Evolution Of Inventions

Patentability and Patent Term Extensions

IP Protection – In the pharmaceutical industry, the discovery of a new compound is often just the beginning of a series of inventions. During various steps of the development, different medicinal uses of the compound may arise. The evolution of a patent portfolio is often accompanied by a series of patent applications. An effective lifecycle management optimizing the patent protection of the final product should be attempted.

First and second medical indications are examples of new uses for known substances and are patentable according to the European Patent Convention (EPC). If a compound is known as such, but the use as medication is not yet discovered, a patent claim can be directed against the use of same as a medicament. If a further indication is discovered for the compound, said indication could still be protected, provided that it is novel.

A few years ago, the technical board of appeals at the European Patent Office (EPO) had whether such a claim would be patentable if the indication and compound were known, and the invention is the dosage regimen itself (Decision T 1020/30). This question may arise as treatment processes for the human body are excluded from patentability in general (Art. 52(4) EPC 1973 – now Art. 53(c) EPC). The essence of Decisions T 1020/03, T 36/04 and T 836/01 was that a dosage regimen, in a claim directed to a manufacturing process of a medicament, is a technical characteristic which could confer novelty to the claim and therefore such a claim would not violate Art. 52(4).

However, the board of Decision T 1319/04 later on opined differently in this case and posed this question to the Enlarged Board of Appeal (EBA) for clarification. The EBA decided as follows (Decision G 2/08) a few weeks ago:

"Where it is already known to use a medicament to treat an illness, Article 54(5) EPC does not exclude that this medicament be patented for use in a different treatment by therapy of the same illness. Such patenting is also not excluded where a dosage regime is the only feature claimed which is not comprised in the state of the art."

Prior to the EBA, the UK Court of Appeals had a similar opinion which allowed "dosage forms" (Finasterid), thereby explicitly confirming the case law of the EPO although G 2/08 was still pending before the EBA at that time. The German Federal Court of Justice (BGH) however came to a different decision in its decision "Carvedilol II" and denied the relevance of dosage regimens for the evaluation of novelty and inventive step. What is left to hope for is that the decision by the EBA has finally clarified the inconsistent case law and has laid down the rules in this regard.

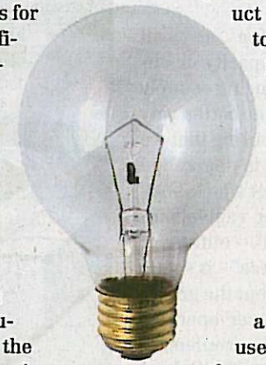
Methods of Treatment by Surgery Not Patentable

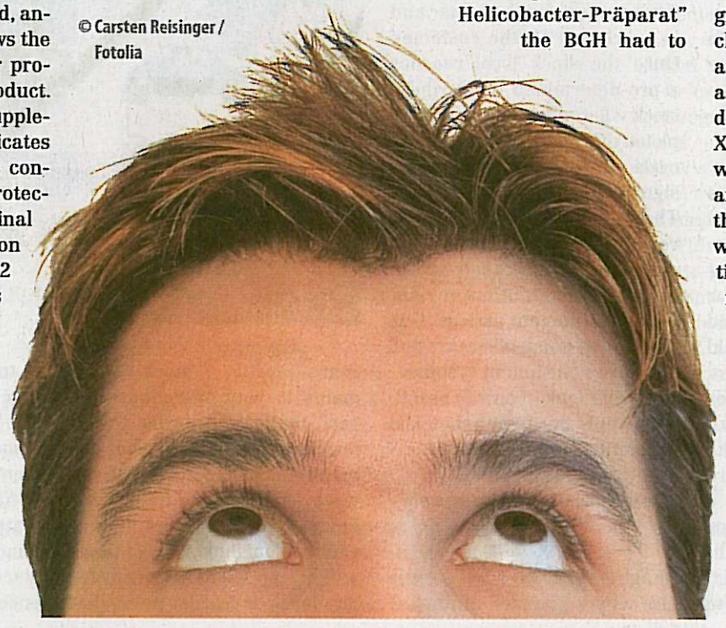
Furthermore, the EBA decided a few weeks ago in G 1/07 that surgical, therapeutic and diagnostic procedures according to Art. 53(c) EPC are to be excluded from patentability if they contain a step which is broadly to be considered surgical, i.e. containing a substantial physical interaction with a human or animal body. This is not only limited to therapeutic concepts but also concerns, for example, imaging processes in which a patient's heart is injected with a contrast agent. In some cases, however, a disclaimer might be used in which "surgical" actions are excluded.

Supplementary Protection Certificates

In the pharmaceutical field, another tool exists that allows the extension of the term for protection of a patented product. The legal basis for the supplementary protection certificates (SPC) are EU regulations concerning supplementary protection certificates for medicinal as well as plant protection products (EEC No. 1768/92 and EC No. 1610/96). SPCs can extend the term of the patent protection for a product up to five additional years. Due to this fact, SPCs are a strong and a widely used tool of optimizing the time frame for "return on investment" in the pharmaceutical industry.

The regulations appear to be a straightforward approach. However, there are pitfalls when applying for SPCs with respect to an optimized lifecycle management. Some pitfalls arise from Article 3 of Council Regulation (EEC) No. 1768/92 which provides the conditions for obtaining a certificate: (a) the product is protected by a basic patent in force; (b) a valid [market] authorization [MA] [...]; (c) the product has not already been the subject of an [SPC]; (d) the [market] authorization [...] is the first [market] authorization [...] as a medicinal product.





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In general, a patent who relates to the protection of the compound per se is rated as the patent with the broadest scope of protection. However, due to the fact that an SPC protects only the product and with respect to the prolonged protection term, it might be desirable to apply for an SPC for a "secondary" patent for which the patent term ends later, e.g. a patent relating to a second medical use. Nevertheless, the product for which the MA was granted shall fall within the scope of the basic patent. In "Anti-Helicobacter-Präparat" the BGH had to decide whether an SPC may be granted for a basic patent protecting a combination of active compounds whereas the MA related to the medical use of one of the active compounds per se (BGH X ZB 1/08). Even though the combination was mentioned in an enclosure of the MA, the Court denied the grant of the SPC.

Another pitfall arises from the definition of a "product" according to Article 1(b) EEC No. 1768/92: [...] (b) 'product' means the active ingredient or combination of active ingredients of a medicinal product; [...]. The BGH decided in 2008 that a mere improvement of the efficacy of an active compound e.g. by providing it as a different salt is not relevant as it is not a new "product" in the sense of EEC 1768/92. An SPC granted for doxorubicin-hydrochloride opposes the grant of an SPC of doxorubicin-sulfate, as the active compound still – doxorubicin – is the same (BGH X ZB 4/08). A similar question was forwarded to the European Court of Justice (EuGH) by the BGH. In this case an SPC was requested for a combination of two compounds in a medicament (Gliadel), one of which is the pharmaceutical active compound (Carmustin) while the other compound acts as a bioerodible matrix (Polifeprosan) and thereby simply renders a pharmaceutical form of the medicine possible. An SPC had already been granted for the pharmaceutically active compound. The EuGH came to the conclusion that the combination of said compounds does not fall within the concept of "combination of active ingredients of a medicinal product" according to Article 1 of (EEC) No. 1768/92 (see EuGH C-431/04) and therefore, an SPC for the combination was not granted.

Collaboration of R&D and IP

In conclusion, this shows that a pharmaceutical or biotech company shall ensure a close collaboration between researchers and IP-experts in an internal department and/or external patent attorneys in order to allow an effective life cycle management. Only this will secure an optimized protection of the IP so that a maximized return on the investment can be reached.

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