Making Medicines Affordable

Patent settlements in the EU
EGA perspective

Ingrid Vandenborre

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EGA Key Objectives

- Find the right balance between IP, innovation and competition
- Increase patient access to affordable high quality medicines
- Ensure sustainable healthcare in Europe
- Create a globally competitive and sustainable EU generic medicines industry and be world leaders in biosimilars

Key facts about generic medicines in Europe

Making Medicines Affordable

Generic Medicines Bring Savings of

35€ Billion p.a.

in the EU 27

Generic medicines account for almost

54%

of volume share and

21%

of value share

One of the Most Competitive Sectors in Europe

More than **1000** Generic Companies Employing

150,000

Employees in Europe

7 % of turnover to R&D

Exporting to more than **100** countries outside the EU.

Criteria for competition law scrutiny of patent settlements

- Settlement agreements are at the intersection of IP and competition law
- The existence of the patent confers legal monopoly to originator and right to legitimately exclude until patent expiry
- Settlement agreements therefore should be presumed to be legitimate unless
  - the settlement goes beyond the scope of the relevant patents
  - the originator abused the patent system
- Absent such exceptional circumstances, generic companies should have the flexibility to negotiate settlements
- Absent this presumption, competition law analysis would necessarily lead to an assessment of the strength of the patent and the outcome of (hypothetical) patent litigation

Patents are presumed to be valid

- Settled case law indicates that patents are presumed to be valid General Court in AstraZeneca: patents are "assumed to be valid" and "assumed to be lawful" and "the mere possession" of a patent "results in keeping competitors away" because "public regulations require them to respect that right.“
- Competition law does not favor patent litigation in court over settlements and does not require confirmation of a patent in litigation
- No legal basis for distinguishing between allegedly "strong" and "weak" patents
- No legal basis for distinguishing between compound and process patents
- No legal basis for distinguishing between pharmaceutical and other industries

Value transfer may be necessary to conclude patent settlements

- No legal and economic basis to argue that existence of value transfer from originator to generic company renders settlement a restriction of competition, let alone a restriction by object
- Value transfer does not imply "weakness" of patent
- Economic theory shows that value transfer from originator to generic may be necessary to conclude a settlement, e.g.
- to "bridge the gap" due to asymmetries of information and significant disparity between value of a day of sales for originator prior to generic entry and days of sales for generic company
- Entry date only settlement may not be possible
- Difference with the US – No first to file rule

Patent settlements with value transfer are often pro-competitive

- Pay for delay"? Delay relative to what? The importance of the counterfactual
- Settlements are important because generic companies can and do lose in patent litigation
- Settlements with value transfer can facilitate early generic entry
- Value transfer settlements may be necessary to avoid protracted litigation that delays entry
- Value transfer settlements avoid significant litigation costs

Patent settlements with value transfer are often pro-competitive

- Litigation in the EU may extend to various Member States and risk conflicting judgments that prejudice entry
- Settlements can avoid launch at risk that may have the potential for massive damages claims
- Example: In June 2013, Teva and Sun settled damages litigation with Pfizer for payment of USD 2.15 billion
- US Tamoxifen example
- Settlements conserve judicial resources – national laws encourage settlements over court litigation

Competition law intervention risks delay of generic entry

- There is no basis for an obligation on generic companies to litigate
- Competition law should not make it more difficult for generic companies to exit litigation
- Limitations on ability to settle may impact generic entry by increasing costs of launch and driving a reassessment of generic product launch strategies
- Ultimately risk of slowing down generic entry

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THANK YOU