Utility Model for pharmaceutical products?

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Hungarian Association for the Protection of Industrial Property and Copyright „Európai IP kérdések: újratöltve”
- Conference of May 8-9, 2014 -
Utility Model as exclusive right for pharmaceutical products

UM: for new technical solutions (three-dimensional articles)

BUT!

- in some countries FOR-
  - pharmaceutical compounds, pharmaceutical combination
  - chemical substances / mixtures, alloys
  - foodstuffs, nutritional supplements
  - second medical use
  - process medical device
## Where in Europe & CIS?

<table>
<thead>
<tr>
<th>in Europe</th>
<th>Subject of protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>AT</td>
<td>similar to patent</td>
</tr>
<tr>
<td>BG</td>
<td>pharmaceutical products, formulations, combinations</td>
</tr>
<tr>
<td>DK</td>
<td>same as patent except method, processes</td>
</tr>
<tr>
<td>CZ</td>
<td>pharmaceutical compounds, combination chemical substances / mixtures, alloys, foodstaffs, nutritional supplements</td>
</tr>
<tr>
<td>DE</td>
<td>similar to patent except processes</td>
</tr>
<tr>
<td>EE</td>
<td>similar to patent</td>
</tr>
<tr>
<td>ES (theoretical)</td>
<td>pharmaceutical products</td>
</tr>
<tr>
<td>SK</td>
<td>pharmaceutical compounds, pharmaceutical combination chemical substances/mixtures,</td>
</tr>
<tr>
<td>in CIS</td>
<td></td>
</tr>
<tr>
<td>UA</td>
<td>similar to patents</td>
</tr>
<tr>
<td>KZ*</td>
<td>medical device*</td>
</tr>
<tr>
<td>BY*</td>
<td>medical device*</td>
</tr>
</tbody>
</table>

There are claim examples in the hand-out!

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Why choose UM for pharmaceutical products?

Variable fields of use

- **national way**
  - broader scope of protection (e.g. in 2nd medical use)

- **conversation**
  - derivation - from patent - (withdrawn / revoked patent)

- **parallel**
  - pending patent application
  - opposed patent

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Advantages

- **national way**
  - inventions without inventive activity (*step)
  - marketing tool

- **parallel**
  - valid protection for the duration of pending patent application

- **derivation**
  - back front

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Advantages 2.

- grace period

- search problem (for competitors)
Disadvantages

- availability: only in few countries
- shorter life-span
- enforcement
Differences in each country

- ruled by national law
  - registration requirements / subject of protection
  - grace period
  - etc....

see hand-out
How to use it?
- a specific case -

- Company filed EP patent application

Scope of protection

„the solid formulation of x or a salt thereof containing the crystal of x, wherein the amorphous content is within a range showing no influence on product stability”

- still pending -
How to use it? 2.
- a specific case -

In CZ & SK filed three UM

**UM1**) Claim 1.

*A pharmaceutical tablet for use in a solid formulation, characterized in that the tablet comprises (i) crystalline “X” or a salt thereof and (ii) an excipient wherein the amorphous content of “X” or a salt thereof is 77 % or less, which is measured by NMR analysis in a solid phase using NMR device or by spectrometry in near-infrared range using Fourier transform infrared spectrometry."

! The “X” has undergone a metamorphosis from amorph to crystals within 20 days
How to use it? 3.
- a specific case -

- The scope of the protection of UM 2)
  is for tablet comprising x with very „general” excipients

- The scope of the protection of UM 3)
  is for tablet comprising x with „specific” excipients

- In CZ & SK (no basic patent was filed either)
  With this 3 UM the company could assure a „similar” scope of protection as a basic patent
How to use it? 4.
- a specific case -

A few competitors filed an opposition in SK and started a nullification procedure in CZ against UM’s / UM applications.

The legal procedures will be as long as the duration of the UM!

- uncertainty for competitors
Conclusion
Why is it good and efficient to use UM?

Variable fields of use
Short term effective
Cheap
Gives similar rights as patent
Thank you for your attention!

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