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# The International Pharmaceutical Compliance Congress and Best Practices Forum

## Competition/Antitrust Law Update: Focus on Patents

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Fiona Carlin, Partner

Baker & McKenzie, Brussels

# Global Enforcement Trends

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| **Misuse of patent procedures** | • EU (*AZ SPC claim, BI, Servier*)<br>• Italy and Spain (*Pfizer (Latanoprost) divisionals*)<br>• UK (*Servier*)<br>• Brazil (*Eli Lilly*, ongoing) |
| **Patent settlements** | • US (*Actavis*, various)<br>• EU (entry agreements, *Lundbeck, Servier, Cephalon/Teva*, ongoing monitoring) Canada (*Alcon*)<br>• Brazil, South Korea (*GSK/Dong AG*)<br>• UK (SO sent to *GSK*) |
| **Misuse of regulatory procedures** | • US (*Abbott Tricor, Reckitt Benckiser*)<br>• EU (*AZ MA withdrawal*)<br>• UK (*Gaviscon prescribing software*)<br>• Romania (*Novartis P&R procedure*)<br>• Italy (*Bayer Crop Science*) |
| **Marketing/Co-promotion** | • France (*Arrow defamation, Janssen-Cilag warnings, Schering-Plough disparagement*)<br>• UK (*Napp hospital vs pharmacy pricing*)<br>• EU (*J&J/Fentanyl*), Turkey, Italy (*Roche/Novartis* – off label use investigations also in Belgium, France, Spain, EC 'closely coordinating') |
| **Bid-rigging** | • Bulgaria, Czech Republic, France, Italy, Hungary, Romania, Serbia, Turkey, UK, US, Russia, Slovenia |
| **Excessive pricing, unfair terms, RPM** | • South Africa, Indonesia, Turkey (discrimination), China (RPM)<br>• Switzerland, Germany (non-prescription medicines)<br>• UK, Netherlands, Italy |
| **Refusal to supply/margin squeeze** | • UK (*Chemistree/AbbVie*)<br>• Russia (*Baxter, Novo Nordisk and Abbott* (parallel trade vs IP protection))<br>• China (*Weifang Pharma API foreclosure*), South Africa |
| **Sector inquiries** | • EU, Russia, Turkey, Poland, Romania, South Africa, Canada, France, China, Ukraine |

# 2009 EU Sector Inquiry

- Alleged abuse of patent/regulatory system to dampen innovation and thwart timely generic entry
- Alleged "toolbox" of dubious practices:
  - defensive patenting
  - evergreening, product-hopping
  - vexatious litigation
  - patent settlements
  - meritless regulatory interference

  - Narrow market definitions = dominance!

# Patent Strategies as ‘Abusive’?

- Competition authorities are increasingly willing to challenge patenting strategies they deem abusive:
  - “*Of the 33 process patents, 21 were described as blocking or paper patents. Three of those 21 process patents were characterised as involving zero inventive step.*” (*Servier/perindopril*)
  - *AstraZeneca/Losec*: Court of Justice tempered strict approach put forward by General Court but failed to set a specific test – uncertainty over line between deception and simple mistakes!
    - Should a different standard apply where the patent office’s express role is to assess accuracy/validity (e.g. in patent applications) vs. where the patent office has little discretion (e.g. granting SPCs)?

# Pfizer/latanoprost

- In 2012, the Italian Competition Authority (*AGCM*) imposed a fine of €10.6 million for abuse of dominance
- Internal documents allegedly showed that Pfizer had obtained patent protection for the sole purpose of delaying generic entry
- AGCM's decision was quashed on first instance appeal: mere use of legal means to protect IP is not sufficient to establish an abuse of dominance
- *Consiglio di Stato* upheld the AGCM's decision and reinstated the fine, holding that:
  - Pfizer had misused the patent system and it was irrelevant whether the rights had been obtained legitimately - competition and IP law are different in scope

# Patent Litigation as 'Abusive'?

"… *litigation can also be an efficient means of creating obstacles for generic companies … In certain instances originator companies may consider litigation not so much on its merits, but rather as a signal to deter generic entrants*" (Sector Inquiry)

– High bar for the European Commission to show that litigation is abusive:

  - A claim in litigation will generally be lawful unless undertaken by a dominant company where it cannot reasonably be considered as an attempt to assert the right of the undertaking concerned and can therefore only serve to harass the opposing party (claim is 'manifestly unfounded') AND it is part of a plan to eliminate the competitor (***ITT/Promedia***)

– ***Pfizer/latanoprost***: numerous warnings of litigation demanding significant compensation was one element of Pfizer's 'complex strategy' to deter generic entry

– ***AbbVie***: US FTC recently sued AbbVie for disgorgement of profits allegedly gained through sham litigation that AbbVie knew would automatically trigger a 30-month stay of FDA approval of Teva's and Perrigo's generic versions of AndroGel

Limited EU precedents but decisions to litigate need to be assessed and documented carefully!

# Patent Settlements - DG COMP approach

- *Lundbeck* and four generics fined €93.8m for Citalopram settlement agreements – a restriction of competition "by object". Lundbeck had paid significant lump sums, purchased generics' stock for destruction and offered guaranteed profits in a distribution agreement. Internal documents referred to a "club" amongst which "a pile of $$$" would be shared…

- *Servier* and five generics fined €427m for a series of Perindopril settlement agreements (*Servier* also includes an effects analysis)

- Originator and generics treated as "potential competitors":
  - Once compound patent expires, competition is possible despite existence of process, formulation patents
  - Inherent uncertainty as to whether patents will be upheld/infringed means that competition is possible

# Patent Settlements – Compliance Issues

- Non-compete and no-challenge clauses – even within the scope of patent claims – treated as "*by object*" infringement

- Value transfers are presumptively illegal if they "substantially reduce" generics' entry incentives so that decision is no longer based exclusively on the IP merits:
  - Large payments, buying stock at market value, side deals (distribution, licensing, co-marketing, co-promotions, agreeing to delay authorised generic *etc*.) will all attract scrutiny

- Contrast with US rule of reason approach (*Actavis*):
  - Reverse payments, where "large and unjustified" can have anti-competitive effects depending upon "its size, its scale in relation to the payer's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification"

- **Red flags**: internal documents speculating on patent weakness, payments equating to expected generic profits and restrictions beyond a narrow reading of the patent scope!

# Patent Settlements – Open Questions

- Is the EU 'by object' standard appropriate for patent settlement agreements?
  - *Cartes Bancaires*: "by object" test must be read narrowly and applied to conduct intrinsically "injurious to competition"
  - Value transfer should not be an evidentiary shortcut - does not denote subjective believe as to "weakness" of patent but reflects asymmetry of risk between generics and originator company:
  - launching at risk even for a short period can cause "irreparable harm" that cannot be adequately compensated by damages after the fact
  - interim relief may not be available or timely enough
  - impact on revenue internationally given prevalence of reference pricing
  - reflects costs of avoided litigation in terms of money, staff resources and opportunity costs for use of those resources in other projects etc.
- Legal and economic context of patent settlement agreements fundamentally different to market sharing arrangements in *Irish Beef* type situations!

# Patent Settlements: Industry Position

- Absent fraud, the generic is blocked by the contested patent (presumption of patent validity)
- Any restriction that is “objectively necessary” for legitimate settlement agreement cannot be anti-competitive
- Competition authorities should not second guess patent offices, nor make value judgments as to patent quality:
  - Formulation and process patents reflect innovation
- Patent litigation is complex and unpredictable and lack of injunctive relief can lead to irreparable harm
- EFPIA "early resolution mechanism" to obviate the need for settlements

# EFPIA Early Resolution Mechanism

- Address patent disputes sufficiently in advance of generic launch through increased transparency:
  - innovator discloses IP position: publishing details of certain classes of patents protecting the product to enable generic companies to assess the risks of early entry
  - medicines agencies disclose fact of generic MA application: enables innovator to assess whether generic might infringe its IP rights
  - application for MA is the legal trigger for normal patent litigation: innovator can then initiate ordinary infringement proceedings - this allows sufficient time in most cases for the dispute to be resolved before planned generic launch
- Consumers get access to competitive pricing on generic entry without undermining legal certainty and innovator investments in R&D