



Master LLM European and International Intellectual Property Law

2015 – 2016

The increasing recognition of second medical use patents

Legal treatment and public health issues

CLARA DUCIMETIERE

Under the direction of Xavier Seuba

Strasbourg, September 2016

CEIPI – Centre d'Etudes Internationales de la Propriété Intellectuelle

Université de Strasbourg

L'Université de Strasbourg n'entend donner aucune approbation ou improbation aux opinions émises dans ce mémoire. Ces opinions doivent être considérées comme propres à leur auteur.

The University of Strasbourg neither approves nor disapproves the opinions expressed in this thesis. These opinions shall be considered as the author's own judgment.

Acknowledgments

I would like to warmly thank Professor Xavier Seuba, for his sound advice and constant supervision during the preparation of this thesis. His help has been most valuable and our discussions a precious guidance throughout this work. Thank you.

I also would like to thank Professor Joshua Sarnoff and Professor Susy Frankel for their bibliographic indications and support.

Synopsis

Introduction

Part 1: The ambivalence of the legal regime governing second medical use patents

Chapter 1: The compliance of second medical uses with the patentability standards

Chapter 2: The disputed implementation of second medical use patents

Part 2: The significance of second medical use patents in the light of public health

Chapter 1: Second medical use patents: a barrier to access to health?

Chapter 2: Infringement issues arising from second medical use patents and their impact on public health

Conclusion

List of abbreviations:

EBA	Enlarged Board of Appeal
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
FTA	Free Trade Agreement
INN	International Nonproprietary Name
PIL	Patient Information Leaflet
SPC	Summary of Product Characteristics
TPP	Trans-Pacific Partnership
TRIPS Agreement	Agreement on Trade-Related Aspects of Intellectual Property Rights
USA	United States of America
WTO	World Trade Organization

Introduction

*“Whilst it is widely recognized that there are valuable, sometimes life-saving, inventions which are made through the discovery of the new use of a known drug, their protection in patent law is problematic.”*¹ Lord Justice Floyd

Until recently, many developing and even developed countries did not allow patents on pharmaceuticals. Progressively, some countries started to change their law to allow process patents for pharmaceuticals². But the real change was introduced by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) which obliged all WTO Members to allow patents on product and processes, therefore opening the door to pharmaceutical patents. Some developing countries had until 2005 to change their patent law, and the term was extended until 2016 for least developed countries. Therefore, today, even if it is still controversial, pharmaceuticals are patentable in almost all countries. The debate around pharmaceutical patents very quickly led to another debate regarding the patentability of the new use of a known compound. Where does this controversy come from? Well, it has been argued that the pharmaceutical industry³ more and more struggles to find new chemical compounds to cure new diseases⁴. To be more precise, the pharmaceutical industry oriented its research and development toward the finding of new uses for known compound instead of developing new chemical compounds. Between 1983 and 1992, around 433 new chemical compounds entered the world market while the number of patents granted in the pharmaceutical field was many times greater⁵.

There can be various explanations for that, the first one being that it is cheaper and quicker to take an existing compound on which research has already been carried out, and keep on doing research on this compound⁶. It must also be pointed out that these new applications for known drugs are also found by doctors in the course of medical treatments. Physicians do sometimes

¹ Warner-Lambert Company, LLC v Actavis Group Pte EHF & Others [2015] EWCA Civ 556, at. 51.

² F. Lobo Aleu, “La evolución de las patentes sobre medicamentos en los países desarrollados”, doc n°009/1989, 1989, p. 6-7, available at: <https://econo.uniovi.ec> (20 August 2016).

³ Throughout this work, we will refer to « pharmaceutical industry » or « pharmaceutical company » as to the companies dealing with brand medications as opposed to generic companies.

⁴ C.M. Correa, *Guidelines for the examination of pharmaceutical patents: developing a public health perspective*, WHO-ICTSD-UNCTAD, 2007, p. 1.

⁵ C.M. Correa, *Intellectual Property Rights, the WTO and developing countries The TRIPS Agreement and Policy options*, Zed Books & Third World Network, Third Printing 2002, p. 54.

⁶ R.A. Castellano, “Patent law for new medical uses of known compounds and pfizer’s Viagra patent”, *IDEA-The intellectual property law review*, Vol. 46, No. 2, 2005-2006, p. 285.

note an improvement in another illness than the one originally treated. For instance, if a patient is taking a drug to cure a headache and he notices an improvement of his eczema, the doctor will be able to identify a second use for the original drug. Therefore, in the case of second medical uses which are the subject of this work, it must be kept in mind that they do not always result from research undertaken by pharmaceutical industries but that they can be experienced by patients during the course of treatments and therefore discovered quite by chance.

The discovery of a new therapeutic application of a known drug is what we call “second medical use” or “second medical indication”. The term “second medical use” refers to the situation where it has been found that a known pharmaceutical can be used for the treatment of a new medical indication. It can be the second or any further medical use. A medical indication refers to a disease or an illness, to specific syndromes or to preventive effects that might have a drug⁷. Therefore when a patent for a second medical use is granted, the chemical compound is exactly the same as the one already disclosed in a previous patent application. What is new is the use made of the drug.

On the contrary, situations where the chemical formula of the drug is changed will not be a case of second medical use patent. We can mention for instance the case where a patent is filed for a new salt, ester, ether or polymorph of an existing chemical entity. New combinations of two or more active ingredients that are already available as single entities are also outside the scope of second medical use patents. It must nevertheless be said that these cases raise important issues in patent law, as new patents are often filed and granted for these incremental changes which have an impact on access to health. This strategy also called “evergreening”, which consists in expanding the duration of the monopoly as much as possible by patenting small changes in the chemical formula without improving the drug, has been widely criticized and addressed by the doctrine⁸. But again, these patents are not second medical use patents, which only refer to the use of the exact same drug for a new indication.

For a long time, second medical uses were considered not to be patentable in Europe, contrary to first medical uses of a known product which were patentable if they were complying with the patentability standard. The Munich Convention of 1973 rejected the patentability of second medical uses, because they were assimilated to method of medical treatment which were

⁷ B. Domeij, *Pharmaceutical Patents in Europe*, Kluwer Law International, Stockholm Studies in Law, 2000, p. 127.

⁸ See C.M. Correa, *Guidelines for the examination of pharmaceutical patents: developing a public health perspective*, op. cit.

considered to lack industrial application. Therefore, only drugs having therapeutic properties for the first time were to be patented. On the contrary, the discovery of a second medical indication for this drug was not patentable. The justifications for such an exclusion vary from country to country and even within the doctrine. Paul Mathély argues that the exclusion is a practical one: when the doctor prescribes a drug to a patient, it will not mention the use for which the drug is prescribed. The pharmacist, once he delivers the drug, does not know for which indication the pharmaceutical is prescribed, or at least there is no disclosure of the use. Therefore, it would be absolutely impossible to protect a second medical use patent, because during the whole “life” of the drug, the use remains secret⁹.

For J. Lavoix, the fact that a new application of a known means was patentable under the 1844 French patent law implies that the same rule could be adopted for second medical uses. But during talks with the ministry of health and the “Ordre national des pharmaciens” (national pharmaceuticals association), he agreed that the need to promote fundamental research in order to discover new pharmaceutical compounds was more important than discover new uses for known compounds¹⁰. This was basically why second medical uses were first excluded from patentability in France, but this exclusion was considered to be a derogation from patent law¹¹.

This absence of patentability of second medical uses was criticized. The main argument was the lack of research in this area, because of the absence of incentive. Some authors even considered that new treatments for cancer for instance would not be disclosed because of the absence of patent¹². We however believe that such an argument is not really justified if taking into account the spirit of patent law. Indeed, patents are supposed to give incentives to innovate, innovations which will benefit to the society, in exchange of a limited monopoly. Therefore, if an industry discovers a new treatment for cancer based on an existing compound, it will have done so without the incentive of patent law and therefore a patent on the second medical use seems not to be necessary, at least at the stage of innovation. But in Europe basically patents on second medical uses were started to be accepted because there was a fear of losing an important industry. Indeed, the objective was to maintain the competitiveness of the European

⁹ P. Mathély, *Le nouveau droit français des brevets d'invention*, Editions du JNA, 1991, p. 142.

¹⁰ M. de Haas, *Brevet et médicament en droit français et en droit européen*, Litec, collection du CEIPI, 1981, at. 487, citing J. Lavoix, *A propos du brevet spécial de médicament : Lab. Pharma.*, 1967, p. 61.

¹¹ Some authors considered the exclusion to be an exception, whereas others argued that second uses were excluded because they lacked novelty, on this important distinction see: M. Vivant, “La brevetabilité de la seconde application thérapeutique”, *La Semaine Juridique Entreprise et Affaires*, No. 25, 1989, at. 2.2.

¹² M. de Haas, *Brevet et médicament en droit français et en droit européen*, op. cit., at. 484, citing F. Coustou.

fledgling biotechnology industry¹³. Therefore the European Patent Office (EPO) started to adapt its case law in order to allow these patents.

In decision G 0005/83, the Enlarged Board of Appeal decided that a patent on a second medical use could be granted if the claims were written in a special form called “Swiss-type claims”¹⁴. These claims read: “use of the compound X for the manufacture of a medicament or use in treatment of Z”. The idea was to transform a use claim into a product or process claim. It also avoided the problems of novelty and industrial application, as the novelty no longer lied in the product itself but in the use that had to be new, thereby creating what is called a “fiction of novelty”. The industrial application was also acknowledged through the manufacture of the medicament rather than the mere use of the compound.

The case law of the EPO therefore opened the door to the patentability of second medical uses, which were eventually sanctioned during the revision of the European Patent Convention of 2000 (EPC). The EPC amendment entered into force in 2007. Article 54(5) as amended allows second medical use patents. Swiss-type claims were no longer necessary but many European countries still used the format. Interestingly, in a decision G2/08, the Enlarged Board of Appeal abandoned the Swiss-type claims and decided that: *“Swiss-type claims could be (and have been) considered objectionable as regards the question as to whether they fulfill the patentability requirements, due to the absence of any functional relationship of the features (belonging to therapy) conferring novelty and inventiveness, if any, and the claimed manufacturing process. Therefore, where the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament, such claim may no longer have the format of a so called Swiss-type claim as instituted by decision G 5/83”*¹⁵.

Surprisingly it recognizes that Swiss-type claims are legally questionable and preferred to abandon them. We will see during this study that allowing second medical use patents must therefore be considered as an exception to patent law requirements. In France like in most European countries, the Intellectual Property Code was amended in order to stick to the European Patent Convention. Article L611-11 of the Intellectual Property Code states that second medical uses are patentable¹⁶. Almost all European countries allow second medical use patents today.

¹³ C.M. Correa, *A Guide to Pharmaceutical Patents*, South Center, 2012, p. 135.

¹⁴ EBA, G 0005/83 (Second medical indication), 5 December 1984, OJ EPO 1985, 064.

¹⁵ EBA, G 0002/08 (Dosage regime/ABBOTT RESPIRATORY), 19 February 2010, OJ EPO 2010, 456.

¹⁶ As amended by the law n°2008-776 of 4 August 2008.

In the United States, second medical uses as well as methods of medical treatment are patentable. There is no exclusion like under the EPC. But this has not always been the case. In an old decision of 1879¹⁷, the judge considered that the use of ether as analgesic was not an invention that could be patented, even if it was really useful to society. This decision was the basis for the exclusion of methods of medical treatment from patentability. In 1947, the judges considered that new uses did not fall within the scope of existing categories of patentable inventions¹⁸ and were therefore not patentable. But in 1952, the Patent Act was amended and article 100b explicitly provided that second uses were patentable¹⁹. This was the start of a long list of patents granted for method of medical treatment and second medical uses. For Bruno Phelip, the first patent for a method of treatment was probably the patent FOX n°23.947 delivered on 15 February 1955. The patent claimed a method of treating tuberculosis with hydrazide, which was a known compound. Under American law, if a new use is claimed but the compound is already known, the inventor can file a patent for the process of obtaining the new use but not for the product itself²⁰. The new use must comply with the patentability criteria, i.e. it must be new, useful and non-obvious.

We have seen that in the Europe as well as in the United States, second medical uses are patentable. Many other developed countries follow this trend. The justification for such patents differ from country to country, but they all have the same objective: trying to make these patents available in all countries in order for their pharmaceutical industry to enter new markets. Yet, we have seen that developing and least developed countries did not allow pharmaceutical patents until recently. The TRIPS Agreement obliged all WTO members to change their patent law in order to allow them, but the Agreement remains silent on the question of second medical use patents. Therefore, countries are free to allow them or not. This is the theory, but in reality, “free” is an euphemism, as developed countries push developing countries to enter into so-called “free trade agreements” (FTAs) that often include parts on intellectual property and on this special issue of second medical use patents. We will come back to situation of Latin America and India in this respect.

This is the current overview of the patentability of second medical uses: some countries allow them, other not, or not yet. The reasons for the acceptance of such patents vary, as well

¹⁷ Morton c/ New York Haye Infirmary, 1879.

¹⁸ Old Town Ribbon & Carbon Co. v. Columbia R. & C. Mfg. Co., 159 F.2d 379 (2d Cir. 1947).

¹⁹ B. Phelip, *Protection et exploitation de la recherche pharmaceutique*, Lyon, 5-6 Avril 1979, Litec, Collection du CEIPI, 1980, p. 66.

²⁰ A. Guesmi, *Le médicament à l'OMC: droit des brevets et enjeux de santé*, Larcier, Droit/Economie internationale, 2011, at. 93.

as the justifications for their rejection. But while almost all countries are bound by the TRIPS Agreement, which sets minimum standards for patentability, how can there be such an important difference between national patent laws? All countries have the same requirements for patentability: an invention must be new, involve an inventive step and be susceptible of industrial application²¹. Therefore, how can the same “invention” be considered to be new and be susceptible of industrial application in some countries, and be considered not to fulfil these criteria in other countries? Throughout this work, we will try to answer the following question: what are the legal justifications for second medical use patents and what is their impact on access to health?

To be able to answer this question, we believe that it is important to come back to the very basics of patent law, to the philosophy behind and justification of the grant of a patent. The key concept is the “social contract” that the society and the inventor enter into. The idea is that the society is willing to give the inventor a monopoly for the manufacture and sell of its product, in return for a socially valuable invention. In the field of pharmaceutical patents, the inventor will be granted a monopoly for a new and inventive drug which has new valuable characteristics, i.e. cure a disease, improve a medical condition, enhance the efficacy of a known drug, and so on. Therefore, it would be contrary to the philosophy lying behind patent law to grant a patent for something that has no intrinsic value. Moreover, patents are supposed to incentivize innovation. The basic idea is that without patents, there will be no innovation, no inventions. The pharmaceutical industry relies on patents to finance the research and development. This is most probably true for the development of new drugs, which suppose a huge financial investment in order to find new molecules which could have special characteristics, and then enter in the pre-clinical and clinical phases to test the new drug. Many compounds are abandoned at the stage of pre-clinical or clinical trial, because they do not have the expected efficiency or have unwanted side effects. The costs incurred to develop a new drug require some kind of certainty that the company will be able to cover its costs and make some benefits. This is the role of patents.

In the case of second medical uses, the reasoning is quite different, because the context of research and development is different. We have said that there are two ways of “discovering” a second medical application for a known drug. The first one is when a company investigates on an already existing drug to try to find a new application for this drug. In this context, the company will be able to take advantage from the pre-clinical and clinical trials done for the

²¹ Noting that some countries like the United States apply alternative criteria: new, non-obvious and useful

drug, and will already have valuable information on the characteristics of the drug, including side effects. Therefore, it seems that the research and development for a second medical use is less expensive and takes less time than for developing a new drug based on a new compound.

But the particularity of second medical uses is that they can also be discovered in the course of a medical treatment of a patient for another indication. The doctors might well be aware that a drug used to treat cardiovascular diseases is also useful to improve diabetes. If a company gets this information and then files a patent application for this special use of the drug, it is clear that the research and development will amount to almost nothing. In these cases, would it be really justified to grant a twenty-year monopoly (and even twenty-five years in most cases) to the future patent holder? If we come back to what we have said before about the justification of patents, that are supposed to incentivize innovation and research and help companies to cover their costs, then we do not think that second medical use patents would be justifiable in this regard. On the other hand, it is true that some new medical applications can be really valuable and useful in the common sense of the word. Would then a patent be justified? If not, what are the legal and practical justifications for such patents in countries where they are accepted? Once this question will be answered, it will also be necessary to focus on the impact of such patents. Indeed, it is important to focus on the patentability of second medical uses because they have a significant impact on access to health. Hence, what are the consequences of the grant of second medical use patents on access to medicines and who are these patents benefiting to? Are there special infringement issues arising and who do they mostly impact?

In the first part, we will see that the legal regime justifying second medical use patents differs from country to country and can be criticized from a legal point of view. Indeed, second medical uses do not comply with international patentability standards, and this is why countries had to resort to legal fictions to grant these patents. At the same time, it is worth noting that developed countries push for more acceptance of second medical use patents, in particular through free trade agreements. Developing countries like India or Latin American countries have developed strong patent regimes that prohibit second medical use patents (Part 1).

Where patents on second medical indications are granted, their impact on access to health is quite significant. In a second part, we will address the issue of access to medicines and in particular the impact of second medical use patents in developing countries. We will see that some legal and practical safeguards are necessary to reduce the negative impact that these patents have on public health. We will also focus on infringement issues arising from second medical use which might impact access to health (Part 2).

Part 1: The ambivalence of the legal regime governing second medical use patents

Patents for new uses of a known substance have been granted in some countries, and firmly rejected in others. The legal justification for such patents is different in every system, as well as the arguments for their rejection. While in most developed countries, second medical use patents are granted on the basis of a fiction of novelty, they are considered to be not patentable subject matters in some developing countries. It is worth noting that the states as well as the courts have used the flexibilities offered by international agreement like the TRIPS Agreement to allow or refuse second medical use patents.

In the first chapter, we will address the compliance of second medical uses with the international patentability standards which are novelty, inventive step and industrial application. We will see that, even in the cases where these second uses are considered to be compliant with these standards, they might still be excluded because of the exclusion of methods of medical treatment. It is interesting to see how these requirements have been interpreted in different areas of the world, and especially in developing countries, which have used the flexibilities offered by the TRIPS Agreement to avoid patents on second medical uses (Chapter 1). Thus, we will see in the second chapter how international and regional agreements have influenced the patentability of second medical indications, and how developing countries like Latin American countries and India have been able to avoid these patents, even if the growing pressure of developed countries through free trade agreements makes it always more complicated (Chapter 2).

Chapter 1: The compliance of second medical uses with the patentability standards

Traditionally, a patent is granted for an invention that is new, involves an inventive step and is susceptible of industrial application. To assess whether second medical uses should be patentable, it is therefore legitimate to confront them to these criteria (Section 2). But even before doing this exercise, the preliminary question is whether a second medical use is actually a patent-eligible subject matter. This question has led to an interesting doctrinal debate and we will try to answer this question (Section 1). Finally, after having determined whether second medical uses are within the subject matter of patent law, the last point that has to be addressed

is whether there are some exclusions to patentability that could cover second medical uses. To make the story short, the exclusion that we will focus on in this paper is the exclusion of methods of medical treatment. We will also see that some countries have excluded second medical uses as lacking industrial application (Section 3).

Section 1: Second medical indications: a patent-eligible subject matter?

In most intellectual property laws, patents are granted for any inventions, whether products or processes. In the case of pharmaceuticals, product patents have sometimes been excluded. In countries where pharmaceutical patents are available, the question will be whether second medical uses fall within the scope of one of these categories (I). Moreover, it has been argued that second medical uses are not real inventions, but should rather be qualified as discoveries, therefore falling outside the scope of patents. We will address this controversial issue (II).

I. Uses confronted to the categories of statutory subject matter

TRIPS Article 27 reads: “patents shall be available for any inventions, whether products or processes, in all fields of technology [...]”. Most national patent laws have introduced a similar rule²². In the United States, patents are available for process, machine, manufacture or composition of matter²³.

The question is therefore whether second medical use patents can fall within the scope of one of these categories. The Guidelines for Examination of the EPO state that use claims should be regarded as equivalent to process claims²⁴. In order to justify this categorization, the guidelines give examples on how a claim should be interpreted. For instance, a claim in a form such as “the use of substance X for the treatment of indication Y” should be considered to be equivalent to “a process of treating Y using substance X”. The problem that we believe arises with this format is that it is equivalent to a claim to method of medical treatment, which is not patentable under the EPC as we will see later on.

An alternative would be to use the format of a product claim, which would read “substance X for the manufacture of a medicament for its use in treatment Y”. Under the EPC,

²² See Article 14 of Decision 486 of the Andean Community and Indian Patents Act 1970 as amended, Section 2 (j).

²³ 35 U.S.C. 101.

²⁴ EPO, Guidelines for Examination, Part F, Chapter 4, 4.16 Use claims.

“use-related product claims” are allowed²⁵. Here, it is the substance related to its use that is claimed. But again, the claim will face the requirement of novelty, and should not pass the test of patentability. Indeed, if the drug is claimed, then the assessment of novelty will have to be made regarding this drug, which is, in the case of second medical uses, already known, as it is exactly the same.

In the end, neither a process claim nor a product claim would allow patents on second medical uses under the EPC. Then how can the current practice of allowing second use patents be legally justified? Well, the only way is to introduce a specific exception in the patent law that would allow second medical use patents.

If we briefly address the categories in American patent law, we see that second medical uses cannot fall within the scope of the last three categories, because these inventions are described in terms of their structural characteristics²⁶. Machines are generally mechanical or electronic devices, manufactures encompass any product that are not machines and “composition of matter, such as chemical compounds, have structural characteristics which are unique to a particular invention”²⁷. While in the case of second medical uses, the compound is already known, the claimed invention is therefore the new use. That’s why the only category in which second medical uses can fit is the process, which refers to a series of steps necessary to make or use a machine, manufacture or composition of matter.

Indeed, in 1943, the Court rejected the patentability of a new use of a chemical compound that had not been structurally changed²⁸. The claimed invention was the new use of a tanning agent for the treatment of diseased tissue. The Court stated that a new use for an old compound without change is not allowed by patent law because it does not fall within the scope of one of the four statutory categories of invention, which at this time were “any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement thereof [...]”²⁹.

Finally, with the 1952 Patent Act, new uses became patentable if claimed in the form of a process³⁰, but some courts were still reluctant to accept the patentability of new uses believing

²⁵ Ibid., 7.1.1. Products that may be claimed for a further medical use.

²⁶ L.L. Hewitt, “The New Use Patent”, *Journal of the Patent Office Society*, 1969, Vol. 51, Issue 10, pp. 634-648, p. 634.

²⁷ Ibid.

²⁸ *In Re Thuau*, 135 F.2d 344 (C.C.P.A 1943).

²⁹ Ibid.

³⁰ L.L. Hewitt, “The New Use Patent”, loc. cit., p. 645.

it would restrict the monopoly of the first patentee. Some authors believe that second use patents have an equal and sometimes greater stature than other inventions, and therefore, considering their merit, a fifth statutory category of invention should be introduced for new uses³¹.

In the United States, there is no exclusion of method of medical treatment or discoveries, the American patent law being a lot more permissive than the EPC. But most of national patent laws around the world follow the scheme of the TRIPS Agreement and therefore get closer to the European model. Therefore second medical uses are legally questionable in most patent laws and it we will now turn to another issue raised by these patents: whether they can be considered to be real inventions or only discoveries of existing technical features.

II. Discovering or inventing a second medical use?

The qualification of second medical uses as discoveries or inventions is crucial as it will determine whether or not the “inventor” will be granted a patent on it. While a discovery is the mere finding of what already exists in nature, an invention consists in an “industrially applicable technical solution to a technical problem”³². Opponents to second medical use patents have argued that they are mere discoveries, and therefore outside the scope of patentability. Latin American countries consider that second uses consist in discovering new technical features of an already known substance, but that these features were already comprised in the originally disclosed substance³³. Therefore, even if not known at the time of patenting the substance, the new uses later discovered are just revealed to the public, but they already existed, therefore they have to be qualified as “discoveries” and are not inventions.

This is not the position adopted by the EPO, which considers that “under Article 54 (2) EPC the question to be decided is what has been “made available” to the public: the question is not what may have been “inherent” in what was made available (by a prior written description, or in what has previously been used (prior use), for example). Under the EPC, a hidden or secret use, because it has not been made available to the public, is not a ground of objection to validity of a European patent.”³⁴ Therefore, for the EPO, second uses might be inventions and are not

³¹ Ibid.

³² EPO, Opp. Div., Relaxin, 8 December 1994, OJ EPO 1995, 388, p. 397, available at: http://archive.epo.org/epo/pubs/oj1995/p373_460.pdf (20 August 2016).

³³ F. Rodriguez Spinelli, “Patentes de segundo uso: nuevas tendencias en el derecho comparado y en los tratados de libre comercio”, *Propiedad Intelectual*, No. 14, 2011, pp. 127-148, p. 128.

³⁴ EBA, G 0002/88 (Friction reducing additive), 11 December 1989, OJ EPO 1990, 093, p. 112.

excluded per se from patentability. We will come back to this interesting distinction made by the Enlarged Board of Appeal when assessing novelty.

If we stick to what we have said, we should be able to conclude that second medical uses are discoveries in the common sense of the word and should not be patentable. But some authors have argued that the distinction to be made is not between an invention and a discovery; rather, to be considered an invention, the whole point is to determine whether the discovery has a technical application³⁵. This is the key concept, as recalled by the EPO in its examination guidelines: “the discovery [...] needs to find an application in the form of a defined, real treatment of a pathological condition in order to make a technical contribution to the art and to be considered as an invention eligible for patent protection”³⁶. So in the case of second medical uses, we would have to determine if they have a particular technical application.

In order to answer this question, the first step is to define the concept of “technical application” which is not an easy task. Several authors have tried to give a definition, while acknowledging that there is no commonly accepted definition of this term. Jérôme Passa notes that the EPO does not give any definition of what is “technical”, first because it would be a very difficult task but also because they want to keep an open concept that might evolve³⁷. So in the end, are second medical uses technical? We could define what is technical by opposing it to anything that is merely artistic or abstract, and if the result is essentially intellectual, without creating any tangible result having an industrial application. Based on this definition, it could be said that second medical uses have a technical application. Actually, second medical uses would have the same technical application as pharmaceutical compounds, that is, the manufacture of a drug and in fine the treatment of a disease. Therefore, if the new use eventually leads to the manufacture of a drug used in the treatment of a medical indication, it could be considered to be an invention having a technical application. But we will see when assessing the industrial application that it is not as straightforward as it seems.

This assessment might also be reversed by a more ethical argument, which is when the second medical use is discovered “by accident”, in the course of clinical trials³⁸, as we have seen in the introduction. In such a case, the investment made to find this medical use is not

³⁵ T. Scassa, “Patents for second medical indications and their potential impact on pharmacare in Canada”, *Health Law Journal*, Vol. 9, pp. 23-59, p. 31.

³⁶ EPO, Guidelines for examination, Part G, Chapter VI, 7.1 Second or further medical use of known pharmaceutical products.

³⁷ J. Passa, *Droit de la propriété industrielle Tome 2*, LGDJ Lextenso éditions, Traités, 2013, at. 58.

³⁸ C.M. Correa, *Guidelines for the examination of pharmaceutical patents: developing a public health perspective*, op. cit., p. 8.

substantial, and might have been fortuitous, which obviously questions the legitimacy of the grant of twenty years of exclusivity. This argument is not directly related to the distinction between discovery and invention but it should be taken into account when trying to strike a balance between the interests of the inventor and those of the society.

We see that the views really differ depending on the region we are addressing and that this question of whether second medical uses are inventions or discoveries has not been settled yet on an international scale. Even in the cases where the second medical use is considered to be an invention, it will still have to pass the test of the patentability criteria which we will address in the following section.

Section 2: The patentability criteria applied to second medical uses

An invention as such is not necessarily entitled to a patent. Indeed, it has to be new, involve an inventive step and be capable of industrial application. These three criteria are the most common ones on an international scale and were reaffirmed by the TRIPS Agreement Article 27. That's why we will focus on them, even though it must be said that some countries like the United States use an alternative criteria: an invention must be new, non-obvious and useful to be patentable. It is not the subject of this work to discuss which criteria are the most efficient and permissive, but in our view these criteria can lead to the grant of patents which would not have been granted applying the three "classical" criteria. We follow the order of the TRIPS Agreement, we will first address the novelty of a second medical use (I), and follow with the assessment of the inventive step (II). The question of the industrial application of second medical uses will be addressed in the last section.

I. What is novel in a second medical use patent?

The title of this section is deliberately provocative, and it reflects the whole debate on the novelty of second medical uses. There are two different ways of addressing the novelty criteria, which correspond to the historical evolution of the case law: the novelty can first be assessed regarding the compound at issue (1) or second, regarding the new use (2).

1. Novelty of the compound: the necessary refusal of patents for second medical uses

The question "what is novel in a second medical use patent?" should actually be phrased in a different way and be: what should be new in a second medical use patent? Let us explain our thought: in patent law, the novelty is assessed regarding a product or process as we have

seen before. Therefore, in the case of second medical uses, the assessment should be the same, and focus on the product or process at issue. The problem with second medical uses is that the product is exactly the same, this is the very definition of second medical indications. Therefore, the novelty should be denied in all cases as the compound has already been disclosed and is comprised in the state of the art³⁹.

The European Patent Office very soon realized that the way the Convention of 1973 was written did not authorize second medical use patents. Hence it developed an ambitious jurisprudence based on the so called “Swiss-type claim” to allow second medical use patents, by avoiding the barriers of the novelty and industrial application criteria. Swiss-type claims are presented in the form: compound X for the manufacture of a pharmaceutical for the treatment of an indication Y. As some authors pointed out, this formulation creates a fiction of “novelty” where the novelty no longer resides in the compound but rather in the “new” use of this compound⁴⁰. The wording also allows to get round the exclusion on method of medical treatment which we will address later on, by allowing patents on compound used to manufacture a drug, and not the use of the compound in a therapeutic treatment itself. With the revision of the European Patent Convention in 2000 (which entered into force in 2007), Swiss-type claims were abandoned and second use patents were explicitly sanctioned in article 54(4)⁴¹. Following this trend, many European countries have adopted second medical use patents.

In the Netherlands, since 2011 Swiss-type claims are no longer allowed but second medical use claims are allowed as purpose-limited product claims, following the format “compound X for the use in the treatment of disease Y”⁴². In Spain the novelty is assessed regarding the format of the claim. If a compound is already comprised in the state of the art, but is not known for having a therapeutic use, and the compound is claimed as a product (compound X for the use as a medicament, as an analgesic, or for the treatment of the indication Y), it will be rejected as lacking novelty. It will only be accepted if a therapeutic use is claimed (use of X for the manufacture of a medicament, for the treatment of a disease Y). More surprisingly, if the compound is not new but a therapeutic use has already been disclosed, then a patent could

³⁹ Article 54 EPC: « An invention shall be considered to be new if it does not form part of the state of the art. The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application”.

⁴⁰ C.M. Correa, “Patent examination and legal fictions: how rights are created on feet of clay”, South Center, Research Paper 58, 2014, p. 15.

⁴¹ This was confirmed in decision EBA, G 0002/08 (Dosage regime/ABBOTT RESPIRATORY), 19 February 2010, OJ EPO 2010, 456: “such claim may no longer have the format of a so called Swiss-type claim as instituted by decision G 5/83.”

⁴² P. Reeskamp, *Second medical use or indication claims*, AIPPI Report Netherlands, 25 April 2004.

be granted for a “new” second medical use⁴³. Spain recently amended its patent law to include two new provisions corresponding to article 54(4) and 54(5) of the EPC, allowing second medical use patents⁴⁴.

Based on a legal fiction, the novelty is no longer assessed regarding the compound but rather regarding the use. But this should not automatically lead to the acceptance of second medical uses, and it has been argued that even the use should not be considered to be new.

2. Novelty of the use: the introduction of a disputed legal fiction

To summarize the argument of the opponents of second medical use patents, it can be stated that these patents claim a particular effect of a chemical compound that is already comprised in the state of the art. Therefore the invention cannot be new as the compound it relies on has already been disclosed, or it was at least included in the original compound. Moreover, the mere fact that the effect was not known before by the public does not mean that the invention can get novelty thereof, because the chemical compound had necessarily this effect even if nobody had realized it before.

This point of view has been defended by authors like Michel de Haas⁴⁵. He considers that, if a second medical use is discovered, the drug does not fulfill a new function, neither does it lead to a new result. The pharmaceutical had already the function of curing or make the patient feel better, and the new use discovered had necessarily happened already, even if it had not been noticed before. He gives the example of aspirin, known to treat inflammation and pain. If somebody discovered that it could also be used to cure cancer, then it means that some patients that had taken aspirin would necessarily have been cured from cancer without maybe knowing it. Therefore, the application is not new and second medical uses should not be patentable in accordance with patent law⁴⁶.

We do not believe that this reasoning should be followed. M. de Haas’ reasoning is based on what we could call “absolute novelty”, which means that anything that has existed in absolute terms, even if it was not known, is not new anymore. We believe that in the field of patent law, a more relative criteria of novelty should be applied. Especially in the case of second medical uses, only known effects and known uses for an existing compound should be

⁴³ Directrices de examen de solicitudes de patente, Departamento de Patentes e información tecnológica, Oficina Española de Patentes y Marcas, Octubre 2006, pp. 151-152.

⁴⁴ Ley 24/2015, BOE-A-2015-9725, de 24 de Julio (which will enter into force on April 1st, 2017).

⁴⁵ M. de Haas, *Brevet et médicament en droit français et en droit européen*, op. cit., at. 496.

⁴⁶ *Ibid.*

considered as not being novel. Now, acknowledging the novelty of a second medical use does not mean it will necessarily be patentable. The new use will still have to involve an inventive step and be susceptible of industrial application to be patented.

In the same line of thought, some authors have argued that it is not right to consider that the second medical use was “available to the public” just because it was included in the original compound. Therefore, they cannot be excluded from patentability for the reason that they are not new⁴⁷. The exclusion is based on other legal grounds.

We understand that the current trend is to expand second medical use patents by applying this “fiction of novelty”, where the novelty lies in the new use and not in the compound anymore. Actually, to be more precise, the novelty lies not only in the new use, but in the use as the consequence of the application of the known substance. Therefore, the novelty has to be assessed regarding the twosome “product-use”. In Europe, the acceptance of second medical use patents is illustrated by a number of changes in national patent laws to stick to the EPO. But novelty is not the only criteria for patentability, and an invention will still have to meet other criteria, like the inventive step, to be patentable.

II. The difficult assessment of the inventive step

When somebody comes up with a new medical use for an existing compound and applies for a patent, the examiners will have to check whether this new medical use involves a so-called “inventive step”. The concept of inventive step comes from the English notion of “non-obviousness”⁴⁸. Therefore, the invention must not have been obvious for the man skilled in art. In other words, the examiners have to determine whether a person having ordinary skill in the art could have found or deduced this new use from what was already existing and known by the public. If the new use was obvious with regard to the prior art, there will be no substantial contribution to the society and therefore no exclusive right should be granted⁴⁹. The European Court of Justice frequently recalls that a monopoly is granted to reward the investments made in the research⁵⁰.

⁴⁷ M. Vivant, “La brevetabilité de la seconde application thérapeutique”, loc. cit., at. 2.2.

⁴⁸ M. Vivant, *Le droit des brevets*, Dalloz, Connaissance du Droit, 2e édition, 2005, p. 30.

⁴⁹ For further information regarding inventive step see: WIPO Standing Committee on the Law of Patents, “Study on Inventive Step”, 6 July 2015, available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_22/scp_22_3.pdf (20 August 2016).

⁵⁰ See Case C-34/10, *Oliver Brüstle v. Greenpeace e.V.*, 18 October 2011, para. 32.

When a second medical use is discovered, the question will be whether the person skilled in the art could have predicted that the pharmaceutical could also have been used to cure the new medical indication. It could be the case for instance, if similar consequences were observed in the same field, or if similar substances have been discovered to have the new medical use. In such cases, the second medical use might be obvious to the person skilled in the art and there will be no inventive step. M. de Haas gave the example of aspirin which is an analgesic to be absorbed orally known to treat pain and inflammation. If somebody discovers that it can be used to treat burns, it would certainly involve an inventive step, because the known substance has a new function leading to new results which were not obvious for the man skilled in the art⁵¹.

More specifically, in the case of selection inventions, the whole question is whether it was obvious for the man of the art to find out that a particular substance claimed for a wide range of uses could be used for a smaller range of uses. For instance, could the man skilled in the art have known that a particular substance used to treat pain in general could also be used to treat headache? In this particular example it might seem obvious, but the judges sometime face much more complex situations⁵². Just because an invention produces a benefit as compared to the prior art does not mean it necessarily involves an inventive step⁵³.

The way the criteria is defined has also a mayor influence on the grant of patent for second medical uses. If the requirement is too low, then it will be easier to grant patents. We will not enter into a detailed analysis of the definition of the person skilled in the art and level of knowledge it has to have, nor will we examine what could be the optimal definition of “obvious”⁵⁴. But what we would like to point out at that stage, is that countries can take advantage of the flexibilities given by the words that have no international definition, to raise the threshold that has to be met in order to be granted a patent on a second medical use.

In the event that a second medical application is found to be novel and involve an inventive step, the last criteria that it will have to fulfill is the industrial application. Indeed, countries that exclude second medical uses from patentability base their argumentation on the

⁵¹ M. de Haas, *Brevet et médicament en droit français et en droit européen*, op. cit., at. 501.

⁵² B. Domeij, *Pharmaceutical Patents in Europe*, op. cit., p. 139.

⁵³ M. Courboulay, “L’assouplissement des conditions de brevetabilité des produits pharmaceutiques”, *Propriétés intellectuelles*, No. 59, 2016, p. 156.

⁵⁴ For further analysis see WIPO Standing Committee on the Law of Patents, “Study on Inventive Step”, loc. cit.

lack of industrial application or on the fact that medical uses are methods of medical treatment. As these bases are often assimilated, we will address them both in this last section.

Section 3: A controversial basis for the exclusion of second medical uses

To exclude second medical uses from patentability, it has been argued that they should be considered to be methods of medical treatment, therefore lacking industrial application. Indeed, both criteria have often been assimilated, and medical uses were considered to lack industrial application because methods lack industrial application. We decided to address both criteria separately, considering first whether second medical uses are susceptible of industrial application (I), and second whether they can be assimilated to methods of medical treatment (II).

I. The industrial application of a new medical use

As a preliminary point, it has to be noted that in some countries like the United States, the criteria of industrial application is replaced by the utility criteria. We have already said that the application of the utility criteria facilitates the access to patents, and thus second medical use patents. It is not the topic of this work to analyze the common points and differences between the criteria, and we will stick to the analysis of whether second medical uses are capable of industrial application. But it must always be kept in mind that the definition and scope of these concepts has an important impact on the grant of patents and therefore access to health⁵⁵.

Second medical uses are often assimilated to methods of medical treatment. Yet, according to the Enlarged Board of Appeal, the methods of medical treatment referred to in Article 54(5) EPC are inventions but based on a legal fiction, they are not considered to be susceptible of industrial application⁵⁶. In the EPC 1973 these methods were expressly excluded as not being susceptible of industrial application. The EPC 2000 as amended excludes these methods but makes no reference to industrial application. Some have said that this criteria can

⁵⁵ L.M., Genovesi, “La aplicación industrial y la utilidad como requisitos de patentabilidad: diferencias y semejanzas. Consecuencias de su aplicación”, p. 3, in: Seuba, Xavier, *Propiedad Intelectual Competencia y Aspectos Regulatorios del Medicamento Determinantes Internacionales y Política Pública*, Grupo Editorial Ibañez, Colección Estudios n° 4, Colombia 2013.

⁵⁶ EBA, G 0001/04 (Diagnostic Methods), 16 December 2005, OJ EPO 2006, 334, at. 4.

still be used in many countries as a safeguard for not patenting second medical uses. But are second medical uses really not capable of industrial application?

According to Mariano Genovesi, and based on the examination guidelines of WIPO, PCT and the EPO, the concept of “susceptible of industrial application” means that the invention must have: a technical character, which means that the invention must pertain to applied arts in contrast with fine arts; it must be “feasible”, which implies the possibility of duplicating the invention; it must be useful, i.e. fulfill some kind of social need and produce some tangible result (and not hypothetical); and finally, it must be credible, and not be impossible to make⁵⁷. In the Andean Community, according to the Decision 486, an invention is susceptible of industrial application if its object can be produced or used in any kind of industry⁵⁸. The Andean tribunal further interpreted the requirement, stating that the invention must have a technical character, the inventor must apply or transform something existing in nature⁵⁹.

If we try to apply these criteria to second medical uses, we can see that again, according to the interpretation given to each word, the solution might differ. But if we try to make a general interpretation of the criteria we have enumerated, if we consider that second medical uses are aimed at using a pharmaceutical compound in a certain way to treat a medical indication, then they have a technical character, they are “feasible”, and credible. The inventor uses a compound that might exist in nature or was manufactured by man to apply it in the medical field. Therefore, second medical uses would not lack industrial application. Furthermore, many jurisdiction have been considering that the industrial application lies in the manufacture of a medicament that will be used to treat the second medical indication and that the second use would therefore comply with the criteria.

This is a way of looking at the issue, but there is also another way that we believe should be addressed. The first way of addressing the industrial application of second medical uses is to consider that a new pharmaceutical will be manufactured for its use in a treatment. But the pharmaceutical manufactured will still be used to treat the first medical indication, and there will be no difference made at the stage of production whether it is manufactured for the first or

⁵⁷ M. Genovesi, “La aplicación industrial y la utilidad como requisitos de patentabilidad: diferencias y semejanzas. Consecuencias de su aplicación”, loc. cit., pp. 6-9: “carácter técnico; ejecutabilidad; útil; creíble”.

⁵⁸ Comunidad Andina, Decision 486, Régimen Común sobre Propiedad Industrial, 1 de Diciembre del 2000, art. 19, available at www.wipo.int (20 August 2016).

⁵⁹ Tribuna de Justicia de la Comunidad Andina, Proceso 12-IP-98, 20 de Mayo de 1988: “Con este requisito, se pretende que la actividad inventiva del ser humano tenga por objeto una actuación del hombre sobre la naturaleza, destacando el proceso industrial y de avance tecnológico cuyos beneficios económicos se obtendrán para quienes los exploten, obedeciendo a que una idea para el obrar humano sólo es útil si se puede poner en práctica”.

any subsequent use. Therefore it could be considered that the pharmaceutical has already been produced. The use that will be made of the drug afterwards is another issue.

From that point of view, it can be argued that second medical uses lack industrial application, because they are not manufactured as such in an industry, as they are based on an already existing drug. To understand this argument, one could agree that using a bicycle for instance has no industrial application; the manufacturing of the bicycle has, but its use as such lacks industrial application. Therefore, by analogy, one can agree that the mere use of something already existing does not have industrial application, and in the case of second medical indications, the use should be approximated to a method of medical treatment. To continue with this reasoning, a further analysis must be made to determine whether second medical uses can be considered to be methods of medical treatment, and therefore excluded from patentability.

II. The exclusion from patentability of second medical uses as being methods of medical treatment

The exclusion of methods of medical treatment from patentability is often based on both legal and ethical grounds. Methods of medical treatment have sometimes been excluded for not being inventions⁶⁰. Under EPC 1973, article 52(4) excluded methods of medical treatment for lacking industrial applicability and therefore not being inventions. Today, under the EPC 2000 as amended, methods of medical treatment are considered as exclusion of patentability. It must be noted that the last sentence of this article provides that “This provision shall not apply to products, in particular substances or compositions, for use in any of these methods” (article 53(c)). We will come back on this important distinction.

Methods of medical treatment have also been considered to be “non-economic” and therefore lying outside the concept of invention⁶¹. On the basis of moral and ethical considerations, an interesting judgement of the High Court of Australia explained that these considerations for methods of medical treatment are the same as for pharmaceutical compounds, “but the costs and benefits of providing a monopoly in respect of a pharmaceutical substance may very well differ from the costs and benefits of providing a monopoly over a method of prevention or treatment of human disease”⁶². The judge concludes that the costs to

⁶⁰ Pfizer Inc. v The Commissioner of Patents [2005] 1 NZLR 362, available at: <http://www.spruson.com/methods-of-medical-treatment-confirmed-patentable-australia-new-zealand/> (20 August 2016).

⁶¹ National Research Development Corporation v Commissioner of Patents (1959) 102 CLR 252, at. 275.

⁶² Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd, [2013] HCA 50, at. 145-146.

discover a pharmaceutical compound are much higher than those to discover a new medical treatment for a known substance⁶³. Methods of medical treatment should therefore not be patentable.

We have seen that the EPC excludes methods of medical treatment from patentability, but the use of a pharmaceutical compound in the course of a treatment of a medical indication is patentable⁶⁴. This subtlety introduced by the Enlarged Board of Appeal has to be explained. In the case G 0005/83 of 1984, the Board made a distinction between the use of a substance or composition as a treatment and the use of a compound in the course of a medical treatment. For the Board, “the use of a substance or composition for the treatment of the human or animal body by therapy” is the same as a method of medical treatment, and therefore excluded from patentability⁶⁵. It follows: “claims directed to the use of a substance or composition for the preparation of a pharmaceutical product are equally clearly directed to inventions which are susceptible of industrial application, within the meaning of Article 57 EPC”⁶⁶. It concludes that: *“For these reasons, the Enlarged Board considers that it is legitimate in principle to allow claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application, even in a case in which the process of manufacture as such does not differ from known processes using the same active ingredient”*⁶⁷.

In our view, the practical consequences are the same: the grant of a patent for a substance that will in fine be used for the treatment of a medical indication. The subtlety introduced by the Enlarged Board of Appeal is just about formulating the claim in a way that encompasses the manufacture of a product, in order to fulfill the criteria of industrial applicability. But in the end, what is claimed is a method of treating a medical indication. Therefore, legally speaking, we believe that second medical use claims are a kind of method of medical treatment claims. Thus, they could only be patentable if there is an explicit exemption in the law for such claims. And these exemptions have been introduced in a number of patent laws, starting with the EPC. It should be added that in the United States, nowadays, method of medical treatment are not

⁶³ Ibid.

⁶⁴ T. Scassa, “Patents for second medical indications and their potential impact on pharmacare in Canada”, loc. cit., p. 12.

⁶⁵ EBA, G 0005/83 (Second medical indication), 5 December 1984, OJ EPO 1985, 064, p. 66.

⁶⁶ Ibid., p. 65.

⁶⁷ Ibid., p. 66.

excluded from patentability and therefore claims directed to second medical uses are patentable under US Patent law in this regard.

The Guidelines for Examination of the EPO give indications on how to formulate a claim related to a second medical use. It makes it clear that the wording “for use” is necessary to distinguish between a claim related to a product suitable for a specified use, and a claim limited to the medical use (which would be banned by article 53(c))⁶⁸. The patent will not be delivered for the method of treatment as such, but for the substance used in a specific way for the treatment of a specific indication, which is a rather narrow claim. In Canada, it has been argued that second medical use patents are not necessarily akin to method of medical treatment. Indeed, the description and the claims in a “use” patent do not necessarily include instructions directed to the physician. For Teresa Scassa, if the patent is formulated in a way that still leaves some space for the “skill and judgement on the part of the treating physician”⁶⁹, it should not be held to be a method of medical treatment. Therefore there would be a difference between a second medical use claim and a claim to a method of treatment, lying in the liberty left to the doctor or physician.

Finally, what can be concluded from this analysis is that the states and regional organizations like the EPO draw their law in a way that satisfies the demands of the major stakeholders. It is clear that the pharmaceutical industry has played a major role in order to push for amendments of the patent laws to introduce an exception for second medical uses. As a general conclusion of this first Chapter, we believe that second medical uses should not be patentable with regard to patent-eligible subject matters, the patentability criteria and the exclusion of methods of medical treatment (at least in countries where such an exclusion exists). We understand that, where second medical use patents actually exist, it can only be legally justified by the introduction of a special exemption for second medical uses, which would be equivalent to a legal fiction allowing such patents.

What is worth noting is that some countries do still not accept second medical use patents. The tendency is nevertheless towards an increasing acceptance of these patents, as developed countries (pushed by their pharmaceutical industry) are trying to pressure the rest of the world, in particular countries that do not yet allow patents on second medical applications. In the second Chapter, we will see that this pressure can be observed at different levels.

⁶⁸ EPO, Guidelines for examination, Part G, Chapter VI, 7.1.2 Therapeutic uses pursuant to Art. 54(5).

⁶⁹ T. Scassa, “Patents for second medical indications and their potential impact on pharmacare in Canada”, loc. cit., p. 33.

Chapter 2: The disputed implementation of second medical use patents

While the global tendency is toward the increasing acceptance of patents for second medical applications, there are still some interesting differences between countries to be observed. On the one hand, developed countries have proposed and pushed for the ratification of various regional and international agreements including sections on patent law that have an impact on second medical use patents. In the first section, we will see that the TRIPS Agreement had a major impact on pharmaceutical patents and therefore raised questions regarding second medical uses. At the same time, developed countries like the United States have been able to impose patents on second uses to developing countries through so-called FTA's (Section 1). But not all developing countries have entered into these agreements, and in the second section, we will focus on the situation of Latin American countries and India that are exemplary in this regard (Section 2).

Section 1: The increasing pressure of regional and international agreements

Most developed countries grant patents for second medical uses today. The situation is quite different in developing countries, which benefited from transitional periods after the implementation of the TRIPS Agreement and may use the flexibilities offered by the agreement to avoid patents on second medical applications (I). The possibility to make full use of these flexibilities is more and more threatened by the entry into force of FTA's, often proposed and imposed by developed countries to developing countries. We will focus on the Trans-Pacific Partnership and its particular implications for second medical use patents (II).

I. The absence of explicit regulation of second medical use patents in the TRIPS Agreement and the flexibilities offered thereof

The Agreement on Trade-Related Aspects of Intellectual Property Rights entered into force in 1995. It is probably the most important international agreement dealing with intellectual property nowadays, as it is binding in all WTO members (162 countries). The TRIPS Agreement introduces important changes in the area of patents. It states that patents must be available for any invention in all fields of technology, for product and processes that are new,

involve an inventive step and are capable of industrial application⁷⁰. Before 1995, over 40 countries did not provide patent protection for pharmaceutical products⁷¹. Some countries only allowed process patents for pharmaceuticals⁷², which has a major impact on access to medicines. Indeed, a process patent only allows to protect the process of manufacture, but not the product itself. This means that anybody would be entitled to produce the same drug but with a different process. A product patent, on the contrary, grants an absolute protection of the drug and nobody will be able to manufacture or sell the drug but the patentee.

This distinction has a major impact on access to medicine in developing countries, as with process patents, countries like India could still manufacture the drug and sell it to a cheaper price to developing countries. But with the TRIPS Agreement, minimum standards were introduced, mandatory in all WTO countries, and thus product patents for pharmaceuticals must be available, which scope is much broader than process patents⁷³.

There is no explicit reference to second medical uses in the TRIPS Agreement. This means that there is neither an obligation, nor a prohibition to provide patents for second medical uses. The real question that has been raised is whether article 27 provides a legal basis for such patents. This leads us back to the question of the nature of second medical uses: can they be categorized as product or processes? If a country choose to protect them as products, it will have to deal with the problem of novelty⁷⁴. As we have pointed out before, these countries will have to apply a “fiction on novelty” where the novelty lies in the new use and not in the product which is already comprised in the state of the art. This is for instance the case in most EU-countries. Other countries like the United States and Australia went beyond the minimum requirements of the TRIPS Agreement by allowing patents on methods. Patents for second medical uses and medical methods more generally are available in these countries if they satisfy the criteria of “process” and the other conditions of patentability⁷⁵. This broad interpretation must not necessarily be followed by developing countries, who can define the concept of “process” in a way that excludes second medical uses.⁷⁶

⁷⁰ Article 27 of the TRIPS Agreement.

⁷¹ WHO, WTO and the TRIPS Agreement, available at : http://www.who.int/medicines/areas/policy/wto_trips/en/ (20 August 2016).

⁷² Ibid.

⁷³ G. Velásquez & P. Boulet, *Globalization and access to drugs: Perspectives on the WTO TRIPS Agreement*, WHO, Health Economics and Drugs DAP Series No. 7, 1999, p. 20.

⁷⁴ See discussion above on novelty.

⁷⁵ UNCTAD-ICTSD, *Resource Book on TRIPS and Development*, Cambridge University Press, 2005, p. 384.

⁷⁶ C.M. Correa, *A Guide to Pharmaceutical Patents*, op. cit., p. 131.

It must be said that the Agreement provides so-called “flexibilities” lying mostly in the absence of definition of the terms used. For instance, there is no definition of “product and process”, nor is there any definition to be found of the patentability criteria. These flexibilities can and should be used by developing countries and more generally any country that does not wish to allow patents on second medical uses, by arguing that “uses” are neither comprised in the concept of product, nor in the concept of process, and are therefore not patentable. As the TRIPS Agreement does not require members to protect discoveries, new uses can also be excluded from patentability on the basis that they are discoveries rather than inventions⁷⁷.

Article 27(3)(a) which provides the possibility of excluding methods of medical treatment from patentability should also be used to avoid second medical use patents⁷⁸. This can seem contradictory with what we have said about the current legal framework in Europe, but we shall recall that the EPO first allowed second medical use patents by means of complicated jurisprudence and construction to avoid the problem of novelty, and that these patents are now explicitly allowed in the EPC as “exemptions” from the basic rule of exclusion of methods of medical treatment. Therefore, in our view, a country can totally use the flexibilities offered by the TRIPS Agreement in article 27 to avoid second medical use patents.

Unfortunately, these statements are becoming more and more theoretical with the development of regional instruments and free trade agreements that erase the flexibilities offered by the TRIPS Agreement and impose much lower standards of patentability leading to the multiplication of patents, including second medical use patents. We will see, through the example of the recent Trans-Pacific Partnership (TPP) Agreement, how developing countries are forced into accepting second medical use patents that are not necessarily advantageous for them.

II. The Trans-Pacific Partnership and its impact on second medical use patents

The negotiations for the TPP started in 2008 and the agreement was finally signed in February 2016 by twelve countries of the Pacific region⁷⁹. During almost eight years of negotiations, the proposals of the different countries at stake have evolved. In a first part, we will focus on the specific proposals about second medical use patents and the negligible impact of the agreement on developed countries (1). In a second part, we will see that the case of

⁷⁷ Ibid. p. 130.

⁷⁸ Q. Qeidarya, “Emerging issues: new uses, whether threat or chance, what is the current and appropriate legal treatment?”, *Oklahoma Journal of Law & Technology*, Vol. 11, No. 78, 2015, p. 7.

⁷⁹ Final Agreement available at: <https://www.tpp.mfat.govt.nz/text> (20 August 2016)

developing countries is a little bit more complex, as some countries allow these patents, other have no provision on second uses and one country explicitly prohibits these patents (2).

1. The statutory obligation to grant patents for second medical uses and its impact on developed countries

Without going into the details of the negotiations, it is interesting to see how the United States pushed for very extreme provisions on second medical uses. The USA, along with Australia and Japan, initially proposed a provision which read: “*A Party may not deny a patent solely on the basis that the product did not result in enhanced efficacy of the known product when the applicant has set forth distinguishing features establishing that the invention is new, involves an inventive step, and is capable of industrial application. [...] The parties confirms that patents are available for: any new use, or alternatively, new methods of using a known product.*”⁸⁰

This provision was opposed by the remaining nine parties, who proposed in the alternative a provision allowing the exclusion of method of medical treatment from patentability. The US proposal would have had the consequence of granting a patent for a second medical use, even if this new use was marginal and brought nothing to the society. In our view, such a requirement would have been in obvious contradiction with the requirement of “inventive step”, or even the requirement of “non-obviousness” which is the basis for the grant of a patent. It must also be stated that the implementation of such a provision would have led to more “evergreening” than ever before, as it would have been legally authorized to patent anything already present in the public domain, for minor changes in the chemical formulation, combination or dosage⁸¹. This kind of patents are those that should never be granted because they are in contradiction with the very spirit of patent law, that is, granting a monopoly in exchange for a benefit to society⁸².

But interestingly, the USA dropped this proposition in the last draft. The final draft signed in February 2016 provides that: “each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step and is capable of industrial application”⁸³. This provision is a copy of Article 27 TRIPS. But the real contribution lies in Article 18.37(2): “*Each Party confirms*

⁸⁰ Article QQ.E.1. of the draft text of May 2014, at: <https://wikileaks.org/tpp-ip2/tpp-ip2-chapter.pdf>.

⁸¹ C.M. Correa, “Intellectual Property in the Trans-Pacific Partnership: increasing the barriers for the access to affordable medicines”, *South Center*, Research Paper 62, 2015, p. 13.

⁸² C.M. Correa, *Guidelines for the examination of pharmaceutical patents: developing a public health perspective*, op. cit., p. 26.

⁸³ Article 18.37(1) of the Trans-Pacific Partnership.

that patents are available for inventions claimed as at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product. A Party may limit those new processes to those that do not claim the use of the product as such.”

With this provision, second medical use patents become mandatory. In our view, it is not really surprising, nor is it absolutely innovative, as second medical uses were already patentable in most TPP countries.

In Singapore, Section 14(7) of the Singapore Patent Act states that: “in the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practiced on the human or animal body, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if the use of the substance or composition in any such method does not form part of the state of the art”. The Austrian Patent Law 1970 also explicitly allows the patenting of second medical uses⁸⁴.

In Canada, patents for second medical uses have been granted even if there is no explicit provision in the patent law. In a decision of 2002, the Supreme Court of Canada validated a patent for the compound azidothymidine (AZT) for its use in the treatment of the VIH⁸⁵. The AZT was already known and had been tested in 1964 for the treatment of cancer. But the second medical use found for the AZT was patented⁸⁶. The United States and the New Zealand allow second medical use patents as well as patents on method of medical treatment.

Japan explicitly recognizes second medical use patents. The Guidelines provide that: “Even if the compounds etc. of the claimed medicinal invention do not differ from the compounds etc. of the cited invention, the novelty of the claimed medicinal invention is not denied when the claimed medicinal invention and the cited invention differ in medicinal use of applying to a specific disease based on the attribute of such compounds etc.”⁸⁷. Finally, the Patents Order 2011 of Brunei provides in Article 14 (7) that “the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken

⁸⁴ Paragraph 3, Section 3 of the Austrian Patent Law 1970.

⁸⁵ Apotex Inc. c. Wellcome Foundation Ltd., [2002] 4 R.C.S. 153, 2002 CSC 77.

⁸⁶ Ibid., at. 10.

⁸⁷ Japan Patent Office, Examination Guidelines for Patent and Utility Model, Part VII, Chapter 3 “Medicinal Inventions”, at. 2.2.2. (3-2-1), available at: https://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/Guidelines/7_3.pdf (20 August 2016).

to be new if the use of the substance or composition in any such method does not form part of the state of the art”⁸⁸.

We therefore see that all developed countries that have signed the TPP already allow second medical uses, whether explicitly sanctioned in the law or resulting from the court’s practice. The impact of the TPP on those countries could be that they will not be able to refuse to grant such patents from once the agreement enters into force, if they decided to change their law or practice. On the other hand, the impact on developing countries is quite of another kind.

2. The impact of the TPP on developing countries

Some developing countries also allow patents on second medical uses. This is the case of Mexico, even if second use patents are not expressly allowed in the Industrial Property Law. Methods of medical treatment are excluded in Mexico, but claims with a Swiss-type format or the actual EPC format are accepted⁸⁹. Chile also allows patents for second medical uses, if the use resolves a technical problem that had no solution before and if the new use is compliant with the patentability criteria⁹⁰. The Patent Act of Malaysia is very close to the EPC, and in particular article Section 14 (4) which allows patents on already known substances for use in a method of treatment⁹¹.

On the contrary, Vietnam has no rule on second medical uses and excludes discoveries and method of medical treatment from patentability⁹². It can therefore be considered that patents for second medical uses are not available in Vietnam. Finally, in Peru, second medical uses are explicitly excluded from patentability. This rule stems from Decision 486 of the Andean Community which we will address in later on in this study.

We would like to emphasize that the situation of Peru is absolutely schizophrenic. Indeed, how can a country sign an Agreement that obliges it to allow patents on second medical uses, and at the same time be part of a Community which expressly prohibits such patents? There is no statutory solution to this contradictory situation. At some stage, Peru will necessarily violate one of these agreements. If the patent office in Peru (INDECOPI) refuses to grant a patent on a

⁸⁸ Available at: http://www.wipo.int/wipolex/en/text.jsp?file_id=253996 (20 August 2016).

⁸⁹ H. Lindner, *Second medical use or indications claim*, AIPPI Report Mexico, 23 May 2014, p. 3.

⁹⁰ Article 37 e) Ley de Propiedad Industrial n°19.039, adopted on 9 March 2006, last revised on 6 February 2012.

⁹¹ Malaysian Patents Act, adopted in 1983, last revised on 29 June 2006.

⁹² Article 59 Vietnam Law on intellectual property No. 50/2005/QH11, adopted on 29 November 2005, last amended on 19 June 2009.

second medical use, the inventor will most probably file a complaint against Peru and a panel will settle the case according to the dispute settlement provisions of the TPP⁹³.

On the other hand, if it allows second use patents, it will have to face the Andean Community and will most probably have to go to the Andean Tribunal like in 1999 when Peru was sentenced for having allowed a patent on “Pyrazolopyrimidinones for the Treatment of Impotence”, a second medical use patent filed by the company Pfizer. Therefore, the only way out will be to withdraw from one of the two treaties. In the case of a withdrawal from the Andean Community, it will probably have severe consequences on the future of the Union which is already in a weak position, as there are only four countries still part of it. The withdrawal from the TPP provided at Article 30.6, would probably have harsh economic consequences on the country, and we believe that the country will not be in a favorable position to do so. Time will tell how this complicated issue can be settled.

The last thing we would like to point out is that the TPP still provides for the possibility of excluding methods of medical treatment⁹⁴. If some countries choose to do so, it might lead to some contradictory judgments, above all if claims relating to second medical uses are formulating in the form of a process claim or use claim, which can be held as a claim related to a method of treatment. Thus, the claim could be rejected as being a method of medical treatment, but at the same time it will have be allowed as second medical use patents are mandatory. It is likely that national courts will have to deal with this tension.

We have seen that international and regional agreements can have a significant impact on national patent laws and national practices regarding second medical uses. Some treaties like the TRIPS Agreement leave some flexibilities to countries to enact a patent law that will serve national interests. Others like the TPP impose very high standards of patentability, leading to so-called “TRIPS-plus” and “TRIPS-extra” provisions. TRIPS-plus are provisions that go further than TRIPS, by imposing higher standards. TRIPS-extra are of another kind, they are provisions that did not exist in TRIPS, and that are “created”. This is the case of second medical uses, that were not to be found in the TRIPS Agreement and that are now explicitly imposed in the TPP. In a second section, we will focus on two interesting systems which do still not allow second medical use patents based on different legal grounds.

⁹³ See Chapter 28 of the TPP.

⁹⁴ Article 18.37(3)(a) of the TPP.

Section 2: The opposition of developing countries and the role of the courts

Since the TRIPS Agreement entered into force, the 162 WTO Members must make patents available for all products and processes in all fields of technology. We have seen that this forces countries to protect pharmaceutical products, but not necessarily second medical uses, because of the use of the flexibilities of the Agreement. This new obligation had a major impact on developing countries, as it would shift in time the development of generic drugs. Indeed, if a patent is granted for a drug, the generic industry will have to wait until the expiry of the patent in order to produce its generic version.

India, which was and still remains one of the biggest producer of generic drugs in the world, has been trying to make full use of the flexibilities of the TRIPS Agreement in order to avoid patents on incremental changes and second medical use patents. We will see why Section 3(d) of its patent act has been particularly disputed in this regard (I). Another part of the world which has been fighting against the imperialism of big pharmaceutical companies and developed countries is Latin America. We will see how the Andean Community in particular has been dealing with the issue of second medical uses (II).

I. India and the controversy around Section 3(d) of the Indian Patents Act

The Indian Patents Act is one of the few patent laws that explicitly refuses second medical use patents. Second medical uses are not considered inventions. Section 3(d) provides that:

“The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant”.

This provision is quite straightforward and has been largely disputed, in particular by the pharmaceutical industry. The Novartis case is a good example of the disputes around Section 3(d). But before looking into this case, it is interesting to see that the Patents Act gives an explanation below Section 3(d) of what should be considered to be “the same substance”. These are: salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance, which “shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy”. This explanation was introduced by the amendment of the Patent Act in 2005 and the aim was clearly to avoid “evergreening”. It is a very useful tool for examiners who review

patent applications in India, as it will allow them to reject patents that claim a change in one of these compounds, as if it was exactly the same compound that was claimed⁹⁵. Any claim made toward the enhanced medical efficacy of a new salt will have to be proved by clinical data. While this seems to be a good means to achieve a balanced patent system, it has to be said that providing such clinical data is sometimes hard if not impossible at the stage of filing a patent, because the industries often file patents even before knowing whether or not their invention will “work”. To make such a system more adapted to the reality of patents, clinical data should be allowed to be given after the filing of the patent. I close this parenthesis and would like to turn now to the Novartis case.

1. The Novartis case and the challenge of Section 3(d)

First of all, it is important to understand the context of the case. In 2005, India was supposed to be fully compliant with the TRIPS Agreement, as the transition period had expired. It was in order to achieve this full compliance that India amended its patent law. It is also important to recall that India is one of the biggest generic producer worldwide and therefore, it is in the interest of its industry to restrain the grant of patents, above all on substances that are already comprised in the public domain.

This is the reason why Section 3(d) was drafted in a narrow way. Novartis AG and the pharmaceutical industry more generally were not satisfied with this new provision and the first filed a complaint against the Union of India in 2006, because it considered that Section 3(d) as amended in 2005 was not compliant with Article 27 TRIPS. It argued that the requirement of “enhanced efficacy” and the grant of patent only in the cases where new compounds are claimed was contravening Article 27. On 6 August 2007, the High Court of Madras rejected Novartis’ complaint but it did not enter into the merits of the compliance of the Section with the TRIPS Agreement because it considered not to have jurisdiction on the issue. It held that: *“Since we have held that this court has no jurisdiction to decide the validity of the amended section, being in violation of Article 27 of “TRIPS”, we are not going into the question whether any individual is conferred with an enforceable right under “TRIPS” or not. For the same reason, we also hold that we are not deciding issue No. (b) namely, whether the amended section is compatible with Article 27 of “TRIPS” or not”*⁹⁶.

⁹⁵ C.M. Correa, *Guidelines for the examination of pharmaceutical patents: developing a public health perspective.*, op. cit., p. 1

⁹⁶ Madras High Court, *Novartis AG vs Union of India*, 6 August 2007, W.P.24759/06, at. 8.

Contrary to the High Court of Madras, we would like to address the question of whether the prohibition of second medical use patents is a violation of Article 27 of the TRIPS Agreement.

2. *The exclusion of second medical use patents and its compliance with Article 27 TRIPS*

We have said before that the Agreement does not mention second uses and therefore, countries are free to choose whether to exclude them or not from patentability. But this is exactly what was disputed by Novartis in this case. Some arguments have been brought to show that the prohibition is contrary to Article 27. First, it has been said that the TRIPS Agreement mandates a form of harmonization and that second medical uses could not be excluded in some countries and accepted in others, therefore they had to be allowed to follow international trend on the issue⁹⁷. In our view, this argument is wrong. The TRIPS Agreement imposes some minimum standards to be followed, but does not oblige all WTO countries to have the same patent law. Therefore any country should be able to use the flexibilities of Article 27 to exclude second medical use patents.

It has also been argued that excluding new uses was equivalent to a discrimination as to the field of technology⁹⁸. This is also a matter of interpretation and in our view, second medical uses are not a “field of technology” in itself, they are a very specific area in the field of pharmaceutical patents. Even if they were considered to be a field of technology, we believe that Section 3(d) does not create any discrimination but rather imposes a “differential treatment”. The Panel of the WTO has differentiated between the concepts of discrimination and differential treatment. In *Canada – Pharmaceutical products*, the Panel stated that the concept of discrimination extends beyond the concept of differential treatments⁹⁹, therefore not all differential treatment is equivalent to a discrimination¹⁰⁰. Hence, the exclusion of second medical uses from patentability should be regarded as imposing a differential treatment between patents on the pharmaceutical compound and claims on the uses of this compound, and is therefore compliant with Article 27 of the TRIPS Agreement.

Finally, it could be argued that Section 3(d) is necessary to protect public health, and therefore allowed by Article 27(2). Indeed, the absence of patent protection might sometimes

⁹⁷ A. Arcuri & R. Castro, “How innovative is innovative enough? Reflections on the interpretation of Article 27 TRIPS from Novartis vs. Union of India”, *SIEL*, Working Paper n°52/08, 2008, p. 7.

⁹⁸ *Ibid.*, p. 14.

⁹⁹ Panel Report, *Canada — Patent Protection of Pharmaceutical Products*, 17 March 2000, at. 7.94.

¹⁰⁰ *Ibid.*, at. 7.100.

be beneficial to the pharmaceutical industry. In the case of India, it was proven that the lack of patent protection for pharmaceuticals enabled the country to develop a very strong generic industry. Before the entry into force of the TRIPS Agreement, India had become the “pharmacy of the developing world”¹⁰¹ by being able to produce generic versions of drugs. Therefore, a parallel could be made between the former absence of patent protection and the exclusion on second medical use patents today. If these patents are still excluded, India will be able to produce generic versions of drugs that have fallen into the public domain, and therefore proposing much cheaper drug to populations that cannot afford the patented pharmaceutical. To really demonstrate this point, some empirical and economic studies would be necessary¹⁰². We will address these particular public health issues in the second Part of this work.

The example of India is interesting to see how developing countries can draft their patent laws in order to avoid second medical use patents. But it must be said that the Section 3(d) is still very much disputed and it is not excluded that some countries will file a complaint against India before the Dispute Settlement Body of the WTO. Some Latin American countries have experienced this before their own tribunal, in particular under the pressure of Pfizer. Let’s see how the countries and the Andean Tribunal of Justice have dealt with the question of second medical use patents.

II. The practice of the Andean Community and the Andean Tribunal of Justice

The patent system in the Andean Community is built by so-called “Decisions”, which are supranational laws, interpreted by the Andean Tribunal of Justice and national courts. The Community is trying to achieve a balanced system to limit the rights of private patent owners and expand access to health¹⁰³. But the most interesting feature in the Andean System is that the courts along with the administration have always tried to rebuff the attempts of the United States and other developed countries to extend the patentability scope and in particular the scope of second medical uses¹⁰⁴. When building the Andean patent law, the drafters made full use of

¹⁰¹ S. Descheemaeker, “India, Pharmacy of the Developing World IP, Trade and the Access to Medicine”, *Jura Falconis Jg.*, Vol. 49, No. 3, 2013, available at <https://www.law.kuleuven.be/jura/art/49n3/descheemaeker.pdf> (20 August 2016).

¹⁰² A. Arcuri & R. Castro, “How innovative is innovative enough? Reflections on the interpretation of Article 27 TRIPS from Novartis vs. Union of India”, *loc. cit.*, p. 13.

¹⁰³ R. Dreyfuss & C. Rodríguez-Garavito, *Balancing Wealth and Health The Battle over Intellectual Property and Access to Medicines in Latin America*, Law and Global Governance Oxford University Press, First edition, 2014, p. 248.

¹⁰⁴ L.R. Helfer & K.J. Alter, “The Influence of the Andean Intellectual Property Regime on Access to Medicines in Latin America”, 2011, in: R. Dreyfuss & C. Rodríguez-Garavito, *Balancing Wealth and Health The Battle over Intellectual Property and Access to Medicines in Latin America*, *op. cit.* Available at SSRN: <http://ssrn.com/abstract=1917608> (20 August 2016).

the TRIPS flexibilities to avoid second medical use patents. Article 21 of the Decision 486 provides that no patent shall be granted for product or processes comprised in the state of the art, for the mere reason that a new use has been discovered¹⁰⁵. But the United States and the pharmaceutical industry has pressured Latin American countries to allow these patents. The result is that some countries like Peru enter into FTAs with the United States, agreeing to provisions that are in violation of the Andean Law, as we have seen with the TPP.

But even without entering into FTAs, the pharmaceutical industry has directly pressured the governments to obtain second medical use patents, forcing countries to change their legislation or just grant patents in violation of their patent law. This was the case with the “Viagra” patent, where the company Pfizer Research & Development Company (Pfizer) filed a patent in 1994 in Ecuador, titled “Pyrazolopyrimidinones for the Treatment of Impotence”. The patent office granted the patent on 19 September 1996¹⁰⁶. But Pfizer had already been granted a patent in the United Kingdom and the European Patent Office for the substance Sildenafil Citrate to treat cardiovascular diseases. Yet it was the exact same substance that was patented in Ecuador, for the new use of treatment of male erectile dysfunction. This patent was therefore in violation of the Decision 344 of the Andean Community, which was in force at the time of the patent¹⁰⁷, and which expressly prohibited second use patents. The Secretary General of the Andean Community filed a complaint against Ecuador before the Andean Tribunal, which eventually issued a sentence against the government of Ecuador, according to which it had 90 days to nullify Pfizer’s patent¹⁰⁸.

A similar case took place in Peru, where the State went even further, taking a Decree expressly allowing second use patents¹⁰⁹, based on which the patent office granted a twenty-year monopoly to Pfizer for its invention “Pyrazolopyrimidinones for the Treatment of Impotence”¹¹⁰. The Andean Tribunal also condemned the government of Peru in 1999 for

¹⁰⁵ Article 21 of the Decision 486 states : “Los productos o procedimientos ya patentados, comprendidos en el estado de la técnica, [...], no serán objeto de nueva patente, por el simple hecho de atribuirse un uso distinto al originalmente comprendido por la patente inicial”.

¹⁰⁶ PI 96-99, No. 476.DPI.DP.

¹⁰⁷ Decision 486 came into force on 1st December 2000.

¹⁰⁸ E. Matos Jaqui, “Las patentes de segundo uso”, *Revista Judicial Derechoecuador.com*, 2008, available at : www.derechoecuador.com (20 August 2016).

¹⁰⁹ Decreto Supremo No. 010-97-ITINCI artículo 4: "Aclárase que de conformidad con el artículo 43 del Decreto Legislativo No. 823 un uso distinto al comprendido en el estado de la técnica será objeto de nueva patente si cumple con los requisitos establecidos en el artículo 22 del Decreto Legislativo No. 823".

¹¹⁰ Resolución No. 00050-1999/OIN-INDECOPI con fecha 29 de enero de 1999.

having issued a Decree that was violating Decision 344. It had 90 days to take the “necessary means” to comply with the Decision.

These cases well illustrate the position of the Andean Tribunal not to let the pharmaceutical industry (supported by developed countries) push for the grant of second medical use patents. But nowadays it seems that the trend is toward the acceptance of such patents, which are imposed to Latin American countries through FTAs.

The patentability of second medical uses is a disputed and unresolved issue. The doctrine as well as the courts have very divergent opinions on the topic, and we have seen that developed and developing countries have a different approach. While developed countries have accepted to patent second medical uses, applying a fiction of novelty, and low threshold for inventive step and industrial application, developing countries have argued that second uses are not inventions, but rather discoveries, and should be assimilated to methods of medical treatment that are excluded from patentability. With the entry into force of the TRIPS Agreement, many countries had to change their laws to allow patents on product and processes, imposing patents for pharmaceuticals. But the Agreement also provides for flexibilities that countries can use to exclude second medical use patents. Developed countries like the United States are trying to impose these patents to unwilling countries through FTAs, the last and most important one being the Trans-Pacific Partnership.

If second medical use patents might have a beneficial impact on innovation in developed countries, giving incentives to pharmaceutical industries to find new solutions for unmet needs, it surely has a different impact on developing countries. In particular, these patents granted for a substance that was already comprised in the state of the art will have the effect of extending the life of the patent, and therefore postpone the development of generic medicines. The final consequence is obvious: second medical use patents have a detrimental impact on access to medicines, especially in countries where the state support is weak. In the second part of this work, we would therefore like to address the public health issues arising from second medical use patents.

Part 2: The significance of second medical use patents in the light of public health

The general trend today is toward the increasing acceptance of second medical use patents on worldwide scale. International and regional agreements have introduced new obligations for countries especially in the field of pharmaceutical patents. The growing pressure of developed countries have forced developing countries to enter into free trade agreements that impose the grant of patents for second medical uses. Patents have an impact on competition, and second medical use patents might delay the entry on the market of generic drugs.

In a first chapter, we will see that the lack of production of cheap medicine affects the access to health in particular in developing countries. Some alternatives should be provided in countries where these patents would really affect public health, while legal and practical safeguards should be respected in countries where second medical use patents are available (Chapter 1). In the second chapter, we will address the infringement issues that arise from second medical use patents and their implications for access to health. Indeed, the threat of litigation often dissuades generic companies to develop generic versions of important medicines which leads to the absence of competition and high prices imposed by pharmaceutical companies. For this reason, it is necessary to address this issue in order to propose some safeguards to avoid excessive litigation and implement some necessary exemptions (Chapter 2).

Chapter 1: Second medical use patents: a barrier to access to health?

Patents are supposed to give an incentive to research and development. This is the commonly accepted justification for the patent system. This assertion is made in very general terms, and therefore the conclusion is that patents are beneficial to all countries around the world, regardless to their level of development. Patents are supposed to provide the same stimulus to innovation in India or Latin America as in Europe or in the United States. Well, it must be said that patents do not have the same impact in developed and developing countries¹¹¹. While in developed countries, patents might have such an impact, it might not be the case in developing countries, due to the fact that the level of development is not the same. This means

¹¹¹ C.M. Correa, *A guide to pharmaceutical patents*, op. cit., p. xiii.

that developing countries do not necessarily have a strong pharmaceutical industry and the technology necessary to develop new drugs. Therefore, patents might have a rather negative impact on these countries.

Can we extend this reasoning to second medical use patents? We have seen that they should be considered as full-fledged patents, but does this mean that second medical use patents have the same impact on countries as other patents? Indeed, there are some particularities in second medical use patents that allow us to say that the impact is not the same, and therefore a special analysis of the consequences of these patents has to be made. The implications can be seen at different levels. In a first section, we will see that second medical use patents might unduly raise the price of already existing drugs. Furthermore, they might delay generic competition, and therefore the access to more affordable drug (Section 1). In a second section, we will see that some safeguards are thus necessary to promote access to health (Section 2).

Section 1: The impact of second medical use patents on access to medicines

While the TPP was being negotiated, the foundation Ifarma – Alianza LAC published a study on the impact of the intellectual property chapter of the agreement on access to medicines in Chile, Peru and Colombia. In particular, the study focused on the costs of implementing a section on second use patents. It found that patenting new uses or dosage would have an impact of almost 33 million dollars per year in Peru, 34 million dollars in Chile and 18 million in Colombia¹¹². Therefore, it seems that allowing second medical use patents necessarily impacts the price of medicines by avoiding generic competition (I), which has a particularly adverse impact on developing countries (II).

I. Raising the price of known drugs by delaying generic competition

When an entity has a monopoly on a particular market, it will be able to impose the price it wants to get for its product, and because there is no competition, there is no incentive to lower this price. Therefore, when a pharmaceutical company has a patent on a particular drug, it will be able to impose a high price for it. Thus, only who can afford such drug will have access to it. In some countries, patients do not pay the price directly, but through the State, insurances and health care. Therefore, only people living in countries where there is a strong support of

¹¹² Fundacion Ifarma – Alianza LAC, El impacto del TPP en el acceso a los medicamentos en Chile, Peru y Colombia, Lima, 13 May 2013, available at: <http://web.ifarma.org/> (20 August 2016).

the State and people who can afford private insurances will be able to have access to these medicines. This very general framework can be applied in the same way to second medical use patents, even if there are some special issues that we have to point out.

A patent gives a twenty-year monopoly, and sometimes even more, for a socially valuable innovation. This is the theoretical concept underlying the patent system. But in the case of second medical use patents, the invention does not lie in a new molecule or a new combination or dosage for a known form, but rather in the mere new use of an existing compound. This is why it is arguable to give a twenty-year monopoly to the inventor (which in most cases is rather a discoverer), as the investment in research and development to reach such a result is lower than the investment made to discover new molecules, and is sometimes even null, when the second use is discovered by doctors in the course of clinical trials.

It is interesting to go into the analysis of the consequences of granting a patent on a second medical use. What happens in practice? A pharmaceutical company is given a monopoly on a use, but in most countries methods of medical treatment are not patentable. Therefore, the patent is granted for the substance in relation to its special use. While the initial patent for the molecule might have expired, further patents related to the use of this molecule might be in force. The consequences of such a situation on the generic industry is clear: while in the first case, it was free to develop a generic version of the drug for any use in order to sell it for a much lower price in countries where these drugs are needed, in the case where a second medical use patent is in force, it will not be able to do so, or at least it will have to select the uses for which it can sell the generic drug, which might be very complicated in practice and lead the generic industry to focus on other drugs.

The direct consequences of that is that the new patented uses will be protected for at least twenty years, during which the pharmaceutical company will have a monopoly on the uses for the substance that is in the public domain and should be available to anyone to exploit. It is widely accepted that a company in such a dominant position will raise prices, and therefore the price of the drug can sometimes be a thousand times higher than a generic version. For another twenty years, a company will be able to charge a very high price for an invention that did not require the investment that would justify such a privilege.

Economists qualify this situation as leading to both static and dynamic inefficiency. Indeed, patents often result in “the inefficient allocation of valuable resources at a given point in time” (static inefficiency) because of the lack of competition and the high prices charged to

patients because of that¹¹³. But they are supposed to provide for dynamic efficiency in the sense that they incentivize the development of new products. In the case of second medical use patents, the balance is not equilibrated: the monopoly revenues will be very high as the investment made was low, but the social benefit will not be raised and the costs of medicines will be still be high. Therefore, static efficiency is reduced. As to the dynamic efficiency, it is also questionable as over a longer period of time, the second medical use patent does not stimulate more innovation, and no new product is introduced, but only an information is disclosed as to the characteristics of the known product.

This analysis allows us to put into question the legitimacy of second medical use patents from an economical point of view. The consequence is that the competition is limited on the market and that the prices are raised. In developed countries, health insurances and social security systems are able to afford the high prices imposed by the pharmaceutical companies, therefore the impact on access to health is reduced. But in developing countries or countries which do not have such a state support, the high prices impede the population to afford the drugs. Such a situation is not acceptable in a case such as second medical use patents, as the balance that we have described before is not respected. We believe that the innovation should be rewarded by other means than a twenty-year monopoly, topic that we will address in the next part.

Finally, it can be concluded that second medical use patents delay the commercialization of generic pharmaceuticals¹¹⁴. When a generic company wants to launch a new drug, it will have to obtain a marketing authorization just like any other pharmaceutical company. But the generic company can take advantage from the data of the first drug after expiry of the exclusivity term if there is one. Therefore, generic companies save some time and money as they do not have to do all the pre-clinical and clinical tests to prove that the drug is safe. Now, if a patent for a certain compound has expired, but a second medical use is still under patent protection, the generic company will have to exclude explicitly the second medical use from the marketing authorization application. The generic drug will therefore be authorized for a smaller range of uses. Hence, even if a second medical use is still under patent protection, the generic industry will be able to launch a generic drug for the uses that have fallen in the public

¹¹³ K. & C. Leffler, "Efficiency Trade-Offs In Patent Litigation Settlements? Analysis Gone Astray", *University of San Fransisco Law Review*, Vol. 39, 2004, p. 1.

¹¹⁴ S. Ünlü & G. Göksu, "Second medical use patents and the skinny label issue", *Managing Intellectual Property*, 2016, available at: <http://www.managingip.com/Article/3532019/Second-medical-use-patents-and-the-skinny-label-issue.html> (20 August 2016).

domain. Following this reasoning, it is true that the commercialization of generic drugs is delayed but only regarding the second use. Still, the direct consequence will be the raise of prices because of the monopoly. The circle is completed.

It must be said that the impact on access to health differs from country to country, and especially between countries with different levels of development. We have seen that in developed countries, health care is funded by the state or insurances. Therefore, the impact of high prices might not be felt at the level of the patient, and second medical use patents might raise some issues but within the circles of funding organisms. On the contrary, in countries where such health care does not exist or is not as efficient as in developed countries, high prices have a direct impact on the population, who must pay for its medicines itself. The issues raised by second medical use patents are therefore specific in developing countries.

II. The adverse impact of second medical use patents in developing countries

Nowadays, the generic production of many essential medicines is possible as the great majority of essential drugs is in the public domain¹¹⁵. But this is not true with new medicines, and in particular second medical use patents, which impede the production of generic medicines.

It has been argued that second medical use patents are often used to extend the monopoly on the drug and to prevent generic competition¹¹⁶. We have seen that this might have a different impact on developed and developing countries, because of their level of resources and the health care financing. The adverse impact of second medical use patents on access to health has led many commentators to argue that developing countries should not allow patents for new uses of known products¹¹⁷.

Let's take a concrete example of the impact of the allowance of second medical use patents in a developing country. When assessing the situation of Latin America, we addressed the Pfizer case. The company pressured Peru and Ecuador which eventually validated its second medical use patent for Viagra. After it was granted its monopoly, Pfizer threatened to sue Peruvian firms that were manufacturing generic versions of Viagra¹¹⁸. The consequences on

¹¹⁵ Anonymous, "Access to Medicines Intellectual Property protection: impact on public health", WHO Drug Information, Vol. 19, No. 3., 2005, p. 238.

¹¹⁶ S.F. Musungu & C. Oh, "The use of flexibilities in TRIPS by developing countries: can they promote access to medicines?", *South Center*, CIPIH Study Paper 4C, 2005, p. 36.

¹¹⁷ Ibid.

¹¹⁸ R. Dreyfuss & C. Rodríguez-Garavito, *Balancing Wealth and Health The Battle over Intellectual Property and Access to Medicines in Latin America*, op. cit., p. 252.

access to medicines are obvious: the generic companies would stop manufacturing cheap versions of the drug, and the price for Viagra would raise significantly, preventing most of the population from benefiting from it. Hopefully, in the case of Peru and other countries from the Andean Community, trade association of generic drug firms filed a complaint with the Andean General Secretariat¹¹⁹. Eventually the countries that accepted second medical use patents were sanctioned, and Pfizer's patent was revoked.

The situation will certainly change with the entry into force of the TPP and other free trade agreements imposing second medical use patents. The direct consequence will be that generic competition will be prohibited on drugs that had already fallen into the public domain. In theory, the companies could continue manufacturing and selling the drug for the non-patented uses, but in practice, we believe that the generic company will just stop manufacturing the drug because of the threat of litigation. Indeed, we will see in the next part how complex infringement issues might arise with second medical use patents, and this will necessarily affect the access to medicines in developing countries like in Latin America.

Carlos Correa stated that second use patents, if granted, “may block the commercialization of products that would otherwise be in the public domain”¹²⁰. Second medical use patents are based on substances that are already comprised in the state of the art. Therefore, after the expiry of the first patent, the substance should be free for everybody to exploit. Generic companies can manufacture the drug and sell it for a much lower price. The problem arising with second medical use patents is that generic companies will be limited when manufacturing a drug: they will only be allowed to manufacture the drug for the first use that is in the public domain, but will be obliged to exclude the second patented uses.

We would like to conclude this section with an interesting quote from Carlos Correa:

“The identification of new uses of known products may be more accessible than the development of completely new products in countries with limited scientific and technological resources. This is, hence, an option that developing countries may consider. It should be noted, however, that due to the national treatment principle, a broadening of the scope of patentability would benefit national as well as foreign investors, and that the latter would generally be better equipped than the former to take advantage of a broad concept of novelty”¹²¹.

¹¹⁹ Ibid.

¹²⁰ C.M. Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options*, Zed Books & Third World Network, 2002, p. 56.

¹²¹ Ibid. p. 60.

Therefore, as a general conclusion, we consider that developing countries should avoid second medical use patents. We believe that various alternatives are possible to promote innovation without allowing these patents.

Section 2: Necessary safeguards to promote access to health

As a forward, we would like to point out the fact that the patent system is not unanimously approved. Some have argued that patents are not even necessary to give incentives to innovate. The example that has been given is the one of India that succeeded in developing a strong pharmaceutical industry without the incentives of the patent system. Therefore, the following question must be raised: are patents really necessary to promote new solutions? The patent system is obviously not as efficient as it should be or is supposed to be, because it does not give sufficient incentive to pharmaceutical industries to develop new drugs for curing neglected disease and orphan drugs for instance. And this is just because “the market is too small or commercially unattractive”¹²². Thus, we understand that the patent system is a business that is sometime far from health considerations. Some alternative models like a pro-competition system have been proposed, which we consider should be applied in developing countries (I). In the alternative, in countries where second medical use patents are already patentable, some legal and practical safeguards should be applied in order to achieve a balanced system (II).

I. Foster a pro-competition system as an alternative to second medical use patents in developing countries

Ten million people die every year because of inadequate access to health¹²³. Various factors can explain this sad record. As we have seen, health care systems are not efficient or underfunded in many developing countries, leading to patients bearing the price of the medicine they need. A reduction of the price of drugs could lead to a greater availability¹²⁴.

One possible way for a country to reduce the price of drugs is to develop a strong generic industry, or at least have access to generic medicine which is generally many times cheaper than the brand-name drug. This has been possible in countries like Brazil or India because these countries did not allow patents on pharmaceutical in a first instance. With the entry into force

¹²² Anonymous, “Access to Medicines Intellectual Property protection: impact on public health”, loc. cit., p. 237.

¹²³ T. Amin, T. Rajkumar, P. Radhakrishnan & A.S. Kesselheim, “Expert review of drug patent applications: improving health in the developing world”, *Health Affairs*, Web exclusive, 2009, p. 1, available at: <http://www.healthaffairs.org/> (20 August 2016).

¹²⁴ Ibid.

of the TRIPS Agreement, all WTO Members had to change their patent law to allow pharmaceutical patents, but they are still able to use the flexibilities offered by the Agreement to avoid second medical use patents. Instead of arguing for the abolition of the patent system, which we do not think would lead to positive results, we support a pro-competition system in developing countries regarding second medical uses only. Some other kind of rewards could still be provided, like international or national prizes or publications in scientific reviews.

A pro-competition system refers to a system where instead of granting monopolies to one entity during a period of time, the companies are competing on the market and every entity is free to manufacture and sell its products. The direct consequence of such a system is the decline in prices because of the competition. When compounds fall into the public domain, and a second use is discovered and patented in a developed country, developing countries like India or Brazil should be able to use this knowledge in order to provide for cheap medicine for the new use. The drug being the same as the one for the first medical use, the generic companies would be able to offer a cheap drug in countries where such drugs are needed and therefore increase access to health.

Economic studies have shown that granting patents on insufficiently innovative products can lead to substantial costs. In the United States, around one billion dollars could have been saved between 2000 and 2004 if only three patents that were considered not to be sufficiently innovative had not been granted¹²⁵. In rich countries like the United States or other developed countries, patients might not suffer from such high prices because they often do not pay for their health expenses themselves. Patents that extend the market monopoly like second medical use patents will have an important impact of health care insurances or the state, but the patients might have access to the patented medicine anyway. On the contrary, in most developing countries, this situation might have disastrous effects on access to health, the people not being able to afford for the patented medicine. This is the reason why a pro-competition system regarding second medical use patents is desirable. Let us recall that we do not argue for the abolition of the patent system in general, but that we argue in favor of competition in the case of second medical uses.

¹²⁵ A.S. Kesselheim, M.A. Fischer & J. Avorn, “Extensions Of Intellectual Property Rights And Delayed Adoption Of Generic Drugs: Effects On Medicaid Spending”, *Health Affairs*, Vol. 25, No. 6, 2006, pp. 1637-1647, p. 1637, available at: <http://content.healthaffairs.org/content/25/6/1637> (20 August 2016).

Finally, in countries where second medical use patents are preserved to give an incentive to pharmaceutical companies to develop new solutions to unmet medical needs, they should be carefully examined and various safeguards should be applied in order to establish a balanced system.

II. Achieving a balanced system in countries allowing second medical use patents

In a country where second medical uses are patentable, some legal safeguards should be applied in order to maintain a balanced system. These safeguards can be applied at different stages. First, at the time of reviewing the patent application, strict patentability standards should be applied to ensure that the second medical use is novel and involves an inventive step¹²⁶. The questions of industrial applicability and exclusion of methods of medical treatment must be addressed ahead, not by judge, but by the law-maker. In other words, if the law explicitly allows second medical use patents, we do not think that judges will have the power to reject a second medical use patent on the grounds of industrial applicability or the exclusion of methods. Therefore, if these use patents are explicitly allowed by the law, the judge will have to determine whether or not the new use is actually new, and involves an inventive step, according to what we have seen in the first part. It is worth noting that in many instances, second medical use patents are rejected on the ground that they lack inventive step, sufficient description or novelty¹²⁷.

Another safeguard would be to facilitate nullity actions after the patent has been granted, to allow generic company or anyone interested to bring a lawsuit to obtain the nullity of the patent. This could be applied more generally to all patents, but we believe that some special rules should be enacted for second medical use patents, as they are often used to achieve an unlawful extension of the monopoly on a substance.

French authors had proposed several solutions even before second medical uses were actually patentable in France. Professor Lemay suggested to admit second medical use patents but as “dependent patent”, as the original patent has a limited duration¹²⁸. He also suggested to

¹²⁶ S.F. Musungu & C. Oh, “The use of flexibilities in TRIPS by developing countries: can they promote access to medicines?”, loc. cit., p. 34.

¹²⁷ A. Gallochat & T. Cuhe, *Second medical use or indications claim*, AIPPI Report France, 21 May 2014, p. 4.

¹²⁸ M. de Haas, op. cit., at. 484, citing R. Lemay, “Les médicaments, particularités du brevet”, *Dr. Social*, No. 1, 1971, p. 15.

allow patents on substances that had fallen within the public domain but with a system of compulsory licenses for the new uses discovered¹²⁹.

Finally, the main proposition that we would like to make in this work, is about the length of second medical use patents in countries where such patents are available. We have seen that these patents do not require as much investment as the research and development of new compounds. The investment made to obtain a drug for a second medical use is much lower than the investment made to discover a new drug based on a new compound, because the costs of medical trials and authorizations are lower. Therefore, we believe that the duration of the monopoly should also be lower. We must always recall the philosophy behind the grant of a patent: to reward the investment made to bring something valuable to society. Therefore, if the investment is on average too times less important than the investment made for finding a drug based on a new compound, then the monopoly should last ten years instead of twenty years. We agree that it can be complicated to implement such a proposition, also because it would create some form of discrimination against a particular category of patents, which is prohibited by international treaties. But instead of granting a patent, the reward could be some form of market exclusivity certificate, which would be distinct from “normal” patents.

This is why we believe that a good proposal to achieve an equitable system would be to grant a protection with a shorter term for second medical uses, as we have seen that they require less investment and would therefore deserve a shorter protection. We could for instance think of a protection of ten years, even if an optimal duration should be based on economic studies.

The acceptance of second medical use patents has a major impact on access to health, because of the lack of competition and high prices. The impact on access to medicines is particularly felt in developing countries where the state and health care insurances do not support patients and are not available like in developed countries. Therefore, it is necessary for these countries to enact patent laws that avoid such patents, and in countries where such patents are already available, they should be granted very carefully, applying strict patentability standard. If not, the patentees will be able to use their patents to block competition by initiating lawsuits. We would like to address the implications of infringement actions in a second Chapter.

¹²⁹ Ibid.

Chapter 2: Infringement issues arising from second medical use patents and their impact on public health

When a pharmaceutical company is granted a patent on a new use for a known substance, it will be entitled to sue other companies that would possibly infringe its patent. But the infringement issues arising from second medical uses are quite different from those arising in general patent law, and it is important to address these special issues to tackle excessive litigation.

In a preliminary part, we would like to address what we have called the relation between the first and the second use patent, that is, whether a patent on a compound encompasses all the known and unknown uses or only the uses disclosed in the patent application. Indeed, this will have a major impact on future infringement issues. Following this short introduction, we will try to identify the parties that can be possible infringers of a second medical use patent based on recent case law. We will see that the conditions for infringement are not straightforward and that these lawsuits can impact access to medicines (Section 1). We believe that some safeguards should be applied in countries where second medical use patents are granted, in order to avoid excessive litigation and promote generic competition, argument we will develop in a last section (Section 2).

Prolegomena - The relation between the first and the second medical use patent

Addressing the question of the relationship between what we call the first and the second use patent obliges us to come back to the fundamental question of whether a patent of a compound should encompass all the potential uses of that compound, or only the uses disclosed in the patent¹³⁰.

If a product patent claiming a specific compound and disclosing one or several uses is deemed to protect the compound only in relation to the uses claimed and disclosed, then further uses that had not been disclosed and were not obvious at the time of filing the patent are not encompassed by the patent. Therefore, anybody would be free to manufacture and sell the patented compound but for another use, if we agree that a patent is granted for a compound in relation to its uses. For Carlos Correa, this would amount to admit “use-bound product claims”,

¹³⁰ In this regard, see: C.M. Correa, *A Guide to Pharmaceutical Patents*, op. cit., pp. 132-137.

where product patents would grant an exclusivity for a product in relation to its specific use and not in absolute terms¹³¹. We believe that this option should be applied in countries where second medical use patents are available instead of admitting dependent patents.

Indeed, some authors have argued that the second patent will be dependent from the first one¹³². This would raise some license issue if the two patentee represent different companies. On the other hand, it will not be a problem if it is the same company that applies for the second medical use patent. For Carlos Correa, this option is also the best because it would allow competitors “to innovate around the product patent and research new uses”, even if third parties would be dependent from the first patent and thus could be reluctant to disclose new uses¹³³.

On the contrary, if a product patent includes all the known and unknown uses of the compound at the time of filing the patent, then competitors will have to wait that the compound falls into the public domain to be able to manufacture and sell it for any use. In the United States, new uses were originally excluded from patentability because they were considered to be comprised in the first patent. In a decision *Roberts v. Ryer* of 1875, the Supreme Court decided that an inventor was entitled to all uses of his invention, therefore excluding the patentability of new uses of known products¹³⁴. Carlos Correa points out that, in practice, a system where a patent encompasses all the uses of the pharmaceutical product “would allow a product patentee to extend its exclusivity beyond the date of the original patent, by subsequently patenting new uses for the product, while excluding others from being able independently to exploit the outcomes of research into new uses during the lifetime of the original patent”¹³⁵.

The difference between these two visions is quite significant and will have a major impact on infringement issues and access to health.

This question has been addressed in a decision of the Court of Appeal of Paris of June 11, 1991. M. Henri X had participated in the elaboration of a medicament based on the compound alfuzosin for the treatment of cardiovascular diseases. After he left the company, the latter was granted a patent on the same compound “alfuzosin” for the treatment of urinary impairment. M. Henri X sued the company to obtain a remuneration for the second patent. The Court of Appeal dismissed M. Henri X’s claims because it considered that the first patent was only

¹³¹ C.M. Correa, “Integrating public health concerns into patent legislation in developing countries”, South Center, 2000, p. 26.

¹³² J. Passa, *op. cit.*, at. 157.

¹³³ C.M. Correa, *A Guide to Pharmaceutical Patents*, *op. cit.*, p. 133.

¹³⁴ *Roberts v. Ryer*, 91 U.S. 150 (1875).

¹³⁵ C.M. Correa, *A Guide to Pharmaceutical Patents*, *op. cit.*, p. 133.

protecting the compound for the claimed use (cardiovascular diseases) and no other uses. It therefore admitted that a patent on a compound disclosing only some specific uses was only encompassing those uses. This decision has also be considered as a precedent admitting the patentability of second medical uses. But it has to be added that the French Supreme Court annulled the ruling based on articles 6 and 8 of the Law of January 2, 1968¹³⁶. The decision of the Cour de cassation has been interpreted by the doctrine in different ways. Some considered that the Court expressly rejected the possibility of patenting a second medical use¹³⁷. Others argued that the Court only made clear that a patent protects a compound for all its uses¹³⁸. We therefore see that the question of whether a patent should protect all known and unknown uses was not settled.

The position of the European Patent Office seems to be a mix of the two options we have seen before. Indeed, the approach of the EPO has been summed up as follows:

“Second indications of this kind are limited to the uses disclosed in the patent application. However, the patent on the product is an absolute product patent, covering all uses of the product. Effectively, the only person who can patent such a second indication under the European system would be the owner of the original product patent, although the possibility of cross-compulsory licensing exists (and article 31(1) of the TRIPS Agreement allows for it). If a third party were to research and discover such a use, they would be obligated to negotiate with original product patent holder”¹³⁹.

The point of view adopted by the EPO is absolutely contrary, in our view, to the very spirit of patent law. What the Office is suggesting is that a patentee that has a patent on a compound will be able to get new patents on new uses thus unduly expending the monopoly they have on the compound. We believe that a patentee should not have it both ways: if the patent encompasses all the potential uses of the compound, then the monopoly should expire after twenty years, and the compound should fall into the public domain for any use; if the patent does not encompass all uses, then the patent gives a monopoly for a compound in relation to the uses disclosed and anybody should be free to exploit the compound for other uses. The option adopted by the EPO suggesting that a patent gives a monopoly on the compound for any use and that third party are obliged to negotiate licenses to exploit the compound, but that the

¹³⁶ Cour de Cassation, Chambre commerciale, 26 octobre 1993, 91-17.944, Bulletin 1993 IV N° 354 p. 257.

¹³⁷ A. Gallochat & T. Cuche, *Second medical use or indications claim*, op. cit., p. 5.

¹³⁸ Ibid.

¹³⁹ C.M. Correa, *A Guide to Pharmaceutical Patents*, op. cit., pp. 136-137.

patentee can still get new patents for second medical uses is not logical and not consistent with patent law. But anyway, the practice is different and such patents are granted.

If we consider that second medical use patents are mostly filed by the same pharmaceutical company that already has a patent on the compound, then few infringement issues would arise. Third parties will not try to find new medical uses because they do not want to be dependent from the first patentee. If a patent is granted for the second medical use, the pharmaceutical company will be able to sue other parties for infringement.

We will not address the situation where a third party finds a new use for a patented compound and exploits it, because it would necessitate a much more sophisticated analysis of infringement and licensing issues¹⁴⁰. We choose to focus on the situation where a pharmaceutical company is doing research on its patented compound to find new uses for it. When a second medical use is found and patented, but the patent on the first medical expires, it can raise some infringement issues when the generic companies start to produce the generic version of the drug. We will address in a first section the possible infringers of a second medical use patents (Section 1), to see in a second section what kind of legal safeguards could be applied to avoid excessive litigation and ensure generic production (Section 2).

Section 1: From the manufacture to the dispensing of the drug: who infringes a second medical use patent?

Infringement issues arising with second medical use patents are different from those arising with “normal” patents. Let us explain this particularity. We are addressing here the specific case where a patent on a drug has expired, but a second medical use for this drug is still under patent protection.

In most patent laws, the exclusive right of the patentee is the right to exclude others from making, using, selling or importing the product where the subject matter of the patent is a product. For a process patent, the exclusive right consists in the right to prevent third parties to use the process and use, sell or import the product obtained thereof¹⁴¹.

The question we would like to answer in this section is who can be held to infringe a second medical use patent from the following four stakeholders: a generic company, a doctor,

¹⁴⁰ On this question, see M. Vivant, “La brevetabilité de la seconde application thérapeutique”, loc. cit., at. 9-10.

¹⁴¹ Article 28 TRIPS Agreement.

a pharmacist and a patient? If the liability of generic companies is predictable (I), it might seem absurd that the last three be considered to be infringers, but in practice, many countries believe that they can on the basis of direct or indirect infringement (II). Therefore, it is important to address this issue in order to prevent excesses.

I. The impact of second medical uses on the liability of generic companies

When a generic company wants to launch a generic drug, it has to wait until the patent on the drug has expired. Only then will it be able to seek a marketing authorization for its generic version of the drug. But what happens if the patent on the compound has expired but some further uses are still under patent protection? Well, in the application, the generic company will have to specify for which uses he wants to obtain a marketing authorization. If some uses are still under patent protection, it will have to exclude them from the Summary of Product Characteristics (SPC), the patient information leaflet (PIL) and the labelling. If it does not do so, the generic company could be liable for patent infringement and the patentee could exclude the generic company from manufacturing a generic version of the drug until all the patents around the original patent have expired¹⁴². This is not desirable regarding the spirit of patent law and access to health issues arising thereof.

In a recent case, the England and Wales Court of Appeal settled the scope of protection to be afforded to “new uses of known medicines” by determining the meaning in second medical use claims that the drug be used “for” a therapeutic indication¹⁴³. Warner-Lambert, a subsidiary of Pfizer, was marketing the drug Pregabalin under the trademark Lyrica for neuropathic pain, generalized anxiety disorder and epilepsy. Patent protection for the molecule expired in 2013, and the last two indications are not under patent protection anymore, while the treatment for pain still is. On the other hand, Actavis obtained a marketing authorization for its drug Lecaent which was considered to be bio-equivalent to Lyrica. It must be noted that the SPC and the PIL identified the drug to be suitable for the non-patented indications, but did not mention neuropathic pain¹⁴⁴.

Warner-Lambert asked Actavis about its intention with regard to the marketing authorization, and Actavis responded that they were launching a pregabalin product for the treatment of epilepsy and general anxiety disorders. Warner-Lambert asked Actavis what

¹⁴² P. England & K. Osgerby, “Carve-outs and skinny labelling”, *TaylorWessing*, 2013, available at: http://united-kingdom.taylorwessing.com/synapse/ti_skinnylabelling.html (20 August 2016).

¹⁴³ Warner-Lambert Company, LLC v Actavis Group Ptc EHF & Others [2015] EWCA Civ 556.

¹⁴⁴ This practice is sometimes referred to as “skinny labelling” or “carving out”.

measures they had put in place to ensure that drug would not be used for the treatment of pain. They responded that the PIL did not mention neuropathic pain and that they would inform superintendent pharmacists that their drug was not to be used to treat pain. For Warner-Lambert, this was not sufficient and they required that the packet of the drug explicitly stated that the generic drug was not authorized for the treatment of pain, and that every pharmacist be well informed. The defendant refused to change its packaging arguing that this was unnecessary and unprecedented. This finally led to Warner-Lambert suing Actavis for both direct and indirect infringement.

It must be noted that meanwhile, the Pharmaceutical Advisors Group emailed all Clinical Commissioning groups to inform that prescriptions for neuropathic pain should be written by brand. Following, the national pharmacy association informed superintendent pharmacists that pharmacists should contact the prescriber and make enquiries of patients if necessary.

One solution proposed by the judge was that of ensuring that each time pregabalin was dispensed for the treatment of pain, doctors would prescribe it only by reference to the brand name Lyrica¹⁴⁵. The Court of Appeal judge recalls that, according to Section 60(1) of the Patent Act 1977, an infringement takes place if the invention is made, disposed of, offered to dispose of, used or imported. The Section distinguishes between product and processes, and it was accepted that the Swiss form claim at issue was a process claim. The judge adds that the process at issue is the manufacture of Lecaent for the treatment of neuropathic pain¹⁴⁶. Therefore, Actavis is infringing the patent when it disposes of the product obtained directly by the means of that process.

Before the High Court, the judge Arnold J acknowledged that it was common ground that the word “for” was understood as “suitable for”, and further that pregabalin was “suitable for” the treatment of neuropathic pain¹⁴⁷. To determine whether there was infringement, the question to be answered was therefore “whose intention was relevant, and what was comprised in the requirement of intention”¹⁴⁸. For Warner-Lambert, it was sufficient that the defendant intended to sell pregabalin and knew that the pharmacist were likely to dispense the drug for the treatment of pain, if positive steps were not taken to prevent it. The defendant argued that this was not sufficient and that a subjective intention that Leacaent would be used to treat pain was required.

¹⁴⁵ Warner-Lambert Company, LLC v Actavis Group Ptc EHF & Others [2015] EWCA Civ 556, at. 42.

¹⁴⁶ Ibid., at. 45.

¹⁴⁷ Ibid., at. 99.

¹⁴⁸ Ibid.

The High Court judge accepted Actavis' argument and therefore rejected the claim of direct infringement, as no subjective intention on the part of the manufacturer could be alleged. It also rejected the claim of indirect infringement because it noted that nobody on the supply chain was "manufacturing" the drug for the said use, as it had already been manufactured by the defendant¹⁴⁹. It is worth noting that under an EPC 2000 claim, the judgement could have been different, as the claims are no longer written in the form of "use of a compound for the manufacture of a drug for the treatment of an indication".

Warner-Lambert appealed the decision of the High Court. On appeal, the judge Lloyd pointed that, if "use for" was understood as meaning suitable for, then a party which would manufacture the drug for non-patented uses would infringe anyway the second use patent because the generic drug is also suitable for the patented indication. This interpretation would give a scope which was far broader than the patentee's contribution to the art¹⁵⁰. Finally, the judge concludes that "an extreme view might be that if the drug is in fact used for the patented indication then it has been made "for" that indication, whatever the manufacturer's intention might be"¹⁵¹. Therefore, the judge concluded that the appropriate test is the "foreseeability that the drug will intentionally be used for the patented indication"¹⁵².

At the same time, it acknowledged that proving the wish or desire of Actavis that Lecaent be sold for treating pain is almost impossible, and adopting such a strict requirement would deprive second medical use claims from enforceability. Therefore, the judge states that the appropriate standard to be applied is that "the manufacturer who knows (and for this purpose constructive knowledge is enough) or could reasonably foresee that some of his drug will intentionally be used for pain is making use of the patentee's inventive contribution, in the same way as a manufacturer who actively desires that result"¹⁵³.

Justice Lloyd finally concluded that Warner-Lambert had an arguable case for direct as well as indirect infringement. But at full trial, Justice Arnold J found that there was no infringement. The judge applied the foreseeability test and found that a two-step reasoning had to be carried out: if only foreseeability is required on the part of the manufacturer, the claimant

¹⁴⁹ Ibid., at. 100.

¹⁵⁰ Ibid., at. 113.

¹⁵¹ Ibid., at. 122.

¹⁵² Ibid.

¹⁵³ Ibid., at. 127.

will still have to prove that there is intention to use the drug for the treatment of pain by the “users”, who are the doctor, the pharmacist and the patient¹⁵⁴.

Thus, he found that the doctor who prescribes the drug using the international nonproprietary name (INN) does not have the intention to prescribe the generic drug Lecaent for the treatment of pain¹⁵⁵. Likewise, if the drug is prescribed by its INN and the pharmacist does not know for which indication the drug was prescribed, the required intention will not be established¹⁵⁶. The only case where the required intention could be established is when the prescription mentions the INN or the brand name drug, and the pharmacist, knowing that it will be used to treat pain, delivers the generic drug¹⁵⁷. But for the judge, this scenario was de minimis. Finally, regarding the patient, Arnold J noted that generally, the patient takes the drug for the indication that the doctor prescribed it for¹⁵⁸. The patient does usually not have the medical knowledge about the efficacy of the drug and relied on the doctor and the pharmacist. Therefore, it concludes that the instances of infringement were de minimis and that Actavis did not infringe the patent¹⁵⁹.

It is worth noting that the court rejected a general injunction prohibiting the sale of the product, in order to achieve a balance of justice. Indeed, the Court had to achieve a balance between the interests of Warner-Lambert and Actavis. Warner-Lambert argued the competition taking place during the trial would force it to lower its price and that it would be impossible to raise the prices after the trial, therefore causing irreparable harm¹⁶⁰. On the other hand, Actavis stated that it had already taken significant step to ensure that its drug would not be used to treat pain and that further steps would be ineffective and cause Actavis irreparable harm¹⁶¹. Arnold J finally settled the case in favor of Actavis.

This case clearly ruled in favor of the generic company, but the judgement can still be appealed and even go to the Supreme Court. Therefore, there is no certainty that the ruling will not be reversed in the future. Furthermore, we have said that the claims at issue were written in the form of “Swiss-type claims”, which are different from the EPC 2000 claim. As we have

¹⁵⁴ Anonymous, “Warner-Lambert v Actavis – Do we have an effective system for enforcing second medical use patents in the UK?”, *JA Kemp*, 2015, available at: http://www.jakemp.com/uploads/files/pdfs/Pregabalin_02_10_15.pdf (20 August 2016).

¹⁵⁵ Ibid.

¹⁵⁶ Ibid.

¹⁵⁷ Ibid.

¹⁵⁸ Ibid.

¹⁵⁹ Ibid.

¹⁶⁰ Warner-Lambert Company, LLC v Actavis Group Ptc EHF & Others [2015] EWCA Civ 556, at. 143

¹⁶¹ Ibid., at. 144.

pointed out before, the ruling might have been different, and the parties downstream the generic manufacturer could be found to infringe the second medical use patent by “putting the invention into effect”. Let’s briefly address the situation of these parties.

II. The controversy around the liability of doctors, pharmacists and patients

Infringement issues concerning doctors, pharmacist and patients depend on the type of claim we are talking about. In the case of Swiss-type claims, that are considered to be process claims, the manufacture of the drug is comprised in the claims so as to ensure that the claim does not touch the doctor, the pharmacist or the patient, who do not manufacture the drug. But with the EPC 2000 claims, the step of manufacturing the drug has been removed so that the claims read: “use of the compound X in the treatment of Y”. In this case, a party that uses the compound X in the treatment of indication Y could be considered to be infringing the patent. But it might be difficult to prove that a party used the drug to actually cure the patented indication, because of confidentiality issues or just because the parties do not know for which indication the drug is prescribed.

Indeed, generally, when a physician prescribes a drug, the prescription does not mention for which indication the patient needs the drug. The physician indicates the name of the compound and only he and the patient will know for which use the drug is prescribed. If the physician explicitly prescribes the generic drug, without indicating the use, he is not infringing the patent. We understand that the only case where a doctor could possibly be infringing a patent is when he prescribes a generic drug for a patented use, which is unlikely to happen. In Austria, doctors might in theory be sued for patent infringement if it is proved that they have prescribed a generic drug for a patented use, but there has been no case law on this issue so far¹⁶². It could be argued that doctors are acting privately and are therefore exempted from patent infringement. But this is not the position of various developed countries like Austria¹⁶³.

Let’s turn now to the pharmacist. In most countries, he is free to substitute the branded drug by its generic version according to a substitution list. Some countries like Austria consider that, if the pharmacist knows for which use the drug is prescribed, and consciously substitutes the drug by its generic version, it could be held to infringe the second medical use patent¹⁶⁴.

¹⁶² M. Keschmann, *Second medical use or indication claim*, AIPPI Report Austria, 12 May 2014, p. 2.

¹⁶³ Ibid.

¹⁶⁴ Ibid.

Even if again some countries provide for exemptions for pharmacists, the issue has been addressed by the doctrine as well as some national courts.

In Canada, most provinces give full interchangeability listing for generic drugs. But in Ontario, generic drugs might be interchangeable for only some indications. Pharmacists are not liable if they interchange drugs according to this formulary. Section 8 of the Drug Interchangeability and Dispensing Fee Act reads:

“If an interchangeable product is dispensed in accordance with this Act, no action or other proceeding lies or shall be instituted against the person who issued the prescription, the dispenser or any person who is responsible in law for the acts of either of them on the grounds that an interchangeable product other than the one prescribed was dispensed”.

Pharmacists are thus protected from liability if they interchange drugs in accordance with the listing. But if they prescribe the drug for another use than the one mentioned in the interchangeability list than the shield of protection does not apply¹⁶⁵.

Finally, can a patient be held to infringe a second medical use patent? This question shows how far some countries have gone in the protection of the interests of the pharmaceutical industry. If the question has been raised by some authors, it is because the possibility has been considered, which is in our view exemplary of the excesses of patent law today. Fortunately, most countries exclude “private uses” from possible infringement, and a patient taking a drug falls within the scope of this exemption.

In Canada and in the USA, any of the four above mentioned parties may be liable for infringement of a second medical use patent. In Canada, doctors, pharmacists and patients are “rarely sued for infringement”¹⁶⁶. In the USA, only patients and physicians are rarely the target of a lawsuit, even if they can be sued in accordance with the US Patent law¹⁶⁷.

Regarding this situation, we believe that some safeguards should be applied in countries where second medical uses are patentable in order to achieve a balanced system.

¹⁶⁵ T. Scassa, *op. cit.*, p. 50.

¹⁶⁶ M. Zischka, *Second medical use or indication claims*, AIPPI Report Canada, 16 May 2014, p. 5.

¹⁶⁷ Dan Altman, *Second medical use or indication claims*, AIPPI Report United States, 21 May 2014, p. 3.

Section 2: Legal safeguards to avoid excessive litigation

In this last section, we would like to focus on two main issues which we believe should be correctly assessed in countries where second medical uses are patentable. The first one is the burden of proof (I), and the second the exemptions from patent infringement (II).

I. Requirements and burden of proof: who proves what in a second medical use case?

If we accept that in some cases the generic industry or any other actor might be held to infringe a second medical use patent, the question that needs to be answered is on who is the burden of proof. Does the patent owner have to prove that its patent was infringed, by demonstrating that the invention was used for the patented indication? Or is it on the alleged infringer to show that it did not use or intend to use the invention for the patented use?

Generally, patent law requires that the patent holder proves the infringement by all means. This is particularly true for product patents. But the burden of proof might sometimes be on the alleged infringer in the case of process patents. And we have seen that in some jurisdiction, second medical use patents are held to be process patents. In this case, some jurisdictions reverse the burden of proof and ask the alleged infringer to show that they have not used the patented process¹⁶⁸. This can be explained by the fact that it is almost impossible to prove that a particular process has been used to obtain a certain result, but the result might indicate that the patented process has been used. Therefore, the burden of proof is reversed to facilitate the proceedings.

In the case opposing Warner-Lambert and Actavis, we have seen that the court required the claimant to show that Actavis had used the invention knowing that the downstream users would have intentionally used Lecaent (the generic drug) to treat pain (the patented use). What the claimant had to prove was also in discussion in this case, and Warner-Lambert had argued that the mere fact that the defendant had used its invention was sufficient. Actavis, on the contrary, argued that a subjective intention was necessary. Eventually the case was settled in favor of Actavis, but we have seen that the case could still be appealed and that this solution is not written in stone.

We believe that a subjective intention should always be proved to establish infringement. This means that the claimant should prove that the defendant has the intention to sell its generic

¹⁶⁸ See Article 34 of the TRIPS Agreement.

drug for the patented use. This is the case, for instance, where the market for the non-patented use is extremely small or non-existent. In a case opposing Warner-Lambert to Apotex, the Australian Court held that in fact, the market for pregabalin for the treatment of seizures (which was the non-patented use) was virtually non-existent or extremely small¹⁶⁹. Therefore, it was obvious that the generic drug was commercialized in order to be used for the treatment of pain, which was the patented use.

On the other hand, if the defendant is able to show that it has taken sufficient step to ensure that its generic version of the drug would not be used for the treatment of the patented use, it should not be liable for patent infringement. Such steps might be, for instance, specifying on the PIL that the drug is intended to be used to treat X and Y (non-patented indications), or send a note to pharmacists and doctors informing that only the brand name drug should be dispensed for the patented use. It might be fair to require that a note on the packaging specifies that the product should not be dispensed for the patented use, but we do not think that it should be framed in a way that could threaten the patient if the drug was indeed dispensed for such use, like “this drug is not authorized for the treatment of X and must not be dispensed for such purposes”. Such a formulation could even induce professionals to believe that the drug is not bio-equivalent to the brand name drug, and such a situation is not desirable.

We reiterate that such safeguards should be applied in countries that allow second medical use patents. Otherwise it might lead to even more proceedings against the generic industry or against any competitor, which could in the end lead to less innovation because of the fear of litigation. It has been argued that the fear of litigation stops some companies from innovating because they fear they will be held to infringe a patent, especially in the pharmaceutical industry. Apart from these safeguards regarding competitors, we believe that some parties should be totally exempted from liability and these are doctors, pharmacists and patients.

II. Necessary exemptions to tackle abuses in the field of second medical use patents

We have seen that some countries believe that doctors, pharmacists and even patients could be liable for infringement of a second medical use patent. In practice however, it is rare that patients be sued for patent infringement. Some exemptions already provided by national and international patent laws also allow to exclude patients and even doctors and pharmacists from liability. This is for instance the exemption of private and/or noncommercial use. Public

¹⁶⁹ Warner-Lambert Company LLC v Apotex Pty Limited [2014] FCAFC 59, at. 83.

policy objectives are pursued with this exemption and various rationale for implementing it have been put forward. Some countries have argued that this exception is necessary to ensure the balancing of legitimate interests. For Brazil, this exception does not unreasonably conflict with the normal exploitation of the patent and does not unreasonably prejudice the legitimate interest of the patent owner¹⁷⁰. For China, prohibiting private and noncommercial uses “would make the patent coverage excessively large, thus interrupting the normal activities of the public at large”¹⁷¹.

In our view, it is obvious that a patient taking a drug or following a treatment should fall within the scope of this exemption. The act of a doctor prescribing a drug is also not a commercial act, neither is the act of the pharmacist delivering the drug. All WTO Members should explicitly exclude private and noncommercial uses from liability, and it has been stated that most national patent laws do so, even if there is no explicit provision in the TRIPS Agreement excluding these uses from patent protection¹⁷². It could be argued that pharmacist and even doctors do not fall under this exception because they are actually making profit¹⁷³. If so, we believe that special exemptions for these actors should be enacted in patent laws.

To determine whether it is legitimate to exclude these parties from liability, we must do a step back to address the rationale of the patent system. The question to be answered is: is the incentive to innovate endangered by such an exception? In the case of second medical use patents, the answer might be different regarding the party answering the question. Patentees might consider that it is, because if doctors, pharmacist and patients are exempted from liability, they will be free to substitute the brand name drug by its generic version for second uses that are still under patent protection. If the patentee cannot take action so as to ensure that there will be no substitution, it might consider that the patent is useless because not enforceable. In fine it might not seek a second medical use patent and not doing research to find new uses for known compounds. On the contrary, it can be argued that the pharmaceutical company should try to settle this question with the generic company, and not with the downstream actors.

¹⁷⁰ WIPO Standing Committee on the Law of Patents, “Exceptions and limitations to patent rights: private and/or noncommercial use”, Twentieth Session Geneva, January 27 to 31, 2014, at. 7, available at: http://www.wipo.int/edocs/mdocs/patent_policy/en/scp_20/scp_20_3.pdf (20 August 2016).

¹⁷¹ Ibid.

¹⁷² H.M. Haugen, *The Right to Food and the TRIPS Agreement With a Particular Emphasis on Developing Countries' Measures for Food Production and Distribution*, Martinus Nijhoff Publishers, 2007, p. 239.

¹⁷³ See the definition of commercial use in: WIPO Standing Committee on the Law of Patents, “Exceptions and limitations to patent rights: private and/or noncommercial use”, loc. cit., at. 16.

We believe that, where second medical use patents are allowed, explicit exemptions from liability should be provided by the patent law. It should not be deduced from exemptions like private use, but be explicitly sanctioned as a further exemption in order to provide for more legal certainty. This is particularly necessary to ensure access to affordable medicines as we have seen before. Indeed, if a strategy of excessive litigation takes place with regards to second medical uses, the consequence will be that generic companies will not try to launch generic version of important drugs because of the fear of litigation. Such companies will prefer to focus on other drugs that are in the public domain. Therefore, even if some uses are not under patent protection anymore, generic companies could decide not to manufacture the drugs for the non-patented uses to avoid any risk of litigation.

Therefore, we believe that the legal system around second medical uses should be carefully drafted in countries that do allow such patents to ensure that existing pharmaceutical compounds are not granted another 20-year monopoly that would in fine exclude generic production. On the other hand, developing countries should not allow second medical use patents to be able to manufacture or buy generic versions of life-saving drugs and take advantage of the discoveries made by other actors to be able to cure new indications. Unfortunately, the international tendency seems not to go in this direction and the relevant actors will have to form strong lobbies if they want to tackle the growing pressure of some developed countries.

Conclusion

The discovery of new uses for existing medical compounds has been at the center of a number of issues from legal acceptance to practical consequences. In some countries, the discovery of a new use is by definition not an invention and is not patentable. In other countries, by means of legal fictions, second medical uses have been granted patents because the use is considered to be new and the manufacture of the drug is supposed to fulfill the criteria of industrial application. As regard to the inventive step, judges face a complex issue that they try to solve as best as possible. In practice, some second medical use patents have been rejected on the basis of the lack of novelty, industrial application or inventive step. But at an international level, they are growingly granted and integrated to international and regional agreements.

Developed countries and especially the United States and the European Union have pressured other countries to change their patent laws and allow second medical use patents. This has been successfully done with the recent Trans-Pacific Partnership that imposes patents for new uses of known products, even if the TRIPS Agreement had remained silent on this issue. Indeed, countries are free to use the flexibilities offered by the Agreement to avoid these patents, but in practice, most developing countries are forced to grant patents for second medical uses if they want to be part of a multilateral or bilateral agreement. The impact of the grant of such patents differs from country to country and depends on the level of development of the country. In any event, second medical use patents have major impact on access to health, that is, on access to affordable medicine.

When patents for second medical uses are granted, the monopoly is actually granted for a compound that has sometimes fallen into the public domain, and if it hasn't yet, the second medical use patent will extend the monopoly on this compound because generic manufacturers will often not want to take the risk of being sued for manufacturing a generic version of a drug only for some uses that are not under protection anymore. Therefore, it can be said that second medical use patents extend the patent monopoly on a given compound, affecting the commercialization of cheaper version of needed drugs. This has a major impact on developing countries where the support of the state and health insurances is not as important as in developed countries and where people have to pay for their medicines. If the drugs are sold at a high price because of the patent monopoly, many people will not be able to afford them thus creating a problem of access to health.

In countries where second medical use patents are granted, several safeguards should be applied in order to avoid excesses and evergreening. Strict patentability standards must be applied and the conditions for initiating a nullity action must be more flexible. Moreover, national patent laws must clearly determine the bounds of the monopoly in order to ensure that first medical uses that fall into the public domain are freely exploitable. Generic companies who want to launch a generic drug for non-patented uses should make clear on the patient information leaflet and the summary of product characteristics the uses for which the drug is indicated. It should be the only party susceptible of being sued for infringement if it does not take such steps or if it can be proved that it was encouraging other parties to use its drug for patented uses, which in practice might be hard to do. The doctor, the pharmacist and the patient should always be excluded from liability.

On the other hand, countries with weak pharmaceutical industries should not allow second medical use patents and should be able to dispense known drugs for any use. Developing countries should not grant monopolies on second medical uses as it would probably affect their populations by reducing access to medicines. But this might become harder and harder in the years to come because of the growing influence of free trade agreements imposing such patents. Some legal and practical safeguards should be applied in any case. To achieve a balanced system, countries might want to grant another kind of protection for second medical uses that would not last twenty years. The optimal duration should be based on economic studies and should take into account the average investment in research and development to discover a new use for an existing compound. The economist Joseph Stiglitz stated that a “poorly designed intellectual property regime can actually impede innovation”¹⁷⁴. Therefore it will be necessary in the years to come to carefully draft the agreements related to intellectual property and in particular those touching upon second medical use patent as they could have negative consequences for innovation and thus public health on an international scale.

¹⁷⁴ B. Mercurio, “TRIPs, Patents and Innovation: A Necessary Reappraisal?” *E15Initiative*, Geneva: International Centre for Trade and Sustainable Development (ICTSD) and World Economic Forum, 2014, available at: www.e15initiative.org/ (20 August 2016).

Bibliography

Books

Correa, C.M., (2002) *Intellectual Property Rights, the WTO and developing countries The TRIPS Agreement and Policy options*, Zed Books & Third World Network, 3rd printing.

(2012) *A guide to pharmaceutical patents*, South Center.

De Haas, M., (1981) *Brevet et médicament en droit français et en droit européen*, Librairies Techniques, Collection du CEIPI, Paris.

Domeij, B., (2000) *Pharmaceutical Patents in Europe*, Kluwer Law International, Stockholm Studies in Law, Stockholm.

Dreyfuss, R. & Rodríguez-Garavito, C., (2014) *Balancing Wealth and Health The Battle over Intellectual Property and Access to Medicines in Latin America*, Law and Global Governance Oxford University Press, 1 edition.

Genovesi, M.L., (2013) “La aplicación industrial y la utilidad como requisitos de patentabilidad: diferencias y semejanzas. Consecuencias de su aplicación”, in: Seuba, Xavier, *Propiedad Intelectual Competencia y Aspectos Regulatorios del Medicamento Determinantes Internacionales y Política Pública*, Grupo Editorial Ibañez, Colección Estudios n° 4, Colombia.

Guesmi, A., (2011) *Le médicament à l’OMC: droit des brevets et enjeux de santé*, Larcier, Droit/Economie International.

Haugen, H.M., (2007) *The Right to Food and the TRIPS Agreement With a Particular Emphasis on Developing Countries' Measures for Food Production and Distribution*, Martinus Nijhoff Publishers.

Mathély, P., (1991) *Le nouveau droit français des brevets d’invention*, Journal Notaires Et Avocats, Paris.

Passa, J., (2013) *Droit de la propriété industrielle Tome 2*, L.G.D.J., Traité.

Phelip, B., (1980) *Protection et exploitation de la recherche pharmaceutique : Lyon, 5-6 Avril 1979*, Librairies Techniques, Collection du CEIPI.

UNCTAD-ICTSD, (2005) *Resource Book on TRIPS and Development*, Cambridge University Press.

Velásquez, G. & Boulet, P., (1999) *Globalization and access to drugs: Perspectives on the WTO TRIPS Agreement*, WHO, Health Economics and Drugs DAP Series No 7.

Vivant, M., (2005) *Le droit des brevets*, Dalloz, Connaissance du Droit, 2e édition.

Articles

Anonymous, (2005) "Access to Medicines Intellectual Property protection: impact on public health", WHO Drug Information, Volume 19, No. 3.

Castellano, R.A., (2006) "Patent law for new medical uses of known compounds and pfizer's Viagra patent", *IDEA-The intellectual property law review*, Volume 46, No. 2, pp. 283-315.

Correa, C.M., (2015) "Intellectual Property in the Trans-Pacific Partnership: increasing the barriers for the access to affordable medicines", *South Center*, Research Paper 62.

(2000) "Integrating public health concerns into patent legislation in developing countries", *South Center*.

Courboulay, M., (2016) "L'assouplissement des conditions de brevetabilité des produits pharmaceutiques", *Propriétés intellectuelles*, No. 59.

Descheemaeker, S., (2013) "India, Pharmacy of the Developing World IP, Trade and the Access to Medicine", *Jura Falconis Jg*, Volume 49, No. 3.

Hewitt, L.L., (1969) "The New Use Patent", *Journal of the Patent Office Society*, Volume 51, No. 10, pp. 634-648.

Kesselheim, A.S., Fischer M.A., & Avorn, J., (2006) "Extensions of Intellectual Property Rights and Delayed Adoption of Generic Drugs: Effects On Medicaid Spending", *Health Affairs*, Volume 25, No. 6, pp.1637-1647.

Leffler, K. & C., (2004) "Efficiency Trade-Offs in Patent Litigation Settlements? Analysis Gone Astray", *University of San Fransisco Law Review*, Volume 39.

Qeidarya, Q., (2015) "Emerging issues: new uses, whether threat or chance, what is the current and appropriate legal treatment?", *Oklahoma Journal of Law & Technology*, Volume 11, No. 78.

Rodriguez Spinelli, F., (2011) "Patentes de segundo uso: nuevas tendencias en el derecho comparado y en los tratados de libre comercio", *Propiedad Intelectual*, No. 14, pp. 127-148.

Scassa, T., (2011) "Patents for second medical indications and their potential impact on pharmacare in Canada", *Health Law Journal*, Volume 9, pp. 23-59.

Vivant, M., (1989) "La brevetabilité de la seconde application thérapeutique", *La Semaine Juridique Entreprise et Affaires*, No. 25.

Online articles:

All the internet sources have been last accessed on 20 August 2016

Amin, T., Rajkumar, R., Radhakrishnan P. & Kesselheim, A.S., (2009) "Expert review of drug patent applications: improving health in the developing world", *Health Affairs*, Web exclusive, available at: <http://www.healthaffairs.org/>.

Anonymous, (2015) “Warner-Lambert v Actavis – Do we have an effective system for enforcing second medical use patents in the UK?”, *JA Kemp*, available at: http://www.jakemp.com/uploads/files/pdfs/Pregabalin_02_10_15.pdf.

England, P. & Osgerby, K., (2013) “Carve-outs and skinny labelling”, *TaylorWessing*, available at: http://united-kingdom.taylorwessing.com/synapse/ti_skinnylabelling.html.

Fundacion Ifarma – Alianza LAC, (2013) “El impacto del TPP en el acceso a los medicamentos en Chile, Peru y Colombia, Lima”, available at: <http://web.ifarma.org/>.

Lobo Aleu, F., (1989) “La evolucion de las patentes sobre medicamentos en los países desarrollados”, doc n° 009/1989, available at: <https://econo.uniovi.ec>.

Matos Jaqui, E., (2008) “Las patentes de segundo uso”, *Revista Judicial Derechoecuador.com*, available at: www.derechoecuador.com.

Mercurio, B., (2014) “TRIPs, Patents and Innovation: A Necessary Reappraisal?”, *E15Initiative*, Geneva: International Centre for Trade and Sustainable Development (ICTSD) and World Economic Forum, available at: www.e15initiative.org/.

Ünlü, S. & Göksu, G., (2016) “Second medical use patents and the skinny label issue”, *Managing Intellectual Property*, available at: <http://www.managingip.com/Article/3532019/Second-medical-use-patents-and-the-skinny-label-issue.html>.

Working papers

Arcuri, A. & Castro, R., (2008) “How innovative is innovative enough? Reflections on the interpretation of Article 27 TRIPS from Novartis vs. Union of India”, *SIEL Working Paper No. 52/08*.

Correa, C.M., (2007) *Guidelines for the examination of pharmaceutical patents: developing a public health perspective*, WHO-ICTSD-UNCTAD.

(2014) “Patent examination and legal fictions: how rights are created on feet of clay”, *South Center*, Research Paper 58.

Musungu, S.F., & Oh, C., (2005) “The use of flexibilities in TRIPS by developing countries: can they promote access to medicines?”, *South Center*, CIPIH Study Paper 4C.

Treaty and Laws

- **International treaty**

Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

- **Free-trade agreement**

Trans-Pacific Partnership, 4 February 2016.

- **National and foreign law**

Austrian Patent Law 1970, Federal Law Gazette 1970/259, adopted in 1970, last revised in 2009.

Chile, Ley de Propiedad Industrial n°19.039, adopted on 9 March 2006, last revised on 6 February 2012.

Comunidad Andina, Decision 486, Régimen Común sobre Propiedad Industrial, 1 de Diciembre del 2000.

Comunidad Andina, Resolución No. 00050-1999/OIN-INDECOPI, adopted on 29 January 1999.

España, Ley 24/2015, BOE-A-2015-9725, adopted on 24 July 2015, will enter into force on 1 April 2017.

European Patent Convention, adopted on 5 October 1973, last revised on 29 November 2000.

France, LOI n° 2008-776 du 4 août 2008 de modernisation de l'économie.

India, The Patents Act, adopted in 1970, last revised in 2005.

Malaysian Patents Act, adopted in 1983, last revised on 29 June 2006.

Perú, Decreto Supremo No. 010-97-ITINCI, adopted on 5 June 1997.

United States Code, Title 35, Patents, adopted on 19 July 1952, last revised on 18 December 2012.

Vietnam Law on intellectual property No. 50/2005/QH11, adopted on 29 November 2005, last amended on 19 June 2009.

AIPPI Reports

Available at: <http://aippi.org/committee/second-medical-use-or-indication-claims/>

Altman, Dan, *Second medical use or indication claims*, AIPPI Report United States, 21 May 2014.

Gallochat, Alain & Cuche, Thomas, *Second medical use or indications claim*, AIPPI Report France, 21 May 2014.

Keschmann, Marc, *Second medical use or indication claim*, AIPPI Report Austria, 12 May 2014.

Lindner, Heidi, *Second medical use or indications claim*, AIPPI Report Mexico, 23 May 2014.

Reeskamp, Paul, *Second medical use or indication claims*, AIPPI Report Netherlands, 25 April 2014.

Zischka, Matthew, *Second medical use or indication claims*, AIPPI Report Canada, 16 May 2014.

EPO Documents

EPO, Guidelines for Examination, Part F, Chapter 4, 4.16 Use claims.

EPO, Guidelines for Examination, Part F, Chapter 4, 7.1.1. Products that may be claimed for a further medical use.

EPO, Guidelines for examination, Part G, Chapter VI, 7.1 Second or further medical use of known pharmaceutical products.

EPO, Guidelines for examination, Part G, Chapter VI, 7.1.2 Therapeutic uses pursuant to Art. 54(5).

WIPO Documents

WIPO Standing Committee on the Law of Patents, “Exceptions and limitations to patent rights: private and/or noncommercial use”, Twentieth Session Geneva, January 27 to 31, 2014, at. 7, available at: http://www.wipo.int/edocs/mdocs/patent_policy/en/scp_20/scp_20_3.pdf.

WIPO Standing Committee on the Law of Patents, “Study on Inventive Step”, 6 July 2015, available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_22/scp_22_3.pdf.

Miscellaneous

Diretrices de examen de solicitudes de patente, Departamento de Patentes e información tecnológica, Oficina Española de Patentes y Marcas, Octubre 2006, p. 151-152.

Japan Patent Office, Examination Guidelines for Patent and Utility Model, Part VII, Chapter 3 “Medicinal Inventions”, available at: https://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/Guidelines/7_3.pdf.

WHO, WTO and the TRIPS Agreement, available at : http://www.who.int/medicines/areas/policy/wto_trips/en/.

Table of cases

International and European case-law

- **European Court of Justice**

Case C-34/10, *Oliver Brüstle v. Greenpeace e.V.*, 18 October 2011, 2011 I-09821

- **European Patent Office**

- **European Board of Appeal**

EBA, G 0005/83, *Second medical indication*, 5 December 1984, OJ EPO 1985, 064

EBA, G 0002/88, *Friction reducing additive*, 11 December 1989, OJ EPO 1990, 093

EBA, G 0001/04, *Diagnostic Methods*, 16 December 2005, OJ EPO 2006, 334

EBA, G 0002/08, *Dosage regime/ABBOTT RESPIRATORY*, 19 February 2010, OJ EPO 2010, 456

- **Opposition Division**

EPO, Opp. Div., *Relaxin*, 8 December 1994, OJ EPO 1995, 388

- **World Trade Organization**

Panel Report, *Canada — Patent Protection of Pharmaceutical Products*, 17 March 2000

National case-law

- **Andean Tribunal of Justice**

Tribunal de Justicia de la Comunidad Andina, *Proceso 12-IP-98*, 20 de Mayo de 1998

- **Canada Supreme Court**

Apotex Inc. c. Wellcome Foundation Ltd., [2002] 4 R.C.S. 153, 2002 CSC 77

- **England and Wales Court of Appeals**

Warner-Lambert Company, LLC v Actavis Group Pte EHF & Others [2015] EWCA Civ 556

- **French Cour de cassation**

Cour de Cassation, *Chambre commerciale*, du 26 octobre 1993, 91-17.944, Bulletin 1993 IV N° 354 p. 257

- **High Court of Australia**

National Research Development Corporation v Commissioner of Patents [1959] HCA 67; (1959) 102 CLR 252 (16 December 1959)

Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd, [2013] HCA 50

- **Madras High Court**

Novartis AG vs Union of India, 6 August 2007, W.P.24759/06

- **New Zealand Court of Appeal**

Pfizer Inc. v The Commissioner of Patents [2005] 1 NZLR 362

- **United States**

Supreme Court

Roberts v. Ryer, 91 U.S. 150 (1875)

Morton c/ New York Haye Infirmary (1879)

Court of Appeal 2nd Circuit

Old Town Ribbon & Carbon Co. v. Columbia R. & C. Mfg. Co., 159 F.2d 379 (2d Cir. 1947)

Board of Patent Appeals of the United States Patent Office

In Re Thuau, 135 F.2d 344 (C.C.P.A 1943)

Table of Content

Synopsis	3
List of abbreviations:	4
Introduction	5
Part 1: The ambivalence of the legal regime governing second medical use patents.....	12
Chapter 1: The compliance of second medical uses with the patentability standards	12
Section 1: Second medical indications: a patent-eligible subject matter?	13
I. Uses confronted to the categories of statutory subject matter	13
II. Discovering or inventing a second medical use?	15
Section 2: The patentability criteria applied to second medical uses	17
I. What is novel in a second medical use patent?	17
1. Novelty of the compound: the necessary refusal of patents for second medical uses	17
2. Novelty of the use: the introduction of a disputed legal fiction	19
II. The difficult assessment of the inventive step.....	20
Section 3: A controversial basis for the exclusion of second medical uses	22
I. The industrial application of a new medical use	22
II. The exclusion from patentability of second medical uses as being methods of medical treatment	24
Chapter 2: The disputed implementation of second medical use patents	27
Section 1: The increasing pressure of regional and international agreements.....	27
I. The absence of explicit regulation of second medical use patents in the TRIPS Agreement and the flexibilities offered thereof.....	27
II. The Trans-Pacific Partnership and its impact on second medical use patents	29
1. The statutory obligation to grant patents for second medical uses and its impact on developed countries.....	30
2. The impact of the TPP on developing countries.....	32
Section 2: The opposition of developing countries and the role of the courts	34

I.	India and the controversy around Section 3(d) of the Indian Patents Act.....	34
1.	The Novartis case and the challenge of Section 3(d)	35
2.	The exclusion of second medical use patents and its compliance with Article 27 TRIPS.....	36
II.	The practice of the Andean Community and the Andean Tribunal of Justice	37
	Part 2: The significance of second medical use patents in the light of public health	40
	Chapter 1: Second medical use patents: a barrier to access to health?	40
	Section 1: The impact of second medical use patents on access to medicines.....	41
I.	Raising the price of known drugs by delaying generic competition	41
II.	The adverse impact of second medical use patents in developing countries	44
	Section 2: Necessary safeguards to promote access to health	46
I.	Foster a pro-competition system as an alternative to second medical use patents in developing countries.....	46
II.	Achieving a balanced system in countries allowing second medical use patents	48
	Chapter 2: Infringement issues arising from second medical use patents and their impact on public health.....	50
	Prolegomena - The relation between the first and the second medical use patent.....	50
	Section 1: From the manufacture to the dispensing of the drug: who infringes a second medical use patent?	53
I.	The impact of second medical uses on the liability of generic companies	54
II.	The controversy around the liability of doctors, pharmacists and patients	58
	Section 2: Legal safeguards to avoid excessive litigation	60
I.	Requirements and burden of proof: who proves what in a second medical use case?..	60
II.	Necessary exemptions to tackle abuses in the field of second medical use patents.....	61
	Conclusion.....	64
	Bibliography	66
	Table of cases	71