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EGA: Legal Affairs Forum

A review of key cases affecting generic companies

experience. creativity. results.

19 March 2011
Brussels
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1. Preliminary injunctions

- Preliminary injunctions against a generic company are the heart of the problem: competition is prevented with a PI on the basis of a patent which eventually turns out to be invalid (speedy PI and slow proceedings on the merits)

- Very popular PI proceedings in Belgian patent litigation:

  - » Very quick decision (1-3 months)
  - » Very often no balancing of interests
  - » Presumption of validity of European Patent
    - Brussels, 26/10/2010 (fluvastatine): "*An appearance of right means that the patent holder proves that his patent rights have a sufficient degree of certainty. This means that the validity of the patent is at first sight reasonably plausible (…). It has to be accepted that the Belgian part of a EP is valid at first sight and justifies preliminary measures to protect the patent, even if the patent is seriously contested, as long as the patent has not been invalidated by virtue of a definitive decision.*"

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1. Preliminary injunctions

- President of the Antwerp Commercial Court, 16/11/2010 (GHA/THV):

  "In summary proceedings, measures can only be ordered if there is a sufficiently strong appearance of rights that justify taking that decision. This appearance should be assessed in light of the procedural quality of the parties.

  In summary proceedings, a published European patent is considered to be prima facie valid. The assessment of the validity of a patent implies an extensive technical analysis, which is thwarted by the prima facie validity of a European patent.

  However, the specific circumstances of a case can lead to the finding that the prima facie validity cannot be held to be absolute, and that it has been affected. The consequences of such finding will be assessed in light of the asserted claims, in particular having regard to the procedural quality of the parties."

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1. Preliminary injunctions

- Antwerp, 09/01/2011 (co-valsartan):

  * "*The Court now has to verify if N. possesses sufficient prima facie valid rights to justify that provisional injunctive relief is granted. When doing so the Court can examine the rights of the parties.*

  Since the validity of the patent is not seriously contested, the validity of the EP is assumed. The discussion will therefore focus on the lawfulness of the SPC.

  Contrary to an EP, an SPC was not subjected to a thorough pre-examination and an SPC therefore does not hold the same intrinsic qualities as an EP. The Court therefore has to verify whether the SPC is prima facie valid. In order to impose the requested injunctive measure, the invoked title has to have a sufficient degree of certainty, in that sense that its validity is made prima facie reasonably acceptable."

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1. Preliminary injunctions

- Antwerp, 09/01/2011 (co-valsartan):

  * Important SPC-decision:

    - Teva intended to launch valsartan ; Novartis' valsartan patent was expired, but there was an SPC for the combination product

    - Teva: combination was not spefically disclosed in the basis patent ↔ Novartis: a product is protected by a patent if it infringes that patent

    - Acceptance of the "infringement test" for PI proceedings

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1. Preliminary injunctions

- Suggested approach in PI proceedings:
  - » Presumption of validity of a European patent
  - » BUT factual circumstances have to be taken into consideration (no dogmatic approach):
  - follow-on patent;
  - has all relevant and known prior art been disclosed/examined to the EPO?
  - status in foreign proceedings
  - limitation of claims (implies partial invalidity)
  - real prima facie assessment of validity (if possible)

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2. Clopidogrel

- Effects of dogmatic approach in PI proceedings:
  - » Basic API patent expired, but EP 901 was invoked (combination product clopidogrel+aspirine)
  - » Sanofi started infringement proceedings on the merits for indirect patent infringement
  - » Sanofi withdrew the litigation provided that the combination therapy was carved out of the PIL
  - » Invalidity litigation was started and Sanofi … did not defend itself
- Abuse?

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3. AZ (abuse of dominance defense)

- (Preliminary) Injunctions for abuse of dominance are possible, but difficult to obtain:
  - » UK
  - possible for a party to be prevented from enforcing its patent rights where there is a behavior falling within article 102 TFEU (abuse of dominant position)
  - This defense may be raised during litigation or a complaint may be submitted to the UK or European Competition authorities
  - » Belgium : similar situation (e.g. alendronate-matter: Merck Generics/MSD)
  - Used as a defense by generic company in PI proceedings initiated by Merck (MSD/EG, CA Brussels, 02/07/2007): "*The enforcement of patent rights cannot be regarded as an abuse of dominance*"

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3. AZ (abuse of dominance defense)

- Generic company filed a complaint with the Belgian competition authorities with a request for preliminary measures

  * Merck Generics/MSD, 05/10/2007 (alendronate)

  * what is the relevant product (ATC 3 or 4?) and geographical market (Belgium)

  * has the patentee a dominant position on these markets (yes, more than 50% which is an indication of dominance)

  * is there a likelihood of an abuse? No

    - no competence to assess the validity of a patent

    - there is no abuse in enforcing the patent pending the invalidity proceedings

  * no need to investigate the required “serious, immediate and irreparable harm”

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3. AZ (private enforcement)

- Damages actions, after a finding of abuse of dominance
  - » Private enforcement: civil action brought after a competition authority has found an infringement
  - » US example: private enforcement constitutes +90% of all antitrust litigation
  - » Europe: private damages claims for violations of competition rules are still rare
  - - Issues: fault requirement, the ways in which damages are calculated, passing-on defense, access to evidence, cost of actions, etc.
  - - EC pushes private enforcement

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3. AZ (private enforcement)

» Private enforcement possible in AstraZeneca-matter?

- Jurisdictional issues: possibility of cross-border damages before the courts of the domicile of the defendant (art. 2 Brussel I-Regulation)
- Not only generic companies, but also healthcare authorities
- Class-actions?

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4. Escitalopram-litigation

- Lundbeck : switched markets from citalopram (R+S) to escitalopram (S), which is protected by a SPC (like citalopram was).
- MA was applied in a DCP with The Netherlands as RMS, with escitalopram as reference product (cf. definition of generic product) and the S-enantiomere is the only active enantiomere ; hybride procedure was applied and bridging data (public documents based upon studies from Lundbeck's ESC-file) were communicated;
- Very important decision in the Dutch MA-litigation regarding the question whether the documents are protected by data exclusivity (2010): ESC is not a NAS but a line-extension of a Global MA;
- The Hague 2011: Quid validity of SPC for ESC as an SPC cannot be granted twice for the same product (article 3(c) SPC-Regulation) + MA for ESC is not the first MA (article 3(d) SPC-Regulation)?

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5. ECJ-decision

- 08/03/2011: ECJ gave its opinion on the “Draft Agreement on the European and Community Patent Courts”)
- Transfer of jurisdiction to a court outside the institutional and legal framework of the Eu would not be compatible with the Eu-treaties.