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Pharmaceutical, Chemical and Biological Inventions – PCBIs at Focus of attention of the EPO Examination Guideline Revision for proceedings in 2020

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The Corona-crisis presently fosters the public interest and attention with respect to a certain group of technological inventions. Pharmaceutical, chemical and biological inventions - short: PCBIs - are highly relevant for modern medical treatment. Unsurprisingly, a high number of patent applications are filed annually in related fields and the numbers show steady growth since 2009[1]. In chemistry, the number of granted patents rose from 12,499 in 2009 to 28,865 in 2019. In the same period, the number of patent applications rose from 36,166 to 43,881. These numbers follow the overall positive filing trend with the EPO. Pharmaceuticals, biotechnology and organic fine chemistry are among the top 10 technology fields by filing. With respect to the year 2018, filing in pharmaceuticals rose by 4.4 %, while filing in biotechnology rose by 1.7 % overall. Conclusively, patent protection sought in the field of PCBIs directly reflects the field's economical relevance.

Seeking patent protection for PCBIs

While medical treatment methods applied to the human and animal body are excluded from patentability under the EPC, medical "devices" or PCBI "substances or compositions" for use in surgical, therapeutic or diagnostic methods are eligible subject matter.

Second medical use claims

Only "substances or compositions" are subject matter eligible for "second medical use" claims. A "substance or composition" suitable for use or the use itself in a respective method does not disclose further ways of its use in respective methods. Therefore, the subject matter of a claim referring to a different use of a known „substance or composition" might still be novel and inventive in the sense of the EPC. This is generally not the case for devices.

[1] EPO annual report 2019: https://www.epo.org/about-us/annual-reports-statistics/statistics.html

"Substance or composition" vs. "device"

Miniaturization of devices in combination with an increase in complexity of PCBIs make it more and more difficult to distinguish both their categories – "devise" and "substance or composition".

The Board of Appeal decision **T 1758/15** bases the differentiation on the effect to a patient's body. In case the effect is a chemical one, the subject matter refers to a "substance or composition". In case the effect is a physical one, the invention relates to a device. What about cases, where one could argue in favor of both, physical or chemical effect? The respective patent application sought protection for a biocompatible, biodegradable filler material injectable between two tissue layers for use in a therapeutic method. As matter of example, collagen is disclosed as filler material. The formed layer functions as a spacer between the two tissues to reduce side effects of radiation-based cancer therapy. From a natural scientist's perspective, one might consider the filler to be a substance. This assumption would be based on the filler's viscous and biodegradable properties. Nevertheless, the Board of Appeal considered the physical properties of the formed layer – the capability to function as a spacer with a 3D form – to rank higher when compared to the substance characteristics. In particular, radiation-shielding properties that are linked to the chemical structure are, according to the Board of Appeal, negligible. Thus, the Board of Appeal drew the conclusion that the filler is indeed to be considered a "device" and as such being excluded from second medical use. Commercially available and widely known collagen was novelty destroying. The appeal dismissed and the patent was revoked.

The decision **T 1758/15** is cited in the Guidelines (**G-VI 7.7**) and thus qualified as "common practice" of the EPO procedures. The above-mentioned considerations might function as basis for mutual argumentation to address the questions if products are to be treated as "substances or compositions" in the future.

Selection inventions

Another highly disputed topic relevant for PCBIs, but not limited thereto, are so-called selection inventions. A selection invention claims a subrange from a known range that is sufficiently remote from any specific examples and respective borders disclosed in the prior art. Up to now, it was mandatory to refer to a purposive selection of the subrange from the known range based on a new technical teaching.

This criterion of a purposively selected sub-range is deleted now from the guidelines. This deletion is based on the decision **T 261/15**. This decision emphasizes that the matter of purposive selection of a subrange is a matter of inventive step, only. An arbitrarily selected subrange is therefore still not patentable. The according rejection of patentability is not based on lack of novelty, but on lack of inventive step. The Guidelines further align here with the EPC.

Expectation of success

In the past, the „hope to succeed" of a person skilled in the art to achieve some positive effect, based on the selection was a valid argument for rendering subject matter obvious. The "hope to succeed" is a vague term and „always present", though. The relevant criterion is the "reasonable expectation of success" of the person skilled in the art, now. This term is clarified in detail in **G-VII 13** regarding inventiveness of biotechnological inventions. The invention is non-obvious over the respective prior art, when the person skilled in the art had to make non-trivial and thought-through decisions during the inventive process. On the contrary, a meandering approach of "try and error" does not fulfill this requirement. One should have this in mind, already when drafting the patent application.

Purity inventions

Purity inventions relate to a known "substance or composition", where purity is the feature to render the claim novel over the prior art. The Guidelines stick to decision **T 360/07**, excluding purity from suitable to render the subject matter of a claim novel. Based on that decision, purity does not qualify the subject matter of a claim to be novel and/or inventive. The revision of the Guidelines ignores the more recent decision **T 1085/13**. According to the latter, novelty can only be destroyed by a clear and unambiguous disclosure. This applies to purity as well. The Guidelines thus appear to commit a specific line of case law.

Usual and unusual parameters

The Examining divisions raise clarity objections quite frequently, in case subject matter of claims seek to define an invention based on parameters, especially in cases where using these parameters is not common practice in the respective technical field of the invention. Part **F-IV 4.11** of the Guidelines refers to the decision **T849/11** and highlights the requirements to define subject matter by parameters to be clear.

A claim that characterizes a product by a parameter is clear in the sense of **Art. 84 EPC**, when (i) the claim is unambiguous to a person skilled in the art, even without consultation of the description, (ii) the claim at least refers to a complete method to measure the parameter and (iii) the applicant makes sure that a person skilled in the art is capable to clearly and easily determine if acting inside or outside the scope of protection. Furthermore, the respective method to define parameters has to be a standard method on the related technical field. For mathematical ratios of parameters, the highlighted criteria have to be fulfilled for each of them. This explicit listing of prerequisites will make it easier to proceed with respective subject matter in claims specified by parameters.

Conclusion

The revision of the Guidelines for proceedings in 2020 focuses primarily on PCBIs - pharmaceutical, chemical and biological inventions - to further harmonize the EPO Examination practice. In principle, from our point of view, the revision is a positive development, because vague and former unclear criteria of examination have been clarified. A profound knowledge about the PCBI-field-specific case law and provisions of the EPC is still important when drafting patent applications in the PCBI field. The Guidelines are in force since Nov. 1, 2019.

In case you are active in the PCBI field and curious about the EPO practice regarding a pending application or you want to get a new application drafted and filed in the PCBI field please do not hesitate to contact us.

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