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2010

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Citation for published version (APA):

Lidgard, H. H. (2010). *Misuse of dominant position in patent enforcement*. Paper presented at Licensing Executive Society,.

Total number of authors:

1

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Misuse of Dominant Position in Patent Enforcement

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Licensing Executive Society

5-7 september 2010

14.00 - 15.00

Radisson Blu Royal Viking Hotel, Vasagatan 1, Stockholm, Sweden

Case T-321/05, AstraZeneca

- On July 1, 2010 the General Court rendered its judgment in AstraZeneca
- The matter concerned an appeal of the 2005 EU Commission decision to fine AZ 60 mEUR for
 - supplying misleading information to the patent authorities and
 - for using the regulatory system to exclude generic competition and parallel trade
- Questions:
 - Relations between competition law & IPR?
 - Is the Union now endorsing a patent misuse principle?
 - What are the consequences for dominant Pharma actors?

AZ a dominant actor

- In the 1980s AZ developed a protein pump inhibitor treatment of gastrointestinal disease with substantial benefits over existing H2 blockers;
- Within a few years Losec substantially replaced the use of H2 blockers for more severe conditions and became the world's largest blockbuster drug
- The relevant market was asymmetric. PPI restrict H2 blockers, but H2 blockers do not restrict PPI.
 - *"It is apparent from the examination of all the pleas and arguments put forward by the applicants against the Commission's definition of the relevant market that the Commission based its assessment on the greater efficacy of PPIs, the differentiated therapeutic use of PPIs and H2 blockers, the trend of asymmetrical substitution that characterised the growth in sales of PPIs and the corresponding decrease or the stagnation in sales of H2 blockers, price indicators, such as they resulted from the regulatory framework in force, and the 'natural events' observed in Germany and the United Kingdom." (219)*
- IPR's do not confer dominance, but are a relevant factor
- AZ had an "overwhelming" market share and satisfied all other requirements for dominance.

AZ's "anti-generic" strategy

- Common R&D industry practice is to protect itself against generics and parallel trade.
- Losec® expected to reach its market peak in 2000 and thereafter to lose 70-80% of market. Each day of prolonged exclusivity had substantial impact.
- Prolonged patent protection through SPC important.
- Other features in LPP Strategy document of 29 April 1997:
 - (short term) diversification of Losec by introducing Losec MUPS;
 - (short term) delaying generic introduction through: documentation protection, upgrade of product quality, additional offensive/defensive formulation patents, broadened IPR base (trade names, tablet shapes), surveillance programme to identify generic competitors, immediate and aggressive infringement actions, switch of Losec® capsules to tablets in e.g. Denmark, Norway, Germany;
 - (long term) introduction of patent protected products with clinical benefits (Nexium).

First abuse – misleading information

- Under the 1992 “SPC-regulation” maximum five year extensions granted to NCEs
 - “... which, on the date on which this Regulation enters into force, is **protected by a valid basic patent** and for which **the first authorization to place it on the market** as a medicinal product in the Community was obtained **after 1 January 1985** ...” (Belgium 1982 and Germany/Denmark 1988).
- First technical authorization in France in April 1987, only price agreed in 1989. First market introduction in Luxemburg in February/March 1988.
- AZ developed a concept of “effective marketing” aimed at Germany/Denmark notified March 1988 to all authorities without disclosure of its theory.
- SPCs were granted in some countries and refused in others.
- In 2003 the Court held in Case C-127/00 *Hässle* that **the first market authorization** concept in the SPC Regulation referred to the first ‘technical authorisation’.
- **In its 2005 decision**, the Commission found the “deliberately misleading representations” were made to agents, patent offices and courts in order to incorrectly acquire or preserve SPCs for Losec abusive. It distinguished between the initial application and the further communications with patent offices and courts.

Abuse?

- AZ claimed that
 - law and case-law did not support using such activities as evidence of abuse;
 - even if abusive, they had no anticompetitive effects as the basic patent lasted until 1999-2004
 - only the bad faith exercise of a wrongfully granted patent could be abusive
 - a stricter approach would chill the innovative climate
 - competition law should not police IPR.
- The Commission argued that
 - misuse of public procedure is abusive if the authority is misled to grant restrictions in reliance on the incorrect information provided;
 - it does not matter whether or not the application has been granted;
 - patent law can only nullify patents, whereas competition law contains stricter remedies.

Abuse established

- The Court held that
 - A dominant company has a special responsibility to compete on the merits. Whether deliberate or not, misleading information conflicts with such an obligation. It is irrelevant if the application is granted and competition eliminated or not.
 - competition law has a broad application and applies irrespective of whether that behaviour may also be caught by other rules;
 - existence of remedies specific to the patent system is not capable of altering the conditions of application of prohibitions laid down in competition law;
 - AZ adopted a consistent and linear course of conduct, characterised by the communication to the patent offices of misleading representations for the purpose of obtaining issuance of SPCs to which it was not entitled (Germany, Finland, Denmark and Norway), or to which it was entitled for a shorter period (Austria, Belgium, Luxembourg, Ireland and the Netherlands).

Second abuse – withdrawal of marketing registration

- In line with its strategy, AZ replaced Losec capsules with a tablet form (MUPS) in Denmark, Norway and Sweden and withdrew its marketing authorization in those countries;
- Under Regulation 65/65 as amended, all medicines must have a marketing approval. In order to facilitate generic entry. Such products may either show biocompatibility with an existing product or rely on published scientific data rather than duplicating all clinical tests.
- In 2003 the Court in Case C-223/01, *AstraZeneca*, established that was necessary but also sufficient that the original marketing approval be in force on the date of the generic/parallel trade application;
- A consequence of AZ's withdrawal was that generic competitors and parallel traders were not entitled to rely on AZ's clinical data for Losec capsules. Sweden recalled its approval for parallel traders, whereas Denmark and Norway did not;
- **In its 2005 decision**, the Commission found the launch on the market of Losec MUPS tablets and the withdrawal from the market of Losec capsules to be abusive behaviour.

Abuse?

- According to AZ
 - the purpose of the abbreviated procedure in the pharmaceutical legislation was, under exceptional conditions to permit use of clinical data provided by the R&D industry;
 - the owner of such data may freely, in accordance with Case C-94/98, *Rhône-Poulenc Rorer & May & Baker*, decide where to use it and when to recall it;
 - generic companies could rely on published scientific data and protected data was not an essential facility;
 - even a dominant entity may protect its commercial interests. Recalling the registration for Losec capsules was competition on the merits;
 - no harmful effect as patent protection lasted until 2007.
- The Commission claimed that
 - the abuse consisted in the parallel acts of introduction and deregistration;
 - when 10 year data protection elapses, the documentation is freely available to others which right was nullified by AZ's acts;
 - even if the deregistration was lawful under Pharma law it could still constitute an abuse under competition law;
 - the alternative registration route was more burdensome for generic companies and parallel traders.

Abuse established

- The Court held i.e.. that
 - after the 10 year exclusive period the R&D retained no exclusive right to make use of the scientific data, which can then be freely used for essentially similar products under the abridged procedure;
 - the fact that AZ was entitled withdraw its marketing authorisations “*in no way causes that conduct to escape the prohibition laid down in Article 82 EC.*” The illegality under Article 82 EC is unrelated to other legal rules.
 - AZ intended to obstruct the introduction of generic products and parallel imports.
 - the fact that an undertaking in a dominant position is under no obligation to protect the interests of competitors does not make exclusionary practices compatible with Article 82 EC.
 - The mere desire of an undertaking in a dominant position to protect its own commercial interests will not justify recourse to practices falling outside the scope of competition on the merits.
 - In the absence of legitimate interests and of objective justification, an undertaking in a dominant position cannot use regulatory procedures solely to prevent or make more difficult the market entry of competitors.
- However, in view of the fact that the Danish and Norwegian authorities did not revoke marketing rights for parallel importers, the fines imposed on AZ were reduced from 60 mEUR to 52,5 mEUR.

General conclusion

- The judgment is another blow to the pharmaceutical R&D industry
 - Legislation is at all times interpreted in a restrictive way disregarding the intention of the regulators;
 - industry has a far reaching and difficult obligation to always supply correct and full information to patent authorities or risk liability for abuse of dominance;
 - Industry does not own its costly and valuable scientific data after 10 years;
 - Industry must not create obstacles for generic competition and parallel trade.
- The strict attitude is in line with the Commission's Report on practices in the Pharma industry. The next battle will consider settlement agreements between R&D companies and generics.
- Will the consequence be more generic industry and less R&D in Europe - in conflict with overreaching goals to promote innovation and creativity?



Competition law takes precedence

- The Court assigns far reaching hierarchical control to competition law.
 - Even if activities are not prohibited by special pharma or IPR legislation, they are subject to control under the broad notion "competition on merits";
- In line with US *Trinco* an alternative position could have been
 - that the antitrust authorities shall not interfere with what comes under the responsibility of regulatory agencies or patent offices;
 - Some of these institutions were fully capable of solving the matters addressed in AZ and the failure by others should not be rectified by competition intervention.
- The special case where a dominant company is aware of and relying on fraudulently obtained rights in order to exclude competition was never addressed in the judgement.
- Did AZ with full knowledge of the fact that the SPC was not valid try to prevent generic competition or parallel trade by bringing infringement actions?

Competition/IPR intersection

- The AZ judgement introduces the US notion of patent misuse into European law.
- Under US theory a wrongfully granted patent used to prevent infringement serves as shield for the infringer and will be revoked. However, if the infringer can show fraud and malicious intent, he has a sword in his hands and can claim punitive antitrust damages.
- AZ leads to the far reaching conclusion that a dominant actor's misleading information to authorities always constitutes a competition law abuse without requiring a showing of intent or competition harm.
- Nothing in the judgment's wording prevents this position to serve as weapon against any type of wrongful information in highly complex patent application matters.

Final comment

- The Commission and the Court stretched in order to find that AZ abused its dominant position;
- It would have been far more interesting if the investigation had focused on whether AZ, in bad faith actually used its SPC in order to prevent competitors entry into the market. There were indications to that effect in the Commission decision, but the judgment did not discuss them.
- It remains to be seen whether the matter will be appealed. The lessons from Microsoft makes such an appeal more likely.