



Utility Model for pharmaceutical products?

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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 ?

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

There are claim examples in the hand-out!

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- derivation - from patent - (withdrawn / revoked patent)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

Advantages

- **national way**

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

- **parallel**

- valid protection for the duration of pending patent application

- **derivation**

- back front



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.

* „X” = API

„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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