COMMITMENT | EXCELLENCE | INNOVATION

ARNOLD & PORTER (UK) LLP

The Burden of Compliance following the European Commission's Sector Study: Where Do We Go From Here?

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- **The Commission's Preliminary Report: findings**
  - Themes
  - Innovator-generic competition
  - Innovator-innovator competition
- **The compliance challenges**
  - Legitimate actions may lead to antitrust exposure
  - Asset protection under attack
  - Life-cycle management under more intensive attack
- **Compliance strategies**

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The European Commission's findings - themes

- Findings of fact only, no finding that any individual company has infringed EU competition law
- **But…**
  - The Commission believes that the patent system has been misused in a way that was not intended or necessary to protect R&D
  - Three companies were dawn raided two days prior to the public consultation
  - Remarks of Commission representatives at public consultation were frequently unsympathetic or hostile to innovator sector
  - Compliance challenges: lawful use of patent and regulatory regime may lead to antitrust exposure

The European Commission's findings – themes (2)

- **Innovator-generic competition**
  - Use of the "tool-box" limits generic competition
    - Generics are delayed and prices are higher
- **Innovator-innovator competition**
  - Innovator companies deploy strategies to defend their products from competition by other innovator companies
    - Companies are distracted from drug development activities
- **Generic-generic competition**
  - No findings!

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"The combined use of life cycle instruments may increase the likelihood of delays to generic entry; delays due to the use of several instruments may sometimes be cumulative. More generally, it may significantly increase legal uncertainty to the detriment of generic entry and can cost public health budgets and ultimately consumers significant amounts of money."

Innovator-generic competition: the "tool-box"

- Innovators use a **tool-box strategy** to delay generic entry

"practically all originator companies have developed a tool-box of measures/instruments that can be used throughout the product life cycles to maximise the revenue stream from existing pharmaceutical products by delaying or dampening the effect of generic entry."

- More instruments are used where the product is more important to the innovator
- Generic entry is delayed by seven months on a weighted average basis and four months for "blockbusters"

The tool-box – patent strategy has changed

"Originator companies confirm that they aim to develop strategies to extend the breadth and duration of their patent protection"

- Patent clusters of up to 1,300 patents, some applied for late in life cycle, and divisional patents applied for
- Generic companies are uncertain as to whether they can enter market

*"patent holders admit internally that some of [*the secondary*] patents might not be strong"*

The tool-box – patent litigation

- Patent owners litigate against generic companies to create obstacles to entry
- Patent litigation takes a long time (ave 2.8 years)
- 62% won by generic companies
- 60% of litigation concerns switch to second generation products
- Application by originators for interim injunctions had 50% success rate

The tool-box – patent litigation (2)

- Litigation may give rise to conflicting judgments
- Generic companies bring a high number of opposition actions against secondary patents and are successful (revocation or restrictions in scope) in 75% of cases, but the cases took 2 years to conclude

The tool-box – patent settlements

- Originator companies assess the advantages of settlement on the probability of winning or losing, and on the importance of the product
- Generic companies are concerned with saving costs and clarifying uncertainty
- Settlements roughly equally divided between restricting and not restricting generic entry

The tool-box – patent settlements (2)

- Of the half that were restricted, some value was transferred to generic company – payment (>20 cases. >€200m), licence or other deal
- FTC scrutiny in the US mentioned
- Innovator companies have made “a large number” of agreements with generic companies for the entry of generics before the loss of exclusivity

The tool-box – intervention before regulatory authorities

- Innovator companies intervened in applications for generic marketing authorisation and reimbursement
  - Safety, efficacy and/or quality claims
  - Patent infringements claims made even though not within authorities' jurisdiction
  - Interventions focussed on blockbuster products
- Intervention delayed entry by approx 4 months

The tool-box – litigation against authorities

- Patent or safety issues
  - 50 in Portugal
- Data protection proceedings
  - 20% of disputes are litigated
  - Most in new Member States
  - Many withdrawn and few cases succeed
- Pricing/reimbursement issues on regulatory status of generic or its entry into reference pricing group

The tool-box – marketing, promotion and distribution

- Innovators spend 23% of revenues on marketing and promotion
- Litigation against wholesalers
- DTP distribution model will weaken wholesale competition and make it more difficult for generic companies to enter the market

The tool-box – second generation products

- Innovators introduced second generation products in 40% of cases, generally 1.5 years before loss of exclusivity
- Patient switching initiatives take place prior to entry of first-generation generic

"Whilst it is generally accepted that innovation is often achieved in incremental steps, patents relating to second generation products are sometimes criticised as weak by other stakeholders who argue that they show only a marginal (if any) improvement or additional benefit to the patients."

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Defensive patent strategies

"in such cases the originator companies do not intend to pursue these patents in order to bring new/improved medicine to the markets."

"From society's viewpoint, (…) restriction of another company's freedom to operate may be problematic where the originator company maintains and uses patents to block the development of a new, competing product rather than for protecting an invention of its own".

- Enforceable rights to prevent third party entry
- Prior art creation to prevent third party patenting
- Licensing opportunities
- Divisional patents prevent R&D

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Compliance challenges

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  - Instruments in the tool-box are legitimate conduct, so step-by-step compliance will still leave companies exposed
  - No bright line between individual legitimate conduct and campaign to foreclose
  - No definitive guide to definition of dominance
  - Patent protection measures (litigation/settlement) and regulatory interventions not protected by any antitrust immunity

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Risk assessment

- Identify risk features
- Two sources for risk assessment:
  - Preliminary Report
  - Commission guidance on enforcement priorities in abuse of dominance (3 December 2008)

Identify higher risk of investigation

- Is the company dominant, or does it have significant power?
- Has the company used a number of toolbox strategies?
- Is the conduct likely to harm patients or intermediaries?
- Is there documentary evidence of exclusionary intent?
- Is there an objective justification?

What degree of market power does my company hold in the relevant market?

- Dominance (Art. 82 EC)
- Significant market power (Art. 81 EC)
- Relevant market

Higher risk feature - dominance

- ECJ definition:
  - *"a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by affording it the **power to behave** to an appreciable extent **independently** of its competitors, its customers and ultimately of the consumers."*
- Commission enforcement priorities
  - *An undertaking which is capable of profitably increasing price above the competitive level , or reduces output, innovation, variety, or quality for a significant period of time (normally two years)*
- Pharmaceuticals
  - AstraZeneca case will deal with dominance issues (judgment due in Spring 2009)

Risk features – use of multiple toolbox instruments

- Pre-patent phase
  - patent clustering – against generics
  - defensive patenting – against originators
  - (also: misleading patent agencies – as per AstraZeneca – subject to appeal)
- Patent enforcement
  - refusals to licence originators
  - vexatious litigation /intervention against originators and generics
- Post-patent phase
  - follow-on products – against generics
  - settlements – affects generics and originators

Risk feature – likely impact on "consumers"

- "Consumers" include final consumers and intermediaries (wholesalers, hospitals, pharmacies, dispensing physicians)
- Sufficient if consumer harm is "likely"
- Foreclosure of competitors can lead to consumer harm

Reducing risk – objective justification

- Objective justification may take two forms:
  - Conduct is objectively necessary and proportionate to achieve legitimate goal (e.g. health and safety), or
  - Conduct produces substantial efficiencies that outweigh anti-competitive effect
    - Likely to be realised
    - The least anti-competitive alternative
    - Outweighs negative impact on competition and consumer welfare
    - Does not eliminate competition