



Recent Competition Law Cases in the Pharma Sector

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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

- **Anticompetitive agreements**
 - patent settlements
- **Unilateral behavior (Abuse of Dominance)**
 - lifecycle management (evergreening)
 - defensive patent strategies (blocking patents)
 - vexatious litigation
 - intervention in national procedures
 - negative marketing

- **Servier investigation opened, July '09**
- **Lundbeck raids, Dec '09**
- **1st Report on Patent Settlements, July '10**
- **AstraZeneca (Losec) GC judgment, July '10**
- **OFT fines Reckitt Benckiser, Oct '10**
- **AstraZeneca/Nycomed raids, Dec '10**

- **UK Heath Service sues Servier, March '11**
- **2nd Report on Patent Settlements, July '11**
- **Boehringer investigation closed, July '11**
- **J&J/Sandoz investigation opened, Oct '11**
- **OFT opens GSK/Generics UK investigation, Oct '11**
- **Italian Authority's Pfizer Decision, Jan '12**

AstraZeneca

- **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)

- **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**

- **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**

- **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

Reckitt Benckiser

- **1999 – Gaviscon Original comes off patent**
- **2000 to 2006 – RB opposes attempts to adopt a generic designation for Gaviscon Original**
- **2005 – RB**
 - withdraws and delists Gaviscon Original Liquid from NHS prescription channel before publication of a generic name
 - searches for ‘Gaviscon’ in prescribing software identify Gaviscon Advance Liquid
 - Gaviscon Advance Liquid patent protected to 2016
- **2010 – RB agrees to pay £10.2m penalty for 2005 behaviour**

- “If we were to change the formulation ... with the rationale that we are doing it for health and safety reasons ... we could withdraw Gaviscon liquid from sale within the NHS and replace it with the new formulation ... We could potentially apply for a new patent on this formulation and effectively protect all our Gaviscon liquid business within the NHS for another 20 years”

Servier

- **2003 – Servier’s original perindopril patent expires**
- **2000 – Follow-on patent obtained**
- **2007 – *Servier v Apotex* (UK CoA)**
 - 2nd patent not only invalid but “very plainly so”
 - crystalline form covered by 2nd patent produced by method disclosed in 1st
 - ‘innovation’ obvious on evidence of Servier’s expert
 - “The sort of patent which can give the patent system a bad name”
- **2009 – EPO revokes follow-on patent**

- **Servier enters into patent settlement agreements with various generic producers**
- **July '09 – European Commission announces investigation**
- **March '11 – UK Govt sues Servier for over £230m alleging:**
 - Servier “had no honest belief” in patent
 - enforced patent through litigation and threats
 - entered into anti-competitive agreements to protect its position

Pfizer

- **1994 – Pharmacia (acq. by Pfizer 2003) obtains original patent, expires Sept ‘09**
- **1996 – 1st MA obtained, after which SPCs obtained that expire in July ‘11. No Italian SPC**
- **April ‘02 – Pharmacia files divisional applications**
- **Jan ‘09 – Divisional patent granted (after opposition)**
- **April ‘09 – Pfizer applies for SPC in Italy**
- **Oct ‘10 – EPO revokes divisional, Pfizer appeals**

- **11 Jan '12 – Italian competition authority fines Pfizer €10.7 m for abuse of dominance:**
 - the divisional constituted 'double patenting' as it involved no new invention
 - Pfizer had failed to disclose in its Italian SPC application that the underlying patent was a divisional
 - Pfizer had artificially extended its patent protection
 - it had not launched a new product under the divisional
 - its Italian SPC application came years after SPCs granted elsewhere
 - Pfizer had not requested SPCs based on the divisional in other jurisdictions

Boehringer/Almirall

- **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**

- **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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- **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”

- **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”