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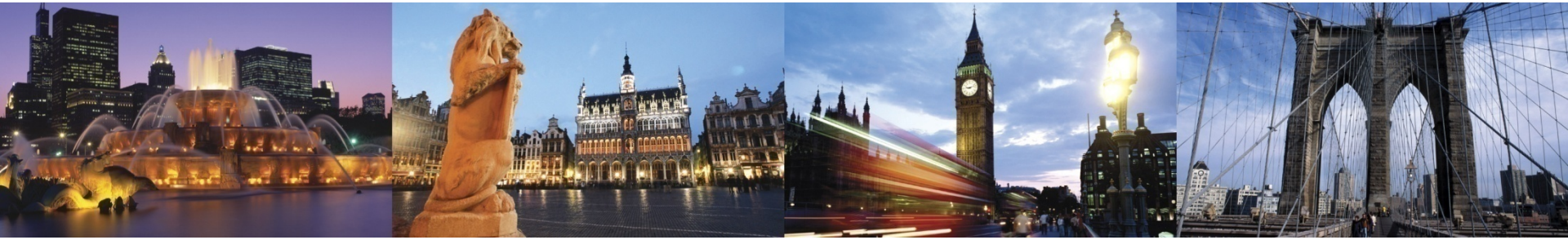

Patenting Practices and Patent Settlement Agreements

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Overview

- Presentation focuses on two areas: 1) Patenting Strategies and 2) Patent Settlement Agreements.
- DG Comp considers many originator patenting strategies are aimed at preventing or delaying market entry by generics or other originators.
- Case law in other areas may give DG Comp ability to attack patenting strategies industry views as standard.
- DG Comp also suspicious of originator/generic settlement agreements - it has been monitoring settlements closely and intends to continue doing so.
- DG Comp's approach seems influenced by US enforcement agencies but U.S. courts have taken a more reasoned view.

1) Patenting practices

- DG Comp's 2008/9 Sector Inquiry alleged existence of a "tool box" of originator strategies aimed at limiting competition from generics/other originators.
- The patenting strategy elements of the "tool box" allegedly include:
  - Patent Clustering: registering patents for additional processes or reformulations to create layers of protection beyond base patent;
  - Divisional Patents: dividing out narrower patents from the parent patent (application). Divided-out patents persist if parent patent is refused or revoked;
  - Defensive Patenting: registering patents which will not be developed commercially but which block competitors.

"Patent Clustering": an example of the difference of views

DG Comp's view	Industry response
"Webs" of patents, intended solely to delay generics	No way to tell *ex ante* which innovations useful; legitimate to protect against generics "designing around" patents
Outrage that blockbuster drug protected by 1,300 patents/applications in EU	1,300 patents figure disregards fact that patents are registered on a national basis in up to 27 MS; also, registrations would be in the thousands in some industries
Weakness of patents is evidenced by the fact that generics won 62% of disputes against originators at trial	Small sample used (149 cases) is not a random one; it reflects only the most contentious cases, thereby excluding strong patents

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How might Commission initiate proceedings against originator strategies?

- Registering patents and asserting IPR is unilateral conduct so Article 102 TFEU (ex. Article 82 EC) most relevant.
- Commission must establish dominance before an infringement of Article 102 TFEU can be found.
- Market definition?
  - Product market: Third ATC level generally forms starting point but can be narrower based on product characteristics (e.g. mode of action, patient sub-groups)
  - Geographic market: National
- But assuming dominance is established, where is the abuse in registering or defending valid patents…?

Conduct of litigation as an abuse of dominance: the *ITT Promedia* case

- Background: Commission rejected complaint that Belgacom had violated Article 82 EC (now 102 TFEU) by taking its business partner to court. Commission considered that there may be an abuse under Article 82 EC where an action:
  1) cannot reasonably be considered an attempt to establish rights and can therefore only serve to harass other party; and
  2) forms part of a plan whose goal is to eliminate competition.
- The complainant appealed to the CFI which held that:
  - the Commission had been correct because the assertion of rights in court is the expression of a general principle of law and only in "wholly exceptional circumstances" will legal action amount to an abuse of dominance.
- CFI did not directly endorse the test applied by the Commission but it did nothing to cast doubt upon it.

Application of the *ITT v Promedia* test to patenting strategies

- It seems, therefore, that a patenting strategy (as opposed to the conduct of litigation) *could* be viewed by the Commission as abusive if:
  1) it involves registration/enforcement of patent rights which could not reasonably be considered an attempt to establish rights and can therefore only serve to harass competitors; and
  2) the registration/enforcement was part of a plan whose goal was to eliminate competition.
- Documentation describing the use of patenting strategies to delay generic entry could be used as evidence of a plan to eliminate competition.
- The Commission claims to have obtained such documentation in the course of its Sector Inquiry.

2) Patent Settlement Agreements

- DG Comp focussed on originator/generic patent settlement agreements that:
  - provide for a “limitation” on generic entry; and
  - involve originator to generic value transfers (including those referred to in the U.S. as “reverse payments”).
- DG Comp suspects that such settlements allow originators to buy protection for drugs which are protected by weak or invalid patents.
- Sector Inquiry identified a need for further scrutiny of settlements between originators and generics.
- But little legal analysis and no plan for a system for notifying patent settlements, as exists in the U.S.

How might competition law apply?

- Article 101(1) TFEU (ex. Article 81(1) EC) prohibits:
  - "*agreements between undertakings…which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition…*"
- Commission suspects the objects of settlement agreements are anti-competitive.
- If the object of an agreement is anti-competitive then not required to show anti-competitive effect.

Criticisms of DG Comp's approach: Exercise vs. existence

- The Commission clearly views settlements as a means by which originators keep "weak" patents in place so that there remain obstacles to generic entry.
- But to challenge a settlement on the basis that it artificially prolongs the life of a "weak" patent brings the patent's *existence* into question…
- The Commission also refers to settlements which place a "limitation" on generic entry.
- But to speak of a "limitation" implies that the settlement prevents entry which could otherwise have occurred lawfully, which presumes that the patent is invalid.

Further criticisms of DG Comp's approach

- Settlements often allow generic entry prior to patent expiry, which is pro-competitive (e.g. via licensing or supply arrangements).
- There are bona fide reasons for reverse payments:
  - Risk aversion;
  - Avoiding the time and costs of conducting litigation;
  - Forming a mutually beneficial cooperative arrangement.
- Settlement is a legitimate means by which litigants bargain to obtain a benefit and avoid burdening courts with unnecessary litigation.

Comparison with approach of U.S. courts

- The Commission cited U.S. enforcement practice, especially by the FTC, as illustrating how settlements can infringe competition rules.
- But DG Comp's and the FTC's suspicion of settlements not shared by the U.S. courts, which have held in a line of cases including *Ciprofloxacin*, that:
  1. settlements which only restrict generic entry within the "exclusionary zone" of a patent are presumed not to be anticompetitive;
  2. there should be no detailed assessment of the patent in suit; a granted patent is presumed to be valid; and
  3. reverse payments are not inherently anti-competitive.

Developments since the sector inquiry

- DG Comp determined to monitor and address perceived issues in relation to patent settlement.
- In January 2010, it requested that selected companies submit details of settlements from the period July 2008 to December 2009.
- DG Comp analysed those agreements and produced a report providing a statistical overview of agreements between originators and generics.
- More targeted requests could follow and may be repeated annually "*for as long as the Commission considers that there is a potential problem*."
- So risks for originators remain high…

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Possible strategies to mitigate risks

- Avoid production of documents which comment on the implications of patenting strategies for generics – they could create the impression of a plan to eliminate generic competition.
- When entering into settlement negotiations with generics, consider the effect of the settlement on the generic's freedom to compete.
- In particular, consider whether the terms of the settlement will limit generic entry after the exclusivity period of the relevant patent has expired.
- If settlement involves transfer of value to generic, ensure business reasons for transfer are documented.

Thank you!

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