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INVENTIVE STEP: STRIVING FOR BETTER QUALITY OF PATENTS

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What is meant by quality of patents?

“It is quality rather than quantity that matters.”

Seneca

- ▶ **Rigorous standards and criteria in examination and prior art search**
- ▶ **Higher level of inventive step**
- ▶ **No more weak patents granted**

Standard for inventive step/non-obviousness

The standard for inventive step is defined in the Romanian patent Law by Art. 11 which corresponds to Art. 56 EPC.

Art. 11:

(1) An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is **not obvious** to a **person skilled in the art**.

The person skilled in the art

- ▶ Hypothetical person
- ▶ Normal skills
- ▶ Ordinary creativity

Obviousness

- ▶ The term "**obvious**" means something which does not go beyond the normal progress of technology but merely follows plainly or logically from the prior art, i.e. something which does not involve the exercise of any skill or ability beyond that to be expected of the person skilled in the art.

THE APPROACH

The problem-solution approach:

- i) identifying the closest prior art:
 - a) identify the technical features and the technical purpose or intended use of the invention;
 - b) compare the features of the invention with those of preselected items of prior art (PA);
 - c) select the closest prior art (CPA).
- ii) establishing the technical problem to be solved:
 - a) identify feature(s) distinguishing the invention from the CPA;
 - b) identify the technical function/purpose/effect of the distinguishing feature(s);
 - c) formulate the objective technical problem as: “how to provide the technical effect that the invention provides over the CPA”.
- iii) examining whether or not a skilled person, having regard to the closest prior art, would have suggested the claimed technical features in order to obtain the results achieved by the claimed invention:
 - a) same solution to the objective problem in the CPA and indication to combine this with the CPA
 - b) indication in the PA to adapt/modify the CPA to arrive at the invention.

Inventive step

A pharmaceutical composition comprising **fingolimod** and/or a pharmaceutically acceptable salt or ester thereof, **calcium lactate pentahydrate** and, optionally, a **lubricant**.

Inventive step

Prior art:

- ▶ **D1:** refers to binary blends comprising **fingolimod** and several different excipients. The document presents a stability test of said blends (cited in the application).
- ▶ **D2:** presents a list of excipients for direct compaction. Calcium lactate pentahydrate is a suitable excipient for formulation of solid oral dosage forms.

Inventive step

Inventive step analysis:

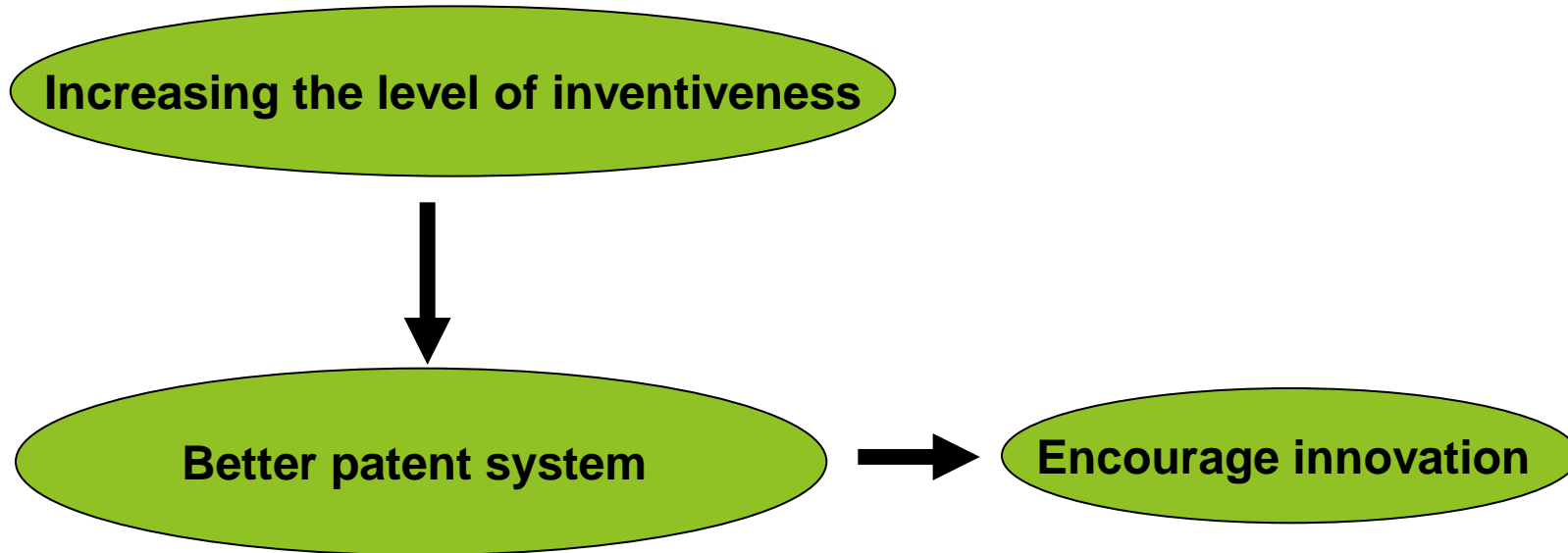
The person skilled in the art is a **medicinal chemist**.

- ▶ The CPA is **D1**.
- ▶ Present composition **differs** from D1 in that calcium lactate pentahydrate is included in the composition.
- ▶ The **effect** of this difference is not known, since in D1 the results of the stability test show that for the majority of tested excipients, such as e.g. lactose, mannitol, microcrystalline cellulose or HPMC, the sum of impurities of fingolimod after one month at 500C varied between 0.0% - 0.6%; thus said formulations are considered stable.
- ▶ The **objective technical problem** must therefore be regarded as the provision of an alternative pharmaceutical composition comprising fingolimod.
- ▶ Calcium lactate pentahydrate is known from D2 as a suitable excipient for formulation of solid oral dosage forms.

Obviousness:

- ▶ Starting from D1 and in the absence of an unexpected effect with respect to the compositions described herein, the choice of calcium lactate pentahydrate as excipient in the formulation of a composition comprising fingolimod is merely one of several straightforward possibilities from which **the person skilled in the art would select**, in accordance with circumstances, without the exercise of inventive skill, in order to solve the technical problem, particularly taking the teachings of D2 into account.

CONCLUSIONS



THANK YOU!