Synthon

THE CONCLUSIONS OF THE PHARMA SECTOR INQUIRY; HELPFUL FOR THE GENERIC PHARMA INDUSTRY?

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TOPICS

I. Follow-up by the EU commission

II. The view of the generics industry

III. Observations

I. Follow up by the EU Commission

The third report on monitoring of patent settlements of DG comp (25 July 2012):

- Steep increase of the number of INN's covered by patent settlements and patent settlements itself;
- Sharp increase in patent settlements concluded during last 3 years;
- Category A:
  - 71% of settlements without any value transfer
  - in 18% of settlements value transfer is foreseen;
- Category B:
  - 83% of settlements contained limitation, but no value transfer
  - in 17% of settlements generic company agreed to pay damages.

II. The view of the generics industry

Concern about conclusions of the EU Commission's view on patent settlement agreements, inspired by view of FTC.

EU Commission should learn from arguments in the US:

A. No illegality of patent settlements per se, no anti-trust injury;
B. "Scope of patent approach" as a basis;

and

the entirely different framework in the US (Hatch Waxman).

II. The view of the generics industry - 2

1. Why would value transfers per se be anti-competitive?
2. Necessity of a European equivalent of Hatch Waxman para IV.
3. Settlements are complex and comprise many elements.
4. Less generic introductions pre patent expire due to absence of para IV and per se illegality of patent settlements with a value transfer.
5. Imbalance between interests or originators and generics.
6. Settlements do not limit the ability of other generic companies to launch products.