Antitrust in the Pharma Sector: Recent Developments

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• “Competition in this industry does not work as well as it should”

  Commissioner Kroes, 28 Nov 2008

• “The Commission will apply increased scrutiny under EC antitrust law ... First enforcement action is already underway”

  Final Report, 8 July 2009
Main issues

• Anticompetitive agreements
  • patent settlements

• Unilateral behavior (Abuse of Dominance)
  • lifecycle management (evergreening)
  • vexatious litigation
  • intervention in national procedures
  • negative marketing
  • defensive patent strategies (blocking patents)
Since then ... 2009-2010

- Servier investigation opened, July ‘09
- Lundbeck raids, Dec ‘09
- 1st round of settlement monitoring, Jan/July ’10
- AstraZeneca (Losec) GC judgment, July ‘10
- OFT fines Reckitt Benckiser, Oct ‘10
- AstraZeneca/Nycomed raids, Dec ’10
• 2nd round of settlement monitoring, Jan/July ’11
• Boehringer investigation closed, July ‘11
• J&J/Sandoz investigation opened, Oct ’11
• OFT opens GSK/Generics UK investigation, Oct ‘11
Settlement Agreements
Issues

• **Reverse payment settlements**
  - value transfer from originator to generic
  - delayed/restricted generic entry
  - inspired by FTC enforcement in US

• **Overbroad/sham settlements**
  - settlement extending beyond patent scope
  - or patent holder knows patent not valid
FTC on reverse payments

- **Schering-Plough (2001 – 2006)**
  - “[If] the patent holder makes a substantial payment to the challenger as part of the deal, absent proof of other offsetting considerations, it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable compromise”

- **Presumption of illegality if**
  - substantial reverse payment
  - generic entry not immediate, and
  - no proven rationale for the payment other than delayed generic entry
Actual US Law

• Courts consistently reject FTC approach
  • *Schering-Plough v. FTC* (11th Cir)
  • *In re Ciprofloxacin* (Fed. Cir.)
  • *In re Ciprofloxacin* (‘Arkansas Farmers’) (2nd Cir, cert denied)

• Settlements presumed lawful if
  • generic entry not restricted outside patent term/scope
  • no evidence of sham litigation or fraud
An EU presumption of illegality?

- Sector Inquiry Final Report, July ‘09
  - “any assessment of whether a certain settlement could be deemed compatible or incompatible with EC competition law would require an in-depth analysis”

- Dominik Schichels, Nov ‘09
  - Commission “will not take the view per se that patent settlements are probably illegal”
An EU presumption of illegality?

- **1st Monitoring Report, July ‘10**
  - categorize settlements on “two main criteria”
    - limitation on the generic company’s ability to market its own medicine
    - value transfer from originator to generic

- **Dominik Schichels, Oct ‘10**
  - “we do not like to see a value transfer, as without it, the companies would likely have found a different date”

- **Commissioner Almunia, Oct ‘11**
  - “Paying a competitor to stay out of the market is a restriction of competition that the Commission will not tolerate”
AstraZeneca, 1 July 2010

- 1st Abuse of dominance case in pharma sector

- Addressed central issues for Sector Inquiry
  - market definition and dominance in the pharma sector
  - abuse of patent/IP rights

- AZ found guilty of two abuses
  - unlawfully obtaining IP rights (1st abuse)
  - misuse of IP rights/processes (2nd abuse)
Dominance

- **Separate PPI market (ATC 4)**
  - focus on actual prescribing practice of doctors
  - no special treatment for pharma
  - healthcare systems reduce price competition and promote narrow markets

- **Dominance**
  - no special treatment for innovation markets
  - healthcare systems also promote dominance

- Potentially opens door to ‘molecule’ markets and routine dominance for patent holders
1st Abuse: Facts

- AZ dominant in PPIs via patented drug Losec
- Submits misleading SPC applications
  - incorrect/incomplete information re date of 1st MA
- As a result of which
  - AZ wrongly granted patent right extensions
  - market entry of generic PPIs delayed
  - AZ’s dominance in PPIs prolonged
• Dominant companies have “special responsibility” to
  • avoid misleading authorities
  • clarify ambiguity in submissions, and
  • seek to correct errors

• Intention to mislead not necessary
  • “could not reasonably be unaware” submissions misleading

• AZ had “refrained from disclosing”
  • its interpretation of the legislation, and
  • the facts relevant if its interpretation was wrong

• Duty to inform authority once it became aware that
  rights granted in error
• AZ launches new formulation of Losec
  • tablet rather than capsule

• Deregisters capsule MAs
  • in certain selected countries only
  • offers no objective justification (e.g. public health)

• Entry by generics hampered as a result
2nd Abuse: General Court

• AZ argued there was no abuse as
  • legally entitled to withdraw MAs
  • no obligation to assist competitors by maintaining them
  • withdrawal objectively justified

• General Court found
  • existence of abuse unrelated to legality of action under other legal rules
  • no basis for withdrawal in competition on the merits
  • no other objective justification
  • purpose was “solely” to exclude competitors
May ‘03 – Boehringer scientist photographs poster of Almirall substance (anticholinergic)

July ‘03 – Boehringer submits 3 combination patents covering Almirall substance + combinant

Each patent similar – 1st starts

“an unexpectedly beneficial therapeutic effect can be observed in the treatment of inflammatory and/or obstructive diseases in the anticholinergic … is used with one or more PDE IV inhibitors”

Feb ‘07 – Almirall complains to European Commission
Boehringer/Almirall settlement

• Jan ‘09 – UK High Court finds
  • Boehringer 1st patent invalid on grounds of obviousness and insufficiency
  • “observed” statement in patent is “false”

• July ‘09 – Commission re-launches investigation
  • “main focus” is whether Boehringer obtained patents by providing misleading information

• July ‘11 – Commission closes file having “encouraged” settlement between parties
  • “As Boehringer agreed to remove the alleged blocking positions … the Commission no longer needs to pursue the case”
Thank you!

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