



NEWSLETTER

/ Revision of the German Opposition Proceedings / ECJ limits Supplementary Protection Certificate for medicinal products to active ingredients

August 2006

Revision of the German Opposition Proceedings

With effect from July 1st, 2006, the German Patent Law was revised regarding the opposition proceedings.

A) Responsibility for Opposition Proceedings

Due to work overload at the German Patent and Trademark Office (GPTO), opposition proceedings were handled exclusively by the Federal Patent Court (FPC) in the recent years. As a consequence, an appeal against a decision of the FPC in opposition proceedings was not possible. Only an appeal on a point of law was possible at the Federal Supreme Court in exceptional circumstances.

Since July 1st, 2006, German opposition proceedings are handled by the GPTO again. The Federal Patent Court is then the second level of jurisdiction, i.e. the appeal authority, as it was already before January 1st, 2002.

There is the possibility, however, to transfer an opposition directly to the FPC. If a party of the opposition proceedings files a request for a transfer of the proceedings to the FPC, this request is granted if no other party objects within 2 months, or if the request were filed more than 15 months after the end of the term for filing an opposition and a date for oral proceedings is not yet announced. In this case, an appeal is not possible anymore.

B) Divisional Application

Similar to the proceedings at the European Patent Office, from now on, filing a divisional application during opposition proceedings is no longer allowable in Germany according to §60 German Patent Act (PatG). A divisional application can only be filed according to §39 PatG until the end of the term for an appeal after the grant or rejection of an application, or during appeal proceedings at the FPC.

Terms: A divisional application can thus only be filed until the final disposal of the patent application, i.e. until the non-appealability of the decision to grant a patent or to reject the application. During the application proceedings (first instance procedure), the filing of a divisional application is allowable until the end of the one month appeal term after the decision to grant, until the withdrawal of an appeal against this decision, or in the case of a rejection until the final rejection comes into force. In case of an appeal procedure (second instance), a divisional application can be filed until the decision of the appeal senate FPC is ruled. A divisional application can not be filed at the Federal Supreme Court, as this court is not an instance dealing with facts.



ECJ limits Supplementary Protection Certificate for medicinal products to active ingredients

On May 4, 2006, the European Court of Justice (ECJ) issued a judgement regarding the grant of a Supplementary Protection Certificate (SPC) on medicinal products comprising an active ingredient known per se in combination with an auxiliary component. In this judgement, the Court interpreted a combination of an active ingredient with an auxiliary component, which is essential for the release or therapeutic effect, respectively, in order to be used for a specific indication, as not being a combination of active ingredients of a medicinal product within the meaning of the Regulation No 1768/92 concerning the creation of a Supplementary Protection Certificate for medicinal products in the EU. The grant of an SPC for a combination of a known active ingredient and an auxiliary component is thus not possible. The reasons for this decision are detailed in the following.

1. Case history

The medicinal product Gliadel 7,7 mg Implant ('Gliadel') was developed by the Massachusetts Institute of Technology (MIT) and is protected by a European Patent. Gliadel comprises the alliance of two elements, polifeprosan, a polymeric, biodegradable excipient, and carmustine, an active ingredient already used in intravenous chemotherapy with inert excipients and drug additives for the treatment of brain tumours. Gliadel is in the form of a device which can be implanted into the cranium for the treatment of recurrent brain tumours. The active ingredient carmustine is released slowly and gradually by the polifeprosan, which acts as a bioerodible matrix.

A marketing authorisation for Gliadel was granted in Germany by a decision in 1999. The request for granting an SPC was rejected by the GPTO. Equally, the appeal at the Federal Patent Court was rejected. Following an Appeal on a point of law at the

rejected. Following an Appeal on a point of law at the Federal Court of Justice in Germany, the Court referred the question to the ECJ for a preliminary ruling, whether 'a combination of active ingredients of a medicinal product' is also given by a combination of substances comprising two components, the one of which is a known substance with a therapeutic effect for a specific indication and the other renders possible a pharmaceutical form of the medicinal product that brings about a changed efficacy of the medicinal product for this indication.

2. Basis for the judgement

The referral by the Federal Court of Justice was received with interest throughout Europe. Besides the governments of France, Lithuania, the Netherlands, Poland, Finland and the United Kingdom, also the Commission of the European Community filed observations. The judgement hinged on the definition of the active ingredient or the combination of active ingredients, respectively. In contrast to the terms 'medicinal product' and 'product', none of the two former terms is defined in the Regulation No 1768/92.

In his opinion, Advocate General Léger came to the conclusion that the combination of an active ingredient and an auxiliary component which alters the effects of the active ingredient fundamentally can be considered a combination of active ingredients according to the Regulation No 1768/92.

3. Decision

In contrast to the request by the Advocate General, the ECJ decided that an auxiliary component cannot be understood as an active ingredient, and thus, a combination of an active ingredient and an auxiliary component cannot be a combination of active ingredients. Especially, this view is based on the general understanding of a person's skilled in the art of an active ingredient. According to the understanding of the skilled person, an active ingredient is only a component which is active, and not an auxiliary component which modifies the effects of another component. It is especially pointed out in the grounds of the

decision that an active ingredient is defined in the parallel Regulation No 1610/96 on Supplementary Protections Certificates for plant protection products as a substance having a general or specific action. From this definition of an active ingredient, the definition of an active ingredient in the meaning of the Regulation No 1768/92 can be concluded in an analogous way as the Supplementary Protection Certificate for plant protection products is supposed to give the same protection as for medicinal products.

Thus, the ECJ came to the conclusion that the term 'composition of active ingredient of a medicinal product' has to be interpreted in such a way that a composition of two substances wherein only one of these substances has a therapeutic effect for a given

indication and the other substance is used to obtain a certain pharmaceutical form of the medicinal product which is essential for the therapeutic effect of the first of the two substances for the given indication is not covered by the concept of 'active ingredient'.

Summary

The ruling of the ECJ dated May 4, 2006 is based on a very narrow interpretation of the term 'composition of active ingredients'. The grant of an SPC for new pharmaceutical forms of known active ingredients or combinations of known active ingredients which allow for a new therapy due to their combination with other auxiliary components is not possible.

News at RSW

We are pleased to announce that our team will be enhanced by:

INA-MARA HELBIG ATTORNEY AT LAW

Ina-Mara Helbig as an adapted specialist will assist our trademark department with her skills in trademark matters, unfair competition, copy right and license agreements.



GERO HERRMANN PHYSICIST

Gero Herrmann will assist our technical team as a patent engineer as well as our Japanese Department with his excellent knowledge of the Japanese Language.



News at RSW

As a further patent attorney we would like to introduce

DANIEL G. PAPST

who will join our team supporting us with his special technical skills in the field of automotive engineering and electronics.



Daniel Papst will manage our branch office in

St. Georgen/Schwarzwald

Our new office is located in

D-78112 St. Georgen, Bahnhofstraße 33
phone +49 7724 918476, facsimile +49 7724 918476



Please, note that this newsletter provides information about recent developments in national and international IP matters. We have carefully elaborated the contents. However, do not assume any liability for its correctness and completeness. Should you have specific questions on these subjects, please feel free to contact us by email or under the address given below.



Dr. Werner Behnisch
Patent Attorney and Partner at
REINHARD · SKUHRA · WEISE & PARTNER GbR
Werner.Behnisch@isarpatent.com
Ref.:
| ECJ limits Supplementary Protection
Certificate for medicinal products to active
Ingredients



Oliver Hassa
Patent Attorney and Partner at
REINHARD · SKUHRA · WEISE & PARTNER GbR
Oliver.Hassa@isarpatent.com
Ref.:
| Revision of the German Opposition
Proceedings