General Court’s Judgment in *Lundbeck*: A Critical Review

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The Agreements

Lundbeck

Arrow

Alpharma

Merck

GUK

Ranbaxy
Facts

Facts relating to Alpharma settlement:

• Lundbeck manufactures citalopram, a blockbuster antidepressant

• Alpharma preparing to enter the market upon expiry of the compound patent and had purchased product from supplier

• Just before expiration of compound patent, Lundbeck granted patent on process

• Lundbeck sued Alpharma in UK and threatened to sue elsewhere for infringement of process patents

• Parties settled: Lundbeck paid Alpharma and Alpharma agreed not to enter for 18 months.
Potential Competition

Lundbeck and generics were potential competitors as generics had “real concrete possibilities” to enter the market
  -- Generics had obtained or taken steps to obtain marketing authorizations
    -- Some generics concluded supply contracts in anticipation of entry

Existence of process patent did not block entry
  -- 50 to 60% chance of invalidity
  -- generic could launch “at risk”
  -- possible to obtain non-infringing product
  -- presumption of validity of patent not the same as presumption of illegality of generic products
    -- Patent did not prevent generics from entering
“By Object” Infringement

-- Payment not linked to strength of the patent, but the expected profits of generic entering market
-- Akin to a straight-forward market-sharing agreement exchanging uncertainty of patent litigation for certainty of no generic entry in return for a payment.
What’s Wrong With This Picture?

Monopoly

Originator's Profits

No Reverse Payment Settlement (Commission's Counter-Factual)

Generic's Profits
Originator's Profits
Consumer savings

Reverse Payment Settlement

Payment to Generic

Originator's Profits
No Settlement: 2 Possible Outcomes

Generic Wins

- Generic’s Profits
- Consumer savings
- Originator’s Profits

Originator Wins

- Originator’s Profits
Criticisms of Counter-Factual

- It assumes that Generic is more likely than not to win in litigation, which is an incorrect assumption.

- Subtext of Commission decision and General Court’s judgment is the notion that Lundbeck’s process patent not very strong – but Commission ill-equipped to judge likely validity of patent
Settlement of patent case

Competition law case about settlement of patent case

Patent case
A Better Approach

• Assume that patent is valid and infringed unless compelling evidence that Originator would lose in patent litigation.

• Assumption that patent is valid is more consistent with patent system than an assumption that it is invalid.
Relevance of Reverse Payment

Is the direction of the payment relevant?

- Commission/General Court: 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.