

The Hungarian Pharmaceutical Industry: Best Practices

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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

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- 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