SECOND INDICATION

GBH, Carvedilol II – the End?

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It's the 1930s: In the borough of Wedding in Berlin, Progynone and the male sex hormone testovirone are the subject of intensive research. The instruction leaflets accompanying the drugs vaguely hint at an alleged immoral use for the product. Years later, a scientist in Wedding realises that the hormones have a further therapeutic effect and a patent application is filed. The first patent claim reads: Wedding 1 – A method for the treatment of a patient who suffers from XY, wherein progynone is administered to the patient. Was this patentable or not? The answer is a definite "No!". The claim is a so-called 'therapeutic method claim'. Had the applicant worded the claim differently or had he been better advised, he would have been more successful at the European Patent Office, as was this not-so-different claim: Wedding 2 – Use of the substance progynone for the production of a medicament for the treatment of a patient suffering from XY.

A few years later, research is carried out in Leverkusen to further develop the technique. At the time, a complicated administration regimen is considered best, as the traditional application had not achieved the best possible results. A patent claim is filed with the EPO: Leverkusen 1: Use of the substance progynone for the production of a medicament for the treatment of a patient suffering from XY, wherein the medicament is administered to the patient daily within the first week and subsequently every 48 hours.

At first sight, this claim seems similar to patent claim "Wedding 1" and "Wedding 2". After the EPO had contemplated this issue, the Federal Court of Justice also had to come to a decision with regard to such patent claims, "Leverkusen 1" in this instance. For the Carvediol decision of December 2006, they arrived the following conclusion: "If a non-patentable dosage instruction is one of several features of a patent claim, it should not be considered for the question of novelty and inventiveness." But what does that mean?

Harmonisation

Over the last few decades, the international harmonisation of Patent Law has often failed because of a number of basic but seemingly non-reconcilable differences between the national patent law in the US and Japan, with the European Patent Convention (EPC) also involved. In the US, for example, there is a grace period regarding novelty, whereas, according to the EPC, the principle of absolute novelty applies. In the USA, therapeutic methods are patentable without issue. According to the EPC, however, methods for the therapeutic treatment of the human or animal body and which are practised on the human or animal bodies, are not applicable to industrial application and, thus, are not considered patentable inventions. Nevertheless, these kinds of patents would be of essential importance for the pharmaceutical industry. Similarly, in Germany, patent law practice is not necessarily identical with the practices of the EPO – even if the text of the German Patent Law is identical to that of the EPC.

Differences regarding the patentability of medicinal indicators are particularly essential due to the fact that the market share of generics has increased drastically and the costs for the development of pharmaceutical products has increased even more drastically. Furthermore, future medicaments will not only be personalised and be population-specific but also, for example in parallel to a simultaneous individual diagnosis, more detailed regarding dosages and more specific. This means that money is not only spent for clinical studies in the attempt to find a new medicament but also in order to establish suitable administration regimens.

A historical survey

In Germany, applicability to industrial application has always been one of the requirements for patentability. In 1967, an essen-

tial decision (BGH1, GRUR2 1968,142, 146 – Glatzenoperation [baldhead operation]) provided the opportunity for the Federal Court of Justice to have a lasting influence on the future European Patent Law. Public health was considered an essential part of common welfare, to be achieved by the state – corresponding to the principle that the medical profession is not considered a trade and that a medical practitioner should be free as regards the application of therapies. Shortly after the decision was made, the exclusion of therapeutic methods from patentability was adopted into the Strasbourg Convention and, consequently, into the EPC and German Patent Law.

In the USA, the issue that a medical practitioner should not be hampered by patent law when practising his profession was solved in a completely different way. The legislative authorities dealing with patent law in the United States have always pursued the promotion of US industry. That is why, in the United States, there are no obstacles to granting a patent for the above-mentioned methods. With a view to protect common welfare, the legislative authorities have, however, laid down that the practice of the medical profession shall not be regarded as patent infringement.

In any case, in Germany and under the EPC, methods for treatment of the human or animal body by surgical or therapy and diagnostic methods practised on the human or animal body are excluded from patent protection. This does, however, not extend to products to be applied in one of the methods previously mentioned. Consequently, the use of active ingredients for therapeutic treatment is susceptible to patentability issues. If the indication is not part of the state of the art, it may support novelty, which is a necessary requirement for patentability. For example: It has been long known that aspirin has analgesic effects. At some point, it was also proven that aspirin has hypotensive effects on patients with hypertension. The newly found indication is patentable even if the substance has already been used.

This approach is the basis of patent claims relating to the "use of active ingredient X for the preparation of a medicament for the treatment of disease Y". This type of claim was first allowed by the Swiss Federal Institute of Intellectual Property, who offered the possibility of granting protection for the second and any further medical indication, which is highly valuable for research pharmacology. Otherwise, no further protection could be granted after the initial invention and disclosure of a substance for a first medical indication. Remember that, in Europe, therapeutic methods are not susceptible to patentability.

New administration regimens

Recently, a technical board of appeal at the EPO has opened up a possibility for the patentability of administration regimens. In its decision, T 1020/03 - "Method of administration of IGF-I/Genentech Inc.", the technical board of appeal concerned with biotechnological inventions accepted that, when assessing novelty and inventive step of claims for a second medical indication including the features of a specific therapeutic method, all features have to be taken into consideration. The Board has stated in detail that a medical practitioner should not prepare a medicament ("Use of IGF-I in the preparation of a medicament") but 'only' this will apply.

Big chance for the industry

Lately, this decision was followed by another EPO decision. In this case, chronological sequence of the administration of two pharmaceutically active substances had been claimed (p53 protein and DNA-damaging agent). Here it also held that as long as a claim does not relate to a therapeutic method but to the preparation of a medicament, the only question to be answered is whether the intended therapeutic method, which the medicament was prepared for, is new and inventive. Thus, the EPO sanctioned the big chance for the industry and the European patentability disadvantage vis-à-vis the United States was slightly "made up for".

Meanwhile, however, the issue as to whether technical contributions to medical indications in form of new administration regimens are patentable was resubmitted to the Enlarged Board of Appeal: Due to the new wording of Article 54(5) EPC, "Swiss Type Claims" will no longer be necessary. It will be possible to formulate second medical use claims as substance claims containing a restriction to a specific use.

A turning point

Subsequently, the Federal Court of Justice had to decide on the following claim: Karlsruhe – Use of carvedilol for the preparation of a medicament for reducing mortality resulting from congestive heart failure in conjunction… with an angiotensin-converting enzyme inhibitor, the medicament being administered in an initial dosage of 3.125mg or 6.25 mg carvedilol twice a day over a period of 14 days, etc.…

The Federal Court of Justice did not adopt the EPO decision: "The administration of a medicament intended for the treatment of a specific disease as such is a therapeutic method for the treatment of the human body. It is not part of the preparation of a substance for use in the treatment of a disease.… From Article 52 Paragraph 4 EPC, which protects the freedom of medical therapy, it has to be inferred that the dosage regimen is not to be taken into account when assessing novelty and inventive step." However, the Court of Justice stated: "It remains open whether the inclusion of the dosage regimen will result in the exclusion of the claim in its entirety from protection." Hence, the claim as such does not necessarily have to be dismissed as to patentability.

The point of view held by the Federal Court of Justice is not relevant for other EPC member states. Hence, the applicant should file claims with the EPO. However, another adapted wording should be provided for Germany as well, since in fact, the Carvedilol II decision of the Federal Court of Justice can also be seen in a positive light. That is, if the dosage of the administration regimen is reflected in the appropriate preparation defined in the claim, the situation might be different. This assumption is suggested – though not reliably confirmed – by the decision.

References

1 BGH [Bundesgerichtshof]: Federal Court of Justice

2 GRUR : Society for the Protection of Industrial Property and Copyright

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