Making Medicines Affordable
WIPO Symposium:
Test Data Protection - generic and biosimilar industry perspective

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Generic Medicines: Key to Healthcare Sustainability and Patient Care

- EGA represents over 700 companies in 34 European countries
- Generic medicines companies employ over 150,000 people in the EU
- Generic medicines account for nearly 50% of packs dispensed in the EU and 18% of pharmaceutical expenditure
- Generic medicines bring savings of over €25-30 Billion per annum in the EU 27
- Generic medicines companies cover a full spectrum of pharmaceutical needs
- Generic medicines companies also undertake incremental innovation
Terminology: Data Protection/Data Exclusivity

- Misleading terminology
- Data submitted to the regulators remain undisclosed vis-à-vis third parties
- Generic companies never have direct access to the pre-clinical and clinical data submitted by originator companies
- Generic companies do not use the originators’ data
- Generic/biosimilar application cross-refer to originators’ data after expiry of exclusivity
Terminology
Data Exclusivity (DE)

Data exclusivity
- Completely independent of IP laws
- Administrative Regulatory Exclusivity
- Determines the length of time during which
  - the generic/biosimilar application cannot cross-refer to the originators’ data and
  - the Regulatory Authorities cannot rely on originator’s data to approve a generic/biosimilar version of the relevant originator product
WHO Briefing Note-Access to Medicines- March 2006

Article 39.3 requires countries to protect undisclosed registration data
  i) against disclosure and
  ii) against unfair commercial use

Article 39.3 does not make any reference whatsoever to exclusivity or exclusive rights
What is Meant by ‘Unfair Commercial Use’? (WHO)

- ‘Does the use of bioequivalence studies instead of full clinical trials represent ‘unfair commercial use’?
- ‘Clearly, there is no ‘unfair commercial use’ by the generic company’
  - Never use of originator data
  - Never access to originator data
- ‘Even if regulators would use those data, this is not commercial use, since the regulatory agency is not a commercial organisation.’
The term ‘unfair commercial use’ refers to, and prohibits practices such as industrial espionage, but was not meant to provide exclusive rights

- Carlos M. Correra: Protection of data submitted for the registration of pharmaceuticals: implementing the standards of the TRIPS Agreement

http://www.southcentre.org/
Data Exclusivity classified as a ‘TRIPS PLUS Measure’

‘Legal and public health experts believe that TRIPS requires data protection, but not data exclusivity - and national laws do not need to be more stringent or more restrictive than TRIPS’

March 2006
Impact of Data Exclusivity

**DE period becomes Market Exclusivity**

- When there is no patent or when weak patents are invalidated
- When a country has no patent law
- When no patents are granted for originator
- When data exclusivity period goes beyond patent/SPC expiry

- The EU- About 7% of generic product launches were limited by Data Exclusivity (not by patent/SPC) *(EC Report on Pharmaceutical Sector Inquiry 2009)*
Impact of Data Exclusivity in Developing Countries

- Interpreting that TRIPS requires implementation of DE has serious worldwide implications on access to medicines.
- ‘Essential drugs are not simply another commodity—TRIPS safeguards are crucial’

WHO Globalization, TRIPS and Access to Pharmaceuticals 3 March 2001
1987 Initial purpose

- DE as protection mechanism for insufficient protection of biotechnological inventions
  - 6 years DE with a possibility to extend to 10 years (individual decision of each country); no longer than patent
  - 10 years for biotech/ high tech products

Overview before a change in 2004

- 6 years in 19 MSs (+2): AT, BG, CZ, CY, DK, EST, EL, FI, HU, IR, MLT, LV, LT, PL, PT, RO, SP, SK, SLO, (NO, IS)
- 10 years in 8 MSs (BE, LU, FR, IT, DE, NL, SE, UK)
- 10 years for biotech/ high tech products
2004- General Increase of Length of DE in the EU

- Significant revision of pharmaceutical legislation in 2004
  - Increase of basic DE to 8+2(+1)
  - Additional exclusivity
    - 1 year DE for new indication for well established use substance (WEU)
    - 1 year DE for change of classification (eg, OTC switch)

- Final achievement seen by the European Commission as a balance between originator and generic medicine industry
Balance Reached in 2004

**Exclusivity 8+2(+1)**
- Harmonised for both types of products (generics/biosimilars), all MA procedures and all countries
- 1 year DE for new indication for well-established use substance (WEU)
- 1 year DE for change of classification (eg, OTC switch)

**No additional data exclusivity for line extensions** *(new indication, new strength, new form etc as a part of so called: “Global Marketing Authorisation”)*

- Bolar provision
- No patent linkage in Marketing Authorisation process
Data Exclusivity
‘8+2+(1)’ Formula

- Applies to all reference products (chemical & biological) independent of the registration procedures
- No additional data exclusivity for line extensions

0-8 years Data Excl. | 2 years Market Excl. | (1 year ME)

Marketing Authorisation of Reference Product | Generic or biosimilar Application | Assessment, approval, price, reimbursement

Additional 1 year Market Excl. if significant new indication registered for reference product during first 8 years
Global Marketing Authorisation’ Concept

No data exclusivity for line extension:
- any additional strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions shall be considered as belonging to the same global marketing authorisation
- even if authorised through a separate procedure and/or full dossiers and/or under a different name
**Intention to Mix the US and the EU System Stopped**

<table>
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<tr>
<th>US system:</th>
<th>EU system:</th>
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<tr>
<td>5 year DE</td>
<td>8 DE+2 ME+(1ME)</td>
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<td>3 year DE for each new indication</td>
<td>+ 1 year ME for entire product (only once) if new indication brings a significant clinical benefit in comparison with existing therapies</td>
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<td>Patent linkage in Marketing Authorisation (MA)</td>
<td>No data exclusivity for line extension</td>
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<td>4 year DE if Orange Book patent is challenged</td>
<td>1 year DE for new indication</td>
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<td>if significant trials</td>
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<td>No patent linkage in MA</td>
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Intention of Rewarding a Significant Innovation

- **1 Year Data Exclusivity for New Indication of Well Established Use (WEU) Substance if significant pre-clinical or clinical studies**
  - 1 year DE refers exclusively to the data concerning the new indications

- **1 year of Data Exclusivity for changing classification (eg, OTC switch)**
  - If a change of classification based on significant pre-clinical tests or clinical trials
Possible Scenario for Changing a Classification

Submission of documentation for switch

- Positive decision about the OTC but NO 1 year exclusivity
- Documentation assessed as non sufficiently significant to grant the exclusivity

- Positive decision about the OTC plus 1 year exclusivity granted
- Documentation assessed as sufficiently significant to grant the exclusivity
Current Experience with the OTC in the EU

Three cases via Centralised Procedure:

- Viagra - erectal dysfunction - refusal
- Orlistat - weight loss aid - OTC accepted but no 1 year DE
  - Justification: Studies provided were not relevant and necessary to change a classification, did not give more insight into the safety of orlistat
- Pantoprazole - OTC accepted but no 1 year DE
  - Justification: Studies provided were not relevant and necessary to change a classification
Various Possibility of Market Protection in Addition to DE

- Data Exclusivity is only one of several existing mechanisms of protection
  - Patent
    - including a possibility to patent an indication (so called “second medical use patent”)
  - Supplementary Protection Certificate (SPC)
    - max 5 years
  - SPC extension due to paediatric trials
    - 6 months
  - 10 years market exclusivity for orphan medicines
Parallel mechanism to achieve 15 years Market Exclusivity for Originator:

- **Patent Duration**
  - 10 years
  - 12 years

- **Data exclusivity period**
  - 6 or 10 or ‘8+2+1’

- **Maximum 5 years extension of Supplementary Protection Certificate (SPC)**
  - 20 years

- **6 months paediatric SPC**
  - 25 years

- **Submission of generic/biosimilar applications possible after data exclusivity expiry**

  - e.g. the marketing authorisation is granted to originator in year 12

  - Generic/biosimilar registration possible
“The inquiry showed that originator companies use a variety of instruments to extend the commercial life of their products without generic entry for as long as possible.”

8 July 09

Neelie Kroes, European Commissioner for Competition
Data exclusivity used as a anti-competitive tool

- Originator companies had a low success record (19%) in cases concerning data exclusivity, i.e. when they claimed that marketing authorisation for a generic product cannot yet be granted due to data exclusivity rules protecting the originator product.
Conclusion of the Sector Inquiry (2)

The combined use of life-cycle instruments may increase the likelihood of delays to generic entry. Delays due to the use of several instruments may sometimes be cumulative.
Conclusion of the Sector Inquiry (3)

- Intervention and litigation by originator companies in administrative proceedings for generic medicines delay generic market entry on average four months.
  - The sector inquiry produced evidence that such practices generated significant additional revenues for originator products.
The European Commission has opened a formal antitrust investigation into Lundbeck

- potential breaches of EU rules on restrictive business practices and on the abuse of a dominant market position
- To investigate unilateral behaviour and agreements by Lundbeck which may hinder the entry of generic citalopram
Conclusion (1)

- Art 39.3 of TRIPS should not be interpreted as an obligation to introduce Data Exclusivity.
- Current EU system gives the highest protection by Data Exclusivity in the world.
Every system of protection in each country should be developed on its own:

- After careful assessment of other existing IP protection tools
- Without mixing the elements from other systems
- Taking into consideration its own health care and economics factors within the flexibility of TRIPS.
Thank you for your attention!
Acronyms

- DE Data Exclusivity
- MA Marketing Authorisation
- ME Market Exclusivity
- SPC Supplementary Protection Certificates
- CP Centralised Procedure
- TRIPS Trade Related Intellectual Property Rights
- MS Member State
- EU European Union