Data Exclusivity and the Preliminary Report

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Intro: Data Exclusivity

- Number of allegations made by the Commission in the Preliminary Report with regard to data exclusivity and actions taken by originators
- Brief overview of some of the allegations in the Report, and factors for additional consideration
- Starting point: **Data exclusivity – What is it?**
  - In short, the period of time during which a generic **may not refer** to the pre-clinical and clinical trial data of the originator

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    - **Note**: considered an IP right under Article 39.3 of the TRIPs Agreement
    - « **Enforced »** by the regulatory authorities – **they determine** when they will accept a generic marketing autorisation application that refers to an originator's data

- **Why is it critical?**
  - For products that have no or little patent protection, data exclusivity is the only protection available for the product

Old/New rules on Data Exclusivity

- **Old** Rules**:**
  - 10 yrs centralised procedure
  - 6/10 yrs mutual recognition depending on the Member State
- **New** Rules
  - 8+2+1 all procedures
    - (first **8 yrs data exclusivity**; generic may file after yr 8, but can only market at yr 10. If a significant new indication is granted, then generic may only market the product after 11 years
    - **New rules** begin to apply for products filed under the centralised procedure **after Nov. 20, 2005** and under the other procedures **after Oct. 30, 2005**.
    - Generics will only be able to file applications 8 years after the first marketing authorisations have been granted under the new rules, so after **November 2013 at the earliest!**

Main difference between old and new rules

- Under old rules, generics can **only file after** the period of data exclusivity **has expired.**
- Under the new rules, generics can file after **8 years** and **then market after year 10** or **11.**

Commission's Preliminary Report
LoE

- Commission **LoE definition** (p. 19) refers to both **patents and data exclusivity**
- However, the LoE provision as defined by the Commission **does not apply in the same way** for patents and data exclusivity (under the old rules)
- Commission's allegation is that generic entry occurs later than could be expected

  « For a sample of medicines ... which had lost exclusivity in 2000 to 2007 the average time to enter after loss of exclusivity was about seven months on a weighted average basis, whereas also for the most valuable medicines it took about four months » (Executive Summary, page 5-6)
- Under **old data exclusivity rules** (which apply to all generic products considered by the Commission in its Report), **a generic may only file and a regulatory authority may only validate the application after the loss of data protection (LoE)**
  - By definition, the **generic application may not be considered** by the authorities **before the LoE.** There will generally be at least a **9 month time** lag (which is the time it takes the **authorities to consider the generic application)**

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  - Was this factored into the Commission's analysis? Not clear

Commission's Preliminary Report Litigation

- The Commission has divided its analysis of cases involving litigation against regulatory authorities between
  - (1) **patent infringement** and **safety issues** ; and
  - (2) **data exclusivity** (see paras. 728 and 730 and Tables 25 and 26)
- This division is strange. It would be more usual to see the safety issue being litigated in the context of data exclusivity.
- Why? Litigation in the past years has centered on the definition of an « essentially similar product » and what this means for a generic product

Commission's Preliminary Report Litigation -- 2

- SB Paroxetine case (Case C-74/03, January 20, 2005). Issue: whether use of an alternative salt and bridging data allow the product to be considered as a generic.
  - ECJ said yes, but issues of safety raised and discussed in the course of the judgment

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  - **Note**: case only decided in 2005, which is towards the end of the 2000-2007 Commission review period
  - Paroxetine: one of the INNs in the report
- With change in new legislation (which came into effect in late 2005), it is now stated that **alternative salts may be considered under the abridged generic procedure**
- Synthon (Case C-452/06, October 16, 2008). Mutual recognition of product using alternative salt required upheld – no re-review of definition of essential similarity.

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  - **Note**: US FDA requires certain clinical trial data when alternative salt is used

Commission's Preliminary Report Litigation -- 3

- Underlying allegation seems to be that **the litigation involving data exclusivity is excessive**
- Report outlines that litigation initiated in numerous countries (Tables 26 and 27)

- Such an outcome is not strange at all. For products not approved under the centralised procedure, there is a national marketing autorisation. Therefore, **litigation on a data exclusivity** issue is required **in all countries where there is a marketing authorisation.**

Commission's Preliminary Report Litigation -- 4

- Commission states that the rules were changed in 2005 so that generics could file under the centralised procedure. (Footnote 150).
- In fact, prior to the legislative change in 2005, **generics could file** under the **centralised procedure** after the expiration of the 10 yrs of data exclusivity.
- As the centralised procedure went into effect in 1995, the first generics could only be filed after ten years (2005) and hence approvals in 2006 would have been anticipated under the legislation.
- The 2004 legislative changes (that went into effect in 2005) now allow generic applications of a centralised authorisation to be filed with EMEA, or the national authorities.

Commission's Preliminary Report Litigation -- 5

- Underlying allegation that much of the litigation by originators concerns the new Member States
  - New Member States not supportive of data exclusivity generally.
    - A number of new Member States sought a derogation to the data protection rules (which the Commission did not grant)
    - Prior to accession, large numbers of « ghost applications » were approved at the last minute.
    - Given differences in interpretation, the additional litigation is not surprising.

Commission's Preliminary Report Litigation -- 6

- Commission allegation:
  - « Figure 119 and Figure 120 **demonstrates** that originator companies are often defeated in court cases concerning data exclusivity. Nevertheless, even though most data exclusivity cases ultimately have no impact on the marketing authorisation, they may still effectively delay market entry and can therefore have a financial impact on generic companies, health systems and patients. Table 28 provides an overview of the number of litigations begun in the period 2000-2007 and shows a peak in 2004-2005. » (para 738)
  - Figure 119: 67% -- action dismissed by court; 19% -- final court decision confirmed claims of originator company; and 14% withdrawn by originator company.
    - More info needed on the types of cases

Commission's Preliminary Report Litigation -- 7

- Major issue outstanding related to alternative salts (which cases were litigated in the 2004-2005 time frame)
- However, Commission suggests that the litigation is a « deliberate strategy to delay generics, even though they rate the chances of winning in court as low. » (para. 740)
  - Litigation on alternative salts addressed key outstanding issues