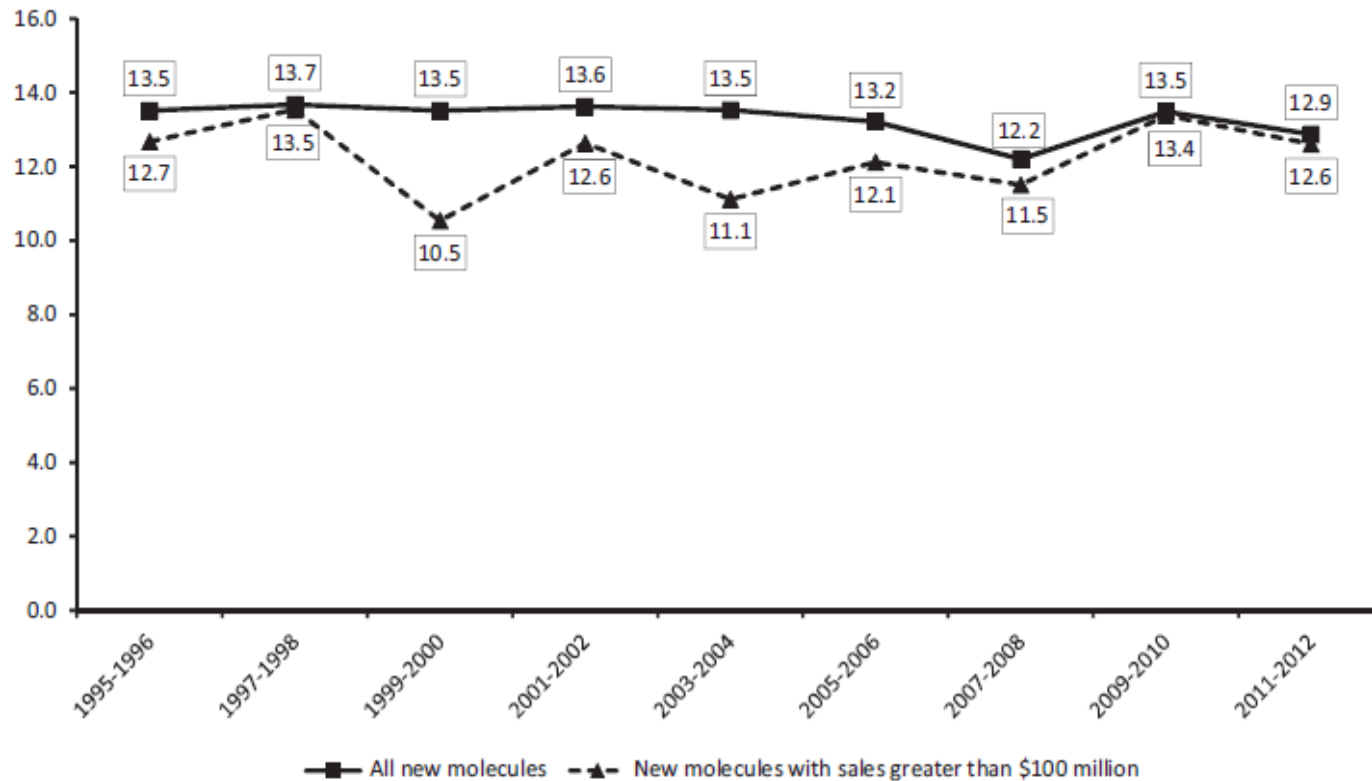
- Name comes from US 1984 Fed. Circuit case Roche Products Inc. v. Bolar Pharmaceuticals Co. Inc. 733 F.2d 858 (1984)
- Certain acts done during the patent term for obtaining regulatory approval for the marketing of products after patent expiry are considered to be exceptions to patent rights.
 - Sometimes laws/jurisprudence specify excepted acts or time periods, for e.g. only trials and studies needed to obtain regulatory approval, whether generic or innovative products; or only applicant for regulatory approval exempt, not his suppliers (?); or only within 8 years/3 years of patent expiry. Sometimes, extends to foreign regulatory approvals also; or covers post-approval marketing acts.http://www.wipo.int/wipo_magazine/en/2014/03/article_0004.html
- Basic rationale is to maintain the balance in the patent system between patent holders and users/general public

Some facts about patented and generic medicines

- In pharma sector, patents rarely confer full monopoly market power as there are similar but slightly different therapeutic substitutes.
- Even break-through drugs with novel mechanisms usually face competition from other follow-on products within 1-6 years (US CBO, 1998) but effect of inter-brand on average prices difficult to estimate – more the competition and less differentiated the product, the greater the price discounts
- Generic entry brings average prices down rapidly and originator product loses half the market share within one year of generic entry.
 - But this depends on number of generic entrants, which in turn depends on size of market, ease of copying product and other factors such as ease of distribution, generic substitution laws etc.
- In US pharma market studies on effect of Hatch-Waxman Act show that **average delay in generic entry after patent expiry decreased from more than 3 years to less than 3 months (US CBO, 1998)**.
 - But included changes to abbreviated new drug application – only need to prove bioequivalence.
- Some recent trends in the US and EU pharma markets on generic entry

Average market exclusivity period by year of first generic entry in the US market

(<http://fds.duke.edu/db/attachment/2575>)



Source:

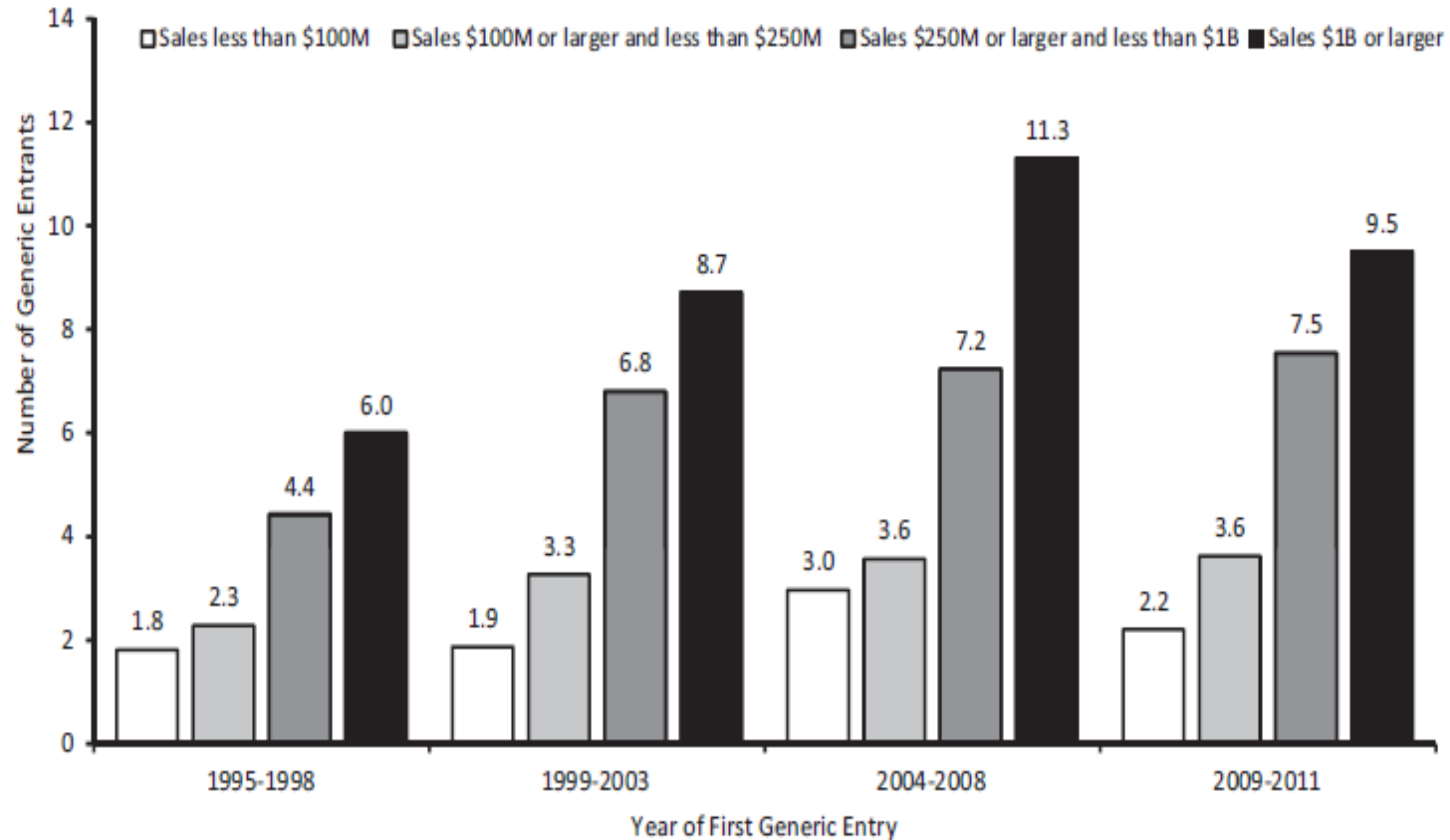
IMS Health data on all new drugs with initial generic entry in the period 1995 through September 2012.

Notes:

New molecules with sales greater than \$100 million based on sales in the year prior to generic entry and inflation adjusted to 2008 dollars using the Consumer Price Index for All Urban Consumers.

Figure 1. Average market exclusivity period by year of first generic entry: new molecular entities.

Average number of generic entrants within 1 year of first generic entry in US pharma market



Source:

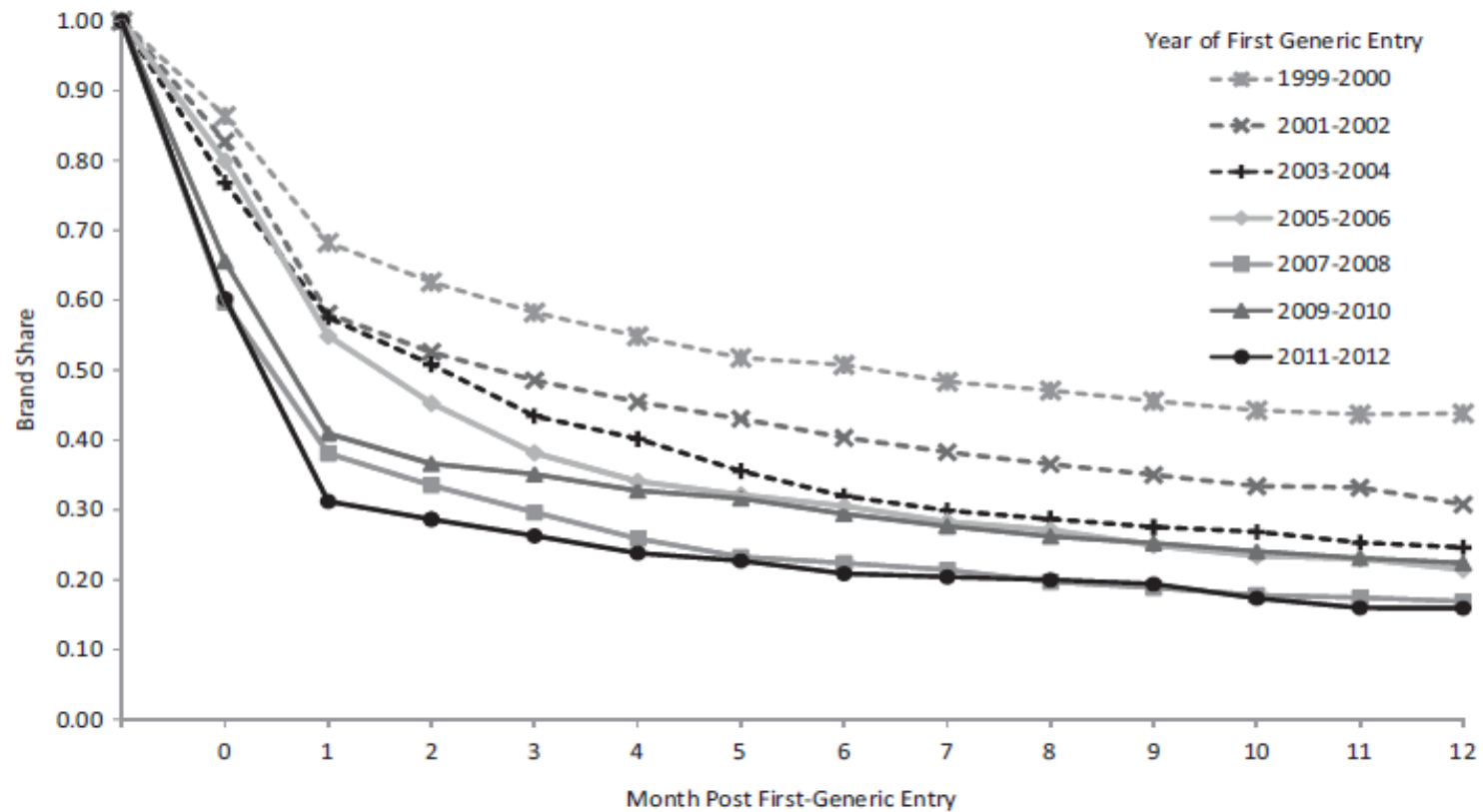
IMS Health data on all new drugs with initial generic entry in the period 1995 through September 2012.

Notes:

New molecules with sales in the year prior to generic entry, inflation-adjusted to 2008 dollars using the Consumer Price Index for All Urban Consumers.

Figure 2. Average number of generic entrants within 1 year of first generic entry: new molecular entities.

Average monthly brand share of standard units of the molecule/form following first generic entry



Source:

IMS Health data for all new molecular entities with first generic entry in the period 1999 through September 2012.

Note:

Initial generic entry occurs at some point during month "0". Month "1" is the first full month of generic competition.

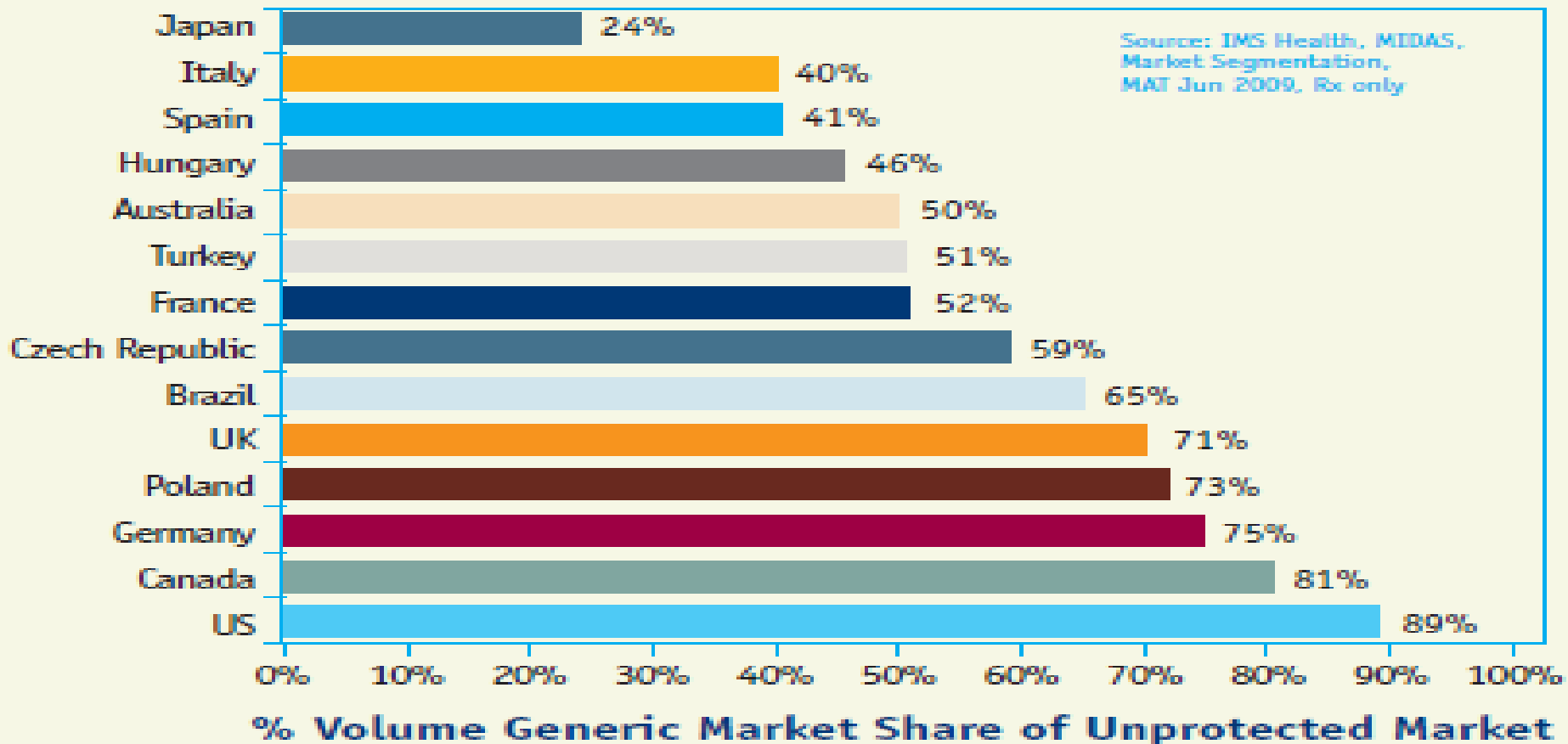
Figure 4. Average monthly brand share of standard units of the molecule/form following first generic entry.

Recent trends in generic entry in the US pharma market: conclusions

- For drugs experiencing initial generic entry in 2011–2012, the market exclusivity period (MEP) was 12.6 years for drugs with sales greater than \$100 million (in 2008 dollars) in the year prior to generic entry, 12.9 years overall.
- After generic entry, the brand rapidly lost sales, with average brand unit share of 16% at 1 year; 11% for NMEs with pre-generic entry sales of at least \$250 million (in 2008 dollars).
- Over 80% of NMEs experiencing 2011–2012 initial generic entry had faced at least one patent challenge from a generic manufacturer. These challenges were filed relatively early in the brand-name drug life cycle: within 7 years after brand launch, on average.

Source: IMS - Generic Medicines: Essential contributors
to the long-term health of society
SECTOR SUSTAINABILITY CHALLENGES IN EUROPE

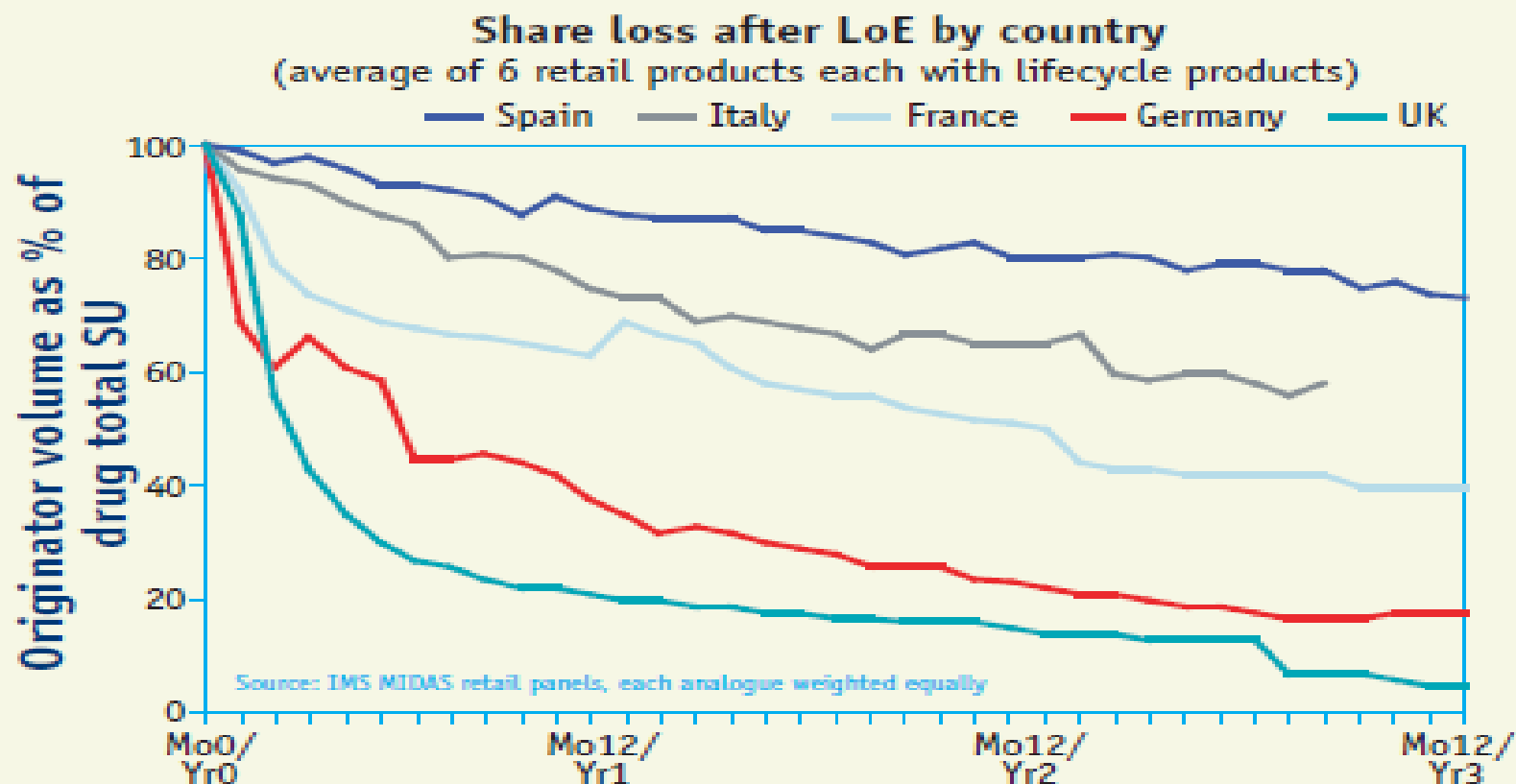
FIGURE 4. Utilisation of generic medicines within the unprotected markets.



Source: IMS - Generic Medicines: Essential contributors to the long-term health of society

SECTOR SUSTAINABILITY CHALLENGES IN EUROPE

FIGURE 11. Degree of generic erosion following loss of exclusivity.



The impact of biosimilars' entry in the EU market: Joan Rovira et al
http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/biosimilars_market_012011_en.pdf

Table 5 shows the time of total exclusivity enjoyed by the originators in the selected countries. The average total exclusivity is 14.7 years. This figure is highest for UK and Spain and lower for France and Germany.

Table 5. Duration of the competition free market position of the reference products (years)

	Genotropin	Neupogen	Epex	All
ITALY	18	16	15	16.3
UK	19	18	17	18
FRANCE	10	17	7	11.3
GERMANY	18	7	6	10.3
SPAIN	15	18	19	17.3
MEAN	16	15.2	12.8	14.7

Source: Own elaboration based on IMS data

Source: IMS - Generic Medicines: Essential contributors
to the long-term health of society

SECTOR SUSTAINABILITY CHALLENGES IN EUROPE

- In order to derive the maximum benefit from a generic medicine it must be available from day one following patent expiry.
- in certain markets, generic medicine entry is often delayed, partly by the need to gain pricing and reimbursement approval.
- Depending on the sales value of the originator product, lost savings can amount to tens of millions of Euros within the first year.
- The final report on the EU Pharmaceutical Sector Inquiry (2008/9) suggested that the additional savings on the 219 prescription medicines investigated could have been as much as 20% higher if there had been no delays to entry.

Article 30, TRIPS Agreement

- No agreed list of exceptions to patent rights in TRIPS in Article 30
- Exceptions may be provided (such as prior use, private non-commercial use, experimental use) if they meet the **three-step test**:
 1. They are limited
 2. Do not unreasonably conflict with the normal exploitation of the patent
 3. Do not unreasonably prejudice the legitimate interests of the patent owner
 - Taking account of legitimate interests of third parties

EU-Canada case in brief

- Complaint by the EC against Canada. Panel report adopted on 7 April 2000 (WT/DS114/R).
- Two measures at issue: regulatory review exception and stockpiling exception (that allowed unlimited production of patented medicines during the last six months of the patent term).
- Panel ruled that the “stockpiling exception” failed the first step “Regulatory review exception” passed each of the 3 steps.
 - Is limited (small and narrowly bound)
 - Use of patent rights to preclude submissions for regulatory authorizations should not be considered a normal exploitation
 - No conflict with legitimate interests, thus no need to consider whether this was unreasonable
- Canada implemented the findings by repealing the “stockpiling exception” in its legislation.

Negotiating history of TRIPS Article 30 in DS 114

- **EU position:** "Limited exceptions to the exclusive rights conferred by a patent may be made for certain acts, such as rights based on prior use, **acts done privately and for non-commercial purposes** and **acts done for experimental purposes**, provided that they **take account of the legitimate interests of the proprietor of the patent and of third parties.**" GATT document MTN.GNG/NG11/W/68, p. 10, Art. 24(2)
- **Developing country position:** "Nothing in this Agreement shall be construed to prevent any Party from taking any action necessary:...for granting to any person applying for the same a licence limited to the use of the invention for the purposes of the preparation or production and distribution of food and medicines."
Communication from Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay, MTN.GNG/NG11/W/71, p. 9, Art. 6
- **United States' position:** was intent on securing an exception that allowed its pre-existing "Bolar exemption" to be preserved. This was confirmed by the United States Trade Representative (and subsequently reiterated by his successor): "[O]ur negotiators ensured that the TRIPS Agreement permits the Bolar exemption to be maintained."
 - FN. Letter from Michael Kantor to Alfred B. Engelberg, 1 February 1996. Confirmed in a letter from Charlene Barshefsky to Greg Perry, 1 January 1997

Economic arguments made by Canada in DS 114

- Not much difference in effective patent term before and after legislative changes
 - Para 4.5. “...in practical terms.., under the present patent law provisions of Canada, a holder of a pharmaceutical patent enjoyed an effective patent term of eight to 12 years in which he could claim exclusivity on the market and it was during this period that all R&D costs had to be depreciated on sales. Under the pre-C-91 system, compulsory licences were automatically granted to all Canadian operators who wanted to copy the invention after the patented pharmaceutical product had been on the Canadian market for at least seven years (or ten years if the active ingredients for the generic product were imported). Furthermore, a period of at least two-and-a-half years for obtaining marketing approval in Canada for the copy product had to be taken into consideration because, under the previous Canadian patent law, producers of copy products could only start to generate pre-marketing approval testing activities once the compulsory licence had been granted. For the holder of the patent for the original product this system provided for a period of effective market exclusivity from nine-and-a-half years to 12½ years. This also had as a consequence that the effective market exclusivity for the patent holder went in certain cases beyond the end of the 20-year patent term. To put it in a nutshell, the economic situation in terms of effective market exclusivity for the holder of the patent under the old 1989 to 1993 system, which granted on average 11 years, was indeed very similar to the C-91 system from 1994, which granted on average a market exclusivity for the patent holder of ten years.

Economic arguments made by Canada in DS 114

- Para 4.14. (i) **The early working exception** was restricted to the narrow circumstance where a third party made, constructed, used or sold a patented invention solely for purposes reasonably related to regulatory review. The **stockpiling exception** could only be used by the person who had relied on the first exception, and was limited to the last six months of the relevant patent. **Neither measure affected commercial sales by the patent holder during the term or any other economic benefit of a patent**, such as the profit that could be earned through licensing royalties or the sale of the right..
- (Iii) ...notwithstanding the private economic advantage that would be obtained by doing so, a **patentee could have no legitimate interest** deriving from patent law in exercising its exclusive use and enforcement rights within the term of protection to achieve, through exploitation of regulatory review laws, **a de facto extension of that term of protection beyond the prescribed period, thereby unilaterally altering the bargain between the patentee and society**. In this respect, the interests of a patentee of a pharmaceutical invention could be no different from those of patentees in other fields of technology.
- (iv)..Public health was a value whose importance was recognized as a matter of principle in **Article 8.1 of the TRIPS Agreement**. Accordingly, the exercise of exclusive rights in respect of regulated health care products during the term of protection **to extend the patentee's monopoly into the post-expiry market was of particular concern in the pharmaceutical products sector**

Economic arguments made by Canada in DS 114

- **Evidence on rate of decline in prices of pharmaceuticals with Bolar:**
 - FN 112....Canada did have reasonably reliable information to demonstrate that generic versions of innovative medicines traded at a significant discount to the innovative version of the medicine. In this respect, it could be shown that
 - on average: the first and second generic versions of a previously patented product came on the market at just less than 75 per cent of the innovator's price;
 - when a third and a fourth generic entered, the average price dropped about 20 percentage points to about 54 per cent of the innovator price;
 - and when a fifth entered, the average fell another ten percentage points to just under 46 per cent of the innovator's price for the same medicine (*Savings to Canada's Health Care System*, Canadian Drug Manufacturers Association, January 1997).
 - While such discounts suggested substantial savings, the quantum of the savings realized would, of course, depend on the degree of market penetration that the generic products achieved.
 - The quantum of the savings would also vary if the innovator adjusted its prices downward in an effort to retain market share.

Economic arguments made by the EU in DS 114

- Para 4.7. “The European research-based pharmaceutical industry (EFPIA) had made an analysis of its alleged **losses suffered in Canada**, which **exceeded the amount of C\$ 100 million per year**.
- This analysis was based on the conservative assumption that, while the operation of the provisions referred to above would allow copy manufacturers to market the product immediately upon patent expiry, in the **absence** of these provisions **effective marketing would only be possible at the earliest two years after patent term expiry**.
- The **extrapolation was based on sales of the top 100 original pharmaceutical products sold in Canada between 1995 and 1997.**”
- FN. 138. In response to a question from the Panel, the EC explained that ...[the] effective period of protection would ... be **12 years at a maximum and eight years at a minimum**. **Generic producers needed three to six-and-a-half years of pre-marketing activities** in Canada to obtain marketing approval for their generic copies of a patented drug. The shortest period that the generic producers would need (3 years) combined with the longest effective period of protection for the patented drug (12 years) left a period of 9 years of fully effective protection.
- **The longest period needed by the generic producers (6 ½ years) combined with the shortest effective period of protection for the patented drug (8 years) left a period of 1 ½ year of fully effective protection.**

Economic arguments made by the EU in DS 114

- Para 4.30 (iii). “Both research-based and generic enterprises operated for commercial gain and none could claim any priority interest over the other. This meant that, from the perspective of Article 30, the legitimate interest of both could be nothing else but a full respect of the existing intellectual property rights.”
- “...there existed no reason why the research-based pharmaceutical enterprise was obliged to accept the economic consequences of marketing approval requirements which reduced its effective term of protection to eight to 12 years, while the copy producer could completely ignore the economic consequences of the need for marketing approval for his generic products, and this at the expense of inventors and patent holders....
- Already the fact that the marketing approval requirements for generic products only required a fraction of effort as compared to the original product, which also led to much shorter periods of time for obtaining marketing approval, gave the generic product a competitive advantage at the expense of the producer of the original product. ”

Concluding remarks on economic implications

- Without Bolar exception, generic entry would be delayed by 2-3 years or more in economies with generic pharmaceutical manufacturing capability
- Consequently, economies importing generic products would also be affected by such delays
- Rapid market share ranging from 50% to 90% could accrue to generic drugs, depending on market size, nature of technology
 - Biosimilars may have to incur higher expenses to conduct trials to prove similarity and price reductions, therefore market penetration may not be as much.
- Other policies to encourage generic drugs, notably abbreviated approval procedures, may be needed in addition to Bolar-type policies.
- Economies that want to attract investment from companies engaged in clinical trials may want to ensure Bolar-type exemptions, in addition to other policies