The Hungarian Pharmaceutical Industry: Best Practices

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3rd May 2005
Introduction

- Driving forces of implementation strong IP protection
- Implementation stages of strong IP protection
- Effects of implementation
- Best (?) practice
- Events and consequences
Driving forces of implementation

- Country specific history exists
- Type of IP (patent, trademark, design, utility models, copyright)
- Type of interested industry
- Type of patents (product vs. process)
- Differences between technical (patents, utility models…) and other type (trademark, copyright…) of IP
Driving forces of implementation

- Country as a part of world economy
- Stagnating or developing
- Market of developed world, premium prices
- For fair competition rules must be the same
- But the start line as well!
- If an economy is strong enough to enter into developed markets it has to adopt IP rules
- And open its market to developed world (if it wasn’t like that)
Driving forces of implementation

- People need best product or service by nature
- Up to date, state of the arts products have to incorporate inventions
- Economical need is the return of investment or even more
- Result: your country market has to ensure the exclusivity or you have to import them
Implementation stages of strong IP protection

- The most critical issue will be targeted (product patent)
- Day of implementation
- Mode of implementation (pipe line, cases in progress)
- Political and economical pressure
- Party of negotiations: lobbyist and government rep.
- When and how will you be involved?
- Role of industrial and IP associations, experts
- Topics have to be in your hand in due time
- You must be unified, its a critical situation
- But separate different stakeholders (NCE and generic producers)
Implementation stages of strong IP protection

- Trying to find the most persuasive arguments
- For politicians say political arguments
- As they reached their goal in this issue, go for more
- Secondary IPs, like trademark, designs...
- They ask for „effective” law enforcement system
- You have to use the same economical, political tools
- Developed word is strong enough to say yes for promises and not to keep them
Effects of implementation

- Bad and good effects
- Cultural change
- Prices are remarkable higher
- R&D development (strong IP protection neither necessary nor enough!)
- Domestic production has got a big challenge
- Survive needs reserves and step by step implementation
- Time scale can reach ten years
- Producers have to manage their export to less developed countries
Effects of implementation

- Features of Hungarian pharmaceutical industry
- Past: several state owned company
- Mainly generic producers
- Present: Just one independent co.
- Others owned by multinational companies
- Domestic price competition
- Strategy of most of them is defined abroad
- Richter’s answer for challenges
Best (?) practice

- Richter had to restructure its business model
- Defining real competitive edge of company
- Niche markets and activities
- Cost of restructuring
- Easier access to developed market, but IP is not the only barrier
- Managing export to less developed countries
- Strong and reliable IP experts and advocates
- Several court cases
Events and consequences

● Hungarian pipe line protection of products (1994)
● Result of negotiations:
  ● Priority day: 01.01.1987
  ● Bases can be any granted patent
  ● Application under examination can be completed with product claims
● Unfortunately the law itself did not exclude applications with earlier priority (c.i.p.)
● Result: product patent was granted with earlier priority date (serious effect on generic industry!)
Events and consequences

- Hungarian pipe line protection of products (1994)
- Result of negotiations:
  - Priority day: 01.01.1987
  - Bases can be any granted patent
  - Application under examination can be completed with product claims
- Unfortunately non examined patent was also considered
- Nullification procedure is necessary even if in EU and US patent was not granted (5 to 7 years)
Summary

- For development all of us has to pay price
- Domestic industry is in big danger
- Strategy change is vital, don’t be late
- Speed of implementation is crucial (if it is decided)
- Strong negotiation teams are necessary
- Multiple action and counter action could happen
- Law making and enforcing needs delicate attention to avoid fatal mistakes
- Support from government is a basic requirement for survival