Patent Settlements under EU Competition Law

Competition Law in the Pharma Sector

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## Patent Settlement Cases

<table>
<thead>
<tr>
<th>Year</th>
<th>Companies</th>
<th>Investigated Practice</th>
<th>Country</th>
<th>Fines</th>
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</thead>
<tbody>
<tr>
<td>2016</td>
<td>GSK &amp; Generics</td>
<td>Illegal patent settlement agreements</td>
<td>UK</td>
<td>£45 million</td>
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<tr>
<td>2014</td>
<td>Servier &amp; Generics</td>
<td>Illegal patent settlement agreements and illegal acquisition of a competing technology</td>
<td>EU</td>
<td>€427.7 million</td>
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<tr>
<td>2013</td>
<td>Lundbeck &amp; Generics</td>
<td>Illegal patent settlement agreements</td>
<td>EU</td>
<td>€146 million</td>
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Commission’s Analytical Framework

All Settlement Agreements

A. No limitation on competitor entry (low risk)

B. Limitation on competitor entry

B.1. No value transfer to the competitor (low risk unless originator knows its patent is invalid or not infringed or if the restrictions on the competitor exceed the scope of the patent)

B.2. Value transfer to the competitor (high risk)
The Commission’s Simplistic Analysis

**Question 1:** What is the counterfactual? Generic enters and wins in litigation? Less restrictive settlement?

**Question 2:** Has the Commission proven that its counterfactual is likely (or – in a by object case – so likely that a detailed assessment is redundant)?
Many Counterfactuals Are Possible

- **Originator Wins Injunction and on the Merits**
- **Generic Decides Not to Enter Due to Patent Risks**
- **Generic Enters At Risk and Loses in Litigation**
- **Split the Time Deal**
- **Generic Enters and Wins Litigation**
Relevance of Reverse Payment

- Is the direction of the payment relevant?
  - Commission: reverse payment is anti-competitive because it suggests that Originator must think that it is likely to lose in litigation, so it must make a payment to keep Generic off the market.
  - But direction of payment is a red herring – it is a function of the parties’ relative bargaining positions and does not necessarily reflect the strength of the parties’ claims.
Relevance of Reverse Payment

- Asymmetry of risk:

Reverse payment by Originator to Generic simply reflects asymmetry of risk – even if Originator very likely to win, this asymmetry means that it may not want to take a chance of losing.
Relevance of Reverse Payment

Key factors creating asymmetry of risk:

- Originator may face mandatory price reductions in jurisdiction of the litigation.
- Originator may face cascading price reductions in other jurisdictions due to reference pricing.
- Originator may incur significant damages due to length of litigation that it may have difficulty recovering.