Making Medicines Affordable

Update on the Enforcement of IP Rights & Counterfeiting of Medicines in the EU

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Introduction

- Counterfeiting and Piracy have grown into an international phenomenon with major social and economic repercussions
- From 2005 to 2006:
  - **Cases of counterfeit articles seized at EU borders increased by 234%** ***Source: EC statistics DG Customs***
- To fight counterfieting and piracy is now a priority for the European Commission's agenda

European Commission's policy

- Stronger enforcement of all IP rights
- Harmonisation of enforcement measures available in Member States.
- To achieve this goal, 2 legal instruments:
  1. Directive 2004/48/EC on the enforcement IP rights
  2. Proposal for a Directive on criminal penalties to enforce IP rights

Directive 2004/48/EC on the enforcement of IP rights

- Adopted in April 2004 & already implemented by Member States
- Provides for hard hitting measures to enforce IP rights
- The Commission, while negotiating trade agreements, should not try to impose the Directive in countries like Russia and the Balkans without the safeguards available to EU countries that protect legitimate competition & stop abuse of interlocutory injunctions

Hard hitting measures

- Pre action ex parte court orders on low standard of proof for defendant to produce information
- Seizure of banking documents
- Seizure of goods/records
- **Injunctions granted on low standards of proof**
- No automatic review
- Seizure of offices/equipment
- Freezing of assets/bank accounts

What is wrong with the Directive

- A faked Louis Vuitton hand bag is an obvious trademark infringement!
- Patent infringements are not crystal clear: it can take up to 3 years to solve case & decisions can be different in each country
- So why are alleged patent infringers treated as criminals i.e. pirates/counterfeiters?

Conclusion

European Commission's view:
"Best Practice to fight counterfeiting and piracy"

Generics's view: "Everything you wanted to know on how to block generic competition in one go!"

- Directive could be abused by originators to 'try to keep unwelcome legitimate competitors out of market'.

Further Actions

Criminalisation of patent infringement

- April 2006: EC's new Proposal for a Directive to establish criminal penalties to enforce IP rights.

- AIM: to enforce IP rights by supplementing the civil procedures and remedies provided for in Directive 2004/48/EC

Content

Art. 3: Obliges Member States to consider **all intentional** infrigements of an IP right on a commercial scale as a **criminal offence**

Harmonization of criminal penalties

- At least 4 years imprisonment if offence involves criminal organisation

- Fines from 100.000 to 300.000 euros when criminal organisation involved or existing risk to public health and safety

What is wrong with the Directive

- Once again, all IP infringements are put in the same ‘basket’, punished in the same way and equated with counterfeiting and piracy, but:
  - Counterfeiting and piracy are clearly intentional and criminal
  - Patent infringements may not be
- Civil proceedings can deal with patent infringements, as now

Implications for generic competitors

- Patent infringement during normal legitimate business development of product will become a crime instead of remaining a civil matter.
- Fear of criminal prosecution + uncertainty about validity of patents will inhibit competition and innovation.
- Licensing & Professional advisers discouraged.

A quote from Nokia's Director of Intellectual Property . . .

- " . . . With patents, it's never black-and-white. Sometimes third-party patents are so weak that I advise managers to go ahead because, after making a risk analysis, we feel we can safely challenge the existing patent. But with this law, even if I'm certain the existing patent is no good, the manager would be criminally liable."

Current situation

- Draft law was voted in April by the whole European Parliament
- Good news: Patents, SPCs and utility models have been excluded from scope !
- At Member State level: some countries are against Proposal because not necessary.
- When will the new law be adopted (if adopted)? Maybe end 2008/2009

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Update on policies to fight counterfeiting of medicines in the EU

Initiatives against counterfeiting

- EC survey: 2006, cases of counterfeit medicines seized at EU borders increased 384% since 2005.
- EC has done a consultation on how to 'combat counterfeit medicines'. Next steps: will issue a strategic paper in 2008 & a legislative proposal might follow
- Originators support a project to harmonize a coding system in the EU for all pharmaceutical products at indiv. pack level
- WHO has created IMPACT in 2006

EGA's policy on how to fight counterfeit medicines

- Generic medicines are less likely to be counterfieted because of their low cost.
- According to EGAs's survey in 2006:
  - **No counterfiets of generics found in the EU**
  - **Isolated cases in Russia, Uzbekistan and Ukraine**
- However, serious problem in India for generic medicines and everywhere for branded products.
- In UK, in the last month fake versions of Cialis, Lipitor & Reductil where found in the supply chain

EGA's policy on how to fight counterfeit medicines

- In favour of securing the supply chain

- Technology solutions are no solution, being easy to copy in a digital world. "Better Barcodes" are neither an option to prevent counterfeit nor to increase patient safety. There is no scientific proof that technology will erase counterfeiting completely.

WHO definition of counterfeit medicine

- *'A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity or source'*

→ No reference to patent infringement

EGA's policy on how to fight counterfeit medicines

- Counterfeiting is essentially a trademark issue and **NOT** a patent issue

- Counterfeiting **cannot** be used as a reason to justify:
  - **Patent extensions or increases of data exclusivity**
  - **The use of harsher civil sanctions & criminal sanctions to punish patent infrigements**

This would be ineffective as well as unjustified.

Technological approach

- EGA is against the current proposal to create a compulsory harmonized system for coding and identification of pharmaceutical products at individual pack level.
- It will dramatically increase costs for our industry
- We could support it as one part of the solution, but only on a voluntary basis.

EGA's recommendations (1)

- Strenghten the existing healthcare system and its legitimate supply chain
  - **Appropiate strengthening of current GMP & GDP certification systems for ALL partners in the supply chain:**

Wholesalers, shortline wholesalers, paralell importers, pharmacists, manufacturers…

- Certification to be provided by competent authorities

EGA's recommendations (2)

- Joint Declaration to do 'Business only with certified partners' which means those approved and licensed by the competent authorities.

- Non certified companies should be checked and audited

EGA's recommendations (3)

- Specific attention should be given to wholesalers, shortline wholesalers, and paralell importers: vulnerable entry points
- A harmonized coding system should be voluntary and only applied to 'commercially interesting' medicines
- Monitor the selling by internet
- Enforce and punish severely the 'pharmaceutical crime'
- Consumer education

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THANK YOU