

The EU Pharma Sector Inquiry: Patent Litigation and Settlements

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Patent Litigation

Interim Report's Key Findings

- 700 cases of patent litigation between originator and generic companies
- 149 cases went to final judgment (remaining pending, settled or no outcome reported)
- Generics won 62%
- Patent litigation part of the infamous “tool box” of instruments used by originators to delay entry of generics

Patent Litigation

Legal/Policy Considerations

- Unless sham litigation, companies – even dominant ones – have a basic right to protect their rights through the court system
- Limitations on an IP owner's ability to protect its IP undermines value of IP to the detriment of innovation

Patent Settlements

Interim Report's Conclusions

- More than 200 settlement agreements
- 48% restricted generic company's ability to market its product
- Significant number of these settlements involved transfer of value from the originator to the generic – direct payments exceeded €200 million
- FTC has scrutinized patent settlements involving direct payments

Patent Settlements

The Issue – “Reverse Payments”

- Highly controversial topic – in the United States, courts, antitrust agencies and commentators disagree
- Wide variety in how settlements structured and the form that reverse payments take, so *per se* rule would seem inappropriate

Patent Settlements

Example of Typical Settlement

- Product X generates €10 million in profits per year
- Generic enters market and Originator sues for injunction
- Patent on Product X valid for 10 years
- Originator considers that it has a 60% chance of winning; Generic believes that it has a 40% chance of winning
- Parties enter into settlement – Originator grants Generic license to enter at the beginning of Year 6.

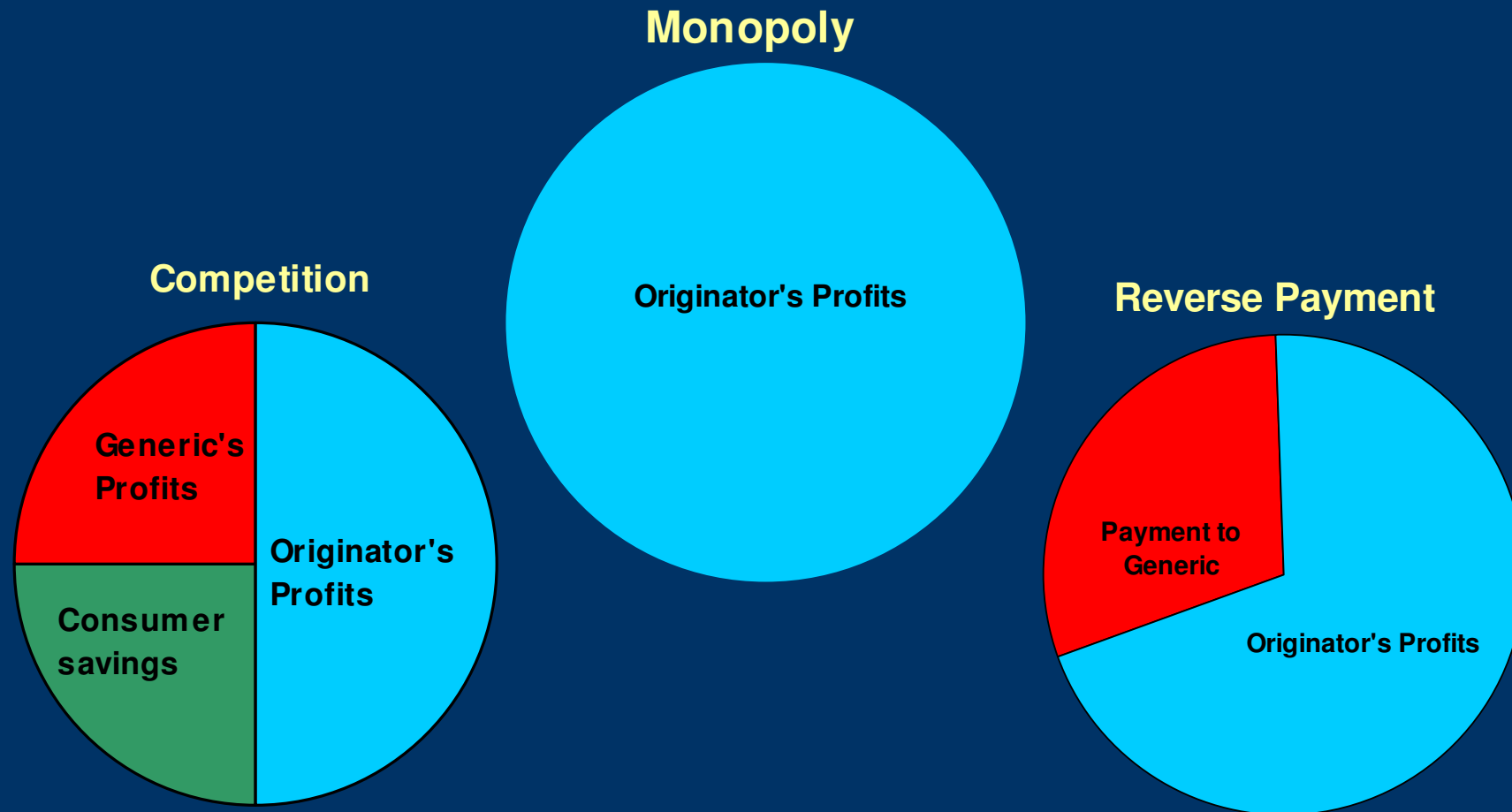
Patent Settlements

Example of Reverse Payment

- Same as previous example except: Originator grants Generic license to enter at the beginning of Year 8 plus payment of €6 million
- “Reverse” because incumbent paying entrant

Patent Settlements

What's the Problem?



Patent Settlements

Criticisms of Presumption that Reverse Payments are Anti-Competitive

- Undermines value of patent
 - patent gives owner right to exclude until expiry of patent
 - any settlement allowing entry prior to patent expiry is pro-competitive
 - while consumers may pay more in the short run, in the long run, settlements pro-competitive because they do not undermine IP and encourage innovation

Patent Settlements

Criticisms of Presumption that Reverse Payments are Anti-Competitive

- Payments bridge gaps caused by asymmetries
- Strong public policy reasons for encouraging settlements – should not limit parties' options in structuring settlements
- Reverse payments just a more conspicuous form of compensation that takes place in many settlements – direction of payment a red herring
- Competition authorities ill-equipped to evaluate strength of patent

Patent Settlements

U.S. Approach Not Necessarily a Good Guide for the EU

- Regulatory environment much different – Hatch-Waxman gives first generic on the market 180-days of exclusivity.
- United States is a single market, while European Union comprises 27 different markets due to national patent regimes
- U.S. courts, antitrust agencies and commentators deeply divided over proper analytical approach to patent settlements in pharma industry

Patent Settlements

EU-Specific Considerations

- Originator may have incentive to make a payment to keep Generic off of the market until final judgment – otherwise, Originator would have suffered irreversible damage even if it prevails
- Asymmetries – Originator will be concerned about effects in other markets and on other potential generic entrants, whereas Generic may only be concerned with the case at hand

Conclusion

- Patent litigation: will rarely raise competition law concerns
- Patent settlements: analysis of patent settlements should be dealt with on a case-by-case basis and no justification for presumption that reverse payments are restrictive of competition