Kluwer Patent Blog

‘Importance of second medical use protection is growing’

Kluwer Patent blogger · Saturday, May 22nd, 2021

Although second medical use protection has had limited importance in the treatment of COVID-19, it has put in the spotlight the overall need for quick reactions to new diseases, which is one of the many factors justifying such protection, according to Jochen Bühling, partner of the German law firm of Krieger Mes & Graf v. der Groeben and editor of ‘Patent Protection for Second Medical Uses’. Kluwer IP Law interviewed Bühling on the occasion of the publication of the second edition of the book.

Let’s begin at the beginning: what is meant with second medical uses? Is there a definition which has been accepted worldwide?

“Second Medical Uses describe the use of a medicament for a new indication for which it had not previously been authorized. Before a medicament (pharmaceutical or biologic) can be marketed it needs approval and a marketing authorization from the competent body (authority), such as the FDA in the US or the EMA in the European Union.

The medical indication designates the therapeutic purpose for which the pharmaceutical is intended. This may be the treatment of a specific disease or pathological condition, a diagnosis or the prevention of a disease or others. The specific indication for which the pharmaceutical is intended must be revealed and must be supported by various tests, experiments and clinical studies. Once the requirements are fulfilled the pharmaceutical is approved for use for the specific medical indication. It may be prescribed by the doctors for patients with that indication and the prescribing person may rely on the marketing authorization. The marketing authorization (and also the medical indication) also comprises information about the patient group, the administration of the medicament and the dosage, and other important information.

Apart from that doctors are usually free to use a certain medication for whatever other medical indication they find it fit and appropriate according to their own discretion.

This is usually designated as an “off-label” or “cross-label” use. The term “off-label use” describes the situation in which a drug is used for an indication which has not yet been approved. The term “cross-label use” means the use of a drug for another indication which has generally been authorized but which is not included in the authorization of that respective drug.

The relevance for patent law occurs when the original indication for which the drug has been developed and used has become patent-free, but patent protection is still in force for the second indication so that the second medical use may be covered by a patent and would then constitute an infringement of that patent. This is generally a separate patent which has been granted specifically for the second medical use of the respective medicament.”

Could you give an impression of how important the field of second medical use is, compared to patent protection for first medical use?

“There is no doubt that patent protection for the first medical use is of fundamental importance. In this regard, one has to recognize that a new medication, i.e. a new pharmaceutical composition or a new active ingredient or a new biologic, may enjoy patent protection per se as a product. That means that the protection of the respective compound or composition is not limited to a specific therapeutic purpose (the indication). If a new composition is invented, the exclusive right of the patentee covers all medical indications for which this invention could be used.

The (first) medical use covers situations in which a chemical compound is used as a medicament (drug) for the first time. Patent protection may also be granted for such a medical use even where the compound as such was already known but just not used as a medicament. Consequently, also the first medical use is of great significance.

In comparison, the second medical use covers different situations. It comes into play where a medicament has already been used with a specific marketing authorization and has been approved for specific medical indications. The second medical indication aims at making the medicament usable for other diseases or pathological conditions. It expands the possible use of a medicament and is one way of finding treatments for patients without having to start from scratch. From a scientific standpoint this is extremely important, since it allows the scientist to build on the already known characteristics and mechanisms of a medicament. This may save time, financial and human resources when trying to find treatments.

Especially the COVID-19 pandemic has made very visible how important it is to be able to find treatments for new diseases in a short period of time. One of the ways is to apply medications which have already been successfully used for other purposes (indications). Although this has had limited effect in the treatment of COVID-19, it is overall still of great importance. Patent protection for the first medical use and the second medical use covers different situations. In my view, they are equally important from a scientific and from an economic standpoint. I would personally not rate one over the other.”

Is it of growing importance?

"Although the legal provision for the protection of second medical uses is not new and has been established in many national and international laws (including the EPC) for quite a while, it seems that the importance is growing. This can be seen not only in the field of classic medicaments (small molecules), but also in the development of new drugs, biosimilars and biologics. The need for quick reactions to new diseases is obvious and one of the many factors justifying second medical use protection.

At the same time, the pharmaceutical companies have an economic interest in developing such inventions and obtaining patent protection for second medical uses. The former strict distinction between originators on the one hand and generic companies on the other hand has clearly changed. Originators are now also active in the business of generics and generic companies have entered the field of developing their own new medicaments. The importance of second medical uses for the individual companies as well as for the overall system is of growing importance.

Another factor is the increasing significance of personalized drugs. A second medical use may also be defined by a specific subgroup of patients and patent protection may be granted for that specific second medical use."

You're the editor of the Wolters Kluwer publication 'Patent Protection for Second Medical Uses'. The second edition of this book has recently been published. Could you mention some major developments in the last three to four years that have been included in this new edition?

"In most jurisdictions covered in the book, there are smaller developments in patent law which also affect second medical use patents and their enforcement. Apart from that, in several jurisdictions we find new developments of a broader significance. It should firstly be mentioned that the book now covers four new jurisdictions (Argentina, Chile, Belgium, Finland) which were not contained in the first edition.

A few examples of major developments concern first of all the EPO and the availability of patent protection. With regard to patentability several new decisions have been issued by the Technical Boards of Appeal which concern the sufficiency of disclosure (Art. 83 EPC) and the role of new data which have been obtained after the application date.

In Germany, there has been a shift in the case law regarding issues of indirect infringement and the liability of a company offering a product on the market. The criterion of the 'manifest preparation' has been loosened so that, depending on the objective circumstances of the case, an indirect infringement may already occur when it is obvious for the public that a specific product will be used for the patented purpose. In those cases, also without a manifest preparation there may be indirect infringement of the second medical use patent.

Similarly, there have been developments in the UK under their latest case law. This case law deals with questions of claim construction and the scope of protection and affects the issue of the 'skinny labelling' by which a manufacturer tries to avoid infringement. Finally, in Australia there have been various clarifications on the availability of Swiss-type claims and the scope of protection."

AIPPI's Resolution Q 238 'Second medical use and other second indication claims', adopted in 2014 at the AIPPI Congress in Toronto, serves as a reference for the new publication. Why?

"The AIPPI Resolution Q 238 was the trigger for the book, which was edited in the AIPPI Law Series as a joint project of Wolters Kluwer and AIPPI. Although this resolution was adopted several years ago it still remains a valid source of information. It is not only the resolution itself but also the underlying group reports that serve as the basis for comparative law studies. This aspect of law remains valid even a number of years later. It also helps to understand certain developments in the various jurisdictions covered by this book."

Resolution Q 238 'strives to harmonize patent eligibility of second medical uses and the available protection, independent of any specific claim format'. At what point are these harmonization efforts?

"Harmonization of the national laws is one of the fundamental tasks that AIPPI undertakes and supports. A lot of harmonization has been achieved over the last years also in the field of second medical use patents. This concerns e.g. the admissibility of claims, the scope of protection and the enforcement. Nevertheless, there are still significant differences between the jurisdictions. These differences are very often linked also to factors which are located outside patent law. Inevitably, patent protection for second medical use claims cannot be separated entirely from policy issues, issues of social welfare and security and others. In this regard, patent law in itself cannot be harmonized without finding solutions for the other problems."

Could you give some examples of jurisdictions where patent protection is lagging behind, as far as it concerns second medical use protection?

"There are still a number of jurisdictions where there is no protection for second medical use claims. This concerns in particular certain countries in Latin America, namely Argentina as one of the major economies in South America. Another example is India where one can find a fast-growing sector of pharmaceutical manufacturers. India is probably still the greatest producer of generics worldwide. Second medical use claims are still not patentable in India."

The chapter on The Netherlands points at a controversy: 'It is likely that allowing patent protection of second and further medical uses encourages research and development into new uses of known medical substances. This is a positive consequence, since the side effects and (optimal) dosage regime of the substance are already known. The need for less research into the side effects and (optimal) dosage regime for second and further medical uses decreases the costs and risks of the medicine. However, granting further medical use protection enhances the monopoly of pharmaceutical companies. This is controversial, especially when pharmaceutical companies purposely extend the lifetime of patent protection for inventions with minor, insignificant improvements to the original invention.' The EPO chapter discusses the strategy, 'popularly known as 'life-cycle Management' of drugs', leading to 'monopolization of the market and ousting of generics/biosimilars'

as well. What is your view on this issue?

"The statements you have extracted from the chapters on the EPO and on the Netherlands must be seen in context. They both deal with certain aspects of an extremely complex situation. The statements as such describe very specific issues of a broader picture.

This broader picture has to do with the overall functioning of a balanced patent system in general which goes much beyond pharmaceutical patents and even the second medical use patents which are covered in this book. There is an inherent tension between the monopoly granted by a patent on the one hand and the freedom of competition on the other hand. Patents are granted for a limited time during which there is an exclusive right of the patentee. In practice, the maximum of 20 years is significantly reduced with regard to pharmaceutical patents due to the requirements of extensive research, development and testing before a marketing approval can be given. That is the main reason for the existence of SPCs. On the other hand, there is a great interest of generic companies to enter the market immediately after the expiration of a patent when the subject matter of the expired patent becomes a public domain.

Unlike in most other economic sectors the markets for pharmaceutical products are highly regulated. The regulatory regimes vary significantly from jurisdiction to jurisdiction. Those requirements affect both originators and generic companies. The life-cycle management of drugs has to take into consideration all these factors. In this regard, pharmaceuticals principally do not differ from any other patented product, be it a car, a product for an industrial plant or a software product. At the same time, the pharmaceutical market is much more in the limelight and under close monitoring and investigation in every country and society. One should also not forget that the market is not simply split in two between originators on the one side and generic companies on the other side. Often enough, there are different interests and disputes within the groups among originators or also among generic companies. This becomes in particular true where also generic companies more and more go into the field of doing additional research and obtaining patent protection.

As I mentioned earlier, in particular the COVID-19 pandemic which has affected everybody worldwide has shed a different light on patent protection and on the way countries and companies and individuals deal with those issues. The research and development of new uses of non-medical substances is fundamentally important to find fast solutions to medical challenges. This applies equally to medicaments for the treatment of COVID-19 as for vaccines. We have seen that the extremely fast development of vaccines was possible and was not at all hindered by existing patent protection. And it would certainly be desirable to find a similarly quick solution for the treatment with already existing drugs. This in itself shows the need for research into second medical uses. Patent protection for second medical uses is a generally accepted incentive for such R&D efforts.

As long as the system as a whole applies the same principles to second medical use patents as it does for any other patent, the criticism should lose a lot of its basis. Finding new medical uses and obtaining patent protection is a legitimate part of the

life-cycle management. At the same time, there are safeguards in place which prevent unreasonable and unjustified 'evergreening' of patent protection. An attempt to extend patent protection for inventions with minor, insignificant improvements to the original invention should be properly dealt with during the examination of that patent application and the existing standards and guidelines should be properly applied."

The pharmaceutical industry obviously has an interest in broadening patent protection for second medical use as much as possible. Which (inter)national authority has the ability to counterbalance this and make sure the protection doesn't stretch as far as to harm the public interest – and, for instance, lead to unreasonable price hikes?

"Firstly, I do not agree with the general statement that the pharmaceutical industry has an interest in broadening the patent protection as much as possible. One should not forget that a pharmaceutical company – be it an originator or a generic company – never only acts as a patentee. It may equally face a situation where it may get in conflict with a patent of its competitor. The reasonable interest of all players in the market must be to have a balanced patent system with strong protection which still allows enough room to maneuver and which also provides sufficient legal certainty for everybody including the public at large.

As far as patent protection is concerned it is first and foremost the task of the patent authorities to ensure that the existing guidelines and principles are applied correctly. That includes a thorough examination of the patent applications and a clear rejection of those applications where the standards for patentability are not met. The discussion about the quality of the granted patents and the avoidance of 'trivial patents' has been going on for years if not decades and is still a valid and necessary discussion which does not only apply to the pharmaceutical sector but also in the same manner to other important sectors, such as telecommunications, automotive and others.

The pricing issues are to be considered differently from these pure patent law issues although both are certainly linked with each other. Pricing in the health sector follows different principles than in free unregulated markets. Patent protection has an impact on pricing but is not the only decisive factor. An example for this is the fact that the public authorities more and more require the prescription of generic drugs provided they do not interfere with patent protection. The issues of affordable prices, however, must be generally addressed elsewhere. This concerns the entire health system in each individual country, the way how medication costs are reimbursed and other issues. Nevertheless, the Patent Offices have to do their fair share to contribute to an improvement and solution of the existing problems."

Is there anything else you'd like to mention?

"The current situation of the COVID-19 pandemic illustrates how patents may boost or hinder the technical development. We have seen a number of renown pharmaceutical companies struggling to find the right vaccine. And independently from each other they have come to different solutions. There has been a lot of discussions about patents and the patent system, the latest just a few days ago when over 100 countries in the world supported movements to stall patent protection. Interesting enough,

Germany has voted against this – also for good reasons. The national and international dimensions of this pandemic go way beyond our rather limited patent law issues. Nonetheless, those issues cannot be left aside. One will certainly have to monitor closely how the future development of the patent protection will be affected by the pandemic or how vice versa the patent system will shape solutions for this crisis."

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This entry was posted on Saturday, May 22nd, 2021 at 11:07 am and is filed under Second Medical Use
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