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THE PATENTABILITY AND RELATED PROTECTION OF INVENTIONS FOR SECOND MEDICAL INDICATIONS

Abstract

Nowadays purpose-related product protection is permitted for each second medical use inventions. In that manner the range of old dilemmas and inconsistencies relating to the format of German-type use claims and Swiss-type claims have been resolved. The introduction of purpose-related product protection resulted in the limitation of a physician's activities. Therefore, in a number of countries the potential introduction of a solution, according to which physicians' activities may be exempted from the effects of a patent under certain circumstances, is being analysed.

Key words: *augenfällige Herrichtung, generic manufacturer, physician's activities, indirect infringement, direct infringement.*

1. INTRODUCTION

The original meaning of the term inventions of second medical indication entails inventions of composition of matter or material already used as a medicament for the treatment of one or more specified diseases, conditions or symptoms and ongoing or later research finds that the medicament is useful for the treatment of other diseases as well. This concept has a more broader interpretation nowadays and it can refer to a new therapeutic use of a known pharmaceutical composition or substance for treatment of specified diseases, conditions or symptoms not originally contemplated by the medicament, use of known pharmaceutical composition or substance for treatment of a known indication in a new patient group, use of a known pharmaceutical composition or substance for treatment of a known

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indication in a new dosage form, use of a known pharmaceutical composition or substance for treatment of a known indication with a new dosage regime; complete with a new therapeutic use of a known pharmaceutical composition or substance based on various levels of its technical effect.

Second medical use inventions cannot be patented in all countries. However, even in the countries where they are considered patentable subject matter, there are notable exceptions relating not only to the type of second medical uses which are considered as an invention eligible for patent protection but to the format of patent claims as well. The examples of second medical use claims found to be acceptable: use of a composition (or substance) X in the manufacture/preparation of a medicament for treating disease Y; use of a composition (or substance) X in the treatment of disease Y and a composition (or substance) X for use in the treatment of disease Y. Even regarding use claims of the same type, there is a notable difference in protection obtained based on patent eligibility. Lack of harmonisation of patent protection for second medical uses and adequate regulations impact both originator and generic pharmaceutical companies by creating uncertainty both for patent holders and assumed infringers. According to the relevant provisions found in Articles of the TRIPS Agreement, patents shall be granted to second medical use claims provided that they fulfill all the other requirements of patentability. It means that they are new, involve an inventive step and are capable of industrial application.

The potential forms of patent protection for second medical use inventions, complete with the impact they have on the typical activities of medical practitioners and generic manufacturers are contemplated in the paper itself. In this respect, the questions of indirect and direct patent infringement were analysed in the cases of different forms of patent protection of the abovementioned inventions.

2. PATENT FOR USE IN GERMAN PATENT LAW AND SWISS-TYPE PATENT CLAIMS

The content and effects of the German-type use claims have considerably been transformed in the German patent law over the course of time. Initially, the starting point of the use of a patent as the relevant patent-related action, was not considered to be the point of a composition of matter formulation,

but the point of its putting to a particular purpose.[1] However, the abovementioned solution indicates that the patent for use is of no practical significance in the pharmacy field.[2] Namely, the treatment of the human (or animal) body by therapy was excluded from patent protection. The exclusion of treatment procedures from patentability used to be based on a legal fiction referring to such actions as not being susceptible or capable of industrial application.[3] An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry. Medical procedures are not considered as industrially applicable, because the term industry does not include a medical profession as a liberal profession.[4]

In the earlier period of German patent law, the patent protection of second medical use inventions was provided in the following form of patent claims use of compound X for treating/preventing disease Y.[5] Such a solution was based on the fact that there were no regulations addressing protection of second medical use, compared to first medical use inventions. Taking into consideration the fact that purpose-related protection in respect of a chemical compound was obtained for first medical use inventions, that kind of protection could not be obtained for second medical use inventions. Therefore, the only prospective form of protection was a use claim.[6] However, second medical use inventions are employed in therapeutic procedures which are not susceptible of industrial application. It implies that the major problem regarding the abovementioned form of a patent claim was related to the manner in which its industrial applicability could be construed.

Accordingly, the German Federal Supreme Court reached a solution on the abovementioned issue and concluded in its decision

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[1] Rechtsprechung Bundesgerichtshof vom 24.02.1970, Az. X ZR 49/66 „Schädlingsbekämpfungsmittel", Gewerblicher Rechtschutz und Urheberrecht, 7/1970, 361.

[2] Z. Miladinović, S. Varga, M. Radojković, *Patent law protection of inventions in medicine and pharmaceutical industry,* Vojnosanitetski Pregled, 6/2013, 600–605.

[3] B. Vlašković, *Patentna zaštita pronalazaka druge medicinske indikacije*, u: Međunarodna konferencija o pravu intelektualne svojine-Aktuelna pitanja prava intelektualne svojine i prava konkurencije: pogled sa Balkana (ur. S. Marković, D. Popović), Pravni fakultet Univerziteta u Beogradu, Biblioteka Zbornici, Beograd, 2016, 71-87.

[4] J. Straus, K. Herrlinger, *Zur Patentierbarkeit von Verfahren zur Herstellung individuumspezifischer Arzneimittel*, Gewerblicher Rechtschutz und Urheberrecht Int, 11/2005, 869-876.

[5] B. Vlašković, *Tehnički efekat i obim patentne zaštite hemijskih i biotehnoloških pronalazaka,* Zbornik radova Pravnog fakulteta u Novom Sadu, 2/2013, 7.

[6] *Ibid.*, 16.

"Benzolsulfonylharnstoff"[7] that the use of a substance for combating a disease, in which the medicinal benefit of the substance is exploited, does not take place only by the physician's use or prescription of the medication, but also routinely includes a number of activities which do not, like the physician's activities, exist ouside the scope of commercial use, for instance: the formulation and the confectioning of the medication, its dosage and its packaging in a form ready for use. All these activities preceding physicians precribing a composition for a course of therapy are embraced by the filed use claim. In that manner, the viewpoint according to which the application does not start with a composition formulation itself, which is sporadically expressed at the earlier stage of court practice, is disregarded. Based on the abovementioned activities, a use claim is considered as industrially applicable, due to which one of the fundamental patent eligibility requirements is met.[8]

Products are not excluded from patentability in the circumstances when there are other ways of patent application which are not considered to be of an industrial character. The abovementioned case is found in other technical fields. A contradictory viewpoint has the following consequences: inadequate limitations of patent granting procedure. Namely, the patent eligibility requirement means that an invention is susceptible of industrial application and certainly it does not mean that any other possibility of a non-industrial application is being denied. This viewpoint is not contrary to the ''Glatzenoperation''[9] decision due to which the patent claim for a surgical treatment procedure for the purpose of prevention and treatment of baldness is rejected. This type of a procedure lies exclusively in the hands of physicians, meaning that there is no possibility of its industrial application.

The same considerations is supported in the conclusion ''Sitosterylglykoside''[10] rendered while resolving the patentability of an invention entailing the use of a known active substance for the treatment of a specific disease. Namely, the substance had already been used for plant growth promoting, and its effect at reducing blood sugar level had been

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[7] Beschluss Bundesgerichtshof vom 20. 1. 1977, Az. X ZB 13/75 „Benzolsulfonylharnstoff", Neue Juristische Wochenschrift, 11/1977, 1104.

[8] *Ibid.*, 1107.

[9] Beschluss Bundesgerichtshof vom 26.9.1967, Az. Ia ZB 1/65 „Glatzenoperation", Gewerblicher Rechtschutz und Urheberrecht, 3/1968, 142.

[10] Beschluss Bundesgerichtshof vom 3.6.1982, Az. X ZB 21/81 „Sitosterylglykoside", Gewerblicher Rechtschutz und Urheberrecht, 9/1982, 548.

presented as well. So far it has been established that the abovementioned substance can be used for the treatment of benign prostate hyperplasia and rheumatic diseases. In other words, any piece of knowledge for which a patent claim is filed – is comprised of indicating a new purpose for a known active substance. However, according to the German Federal Patent Court in this case it is the knowledge which is not considered as industrially applicable. Additionally, it is of no relevance whether it is comprised of measures referring to the industrial application. Namely, they are already known and they neither express the knowledge indicated in the application itself nor is an expert encouraged to undertake some new activities such as the specific formulation of a known active substance, its confectioning or its dosage and the use of such a dosage form in medicine.

The German Federal Supreme Court did not comply with the arguments rendered by the Federal Patent Court. Namely, the patentability of knowledge presented in a patent claim is exclusively based on the surprising effect of an active substance in the treatment of the abovementioned diseases. It means that the key points relevant in granting patent procedure are: novelty, technical advancement and inventive level of the compound use in the treatment of the diseases given[11]. Referring to its previous decision ''Benzolsulfonylharnstoff", the Court specifically emphasizes that for establishing the industrial application of an invention related to the use of a substance for the treatment of a disease – it is of no significance whether the substance is already used for the claimed purpose. This particular question exclusively refers to novelty and an inventive step of an invention and does not refer to its industrial applicability. The patent eligibilty requirements have to be examined separately and must not be combined. When meeting the requirements for industrial applicability it cannot be demanded that the treatment of another disease, performed by using a substance already known as a medication, is conducted in a form differing from the existing one in terms of the substance preparation intended for use. Namely, even the form which does not differ from the existing one is realized in an industrial area, which is considered as the grounds for its industrial applicability criterion of patentability.[12]

In this context, the German Federal Supreme Court made a particularly significant decision ''Hydropyridin''[13]. A leading decision of the Federal

[11] *Ibid.*

[12] B. Vlašković, *Patentna zaštita pronalazaka iz oblasti hemije,* Beograd, 1989, 152.

[13] Beschluss Bundesgerichtshof vom 20.9.1983, Az. X ZB 4/83 „Hydropyridin", Neue Juristische Wochenschrift, 5/1984, 663.

Supreme Court is the following: an invention, which involves the use of a substance already known as a pharmaceutical for the treatment of a disease which has not previously been treated with this substance, is not excluded from patentability and is not in contradiction with Article 3 (3) Patentgesetz 1981.[14] In the concrete case the compound was known as a pharmaceutical for the treatment of coronary diseases, and it was later found to be effective against changes in cerebral blood flow.

According to the viewpoint of the German Federal Patent Court, essential parts of knowledge presented in a patent claim are related to the use of a substance already known as a pharmaceutical for the treatment of a disease which has not previously been treated with this substance. Namely, according to the opinion of the Court: the making of a galenic medicinal product which involves the use of a known active substance, its packaging in a form ready for use, the use of a known substance or composition for a specified new and inventive therapeutic application, storage and distribution of a known pharmaceutical product for a new purpose, the first steps in the patent registration procedure and product information provided by written labels on the packaging and package inserts for patients or directions for use and cautionary statements enclosed within the packaging itself – are not covered in the patentable subject matter. On the contrary, technical knowledge reflects in a purposefully attained application, that is, prescribing and administering of a known pharmaceutical for a new purpose. It is a procedure intended to be used for the treatment of human body by therapy, which is not considered as industrially applicable. The treatment of cerebral insufficiency does not demand the use of a product manufactured in a different manner in comparison with the one that has previously been described. The novelty of the manufacturing process is not based on referring to the use of a known substance for achieving a new effect untill the moment of all its variations being presented.[15]

However, the German Federal Supreme Court disagreed with that view, thus referring back to its previous legal practice. Moreover, it emphasized that the subject matter of the patent directed to the protection of its use does not depend on the kind of a substance applied, for the patent used as protection of the substance for the purpose of attaining a specific aim

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[14] Z. Miladinović, *Zaštita prava intelektualne svojine u EU: stanje i perspektive,* u: Pristup pravosuđu-instrumenti za implementaciju evropskih standarda u pravni sistem Republike Srbije (ur. N. Petrušić), knj. 4, Pravni fakultet Univerziteta u Nišu, Centar za publikacije, Niš, 2008, 18-20.

[15] Beschluss Bundesgerichtshof vom 20.9.1983, Az. X ZB 4/83 „Hydropyridin", op. cit., 667.

provides protection against evident measures of a substance manufacturing, irregardless of whether it is used to attain a therapeutic aim or any other aim, such as the prevention of weed gemination and harmful insects or other animals.[16] Based on the patent for use one cannot file any claims against the third party involved in the manufacturing process of a known substance and its use as a medication in the treatment of conorary diseases. Namely, its manufacturing and administration for the purpose stated in the indications falls into the category of a technics state. The treatment of cerebral insufficiency by therapy does not request a different method for manufacturing a substance compared to the manufacturing process of a substance applied for the treatment of conorary diseases. However, the patent protection directed to the use and cerebral insufficiency treatment indications by all means comprises manufacturing of drug packaging including specifications stating that the substance is to be administered for the purpose given in the indications. In other words, the preparation of a composition of matter or material can additionally be reflected within the patient's instructions for use enclosed.[17] This action is not part of a genuine manufacturing process per se, but in theory it has to be attributed to the process for the purpose of its differentiating from the state of technics. In general, marketing and advertising campaigns related to the patented use, not taking into account distribution of a pharmaceutical product itself, are not sufficient and can be perceived as the grounds for indirect infringement of the patent for use in circumstances of a concrete case. The aforementioned campaigns are not considered as the ''augenfällige Herrichtung''[18] of matter or material which is put on the market. Such general marketing and advertising campaigns do not demonstrate necessary and indirect link with the product itself, which may only guarantee that the composition of matter or material is going to be used for the patent-protected purposes. Unlike the activities included in the preparation of mattter or material itself, instructions and usage information given in generally used marketing leaflets are not

[16] B. Vlašković, *Apsolutno dejstvo patenta u vezi sa pronalascima sekvenci gena,* Pravo i privreda, 7-9/2012, 218-232.

[17] Urteil OLG Düsseldorf vom 31.1.2013, Az. 2 U 54/11 „Cistus incanus Präparate", http://openjur.de › OLG Düsseldorf › Rechtsprechung, date of visit: 23.8. 2015.

[18] In German national law the subject - matter of a claim directed to the use of a chemical substance to treat an illness extends beyoned the treatment of the illness to the "augenfällige Herrichtung", which, as has been said, includes at least the packaging of the substance with instructions for use in the treatment of the illness.

likely to be noticed by the drug user.[19] Accordingly, it is not clear whether the matter or material will be used for the patented purpose as well. In the practice of the German courts, it has not been given a complete clarification of whether the subject matter of a patent, within the meaning of the definition, refers specifically to a drug administration and not to other types of a substance. The German Federal Supreme Court finally resolved the abovementioned dilemma by pointing out the following: ''Contrary to the belief of the Enlarged Board of Appeal, the patent protection whose claimed subject-matter, within the meaning of the definition, is not limited to the use of an active substance contained in medications – does not depend on the type of a substance applied. On the contrary, this subject-matter protected by the patent is inherent in all patent use claims, whereas a known composition of matter or material or an object is used for a new and inventive purpose. A patent for use of a known object does not include exclusively the activities directly referring to the protected use, but non-industrial activities as well, used in the evident preparation of the subject-matter for uses according to the patent itself.''[20]

3. PURPOSE-RELATED PRODUCT PROTECTION

Purpose-related product protection conferred to a very substance or composition refers to its being protected as a means of realization of a particular goal. According to the prevailing view in German court practice, a final element, namely a particular attainment of purpose, is inherent in purpose-specific product protection, which constitutes an essential component of the protected invention.[21] If this purpose is neither striven for nor purposefully attained, but rather another purpose than that claimed is attained, then no use of the subject matter of the patent exists.

In a concrete case the inherent nature of patent purpose is considered as prevention and treatment of viral diseases by therapy.[22] Patent-eligible

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[19] B. Vlašković, *Ponovna proizvodnja pronalaska i zamena nekih njegovih delova*, u: Slobode i prava čoveka i građanina u konceptu novog zakonodavstva Republike Srbije (ur. S. Bejatović), knj. 4, Pravni fakultet Univerziteta u Kragujevcu, Institut za pravne i društvene nauke, Kragujevac, 2005, 233-241.

[20] Rechtsprechung Bundesgerichtshof vom 21.11.1989, Az. X ZR 29/88 „Geschlitzte Abdeckfolie", Gewerblicher Rechtschutz und Urheberrecht, 7/1990, 505.

[21] Rechtsprechung Bundesgerichtshof vom 21.11.1989, Az. X ZR 51/86 „Antivirusmittel", Gewerblicher Rechtschutz und Urheberrecht, 11/1987, 794.

[22] *Ibid*., 796.

subject matter is used by actions devoted to realizing this specific goal. On the contrary, the subject matter is not used by actions directed towards the prevention or treatment of other types of diseases. It is necessary to establish a practically reasonable degree in order to differentiate whether it is the purpose recited in the patent claim that is being achieved or another one. The fact itself that a means is eligible for achieving the purpose defined in a patent claim still does not imply that it is the very means by which the abovementioned purpose is being achieved. On the contrary, the fact that the purpose inherent to the invention is being achieved to a practically reasonable degree – has to be taken into consideration in case of the use of purpose-related product inventions.

The German Federal Supreme Court emphasizes the fact that the answer to the question of what is the protected subject matter may be found in the patent claim, that is, patent records data. The purpose of the patent achieved in practice by the patent holder is of no significance for defining the subject matter, if there is a notable difference between the purpose stated in the patent claim and the one defined in patent records respectively.[23]

The composition, which is protected as a means for the prevention and treatment of viral diseases, was stated by the defendant in the indications exclusively as a means for the treatment of Parkinson's disease by therapy, that cannot be associated with viral infections, for it is characterized by the decline of the numbers of nerve cells in Parkinson's patient brains. Having established a practically reasonable dosage form, in this constellation the use of the abovementioned means in the treatment of Parkinson's disease cannot be considered as the attainment of prevention and treatment of viral diseases. An antiviral drug given to the non-infected patient indicates that a particular attainment of purpose of the patent reflected in the treatment of viral diseases is completely left out. When considering the circumstances of the sporadically occuring cases of prevention of viral diseases reported when administering the medications used to treat the symptoms of Parkinson's disease, they cannot be considered as an attainment of the patent purpose which is achieved to a practically reasonable extent. When administering the medications, the treatment of Parkinson's disease primarily depends on a responsible and conscientious medical therapy management in comparison with the sporadic cases of prevention of viral infections which are not purposefully attained and which are not in the foreground.[24]

[23] *Ibid.*, 799.
[24] *Ibid.*

Taking into consideration the aforementioned fundamental views of the German Federal Supreme Court, The District Court of Düsseldorf reaches a decision ''Az. 4a O 12/03" where it emphasizes that medication usage is exclusively related to the case of the intended specific purpose being striven or purposefully attained.[25] Medication usage is excluded in the case of another purpose being attained.[26] The purpose-related protection of a composition of matter or material includes not only the activities covered in its direct use, but the ones performed during the ''augenfällige Herrichtun'' of a comosition of matter or material for the intended use. Such ''augenfällige Herrichtung'' can be reflected in a specific manner of shaping matter or material. However, the instructions and usage information enclosed should be considered as well. The ''augenfällige Herrichtung'' does not spring from the instructions and usage information enclosed, but merely presents pointing out the uses of matter or material in a combination therapy.

4. DIRECT PATENT INFRINGEMENT IN THE CASE OF SECOND MEDICAL USE PATENTS

A typical German-type use claim, by means of which second medical use inventions are protected, is directly infringed by the act of ''augenfällige Herrichtung'', that is, manufacturing of raw composition of matter intended for application for patent-protected purpose. The same statement applies for Swiss-type patent claims, considering the fact that the act of production is a constituent part of a very claim formulation.

Generic drug manufacturer offering drugs for use as drugs for first medical indications, the protection of which obtained by the patent has expired – is not considered to be a direct patent infringer for second medical uses inventions.[27] Namely, in such a case there is no ''augenfällige Herrichtung'' of a drug. It means that a conditio sine qua non for the infringement of German-type use claims and Swiss-type patent claims is related to the '' ''augenfällige Herrichtung'' of a drug''.

Another issue, which has been raised, is drawing specific attention to the position of a physician who prescribes a medication or directly uses it for particular purposes that are formally approved and covered by a valid patent

[25] Urteil LG Düsseldorf vom 24.2.2004, Az. 4a O U 12/03, http://openjur.de›LG Düsseldorf›Rechtsprechung, date of visit: 29.5. 2016.

[26] B. Vlašković, *Pravo industrijske svojine*, autorizovana skripta, Kragujevac, 1990, 43-54.

[27] Z. Miladinović, *Subjektivna prava intelektualne svojine: sticanje, sadržina, ograničenja, zaštita,* Niš, 2004, 25-33.

for second medical indications. It is associated with difficulties primarily arising from the circumstances of a physician prescribing or using medications during his/her regular treatment activities. In addition, one should bear in mind the circumstance of physician's activities not being exempted from the effects of a patent, meaning that a physician is a patent infringer in the case of his/her using or prescribing a medication that directly infringes the patent. However, regarding second medical use inventions, a physician does not use a medication already infringing the patent, considering the fact that it is not the medication which is ''augenfällige Herrichtung'' for a specific use. On the contrary, in this case the physician is using a medication which is not protected by the patent itself, but due to its being prescribed or used – attains the purpose covered by a valid patent for second medical indications.[28]

5. DIRECT INFRINGEMENT IN THE CASE OF PURPOSE-RELATED INVENTIONS RELATING TO SECOND MEDICAL INDICATIONS

Due to the amendments of the European Patent Convention (Revision Act 2000), the purpose-related protection was introduced for second medical use inventions as well.[29] This type of protection was not limited by existing ''augenfällige Herrichtung'' of a drug in the same manner as it used to be the case in the earlier period. In the year of 2010, the Enlarged Board of Appeal of the European Patent Office made a decision ''G 2/08'' where it emphasized that the patent holder is granted a larger scope of protection compared to the one obtained by the analyzed forms of German-type use claims and Swiss-type patent claims. Simultaneously, it was emphasized that the freedom of physicians while prescribing or administering generic substances can be limited by extending the scope of protection.[30] Tight linking with the qualified act of manufacturing of a drug is not immanent in the purpose-related patent protection, which means that the patent-protected purpose of the use given may derive from other accompanying circumstances as well, even at the point when a drug as such is still not ''augenfällige Herrichtung'' for the patent-protected purpose. Therefore, even a drug prescription and its

[28] F. Hufnagel, *Der Schutzbereich von Second Medical Use Patente*n, Gewerblicher Rechtschutz und Urheberrecht, 2/2014, 124.
[29] Z. Miladinović, *Pravo industrijske svojine,* Niš, 2007, 135.
[30] Entscheidung EPA vom 19.2. 2010, G 2/08 „Abbott Respiratory LLC", Amtsblatt EPA 10/2010, 456-493.

administration for the patent-protected purpose can be considered to be one of the accompanying circumstances. In other words, at that point a physician is considered as a direct patent infringer for second medical use inventions.[31] The fundamental difference between a use claim, whether it is a German-type use claim or Swiss-type patent claim, and purpose-related protection is the meaning of the ''augenfällige Herrichtung'' or drug manufacturing with a view to use it for the patent-protected purpose. In the case of the first two patent claim forms such preparation or manufacturing are considered as the essential condition for patent infringement. On the contrary, in the case of purpose-related protection such preparation or manufacturing is only one of the relevant accompanying circumstances, but not the condition for patent infringement.

6. INDIRECT PATENT INFRINGEMENT IN THE CASE OF SECOND MEDICAL USE INVENTIONS

Apart from direct patent infringement, in some countries there is indirect patent infringement as well, which is the result of a joint endeavour to expand the effects of a patent to non-patented invention parts. This institute can be regulated in various manners. In currently valid German law the content of the aforementioned institute means that without the grant issued by the patent holder the third party is forbidden to offer or deliver the means related to the essential part of the invention under the condition that the third party possesses the knowledge, or that it is obvious, based on the circumstances of a concrete case, that the abovementioned means are eligible and intended for application while using the invention.

The authorization of the patent holder regarding offering for sale or delivery of non-patented invention parts is not of the same quality and intensity in comparison with the authorization regarding the offer or delivery of the invention itself or invention parts which are patented individually. For instance, based on the patent the third parties may be prohibited from offering for sale or delivering patented invention parts at any time.[32] In contrast, offering for sale and delivery of non-patented invention parts can be prohibited only under the precisely defined terms and conditions. If they are

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[31] A. Schrell, *Zur Anspruchsformulierung bei zweckgebundenem Patentschutz*, Gewerblicher Rechtschutz und Urheberrecht Int, 5/2010, 363-369.

[32] Z. Miladinović, *Neka otvorena pitanja u našim propisina iz oblasti intelektualne svojine,* u: Građanska kodifikacija (ur. R. Kovačević-Kuštrimović), knj. 4, Pravni fakultet Univerziteta u Nišu, Centar za publikacije, Niš, 2004, 105-115.

not fulfilled, the authorization is not valid and consequently the third parties can freely deliver non-patented invention parts.[33] The basic question is whether a generic manufacturer and physician can be considered as indirect infringers of adequate patents under certain circumstances. As regards a physician as an indirect patent infringer, his liabilty is excluded by the very definition of indirect infringement, considering the fact that his activities are not covered in the concept of medication offer or delivery. For instance, prescribing a medication cannot be considered as an offering activity which is an element constituting the term indirect patent infringement.[34] The position of a generic manufacturer is fairly different as opposed to the position of a physician regarding indirect infringement. In that context, there has been raised a considerably significant question of whether the generic manufacturer fulfills subjective conditions for determining indirect patent infringement, that is, whether the manufacturer knows that the composition of matter stated above is eligible and determined for a specific purpose while using the invention, or that knowledge is evident based on the circumstances of the concrete case. Namely, in this particular case subjectively determing the aim by the generic manufacturer is not derived, but the very information is obtained from patient's instructions for use enclosed inside of a drug packaging. Therefore, in the abovementioned instructions the use of a drug intended for the purpose of second medical use inventions is neither pointed out nor is there advertising of its use intended for that particular purpose, generally speaking. Certainly, even the advertising itself can be qualified as indirect patent infringement. For that reason, generally speaking, it is the circumstances of a concrete case that will be crucial for whether a generic manufacturer will find it obvious that the medicines are eligible and determined for the use intended for the purpose protected by the patent for second medical use inventions, although he/she has delivered the medication with a view to be used for the purpose of first medical use not protected by the patent.[35] There may be a variety of such circumstances. For instance, a generic manufacturer can know about its use intended for the purpose protected by the patent for second medical use considering the fact that the expert literature refers to physicians who can automatically use a generic drug for the purpose of second medical indications. In addition, it is possible to take into consideration the quantity of drug prescriptions,

[33] B. Vlašković, *Sadržina i povreda patenta*, Kragujevac, 1999, 175-186.
[34] F. Hufnagel, *op.cit.*, 123.
[35] Z. Miladinović, *Pravilo EU o uvođenju certifikata o dodatnoj zaštiti za medicinske proizvode,* Evropsko zakonodavstvo, 3/2003, 68-70.

particularly if it is known that in practice a number of drug prescriptions for second medical indications exceeds the number of drug prescriptions for first medical indications to a considerable degree.

7. REACTION OF SOME COUNTRIES WHEN FACING THE IMPLEMENTATION OF PURPOSE-RELATED PRODUCT PROTECTION FOR SECOND MEDICAL USE INVENTIONS

After the revised Patent Law came into effect, the Swiss law was adjusted to the provisions of the Convention on the Grant of European Patents of the version of 29 November 2000. This revision came into effect on 1 July 2008. The protection of second medical uses is possible exclusively in the form of so-called ''Swiss claim''. This form of a patent claim provides protection only for the procedure for manufacturing of a drug for the purpose of a new medical use and not for a medicinal use of a composition itself. Considering the very limits of such patent protection, physicians cannot be prohibited by law from prescribing a medication dosage (in case that a medication is no longer protected by the patent) for the treatment of a disease described in another patent claim. Namely, it is about the cases when a patent protection expires for a medication used in the treatment of disease X. That medication as a generic substance is found on the market, and later it is found that the same composition of matter or material can be used in the treatment of disease Y in another dosage form. In that case, a new patent can be obtained for the second medical use claim.

However, the Enlarged Board of Appeal of the EPC reached a decision G 2/08 which radically changed the current legal practice. They took the following stand: patents for second and further medical indications are not limited to the use of a composition of matter for manufacturing a medication intended for the treatment of another disease. The Swiss-type patent claim is no longer allowed. The protection of a broader scope is obtained nowadays, because it refers to the use of a medication as well. In other words, purpose-related protection is obtained for second medical use inventions as well. The subject-matter of patent protection is a composition of matter itself if it is used in terms of a specific indication, not just the use of a composition of matter for manufacturing a medication intended for a specific purpose. The consequence of this decision refers to the European patent holder who could now take some measures against any person prescribing a generic substance for a new medical indication described in a patent claim. Physicians risk infringing the patent for second medical indications and the lawsuit can be

filed against them by the patent holder. The Enlarged Board of Appeal of the EPC comments the aforementioned issue by solely stating that freedom of physicians, if it is necessary, can be protected by using other legal remedies at the national level.

Taking into account a new European practice, the Swiss Federal Supreme Court believes that in the case of an emerging need for the protection of physicians' freedom a law can be applied by implementing a suitable exception from the effects of a patent. However, this court emphasizes that the fact that there is not a specific provision in national legislation, according to which physician's activities are not generally considered as patent infringement, cannot be taken as an argument susceptible to various interpretations of the European Patent Convention and it also cannot be used for the expansion of exceptions from patentability.[36]

Taking a new practice into consideration, it can be stated that physicians are no longer free when deciding on a drug they are about to prescribe. On the contrary, in the case of existing patent protection they have to administer an original medicine, which is valid even in the case of availability of the identical substance in terms of being a generic one in relation to the treatment of other diseases. Otherwise, a lawsuit could be filed against them by the holder of the patent obtaining protection for second medical indications.

The decision made by the Enlarged Board of Appeal is valid for all countries that are members of the EPC, but neither one of the national patent legislations have presented a solution for the existing challenge so far. According to the off-the-record announcement of the EPC not a single member country has started legal actions for defining legal exceptions from the effects of the patent. However, numerous discussions initiated in Switzerland along with the examination of various options have demonstrated that indicating exceptions from the effects of the patent is the most eligible means for the consequent maintenance of freedom during a medical treatment. Accordingly, some amendments of the Patent Laws have been suggested in Switzerland, the purpose of which is resolving possible conflicts between the patent law and freedom of medical treatments, that can arise based on the altered practice of the Enlarged Board of Appeal of the EPC. The Swiss Patent Law should be amended in the following manner: Firstly, the effects of the patent do not refer to the actions performed within a medical activity related to a drug administration, which refers to a person or animal, and particularly to a medication prescription, dispensing or administration performed by the person skilled in the state of the art. This

[36] Z. Miladinović, *Konvencija o evropskom patentu*, Evropsko zakonodavstvo, 12/2005, 48-50.

provision does not entail the production, import, export, transit or distribution of medications. In addition, medical products such as injection syringes, bandage materials or pacemakers are not considered as medications.

Secondly, the effects of a patent do not refer to indirect individual preparation of medications in pharmacies on the basis of a physician's prescription given, nor to the actions referring to the medication prepared in such a manner. This provision refers only to ad hoc preparation, and it does not refer to medication storage either, nor does it refer to the fact of its being manufactured in large quantities or its preparation for a greater number of patients or for the defective state of a medication being prepared and stored in advance, whereas a future user for whom the medication is intended does not have to be known at that moment. It means that this type of manufacturing is something between ad hoc and serial industrial manufacturing.[37]

8. CONCLUSION

The field of patent protection for use in the case of second medical indications is associated with the ''augenfällige Herrichtung'' of a composition of matter. In addition, this field comprises the actions related to the exclusive jurisdiction of the patent only if they refer to the product obtained in such a manner. The actions not referring to such a product or a product obtained in another manner can be performed freely, even in the case of the realization springing from the accompanying circumstances into the patent-protected purpose.

On the contrary, purpose-related protection of second medical use inventions is not unconditionally linked with the ''augenfällige Herrichtung'' of a composition of matter or material. This type of manufacturing is only a possible alternative form of its use, that is, an accompanying circumstance due to which the intended indirect realization of the patented use of a specific composition of matter is pointed out to an expert.

The purpose-related protection of second medical use inventions has been confirmed even in the current German legal practice. It is obtained irrespective of whether the patent claim in its wording is directed towards a medication use, or towards its preparation for a specific purpose of the use,

[37] F. Addor, C. Vetter, *Der* Schutz der *medizinischen Behandlungsfreiheit vor patentrechtlichen Verletzungsklagen,* https://www.ige.ch/en/legal.../patent-law.html, date of visit: 14.2.2015.

or specifically towards the purpose-related protection of a composition of matter or material.

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