Patent Application as an Abuse of Dominant Market Position under Article 82 EC Treaty?

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Points to Consider

• Intellectual property rights - antitrust - basic understanding

• EU Commission's pharmaceutical sector inquiry report & patents & patent strategies & antitrust law

• The Boehringer Ingelheim case

• ECJ & IP rights & antitrust law

• Pleading for a right balance
• They share the same fundamental goals: enhancing consumer welfare and promoting innovation

• They act in tandem to make new and better technologies, products and services available to the consumer at lower prices

• IPRs stimulate innovation by establishing enforceable property rights for the creators of new and useful products, more efficient processes and original works of expression

[US DOJ & FDC 2007]
Antitrust laws ensure that new proprietary technologies, products and services are bought, sold, traded and licensed in a competitive environment.

Antitrust laws strengthen competition by prohibiting anti-competitive mergers, collusion and exclusionary exploitation of monopoly powers.

[US DOJ & FDC 2007]
EU Commission's Pharmaceutical Sector Inquiry

Background

• Increasing R&D investment

• Declining of novel medicines reaching the market

• Delayed entering on the market of generics

• Focussed on practices which companies may use to block or delay generic competition as well as to block or delay the development of competing originator products
EU Commission's Pharmaceutical Sector Inquiry

Legal Basis

• Articles 81 & 82 EC Treaty
• Article 82 EC Treaty prohibiting

"Any abuse by one or more undertakings of a dominant position within the common market… Such abuse may, in particular, consist in:

... (b) limiting production, markets or technical development to the prejudice of consumers;

..."
• IPRs key element in the promotion of innovation - particularly important for pharmaceutical sector

• Underlined the need for high quality patents granted in efficient and affordable procedures and providing all stakeholders with legal certainty
EU Commission's Pharmaceutical Sector Inquiry
Report and Generics

- Competition provided by generic medicines essential to keep public budgets under control and to maintain wide-spread access to medicines to the benefit of consumers/patients

- Competition with off-patent products enables sustainable treatment of more patients with less financial resources

- The generated savings → financial headroom for innovative medicines

- All actors should ensure the market entry of generics after expire of patent and data exclusivity and compete effectively
EU Commission's Pharmaceutical Sector Inquiry

Findings Indicate

• Originator companies developing strategies to extend the breadth and duration of their patent protection

• Filing numerous patent applications for the same medicine (forming so-called "patent clusters" or "patent thickets")

• Filing divisional applications extending the examination period

• All on purpose of delaying or blocking the market entry of generic medicines
EU Commission's Pharmaceutical Sector Inquiry

Findings Revealed

- Increased number of patent litigations between originator and generic companies by factor of four between 2000 and 2007

- Patent settlements between originator and generic companies resulting in payments to generic companies and the increase of health care costs
The Boehringer Ingelheim Case

Background

- Started investigating certain patenting behaviour - filing of patent application(s) in connection with one of its products under Article 82 ECT, because

- "According to information in the Commission's possession, such behaviour has allegedly been adopted to hold up innovation in these products and thereby impair competition."

- "Boehringer's strategies were intended to prevent other research companies from developing or marketing rival innovation for treating certain disease."
The Boehringer Ingelheim Case

Interrogatories under Article 82 ECT - *inter alia*

- The amount of the investment into R&D of the respective invention(s)

- Further R&D investment for follow-on inventions - after the market launch of the first patented product

- The existence of specific plans - incl. cost calculation for clinical trials, etc. needed for FDA approval, at the time of patent filing

- The drafting of patent claims as a function of the existing or expected patent situation of competitors

- Abandonment of an R&D project for reasons other than negative toxicological or pharmacological results of clinical trials
The Boehringer Ingelheim Case

Note!

• Answers requested *sub* poena before establishing whether indeed market dominance exists

• Special patentability requirements imposed on a market dominant undertaking?

• Not existing/allowed under TRIPS, EPC etc.
Do Patent Applications/Patents Obstacle to Innovate?

- Patent application - apart from secrecy - the only means for securing proprietary allocation for inventor (employer) - guaranteed by constitution

- Between publication of the application and the grant - as a rule
  - no injunctions/reasonable compensation - ex post
  - research exemption

- After patent grant
  - research exemption
  - compulsory licenses
  - compulsory dependency licenses
“(46) So far as dominant position is concerned, it is to be remembered at the outset that mere ownership of an intellectual property right cannot confer such a position.“

• In this case broadcasting companies had absolute control over copyrighted information used to compile listings for the television programmes received in most households in Ireland.

• Therefore these companies were in a position to prevent effective competition on the market in weekly television magazines.

⇒ Dominant position: Yes
• The right of the proprietor of a protected design to prevent third parties from manufacturing and selling or importing, without its consent, products incorporating the design constitutes the very subject-matter of his exclusive right.

• It follows that an obligation imposed upon the proprietor of a protected design to grant to third parties, even in return for a reasonable royalty, a licence for the supply of products incorporating the design would lead to the proprietor thereof being deprived of the substance of his exclusive right.

• Therefore a refusal to grant such a licence cannot in itself constitute an abuse of a dominant position.
Under the following circumstances the exercise of an exclusive right by the proprietor of a registered design holding a dominant position can be abusive conduct:

- the arbitrary refusal to supply spare parts to independent repairers,
- the fixing of prices for spare parts at an unfair level,
- the decision no longer to produce spare parts for a particular model even though many cars of that model are still in circulation.
“(17) With reference more particularly to the difference in prices between components sold by the manufacturer and those sold by the independent producers, it should be noted that the Court has held that a higher price for the former than for the latter does not necessarily constitute an abuse, since the proprietor of protective rights in respect of an ornamental design may lawfully call for a return on the amounts which he has invested in order to perfect the protected design.”
If the following three cumulative conditions are satisfied the exercise of an exclusive right by the proprietor of copyrighted material holding a dominant position can be abusive conduct:

• the refusal is preventing the emergence of a new product for which there is a potential consumer demand,

• it is unjustified and

• such as to exclude any competition on a secondary market.
• Difference exists between cases where

• An inventor with dominant market position enforces his/her patent - protecting his/her development work

• An undertaking with dominant market position acquires an exclusive license - merely protecting an investment

[Advocate General Kirchner]
Conclusions from the EC Courts Case Law

• Filing a patent application - no exercise of an IP right

• ECJ & CFI case law - including Microsoft - no basis for an action under Article 82 ECT against an applicant

• Astra Zeneca Commission's decision not applicable

• Whether a patent application ends up as a "worked", "licensed", "sleeping" or "blocking" patent - unpredictable at filing date

• No precedence under the US law - abuse only if fraudulently acquired and knowingly enforced
  [US Supreme Court in Walker Process Equipment v. Food Machinery & Chemical Corp.]
• Art. 295 EC provides that this Treaty shall in no way prejudice the rules in the Member States governing the system of property ownership.

• Art. 13 TRIPS: Members shall confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder.

• No predominance of competition over IP-Rights as demonstrated by high standards of ECJ case law
Pleading for a Right Balance

- Generics can only copy if there is something to be copied

- Highest priority - continuous flow of truly new drugs requiring investments of up to 1 billion €

- Subjecting patent applications of market dominant undertakings to special requirements - violating TRIPS & generally counterproductive

- Article 82 ECT applicable - under exceptional conditions - exclusively to exercising of IPRs
HVALA ZA VASO POZORNOST!