

# Patent Settlements – Policy Issues

## The Originators' Perspective

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# The Big Picture

- Pharma invests most in R&D
- Patents = innovation = growth and good for patients
- Prompt generic entry on patent expiry is also good for consumer welfare
- These goals are not conflicting

## Distrust of the Patent System is Misplaced

- Competition authorities should leave questions of patent validity to specialist patent offices and courts
- We had hoped after the Sector Inquiry that DG COMP would abandon its distrust of the merits of certain types of patents but that doesn't seem to be the case

# Why do Patent Disputes Settle?

- Patent litigation is fact intensive, complex and highly unpredictable
- UK Court of Appeal, 30 April 2013:

*“The widely disputed validity of equivalents to the Patent does at least go some way towards validating an ancient aphorism Quot Homines Tot Sententiae. The different Homines obviously all think that their Sententiae are right. The truth is that they may well be, when they are considered on the basis of the actual evidence and the particular legal submissions before them in the different proceedings in the various courts. Judicial decisions on obviousness turn on the evidence adduced by the parties, on the arguments advanced on their behalf and on the adjudicating body's understanding of all the materials before it.*”

## The Stakes are High

- If injunctive relief is not available, generic launch at risk can have irreversible effects on the reimbursement price
- Settlements are legitimate and efficiency enhancing

# As a Practical Matter, Patents should be viewed as Presumptively Lawful

## The latanoprost case study:

- Pfizer obtains an SPC and pediatric extension based on a patent that is subsequently invalidated before the EPO in opposition
- Italian competition authority fine of €10.2 million for patenting practices allegedly abusing the patent system
- EPO Board of Appeals then reinstates the patent
- Italian Court of Appeal: legitimate actions before administrative and judicial authorities are not anti-competitive without a “plus factor” (September 2012)

## The “Plus Factor”

1. Fraud in obtaining the patent
2. The patent litigation is a sham
3. Restrictions clearly going beyond the exclusionary zone of the disputed patent

## Conclusions

- Absent an “early resolution mechanism”, settlements involving value transfers should be presumptively lawful absent a “plus factor”
- Alternative approaches will generate huge uncertainty and undermine confidence in the patent system
- In the current economic climate, that is a gamble that Europe can ill afford