Patent protection of medical methods

A comparative analysis of European and US law

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1 Introduction
1.1 The topic
The topic of this thesis is the patent protection of medical methods in Europe under the European Patent Convention (EPC) and in US law. Medical methods are methods for treatment, diagnostic methods, and surgical methods. In both jurisdictions, patent protection of medical methods is subject to limitations. In Europe, such methods are in principle excluded from patentability. In the US, medical methods constitute patentable subject matter, but the right of enforcement is limited. I will look at the similarities and differences between the two sets of rules.

European patent law is also relevant nationally in the various European countries that are members of the EPC, including Norway. It is not uncommon to apply only for a European patent, which may become effective in the designated member states. It is also possible to apply in the individual member states separately, where the national patent rules are harmonized with the substantive rules of the EPC. Thus, examining the patent law under the EPC will also reflect the patent law in the member states. The relationship between the EPC and the law of the member countries will be further explained below under 2.1.2. I will use terms such as "European patent law" or “the patent law in Europe” for the law established under the EPC.

The starting point according to EPC Art. 52(1) is that any inventions in all fields of technology “which are susceptible of industrial application” are patentable as long as they are new and inventive. No positive definition of “invention” is provided. The EPC provides, however, certain limitations and exceptions. One of several exceptions can be found in EPC Art. 53(c); patents shall not be granted in respect of "methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body". This thesis focuses on methods performed on humans.

The starting point under US law is that patentable subject matter is defined positively as a “process, machine, manufacture or composition of matter, or any new and useful improvement thereof”, 35 U.S.C. § 101. Exclusions are left to the common law, and include, for instance, laws of nature, abstract ideas and physical phenomena.¹ There is no exclusion for medical methods. Accordingly, whereas medical methods are excluded from patentability in Europe,

they constitute eligible subject matter in the US. However, even though US law allows such patents, they cannot be enforced against medical practitioners executing a medical method, cf. 35 U.S.C. § 287(c). This is referred to as the limited enforcement rule.

The terms used in the statutes are slightly different. The EPC uses the wording “methods for treatment … by surgery or therapy and diagnostic methods”. In the US, the limitations on enforcement refer to "medical activity", which is defined as a "medical or surgical procedure on a body". I will discuss below how similar these concepts are as a matter of substantive law.

The main purpose of the patent law system is to encourage and promote innovation. Granting patent rights for inventions creates an economic incentive for inventors, and promotes development in the scientific arts. The medical field is subject to certain ethical and moral issues due to the fact that it deals so closely with the human body and health. At the same time, there are vast economic interests involved, and the time, money and efforts that go into developing new drugs and methods of treatment require the incentive that patent protection can provide.

Both under the EPC and in the US, the purpose of the limitation on medical methods is that medical practitioners should not be restricted or have to worry about patent infringing when deciding on the best possible treatment for a patient. This would be contrary to public health.²

1.2 The purpose
The purpose of this thesis is to examine the extent of patent protection available for medical methods in Europe and in the US respectively. This must be determined by considering both the patentable subject matter and the scope of protection and right of enforcement of these patents. To the extent that there are differences between the two sets of rules, one objective is to consider the impact these have on the realization of the purpose behind the rules while at the same time fulfilling the general purpose of patent law. This could in turn enable an attempt to decide the question of which regulatory model is best suited to achieve the purpose.

The choice of American and European law for the comparison is not incidental. American patent law has long been considered a leading patent system that have influenced the legal development in Europe. It is also important for the competitiveness of European industry to

have a similar level of patent protection in their national market as their American competitors have in the US. US patents are generally considered more lucrative, since this is the largest market with the most cost-effective grant proceedings.

There are many similarities between the US patent system and that of EPC, particularly with regards to the substantial law. In both legal systems, patentability applies to technical products and methods, and an invention is patentable if it is new compared to the prior art and not obvious to a person skilled in the art. Europe and the US have gotten increasingly similar rules over time due to efforts of international harmonization. For example, the US recently abandoned their previous first-to-invent rule in favor of a first-to-file rule, inter alia to get more similar rules to the rest of the world.

However, there are still remaining differences. For instance, in the US patentability requires utility (the invention must be useful), which is not a requirement under the EPC. Nevertheless, even though there are differences in substantive law, the systematic and structural differences are more apparent. These are mainly caused by the fundamental differences in the legal systems (common law versus civil law). Under the EPC, there are negative definitions in the statutory law regarding what constitutes an invention and what is patentable. Exceptions to patentability must have basis in statutory law. In the US, on the other hand, the statutes provide the positive definition of patentable subject matter, whereas exceptions to patentability are left to case law.

Even though the rules regarding medical methods are different in both substance and structure, they regulate the same problem, are intended to achieve the same goal, function in similar social systems, and they might not yield so different results.

Unveiling similarities and differences between the legal rules on medical methods in the US and in Europe will increase understanding of both US and European patent law, both on a general level and with regard to medical methods specifically. It is useful to learn which set of rules is more suitable and advantageous when dealing with a specific invention, especially if

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3 Both in Europe and in the US, the rule is now that the first person to file for the patent is the rightful owner. The US previously had a rule that it was the (first) inventor that had the right to the patent, regardless of whether he was the first to file for patent. This rule made for more complicated assessments and difficulties obtaining evidence.
one is considering where to apply for or enforce a patent. The comparative method adopted for the purposes of this thesis will be further elaborated on below under 2.2.

1.3 Research questions
In order to compare and analyze the rules on medical methods in accordance with the objectives set forth above, the first step is to examine what is patentable subject matter in both legal systems with regard to these types of inventions. The next step is to determine the scope of rights conferred by these patents. Under each of these main research questions there are several subordinate research questions, which will be somewhat different in Europe and in the US due to the different structure of the rules.

Since the starting point under European is that medical methods are not patentable, one must first decide the scope of this exception; what constitutes an excluded medical method under the EPC? This necessitates a clarification of the divergence between method and product, which also give rise to some remarks on the drafting on patent claims and the specific issue of new medical use patents. The interpretation of the term medical method more specifically depends on what is a therapeutic, diagnostic or surgical method.

Under US law, the starting point is the opposite; medical methods are patentable. However, even though there are no specific rules regarding the patentability of medical methods, the exclusion for laws of nature must be considered, as this can affect the patentability of medical methods in certain cases.

When considering the scope of protection and enforcement of medical method patents, the approach also differs between the two legal systems. Here, the limitation with regards to medical methods can only be found in US law. One must therefore consider the scope of the limited enforcement rule; what constitutes a medical method that is subject to limited enforcement in the US? Where the limited enforcement rule is applied, the ensuing issue is what the remaining enforcement value is of these patents, meaning how much value does the patent have for the patentee in terms of exclusive use and options of enforcement against infringers.

In order to compare and evaluate the rules, it is necessary to look at their application side-by-side in specific scenarios. I will perform case analyses in three different areas of
medical treatment; new medical use, genetic diagnostic testing and gene therapy. The question is repeatedly; do the rules lead to the same or different result in a specific scenario? If they lead to different results, which set of rules provide the best protection, and which have the best solution in terms of achieving the purpose? Deciding on this issue, it is necessary to look at the whole picture and see which rules gives the most beneficial results overall. Having said this, it is of course unfeasible to analyze the broad array of medical methods within the boundaries available for this project. Thus, the results of this study have inherent limitations that are unavoidable and the results must be applied with caution.

1.4 The structure of the thesis
The structure of the thesis naturally follows from the logic order of the research questions. However, it is necessary to begin with a presentation on the methodology that will be used throughout this study, both the legal methodology applied in Europe and the US respectively (2.1), and the comparative method I will apply in order to compare the two sets of rules (2.2). Following this, I will review the relevant rules in Europe and in the US separately (3 and 4). I will discuss some questions of particular interest more thoroughly, but I will endeavor to limit the presentation to what is necessary for the subsequent comparative analyses. In the comparative part of the thesis, I will first discuss the main questions and clarify some structural lines that the thesis has shown up to this point (5.2). I will try to sum up and exemplify 1) the difference in patentable subject matter, and 2) the difference in scope of protection. Following this, I will go deeper into the comparison on a more practical level, with a case analyses in the three selected areas of law mentioned above; new medical use, genetic testing and gene therapy (5.3). The final step is the conclusion, which will sum up the findings made and attempt to assess which set of rules best achieve the purpose.

2 Methodology
2.1 Legal methodology
2.1.1 Introduction
The legal methodology, the method of establishing the current law, have certain common features in Europe and in the US, but there are also some important differences. An overview of the EPC patent system and the US patent system is necessary to understand the structure of the system that the rules function within, and what sources are relevant when interpreting and applying the legal rules.
2.1.2 European patent law
The EPC is an essential element in the harmonization of European patent law. The convention establishes a system of granting European patents, and is administered by the European Patent Office (EPO). The Boards of Appeal acts as the department of final instance of the EPO, and decides cases where an appeal is filed against decisions of the departments of first instance.

2.1.2.1 EPO's legal method and sources
The EPO is the primary judicial body in charge of interpreting and applying the European Patent Convention. The law under the EPC is therefore established according to EPO's method, which is also the methodological role model for the member countries when interpreting the EPC nationally, which I will get back to below. There are three equal and official versions of the EPC, in English, French and German. Being a treaty, EPC is interpreted in correspondence with the Vienna Convention on the law of treaties (No. 18232, of 23 May 1969). The Convention part III, Section 3, sets forth the rules on interpretation of treaties. The general principles of interpretation are familiar from other areas of law. The starting point is that the treaty "shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose", cf. the Convention Art. 31(1). The wording in the statute is the basis for the interpretation.

Previous decisions by the Boards of Appeal are given considerable weight when interpreting the EPC. The most weight is given to the decisions from the Enlarged Board of Appeal, but also decisions from the Technical Boards of Appeal are relevant. There are several Technical Boards of Appeal and the practice from the different boards are not always consistent. It might take some time before a clear legal interpretation is established, which gives cause for some caution when applying these decisions. The European Patent Office has published a book on the case law of the EPO Boards of Appeal, which is continuously updated, the most recent version being the 8th edition of July 2016. Although it has no authoritative status, it is an account of the EPO Boards of Appeal decisions regarding the EPC, which constitutes a valuable source of information. It is particularly useful with regard to locating the relevant decisions in connection with a particular subject.

Administrative practice from the Examination and Opposition Divisions, as expressed in EPOs Guidelines, is only given limited weight by the Boards of Appeal, but is referred to by the
Boards in certain cases. In any case, the guidelines are useful sources of information as they reflect the established practice of the EPO.

There is no international court having jurisdiction over European patents, and EPO has no competence with respect to patent infringement.

In this regard, the Agreement on a Unified Patent Court should be mentioned. The Court will deal with the new Unitary Patents, which will have unitary effect in all the participating states. A Unitary Patent is a specific type of European patent, which will be granted by the EPO. The Agreement on a Unified Patent Court has not yet entered into force, and there have been particular difficulties related to Brexit. It is currently unclear whether and when the Unitary Patent System will enter into force.

With regard to patent infringement, the only source is decisions from national courts in the member countries. The Boards of Appeal have demonstrated in several decisions that they are willing to take into consideration and give weight to decisions from member countries, at least if it is a consistent practice and not only a stand-alone decision. In G 5/83 (para. 6) the Enlarged Board stated that in order to establish harmonized patent legislation in the member states, harmonized interpretation was necessary, and the EPO and particularly the Boards of Appeal thus has to take into consideration decisions and opinions of courts and industrial property offices in the member states. The EPO has also given preparatory works relevance in the interpretation of the convention, in accordance with national courts' practice. The Vienna Convention on the law of treaties explicitly specify that the preparatory work of the treaty and the circumstances of its conclusion are supplementary means of interpretation, cf. the Convention Art. 32.

2.1.2.2 EPC and national law

As of now, 38 European countries are Contracting States to the EPC, including Norway. As a member of the EPC, Norway is obligated to give force to European patents nationally if Norway is a designated country in the patent and the patent is validated here. Furthermore, in accordance with EEA protocol 28 Art. 3 nr. 4, there is an obligation for EFTA States to "comply in their law with the substantive provisions of the European Patent Convention". Thus, the

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4 Stenvik (2001) p. 213
6 See for example G 5/83, T 385/86, T 1002/92, see Stenvik (2001) p. 214
7 Stenvik (2001) p. 208
8 The Norwegian patent Act chapter 10a, §66b(1)
requirements for granting a patent in Norway and the effects of national patents are the same as those for European patents. The rules of European patent law that are presented here correspond to the Norwegian patent rules. The exception from patentability of medical methods in the EPC art 53(c) is adopted in the Norwegian Patent Act (patl.) § 1(5).

Decisions by the EPO are not binding for the courts in the member states when interpreting and applying the convention. However, it is recognized that decisions by the EPO should be given considerable weight, for the sake of coherence of the system as a whole. National patent offices continuously adapt their practice to the EPO’s, and national courts give Boards of Appeal decision considerable weight. Even though they are not "strictly binding", they are recognized to be "of great persuasive authority." Case law from the EPO therefore has a unifying effect in Europe, and remains the most reliable expression of the law.

In Norway, the Supreme Court in Biomar, Rt 2008-1555 (51), stated that it is of great significance that the development in Europe is characterized by uniform rules and practice within the patent area. Nonetheless, the Court added, it depends on a concrete assessment and especially on which instance in the EPO that has made the decision, how much weight it shall be given. Also, the Norwegian preparatory works says in a remark to patl. § 1(5) that it was changed in order to achieve the best possible correspondence between Norwegian patent law and the European patent convention Art. 53(c). The preparatory works also emphasizes the importance of legal coherence, which is achieved by giving EPOs decisions considerable weight, in particular decisions by the Enlarged Board of Appeal.

As the primary sources in this thesis, I will use the EPO Boards of Appeal’s decisions, the book on the case law of the EPO Boards of Appeal, and EPO’s Guidelines for the application of the EPC, along with various literature regarding European law. I will supplement with Norwegian sources when these are relevant. This will result in a portrayal of current patent law that reflects both the law under the EPC and Norwegian law.

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9 Stenvik (2001) p. 211
2.1.3 US patent law

There are two court systems in the US; the federal court system and the state court system, which have separate judicial powers over different areas of law. Patent law is regulated within the federal system. The federal system consists of the United States District Courts as trial-level courts, the United States Courts of Appeal as the first level court of appeal, and the United States Supreme Court as the final arbiter of the law.

In the US there are three primary sources of law – case law, statutes and regulations – that establishes the law. Case law is decisions by the state or federal courts, and statutes are laws enacted by legislatures (state legislatures or the U.S. Congress) and constitutions (the U.S. Constitution and state constitutions). The U.S. Constitution gives the Congress power to enact federal legislation in certain areas of law, and the United States Code, which is enacted by the U.S. Congress, is the official consolidation and codification of the general and permanent federal statutes of the United States. In the US, there are also several secondary sources of law, such as legal encyclopedias, American Law Reports (ALR), treatises, law journals and restatements. Secondary sources can be used to understand and determine the content of the primary sources, or as guidance to locate the primary sources. Primary sources are either mandatory (binding) or persuasive, whereas secondary sources are always only persuasive. The authority of a primary source in the form of case law depends on several factors, including; the jurisdiction of the source versus the case (e.g. federal versus state), how similar the facts are, the authority behind it (e.g. whether it is a decision from the trial-level courts or the Supreme Court), whether it is a recent or old decision and whether the case stands alone or is supported by other decisions expressing a similar view. Being a common law jurisdiction, US courts have to abide by the principle of Stare Decisis, and follow judicial decisions (precedence) from higher level courts within the same jurisdiction that have decided the same issue. However, in many cases, the facts of the cases will not be exactly the same, leaving room for distinguishing the facts and obtaining a different result. This means that the concept of precedents in the US is not as rigid as it might seem compared to the use of case law in Europe.

The U.S. constitution Article I Section 8 gives congress the power to enact patent legislation. US patent legislation today comes from the U.S. Patent Act of 1952, and is codified in Title 35

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of the United States Code. The United States Court of Appeals for the Federal Circuit ("Federal Circuit") is the unified forum for patent appeals, created by Congress in 1982 as the nation's thirteenth federal court of appeal and recognized by the Supreme Court for their "special expertise" in this area.\textsuperscript{13} The Federal Circuit has unlimited geographical jurisdiction nationwide, and limited subject matter jurisdiction; it has exclusive appellate jurisdiction over cases arising "under any Act of Congress relating to patents", and also over cases in certain other areas of law.\textsuperscript{14} The Federal Circuit decides appeals on decisions by the District Courts of the United States, which have first instance jurisdiction in cases regarding patent law\textsuperscript{15}, and decisions by the Board of Patent Appeals and Interferences (BPAI) of the Patent and Trademark Office.\textsuperscript{16} When the BPAI deny an applicant a patent, the applicant may appeal the decision to the Federal Circuit.\textsuperscript{17} The United States Supreme Court is the highest power and can decide cases from the Federal Circuit (at its discretion) on writ of certiorari.\textsuperscript{18}

Here, the most relevant primary sources will be the U.S. Code Title 35 and case law from the Federal Circuit and the U.S. Supreme Court. Secondary sources in the form of literature, articles etc. will also provide useful information.

\textbf{2.2 Comparative method}

\textbf{2.2.1 What is comparative method?}

For the purposes of this chapter on comparative method, I will use the definition of comparative law used by Michael Bogdan in his work "Comparative law". Comparative law encompasses "the comparing of different legal systems with the purpose of ascertaining the similarities and differences".\textsuperscript{19} It further includes working with these similarities and differences, by for example explaining their origin, evaluating the solutions, or searching for a common core. Finally, it involves the treatment of any methodological problems which may arise, including those associated with the study of foreign law. The problems in society that require legal

\textsuperscript{14} Chisum (1998) p. 25.
\textsuperscript{15} 28 U.S.C. § 1338.
\textsuperscript{17} Chisum (1998) p. 27.
\textsuperscript{18} A type of \textit{writ} (an order issued by a legal authority) by which an appellate court decides to review a case at its discretion, meant for rare use. It orders a lower court to deliver its record in a case to the higher court, so that it may review it. The U.S. Supreme Court chooses most of its cases by using certiorari. (https://www.law.cornell.edu/wex/writ, https://www.law.cornell.edu/wex/writ_of_certiorari).
\textsuperscript{19} Bogdan (1994) p. 18.
regulation are often identical or similar in different legal systems. However, they are often regulated independently without regard to other countries’ regulation. Using comparative method, one can compare either the design of the rules or the substantive content (or both). The substantive law will be the main focus in this thesis. In the following discussion of comparative method, I will use Bogdan’s book as the main source unless otherwise specified.

2.2.2 What are the challenges of comparing these sets of rules?

One issue when comparing US and European law lies in the comparison of two fundamentally different legal systems – one common law and one civil law. The differences in role and importance of statutes, precedents, legislative preparatory materials etc. cannot be overlooked. The EPC is a treaty between what is mostly civil law countries (with the exception of England that is a common law country, although with modern continental European influences), and is therefore applied in a civil law landscape. In civil law countries, the law is based on statutes interpreted by the courts, whereas in the US a larger part of the law is made by judges in precedents. Furthermore, legislative preparatory materials plays a minor role in American law, whereas in Europe it is more relevant in the interpretation of rules. However, the differences must not be exaggerated. In many areas of law, precedents and judge-made law plays a huge part also in Europe. In European patent law, as is found in EPC, the study of case law by the EPO is essential in understanding and applying the rules. In the US, the federal judicial decisions, especially those from the Supreme Court, both interpret the legislation and create a vast amount of case-based law.

Regarding the interpretation itself, Bogdan accurately points out that “Foreign sources of law should be interpreted as they are interpreted in the country where they originate”.\(^20\) Whereas US courts tend to stick pretty closely to the literal meaning of the words when interpreting legislation, European courts and appeal boards are often more flexible in relation to the wording, placing more emphasis on the purpose, perhaps as found in judicial preparatory materials. These traditions have in turn influenced the statutory wording, so that American statutes are often more comprehensive in order to prevent a too restrictive interpretation. There might also be differences as to the weight and importance of obiter dicta, and the value of concurring and dissenting opinions.

\(^{20}\) Bogdan (1994) p. 47.
Something that also has to be considered, is the terminology. In both US and European law English is the original language (for the EPC it is one of three official languages). However, even if there are words or terms that are similar in the two legal systems, this does not mean that they have the same meaning. Here, it must for instance be considered whether similar terms in relation to medical methods has the same meaning in both set of rules.

One of the main differences in the area of medical methods is the fact that they are regulated under the patentability requirement in Europe, whereas limited in terms of enforceability in the US. The comparison is not between two exceptions to a rule or two conditions. This complicates a direct comparison, and requires a holistic view, with regards to the different fragmentary rules working together.

3 Patents on medical methods under European law

3.1 Patentable subject matter

3.1.1 Introduction

As noted above, the starting point under the EPC is that "any inventions, in all fields of technology" which are "susceptible of industrial application" are patentable as long as they are new and inventive, cf. EPC Art. 52(1). Any limitation to patentability must have a clear legal basis in EPC, it is not a matter of judicial discretion.\(^{21}\) The concept of invention is not positively defined, but EPC provides certain negative definitions. The most relevant in this context is Art. 52(2)(a), which says that "discoveries, scientific theories and mathematical methods" are not considered inventions, but "only to the extent" that the patent (application) "relates to such subject-matter or activities as such", Art. 52(3). This provision will be explored further under 5.2.2. Further, Art. 53 includes three exceptions to patentability; a) inventions contrary to "ordre public" or morality, b) plant or animal varieties or biological processes for the production of such, and, most importantly in this context, c) medical methods. The latter exception comprises:

"methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods."

\(^{21}\) EPO Case Law (2016) p. 10.
3.1.2 Methods and products distinguished

Since the exclusion only excludes "methods", and explicitly specify that the provision "shall not apply to products … for use in any of these methods", the distinction between methods and products becomes particularly important. There are two categories of patent claims; a claim to a physical entity such as a product, and a claim to a physical activity (method, process, use etc.). A product claim includes any substance, composition or physical entity which is produced by a person's technical skill, whereas a method claim is applicable to all types of activities where the use of a material product for effecting the process is implied; the process may be performed on material products, energy, other processes or living things.

Since the use of a product is categorized as a method, one could easily assume that the new use of a known substance is exempted from patent protection. However, even if the product is known, it is possible to obtain a patent on a first medical use, if the known product has not previously been disclosed for use in a medical method, cf. EPC Art. 54(4). It is also possible to obtain a patent on a second or further medical use, if this new use has not previously been disclosed, even if the product is already known for a different medical use, cf. EPC Art. 54(5).

Patent claims are normally drafted in the form: "Substance X for use in the treatment of disease Y", and can typically be the use of a known drug to treat a new disease. EPC Art. 54(5) also allow patentability on other types of specific use, such as dosage regimes and methods of administration that are not already known. This can for example be in the form "Substance X for use in the treatment of disease Y in dosage regime Z". Claims under EPC Art. 54(4) and (5) are formally worded and treated as product claims, but the novelty and inventive step reside in the new use. The rules are limited to the new use of a substance or composition of matter, they do not include new use of for instance medical equipment. The patents under EPC Art. 54(4) will be referred to as first medical indication patents, whereas patents under Art. 54(5) will be referred to as new medical use patents. The claims according to Art. 54(5) are often referred to as EPC 2000-claims, since this paragraph was included in the revision of the EPC in 2000.

In their official guidelines, EPO has given examples of how to formulate the claims in order to obtain a patent. A claim in the format: "Use of substance or composition X for the treatment

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23 EPO Guidelines Sec. 3.1.
24 EPO Guidelines Sec. 4.2.
25 EPO Guidelines Sec. 7.1.
of disease Y...” is not accepted for patentability, as it is considered a method for treatment excluded from patentability. However, a claim in the form: "Substance X for use as a medicament" is acceptable if the use of X in medicine is not known, even if X is a known substance (first medical indication). Also, "Substance X for use in the treatment of disease Y" is acceptable if it involves an inventive step over prior art disclosing the use of X as a medicament (second and further medical indications). In both of these claims, it is the product (substance X) that is patented, and not the method (the use of substance X). The scope of protection is, however, limited to the use specified in the claims, either “as a medicament” or “in the treatment of disease Y”.

Previously, these types of patents on a known product with a further medical use were also patentable as Swiss type-claims, which were typically in the form; "Use of substance X for the manufacture of a medicament for therapeutic application X".26 These were patented as methods ("use of"), and thus had a slightly narrower scope of protection than the EPC 2000-claims. The difference in scope of protection for products versus methods will be discussed below in Section 3.2.3. Swiss-type claims are only accepted for applications that have a filing or earliest priority date before 29 January 2011.27

3.1.3 Interpretation of excluded categories
3.1.3.1 Medical methods in general
In European practice it has been established that the medical method exception should be interpreted restrictively.28 The scope of the exception should be limited to what is needed in order to achieve the purpose behind the rules.

There are a couple of common features that applies to all three categories of medical methods. First, whether a method is covered by the exception does not depend on the participation of a medical practitioner, neither does it depend on whether all method steps can be practiced by medical or technical support staff, the patient himself or herself, or an automated system.29 Due to difficulties in creating a unified definition of “practitioner” within the EPC, and thereby legal

26 EPO Guidelines Sec. 7.1.
27 Ibid.
28 Stenvik (2016) p. 163.
29 G 1/04 (concerning diagnostic methods), G 1/07 (concerning treatment by surgery).
uncertainty in operating with such a distinction, the patentability should not be dependent on involvement of practitioners.\(^{30}\) Therefore, whether a method is excluded from patentability does not depend on the person carrying it out.\(^{31}\) However, in difficult cases it could be taken into consideration whether medical expertise is needed in the execution of the method.

Second, in order to be excluded from patentability, the method must be “practiced on the human or animal body”. This has been interpreted to mean that the method must be practiced \textit{directly} on the human or animal body, excluding from the exception examinations of blood, urine or tissue unattached to the body. The focus seems to be on whether \textit{the patient's presence} is necessary in the performance of the method, and not whether it requires physical contact between the patient and the medical personnel.\(^{32}\)

When determining whether a method should be excluded from patentability due to having a surgical, therapeutic or diagnostic character, it must be considered whether the method as a whole has such character. This does not mean that each step in the method must have medical character, but that the method must have at least one step that is adequate in giving the method in its entirety such a character. If the patent claims cover at least one medical application, the patent cannot be granted.\(^{33}\) That the method \textit{also} can be used for non-medical purposes does not prevent it from being excluded.

\textbf{3.1.3.2 Surgical methods}

Treatment by surgery is not limited to surgery for a therapeutic purpose. The term “surgery” commonly refers to the nature of the treatment, and not the purpose.\(^{34}\) Therefore, both therapeutic and cosmetic surgery is exempt from patentability.

 Accordingly, it is not necessary to distinguish between therapeutic surgery and other kinds of surgery. However, what constitutes “surgery” still needs to be decided. The term “surgery” in a medical sense is largely a matter of convention. In order to be surgical, the intervention does

\(^{30}\) G 1/04.

\(^{31}\) G 1/07.

\(^{32}\) Stenvik (2016) p. 166.

\(^{33}\) Stenvik (2016) p. 167, citing to T 82/93, G 1/04 T 290/86.

\(^{34}\) G 1/07.
not have to be invasive, and it is not necessary that tissue is penetrated\textsuperscript{35}. However, this definition may change over time, especially with new technical developments.

An interesting question is \textit{the degree of bodily intervention} that is required. In G 1/07 the Board stated that earlier interpretations were too broad, defining surgery as "any physical intervention" (G 1/04) or "all methods involving irreversible damage to or destruction of living cells or tissues of the living body (…) irrespective of the underlying mechanism of the invention".\textsuperscript{36} The Board sought a narrower definition based on the required medical expertise and the health risk involved, that didn't include "uncritical methods involving only a minor invention and no substantial health risks"\textsuperscript{37}. Ultimately, they were unable to conclude on such a definition, but the expected direction of future practice were nonetheless indicated; the exclusion "should not be applied to methods in respect of which the interests of public health, of protection of patients and as a counterpart to that of the freedom of the medical profession to apply the treatment of choice to their patients does not call for their exclusion from patentability"\textsuperscript{38}. This sets forth a purpose-based interpretation of the exclusion, and is in accordance with what is stated above; that the medical method exception should be interpreted restrictively so that it only excludes to the extent that is needed in order to protect public health while at the same time promoting innovation through the patent system. The boundaries of a narrower concept must be considered in each individual case based on technical realities, and is to be defined by the departments of first instance and the Boards of Appeal\textsuperscript{39}.

\textbf{3.1.3.3 Therapeutic methods}

As mentioned above, what is considered to be "medical methods" shall be construed narrowly, in the sense that a method for treatment by “therapy” must be therapeutic in nature.\textsuperscript{40} However, with this limitation in mind, the term covers any treatment “designed to cure, alleviate, remove or lessen the symptoms of, or prevent or reduce the possibility of contracting any disorder or malfunction of the human or animal body”\textsuperscript{41}.

\textsuperscript{35} T 5/04.
\textsuperscript{36} EPO Case Law (2016) p. 53.
\textsuperscript{37} Ibid. p. 53-54.
\textsuperscript{38} G 1/07.
\textsuperscript{39} EPO Case Law (2016) p. 53.
\textsuperscript{40} Ventose (2011) p. 75, T 144/83, G 05/83.
\textsuperscript{41} T 24/91.
Treatment by therapy includes the *curative* treatment of a disease, or *alleviation* of painful symptoms of the disease.\(^{42}\) It covers "any treatment designed to alleviate or reduce the symptoms of any malfunction of the human body".\(^{43}\) In T 0592/98, which involved a lung ventilator device, a method for delivering pressure assist ventilation in response to respiratory efforts of a patient, was considered a method of treatment by therapy. It is neither possible nor desirable to distinguish between basic therapy, which heals or cures, and symptomatic therapy that merely provides relief. Treatment by therapy also encompasses *prophylactic* treatment, which aims to maintain health and prevent ill effects that would arise without treatment.\(^{44}\) However, the method must be *directly related* to the maintenance or restoration of health.\(^{45}\)

The *origin or source* of pain, discomfort or incapacity is irrelevant for its relief to be considered therapy.\(^{46}\) In T 81/84 the relief of painful menstrual discomfort was considered therapy – even though menstruation is not a disease to be “cured”. However, contraceptive methods for preventing pregnancy are not considered therapy, as pregnancy is not considered to be a disease, and "treatment" of it provides neither cure nor relief.\(^{47}\)

However, therapy must be distinguished from “performance improvement”. The purpose of therapy is to restore or prevent the body from a pathological condition, and return it to or keep it in its original condition. A performance improvement on the other hand, aims to improve the body beyond its original condition, making the original condition the starting point and not the goal.\(^{48}\) Therapy must also be distinguished from *cosmetic* methods. Examples of cosmetic methods are methods for skin cleansing and methods for bleaching, coloring or removal of hair.\(^{49}\) The distinction between therapy and cosmetic methods can be difficult. A method for protecting the skin against UV-lighting, in order to prevent aging among other things, was

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\(^{42}\) T 144/83.  
\(^{43}\) T 0592/98.  
\(^{44}\) G 05/83.  
\(^{45}\) Ventose (2011) p. 77.  
\(^{46}\) T 81/84.  
\(^{47}\) Stenvik (2016) p. 164, citing T 74/93.  
\(^{48}\) T 774/89.  
\(^{49}\) Stenvik (2016) p. 164, citing to T 383/03.
considered to be therapy, and not a cosmetic method.\textsuperscript{50} The Board concluded similarly in regards to a method for preventing hair loss.\textsuperscript{51}

An issue is the patentability of methods that have both therapeutic and non-therapeutic (e.g. cosmetic) indications. According to EPO case law these can be patentable in certain cases. Whether they are patentable "depends, in particular, upon the wording of the claim in question".\textsuperscript{52} The fact that there are therapeutic effects in addition to a claimed non-therapeutic use does not make the invention unpatentable, as long as the additional therapeutic effects "can be clearly distinguished from the non-therapeutic use and are not covered by the subject-matter of the claim".\textsuperscript{53} On the other hand, if the scope of the claim includes a non-therapeutic element that is inseparably associated with a therapeutic element that is an essential part of the claimed method, the method is unpatentable under Art. 53(c) as a therapeutic method.\textsuperscript{54}

## 3.1.3.4 Diagnostic methods

A diagnostic method is a procedure to determine whether someone has a disease or condition when this is suspected because of certain symptoms or signs. As opposed to surgical or therapeutic methods that can consist of a single method step, several method steps are required for a diagnostic method due to its inherent multi-step nature.\textsuperscript{55} The method steps necessary prior to making a diagnosis are related to examination, data gathering and comparison. In order to be excluded from patentability, the method must incorporate all necessary steps from the gathering of information to giving the medical diagnosis.\textsuperscript{56} It must include method steps relating to four phases; the examination phase (collecting data), the comparison (data versus normal values), the finding of any significant deviation (symptom), and the deductive decision phase.\textsuperscript{57} Other methods in connection with diagnostics, such as methods for examining, collecting and analyzing medical data, are not considered to be diagnostic methods unless they culminate in

\textsuperscript{50} T 1077/93.
\textsuperscript{51} T 143/94.
\textsuperscript{52} T 0290/86.
\textsuperscript{53} EPO Case Law (2016) p. 59.
\textsuperscript{54} Ibid.
\textsuperscript{55} G 1/04.
\textsuperscript{56} T 382/86, G 1/04.
\textsuperscript{57} EPO Guidelines Sec. 4.2.1.3.
an actual diagnosis. The method must aim to diagnose a disease (or predisposition to a disease), as opposed to for example physiological abilities or intellectual abilities.\textsuperscript{58}

The requirement that the method must be performed \textit{on the body}, is interpreted to imply that the technical elements in the method must be performed in interaction with the patient, necessitating its \textit{presence}.\textsuperscript{59} This does not require a specific type or intensity of interaction with the body, physical contact between the patient and the medical professional is not necessary. The performance of the method steps may or may not involve the use of data collecting devices and diagnostic equipment for purposes of measuring and analyzing. However, if the method steps are carried out by a device without interaction with the patient, for instance by using a software program, the presence of the patient is not necessary, and the method might not satisfy the criterion. Similarly, the criterion is not met by method steps carried out \textit{in vitro}\textsuperscript{60} in a laboratory.\textsuperscript{61}

\section*{3.2 Scope of protection and enforcement}

\subsection*{3.2.1 Introduction}

The scope of protection for patents depends partly on which technical solutions the patentee is given exclusive rights to, and partly on what actions are reserved for the patentee through these exclusive rights. The first of these questions depends on the patent claims in each individual patent, and the interpretation of these (3.2.2). The second question depends on the provisions regarding exclusivity and enforcement. (3.2.3)

\subsection*{3.2.2 Interpretation of claims}

The patent claims define the scope of protection, however, the description and drawings shall also be used to interpret the claims, cf. EPC Art. 69(1). The Protocol on the Interpretation of Article 69 of the Convention\textsuperscript{62}, states that this does \textit{not} mean that the patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims and that the description and drawings should only be employed to resolve ambiguity in the claims. Nor does it mean that the claims are only a guideline and that the actual protection should be conferred

\textsuperscript{58} Stenvik (2016) p. 165.
\textsuperscript{59} EPO Guidelines Sec. 4.2.1.3.
\textsuperscript{60} In vitro tests means studies performed with biological molecules outside a living organism.
\textsuperscript{61} G 1/04.
\textsuperscript{62} This is an integral part of the convention that is binding for the contracting parties, cf. EPC Art. 164(1).
from the description and drawings. The result should be something in between, a position which combines a fair protection for the patentee and a reasonable degree of legal certainty for third parties. The perspective when interpreting the claims is that of a person skilled in the art. The skilled person should avoid illogical interpretations, and attempt to reach a technically sensible interpretation that takes into account the whole disclosure of the patent.\(^{63}\)

When determining whether a patent has been infringed, the all elements rule is applied, meaning the patent is only infringed if all the claim elements read on the accused infringement. There is also the doctrine of equivalents, meaning that substituting an element in the claim with an obvious modification having the same effect could still constitute infringement. The doctrine of equivalents is reflected in Art. 2 of the Protocol, which was included in the revision of the EPC in 2000.

### 3.2.3 Enforcement

The enforcement of patents under the EPC is essentially left to regulation by national law. According to EPC Art. 64(1), a patent should be given the same rights as a national patent in each member country that it is granted in respect of, and any infringement shall be dealt with by national law, cf. Art. 64(3). The only regulation of patent enforcement can be found in EPC Art. 64(2): "If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process." A question that can be raised is what constitutes a product obtained directly by a process. This is given some consideration in EPO Guidelines regarding the corresponding rule in EPC Art. 64(2). There it is said that this provision applies to "processes producing products completely different from the starting materials as well as to the processes producing only superficial changes (e.g. painting, polishing)\(^{64}\).

Even if patent enforcement is only partially harmonized by the EPC, national law is largely harmonized through voluntarily adaptation to the Community Patent Convention (CPC) Art. 25\(^{65}\) (even if the convention has not yet entered into force). A rule corresponding to CPC Art. 25 can for example be found in the Norwegian patent law (patl.) § 3(1).

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\(^{63}\) T 190/99.

\(^{64}\) EPO Guidelines Sec. 4.12.

\(^{65}\) See also the regulation on Unitary Patent Art. 5(3), and the agreement on a Unified Patent Court Art. 25.
The CPC Art. 25 (prohibition of direct use of the invention) gives the patentee the right to prevent third parties: "(a) from making, offering, putting on the market or using a **product** which is the subject-matter of the patent, or importing or stocking the product for these purposes; (b) from using a **process** which is the subject-matter of the patent or, when the third party knows, or it is obvious in the circumstances, that the use of the process is prohibited without the consent of the proprietor of the patent, from offering the process for use within the territories of the Contracting States; (c) from offering, putting on the market, using, or importing or stocking for these purposes the **product obtained directly by a process** which is the subject-matter of the patent." [emphasis added] The latter alternative corresponds to EPC Art. 64(2).

CPC Art. 25(a) sets forth the scope of protection with regard to product claims, whereas Art. 25(b) and (c) applies to method claims. First medical indication claims and EPC 2000-claims are subject to 25(a) being product patents. Swiss-type claims are protected under both 25(b) and 25(c), whereas methods that do not result in a product, for example diagnostic methods, follow 25(b), but not 25(c).

The scope of protection is generally wider for products than it is for methods. Patents on products generally protect all use of the product, including the use of the product in any type of method. A method patent, however, is limited to one particular use, or a group of such. It is a general perception in the patent industry that if you can obtain a product patent this is a better choice due to the stronger protection.

However, the scope of protection for a patent on the new use of a product will not be the same as for a patent on a new product. Even though a new use patent is a product patent it will not give exclusive rights to any use of the product due to the use limitations in the claims. How narrow the use limitation is, depends on the type of claim. For first medical indication patents the scope of protection will be limited to the use of the product as a medicament. For EPC 2000-claims the scope of protection will be limited to the specific new use.

What does this mean for the difference in scope of protection between a new use product patent and a method patent? The main difference is that product claims can be enforced against manufacturers and distributors of the product etc. through the rules on **direct infringement**. Medical method claims, on the other hand, are usually only enforceable under the prohibitions
on indirect use or indirect infringement. This is because the actions that are protected through a medical method claim will typically be directly performed by a doctor or other medical practitioner, not by a manufacturer or a seller. This means that in order to enforce a medical method patent one has to rely on somewhat vague rules regarding indirect use or indirect infringement, with inherent limitations.\(^{66}\) The possibility to enforce such patents against doctors and hospitals is regularly of little importance, since it is not desirable to enforce a patent against these due to publicity concerns and customer relations (more on this in Section 4.2.3). Thus, the enforcement value is higher for product patents on new medical use than for medical method patents. This is particularly relevant for the comparison of new use patents in Europe and in the US, since new uses of know products are patentable as products in Europe and as methods in the US. This will be discussed further in 4.2, and in the comparison in Section 5.

## 4 Patents on medical methods under US law

### 4.1 Patentable subject matter

35 U.S. Code § 101 sets forth the subject matter of patentable inventions under US law. A patent is obtainable to whoever invents or discovers "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof". As medical methods are not per se exempt from patent protection under US law, the presumption is that such methods constitute patentable subject matter. According to one commentator, more than 80 countries exclude medical procedures from patentability, and the US and Australia are the only countries allowing medical methods to be patented\(^{67}\). However, medical method patents can be excluded on other grounds. Laws of nature, abstract ideas and physical phenomena are not subject to patent protection according to case law\(^{68}\), and can prevent patentability of therapeutic and diagnostic methods.

An example of how the exception for laws of nature is applied can be found in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*\(^{69}\) The case concerned patents on diagnostic methods, and they were challenged on the basis that they constituted laws of nature. Prometheus’ patent covered a process of determining the right dosage of thiopurine in the

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66 See CPC Art. 26 on indirect use, and national rules.
67 Rastogi (2014).
treatment of autoimmune, gastrointestinal diseases. The method involved administering the drug to patients, and measuring levels of a metabolite, in order to determine the proper dosage of the drug for each individual. Humans metabolize thiopurine compounds differently, and before using this method, it was difficult for doctors to provide the correct dosage for a particular patient. However, the plaintiff Mayo, claimed that this patent was simply an application of laws of nature, and therefore not patentable. The Supreme Court explained that a method is not unpatentable simply because it contains a law of nature. A concrete application of a law of nature can be patentable, but one needs to do more than simply state the law and add the words “apply it”. In this case, the claimed methods did nothing more than stating the underlying laws of nature, and were therefore not patentable. In Europe, on the other hand, this very same method was considered patentable. This divergence will be analyzed below in Section 5.3, where the exception also will be explored in greater detail.

4.2 Scope of protection and enforcement

4.2.1 Introduction

The protection afforded by a patent depends on 1) the interpretation of the claims as to which technical solutions these comprise, and 2) the rules on enforcement in 35 U.S.C. § 271 that applies to the particular claims.

As in Europe, the scope of a US patent is decided by the claims. Patent infringement is defined in 35 U.S.C. § 271 as unauthorized practice of the "patented invention". The "patented invention" means the subject matter that the inventor has particularly pointed out and distinctly claimed according to the specification requirement in § 112(b). The claims set forth the boundaries of the patentee's right to exclude.70

The rights conferred by a US patent are basically the same as in Europe. It gives the owner exclusive rights to prevent others from making, using, offering to sell or selling the patented invention, which is considered infringement of the patent, 35 U.S. Code § 271(a). It also protects against indirect infringement in the form of actively inducing infringement § 271 (b), or contributory infringement § 271 (c).

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Medical methods is subject to a specific rule on limited enforcement in § 287(c), which prevents patents on medical methods from being enforced against medical practitioners or related health care entities, when performed by a medical practitioner. This rule will be discussed in Section 4.2.3.

4.2.2 Interpretation of claims
There are four types of claims in US patent law; composition claims, process or method claims, apparatus claims, and manufacture claims.\(^{71}\) Composition claims can be "compositions of matter" (chemical compounds), or simply "compositions" (chemical combinations or mixtures of ingredients), the latter can be claimed by naming the compound or ingredients, and if necessary specifying the proportions or other parameters. Process or method claims can be either 1) a process or method of \textit{making} an object or a substance; or 2) a process or method of \textit{using} an object or a substance. The term "process" is defined in 35 U.S. Code § 100(b) as a "process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material". A new use of an old (or new) product can only be achieved in the form of a method claim, more specifically a method of \textit{using} claim.\(^{72}\) This is different from the situation under EPC, where a new medical use patent is patented as a product, and means that a new use patent has less protection in the US, as explained in Section 3.2.3. The rules on indirect infringement are thus particularly relevant here, see further in 4.2.3. The term new medical use patents will be used for patents on the new use of a known product also under US law, but where there is potential for ambiguity as to the type of new use patent, it will be specified whether the patent referred to is a new medical use product patent (under EPC), or a new medical use method patent (US). A new medical use method patent under US law must incorporate at least one step in addition to the mere use.\(^{73}\)

Apparatus claims are generally directed at the mechanical structure of an apparatus. Manufacture claims are directed at articles produced from materials by a process giving these materials new forms, qualities, properties, or combinations of such.\(^{74}\)

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\(^{71}\) Ibid. p. 87-92, USPTO Guidelines Section 2106.01.

\(^{72}\) Ibid. p. 89.

\(^{73}\) USPTO Guidelines Section 2173.05(q).

\(^{74}\) USPTO Guidelines Section 2106.01.
The starting point for the interpretation of claims is the literal meaning of the words, however the patentee may be "his own lexicographer" and define the terms. When determining the meaning of the words used in the claim, guidance can be obtained from the context the language is used in, including the claim itself, the other claims, the written description, the drawings, and the prosecution history. Similar to Europe, the US also applies the all elements rule, and a similar doctrine of equivalents\textsuperscript{75}, even though there are some differences in detail. I will not go further into this.

4.2.3 Enforcement - the limited enforcement rule

According to 35 U.S.C. § 287(c), certain medical inventions have limited enforcement against medical practitioners or related health care entities. § 287(c)(1) states:

"With respect to a medical practitioner’s performance of a medical activity that constitutes an infringement under section 271 (a) or (b), the provisions of sections 281, 283, 284, and 285 shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity"

There are two types of infringement under US law; direct infringement (§ 271(a)) and indirect infringement. Indirect infringement is either active inducement of infringement (§271(b)) or contributory infringement (§271(c)).

According to §287(c), when a medical practitioner performs a patented medical activity, so that it is either directly infringing or inducing infringement, then the patent cannot be enforced against the medical practitioner himself or a related health care entity such as the hospital. The provisions that do not apply, are the patent owner’s right to a remedy by civil action for infringement (§ 281), and the courts’ option to grant injunctions (§ 283), and to award damages (§ 284) and attorney’s fees (§ 285). As a consequence, medical practitioners can freely perform certain patented medical methods without having to worry about remedies, and without their employers having to worry about being held responsible for their actions. The consequence of the limited enforcement rule is that the only available option is enforcement against other entities, such as the manufacturer, importer or merchant of a product used in the patented method. These entities will not directly infringe the method, as they do not perform the steps

\textsuperscript{75} Chisum (1998) p. 1031.
defined in the patent claim. Thus, they can only be responsible through the rules on indirect infringement, either contributory or actively inducing. I will discuss contributory infringement in greater detail below.

In order to assess the effects of the limited enforcement rule, there are two main issues that need to be decided; 1) the scope of the rule; meaning what types of patent claims are subject to the restriction (what constitutes an infringing medical activity) and which subjects are authorized to lawfully perform the claimed activity (what constitutes a medical practitioner), and 2) the scope of rights and “enforcement value" that remains for medical methods subject to the rule (to what extent can patents be enforced under the restriction).

The first question with regard to the scope of the rule is what constitutes a "medical activity". The term is defined in § 287(c)(2)(A) as “the performance of a medical or surgical procedure on a body”. The method must be performed on a body, which, read literally, necessarily requires the presence of the patient. For instance, a diagnostic method performed on tissue that is separated from the patient, is not subject to limited enforcement.

Further, the limitation explicitly excludes certain categories from being a "medical activity", the first one being; “(i) the use of a patented machine, manufacture, or composition of matter in violation of such patent”. If a machine, manufacture or composition of matter that is patented as a product is used in the performance of a medical activity, this constitutes infringement, and the product patent is fully enforceable.

The second category that is not considered a "medical activity" subject to limited enforcement is; "(ii) the practice of a patented use of a composition of matter in violation of such patent” [emphasis added]. This refers to new use patents, which only involve new uses of a known composition of matter. A composition of matter includes “all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids”.76 A drug will always contain a carrier substance in addition to the active substance, thus all patents on new uses of

known drugs are fully enforceable. As mentioned above in Section 4.2.2, new use claims are only patentable as (medical) methods in the US. Thus the specific exclusion is necessary in order not to be subject to limited enforcement.

The third exception is; "(iii) the practice of a process in violation of a biotechnology patent”. A process in violation of a biotechnology patent is not subject to limited enforcement. This comprises patents on genes, proteins, gene therapy and other patents on inventions involving genetic material. Most biotechnology patents are probably also covered by one of the two former categories (i) or (ii), as will be shown in 5.3.3.

The second question that must be answered in relation to the scope of the rule, is what constitutes a “medical practitioner”. The term is defined in § 287(c)(2)(B) as “any natural person who is licensed by a State to provide the medical activity described in subsection (c)(1) or who is acting under the direction of such person in the performance of the medical activity.” This includes, for instance, licensed doctors and nurses, medical students, physicians and dentists. Only natural persons are protected as medical practitioners. Based on the wording, this must mean that medical activities or methods performed by machines are fully enforceable. If the machine is subject to a product patent, then this is already excluded from being defined as “medical activity”, § 287(c)(2)(A)(i). Aside from activities performed by a machine, it is hard to imagine other situations where medical activities are performed by anything other than natural persons, which gives this requirement a rather narrow scope. Where there is a performance of a patented medical activity by a medical practitioner, both the medical practitioner and the related health care entity (e.g. a hospital) is protected from infringement claims regarding that activity.

Two important consequences of the way the limited enforcement rule is structured should be noted. First, the limited enforcement rule only limits enforcement against medical practitioners and related health care entities, meaning that the patent is still fully enforceable against all other subjects. Second, it only limits enforcement when the basis is direct or inducing infringement performed by the medical practitioner, everyone can be liable for contributory infringement.

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Since the limited enforcement rule only protects medical practitioners and related health care entities, pharmaceutical companies and other entities in the medical industry might infringe on medical method patents, either by active inducement or contributory infringement. These are not protected against patent enforcement by § 287(c)(1). For someone to be held liable for indirect infringement, there must be a direct infringement, and a direct infringer. In this case, it is the person performing the method, for instance a doctor, who is the direct infringer. The fact that the doctor’s activity is protected by the limited enforcement rule does not mean that he or she does not infringe, only that there are no remedies available against his or her infringement.

Medical practitioners and hospitals are protected from liability of actively inducing infringement, cf. § 271 (b). However, the patent is still enforceable against active inducement of infringement by entities that are not protected by the rule, such as the manufacturer, importer or merchant of products used in the method. Active inducement of infringement requires at least a minimum level of intent, and the taking of affirmative steps to bring about the desired result;79 “evidence of active steps taken to induce infringement, such as advertising an infringing use, can support a finding of an intention for the product to be used in an infringing manner”.80 Induced infringement requires knowledge that the induced acts constitute patent infringement; the knowledge requirement is the same as for contributory infringement under § 271(c).81 Acts that can constitute active inducement can for instance include providing instructions, demonstrations, or training on how to practice the claimed invention.82 A company that produces a device which it knows is particularly suitable for use in a patented surgical method, and specifically promotes the device for use in conjunction with a patented surgical method, can be held liable.

Since § 271 (c) is not mentioned in § 287(c), the rule does not protect anyone (medical practitioners, hospitals or anyone else) from liability for contributory infringement. A person or entity may be liable for contributory infringement, § 271(c), where it (1) offers to sell, sells or imports a material or apparatus for use in practicing a patented process, (2) which the person or entity knows is particularly suited for use in the patented process, and (3) it is not a staple article or commodity of commerce suitable for substantial non-infringing use. Using the above

example, if a company produces a device which it knows is particularly suitable for use in a patented surgical method, and that machine has no other substantial non-infringing application, the company may be liable as a contributory infringer. Hospitals (or even doctors) can also be liable for contributory infringement if they perform as a distributor of a product used in a patented product.

Based on this, what can be said about the level of protection for patents that are subject to the limited enforcement rule? It typically means that the patent can only be enforced against a company producing products for use in the method. Usually however, this might not be a big disadvantage. Even if the option of enforcing the patent against doctors and hospitals had been available, it would probably not have been used to any significant extent. To my understanding, patent proprietors are generally extremely reluctant to enforce their patents against doctors and hospitals. Doing this would definitely not be beneficial to a company's reputation and public image, and it would also mean that you had to sue your "customers". I am not aware of any examples of doctors or hospitals being held liable for patent infringement. The common approach is to enforce the patent against the manufacturer, the importer or the wholesaler, via the rules on contributory or inducing infringement, irrespective of whether the limited enforcement rule applies or not. This might explain why there is little case law and literature regarding the limited enforcement rule; because the enforcement options that are excluded would not have been utilized even without the restriction.

The limited enforcement rule means that medical methods subject to it can only be enforced through the rules on indirect infringement. As seen in 3.2.3, enforcement against indirect infringers is more complicated than basing a claim on direct infringement. This is also the reason why product claims are usually more advantageous than method claims, and explains why patents on the new medical use of a known product have a larger scope of protection in Europe due to being patented as products, than in the US where they are patented as methods. As such, the rule that new use inventions must be patented as methods in the US, generally have more impact on the scope of protection of medical methods in the US, than the limited enforcement rule, which only block enforcement options that would not have been used. As set forth above, the limited enforcement rule does not apply to new use methods, and does not affect the scope of protection for these types of methods at all.
The distinction between method and product patents is more important with regard to scope of protection than the limited enforcement rule. A product patent generally provides better protection. However, in relation to new use patents, the difference is less significant because product claims include use limitations, see further below in 5.3.1. Again, the scope of protection depends on the specific wording of the claims.

5 Comparison and evaluation

5.1 Introduction

In this final part of the thesis the purpose is to identify the main differences between the US and Europe with regard to patentable subject matter and scope of protection for medical methods. I will begin in 5.2.1, by deciding when there is a difference in patentable subject matter. In which cases are medical methods excluded from patentability in Europe, while being patentable in the US? I will also compare the scope of protection between the jurisdictions with regard to these methods, by deciding the scope of protection for the US patents. In 5.2.2, I will look at the opposite situation regarding patentable subject matter; when is a medical method is patentable in Europe, but not in the US? The difference in scope of protection with regard to these methods does not give cause for a similar discussion as the one in 5.2.1, since there are no limitations on the enforcement of medical methods in Europe. After this discussion of the main differences, I will perform a case analysis in three selected areas of law. Here, I will look at how the rules apply to actual cases and patents. This will show to which extent the differences that are explained in 5.2 on a theoretical level, have practical consequences in terms of different levels of protection.

5.2 Main differences in subject matter and scope of protection

5.2.1 Subject matter that is excluded in Europe and eligible for protection in the US

Even though medical methods in principle are excluded from patentability in Europe, there are several limitations to this rule. A medical method that does not have a therapeutic, surgical or diagnostic character is free to be patented. This can be a cosmetic method, or a method for examining and analyzing medical data that doesn’t culminate in a diagnosis. Further, a method that is not performed on the body, such as an in vitro method performed in a laboratory, is patentable. Since only methods are exempt, new and inventive medical products are eligible for protection. Patent on a product will also cover the use of this product in any method, unless the claim is limited to a specific use of the product. The new use of a known substance or
composition is also patentable as a product, however the scope of protection is limited to the type of use specified in the claim. Aside from these limitations, the remainder of medical methods are not eligible for patent protection in Europe. Based on this, the main difference between patentable subject matter in Europe and the US regarding medical methods is this; medical methods that are performed on the body, that does not include an inventive product, and that does not involve a new-use patent, are excluded from patentability in Europe, and in principle patentable subject matter in the US (unless it is excluded by other rules, see 5.2.2).

The limitation on US patents related to medical methods lies in the scope of protection and enforcement. The protection for inventions related to medical methods depends on whether the exercise of the method is protected by the limited enforcement rule. As explained above in Section 4.2.3, this rule applies to;

1. Medical activities; but
2. Only when performed by medical practitioner

If these two requirements are not met, then the medical activity is not protected and the patent is fully enforceable. According to § 287(c)(2)(A), the use of a patented product, the performance of a patented new medical use, or the practice of a process in violation of a biotechnology patent, does not constitute a "medical activity". Thus product patents, new use patents and biotechnology patents are fully enforceable. A method performed by a machine, and not by a natural person, is not performed by a medical practitioner, and is also fully enforceable. All other medical activities performed by medical practitioners are subject to limited enforcement, which means that many medical method patents are subject to limited enforcement.

In cases where the limited enforcement rule applies, certain enforcement options still remain available. The medical method patents can be enforced against;

1. Anyone guilty of contributory infringement
2. Other entities than medical practitioners and related health care entities guilty of actively inducing infringement

As explained above in Section 4.2.3, medical method patents can’t be enforced against the persons and entities most likely to directly infringe it, i.e. doctors and hospitals. However, other entities such as pharmaceutical companies can in some cases be held liable for indirect infringement. Hence, the value of a patent on a medical method subject to limited enforcement depends on the likelihood that it is indirectly infringed. For example, the likelihood may be
higher if the medical method involves the use of a device that is attractive for competitors to offer. The decision on whether to seek patent protection for a medical method invention should therefore partly depend on the likelihood that companies will manufacture products particularly suited and intended for use with that method.\textsuperscript{83}

Based on this, proprietors of medical patents do have protection for their inventions in spite of the limited enforcement rule, without this protection preventing the purpose of the rule to be fulfilled. The limited protection ensures that patients are not prevented from getting the best possible treatment, and it does not hinder medical professionals from freely choosing among and perform any patented treatment.

The difference between Europe and the US in terms of protection can be illustrated by an imaginary example: Let’s say that a new surgical method for breast reconstruction uses an implant that for a long time has been known to be very good, but has previously been associated with severe side effects. The new method of implanting severely limits the side effects, thereby creating a sudden demand for the implant.

Because it is a surgical method performed on the body, and because it does not include an inventive product or the new use of a substance or composition, it is not patentable in Europe. However, assuming the ordinary patentability requirements are fulfilled, and the method is not excluded by other rules, it is patentable in the US, and it can be subject to limited enforcement. The patent cannot be enforced against medical professional directly infringing by using the surgical method, but it can be enforced against companies indirectly infringing by offering the implant to surgeons knowing that it is especially adapted for use in connection with the patented method and that it has no other substantial non-infringing application, or knowing it is particularly suited for the patented method and actively advertising it to be used in connection with it. In this example the inventor of the new method have no protection in Europe, but a certain degree of protection in the US. The result is that the inventor of the method patent in the US can almost exclusively produce and sell the product (implant) since any competitors starting to produce the implant that has now suddenly become in demand, will likely be guilty of indirect infringement. The inventor’s efforts are thus incentivized and rewarded, without preventing the surgeon from freely performing the method.

\textsuperscript{83} Gornish (2006)
A real life example can be given of a patent that was rejected in Europe due to being a medical method, but was patented and would have had enforcement value in the US. The patent claimed a *method of producing an endoprosthesis as a joint substitute for knee-joints*, US 5,735,277. This patent involved an adaptation of the prosthesis to the individual human body through a surgical step necessary to get the correct measurements. In Europe, the method was excluded from patentability due to being a medical method, EP0704193 (A1). The inventive aspect was the new way of adjusting the prosthesis to the body, not the prosthesis itself, so no product patent was available. Nor did it qualify for a new use patent, as a prosthesis is not considered a substance or composition.

In the US, this patent is subject to limited enforcement, but it can be enforced against indirectly infringing companies producing the industrially manufactured prosthesis used in the method. The prerequisite for such enforcement would have to be that the company knows that the prosthesis is particularly suited for use in this new method, and that *either* the prosthesis has no substantial non-infringing use, for example because this particular type of prosthesis is rarely used in non-infringing methods *or* the company specifically induces the use of the prosthesis in the patented method.

Compared to Europe, where these medical methods have no protection, the level of protection is significantly higher in the US even under the limited enforcement rule.

**5.2.2 Subject matter that is excluded in the US and eligible for protection in Europe**

Medical methods might not always be eligible for protection in the US due to other exceptions. This can lead to situations where a method is patentable in Europe but excluded from patentability in the US.

As mentioned above in Section 4.1, laws of nature, abstract ideas and physical phenomena cannot be patented in the US. The closest corresponding rule in European patent law can be found in EPC Art. 52(2)(a), which excludes discoveries, scientific theories and mathematical methods from being inventions. In order to assess the impact of these exclusions, one has to interpret the rules and determine to what extent they are analogous.
The US exception for laws of nature, abstract ideas and physical phenomena was confirmed in Diamond v. Chakrabarty, which concerned the patentability of genetically modified organisms, more specifically "whether a live, human-made micro-organism is patentable subject matter under 35 U.S.C. § 101". This landmark case is a good illustration of the scope of the exception. The Court initially stated that new minerals or plants found in nature are not patentable subject matter. Neither are laws of nature such as E=mc², or the law of gravity. The micro-organism in the present case was, however, patentable due to the fact that it was a "nonnaturally occurring manufacture or composition of matter -- a product of human ingenuity 'having a distinctive name, character [and] use.'" The Court compared the present case to the previous case Funk Brothers Seed Co. v. Kalo Inoculant Co., which involved the discovery of the existence in nature of specific species of root nodule bacteria that did not have a mutually inhibitive effect on each other. This discovery was used to produce a mixed culture that was capable of inoculating the seeds of leguminous plants. This was nonpatentable due to simply being "handiwork of nature". The combining of the bacteria did not alter or improve their natural functioning, didn’t produce any new bacteria, didn’t change the species of bacteria and didn’t enlarge the range of their utility. The bacteria simply had the same effect as always, which they performed naturally and independently of the patentee's efforts. In contrast, the patentable micro-organism in Chakrabarty was produced by the patentee as a new bacterium, which had markedly different characteristics from the ones found in nature and significant utility potential. Whereas the patentee in Funk simply had made a discovery and combined naturally occurring compositions without altering them, the patentee in Chakrabarty had produced a new and nonnaturally occurring composition.

In Europe, the exception in EPC Art. 52(2)(a) contains language similar to Chakrabarty. It applies to discoveries, scientific theories and mathematical methods, but "only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such" [emphasis added], EPC Art. 52(3). If a patent claim contains both excluded and non-excluded features, it does not relate only to excluded subject matter "as such" and it is thus not affected by the statutory exception. This limitation to the exception serves as a bar against a broad interpretation. The exceptions for discoveries and scientific theories are most

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85 G 2/12 and G 2/13, T 154/04.
relevant in the context of this thesis. The question is how the line is drawn between discovery and invention under the EPC.

A discovery is the mere finding of something that already exists naturally, independently of the patentee's efforts. Discovering a new property of a known material, or finding a new substance in nature is a discovery. However, if the new property is put to practical use or the substance found is utilized to produce a technical effect it constitutes an invention. This requirement is a logical result of the definition of an "invention", which must have technical character and technical effect. How much effort is required to turn the discovery of a new substance into an invention? It is no longer a discovery if the substance no longer appears in its natural form. The substance must at least have been isolated from its natural surroundings. On the other hand, there is no requirement that the substance is changed in terms of structure or properties. It can be emphasized that an invention may reside in a discovery, without the claimed subject-matter being a discovery "as such".

This leads to the question whether the exception for discoveries and scientific theories in the EPC and the US exception for physical phenomena and laws of nature have the same scope. One example can be given of a patent that was rejected in the US under the laws of nature/physical phenomena exception, whilst held to be patentable in Europe. In Mayo Collaborative Services v. Prometheus Laboratories (mentioned above in 4.1), the US Supreme Court concluded that the claimed methods did nothing more than stating the underlying laws of nature, and was therefore not patentable. The same invention was patented in Europe; Method for optimizing the use of 6-mercaptopurine in the treatment of immune-mediated gastrointestinal disorders. The European patent (EP1115403 (B1)) claimed an in vitro method. An in vitro method is not executed on the body, and therefore not excluded under the medical method exception. The method was not exempt from patentability as a discovery either, because under European law it is only a discovery as such that is unpatentable, whereas application of the discovery may be patentable. This particular example will be further explored below in 5.3.2. Accordingly, the US exception for physical phenomena and laws of nature has a wider scope than the European exception for discoveries and scientific theories, which is subject to a more narrow interpretation.

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The discussion above also shows that it is possible for a medical method to be patentable in Europe while being excluded from patentability in the US. This further emphasizes the importance of a holistic perspective. In the example above, the medical method had better protection in Europe, without this having to do with the medical method exception that is the subject of this thesis, but rather with other patent rules that affects the same subject-matter.

5.3 Case analyses in selected areas
In this part of the thesis I intend to put the general conclusions reached above to test in selected cases. I have attempted to identify cases where there are corresponding US and EU patents (unless there is only a patent in one of the jurisdictions because of different rules). Where there is case law regarding the patent, I have include this. When referring to granted patents that are not linked to any oppositions or litigations, the patents serve simply as examples and illustrations of the patent offices' application of the rules, they do not serve as precedents on the law. However, they can reflect earlier precedents on the law, and they illustrate how the law is applied.

The first case – new medical use – has been chosen because of its economic significance, as explained below. The second and third case – genetic diagnostics and gene therapy – are selected because they represent advanced and newly developed technology that is important today, and which importance will probably grow tremendously in the future. Hence, these inventions are of immense medical importance.

5.3.1 New medical use
New uses of known compounds and compositions are as a general rule fully protectable both in Europe and in the US, as they are not excluded from patentability in Europe and not subject to limited enforcement in the US.

New medical use patents are often results of clinical trials aimed at finding out how the drugs are best administered. What dosage shall be used, how often shall the drug be administered, to what types of patients, together with which other drugs, etc.? Clinical trials are usually conducted in four phases; 1) the first trials with healthy volunteers, small, usually with 15-50 people (is it safe?), 2) trials to determine the effectiveness on patients, larger with 25-100 people, 3) trials to compare the safety and effectiveness to the current method/drug used, large, can involve tens of thousands of participants, 4) trials looking at other benefits or side effects
or other uses of the method/drug, usually done after a method is approved and in use, less common, may involve hundreds of thousands of people.\textsuperscript{88} When getting to phase 3 and phase 4 of clinical trials, large investments are required. At the same time, the medical benefits from such studies are often huge. In order to incentivize this type of research and achieve medical innovation, it is considered beneficial to protect the large investments by granting patent rights.

An example of a new use invention is a method for treating hyperlipidaemia invented by Abbott. The European patent, EP0643965 (B1), included both "Swiss-type" and EPC 2000-claims.\textsuperscript{89,90} Claim 1 was worded in the Swiss type-format as follows:

"1. \textbf{The use of nicotinic acid} or a compound metabolized to nicotinic acid by the body (…) \textbf{for the manufacture of a sustained release medicament for use in the treatment} by oral administration once per day prior to sleep, \textbf{of hyperlipidaemia} characterised in that the medicament \textbf{does not comprise} in admixture 5-30\% hydroxypropyl methylcellulose, 2-15\% of a water soluble pharmaceutical binder, 2-20\% of a hydrophobic component and 30-90\% nicotinic acid." [emphasis added]

Claim 8 was in the \textit{EPC 2000-format}:

"8. \textbf{A sustained release medicament} comprising nicotinic acid or a compound metabolized to nicotinic acid by the body (…), \textbf{for use in the treatment} by oral administration once per day prior to sleep, \textbf{of hyperlipidaemia} characterised in that the medicament \textbf{does not comprise} in admixture 5-30\% hydroxypropyl methylcellulose, 2-15\% of a water soluble pharmaceutical binder, 2-20\% of a hydrophobic component and 30-90\% nicotinic acid." [emphasis added].

Judging from the description, the inventive concept was the use of a known compound in a sustained release formulation and administering it once daily prior to sleep. The wording "does not comprise" served to distinguish the formulation from a prior art formulation comprising the same compound. The purpose of the invention was to reduce side effects.

These two independent claims are regulated by two different rules regarding the scope of rights. The Swiss-type claim is formally a method claim, subject to CPC Art. 25(b) and (c), see above

\textsuperscript{88} http://www.breastcancer.org/treatment/clinical_trials/phases
\textsuperscript{89} This patent was filed 19.09.1994 enabling the claims to be formulated as "Swiss-type" claims.
\textsuperscript{90} G 02/08.
under 3.2.3. This claim gives the patent owner rights to the method, and to the product obtained directly by the method, which in this case is the sustained release medicament for use in the treatment of hyperlipidemia and administered once daily before sleep. The EPC 2000-claim, on the other hand, is a product claim subject to CPC Art. 25(1), which gives the patent owner rights to the product; the sustained release medicament for use in the treatment of hyperlipidaemia and administered once daily prior to sleep. In practical reality, there is little difference in terms of protection between claim 1 and claim 8.

There are six US patents in the same patent family; three product patents and three method patents. The product claims are patented as new products, since new use product claims are not available in the US. In order to fulfill the novelty requirement, the US product patents claim a new product with a particular sustained release profile defined in three different ways. Patent US6406715 (B1) specifies the metabolite profile of the active ingredient; when you give the patient 1000 mg of the nicotinic acid formulation you get nicotinic acid in the urine from 4-26%, and Pathway 2 metabolites, a substance that is transformed in the body at a certain percent, from 75-95%. A product with sustained release and this exact metabolite profile is a new product. The US product claim is more limited than the European new use product claim because all sustained release formulations that do not satisfy the exact demands for metabolite profile will fall outside the scope of the patent. The other two product patents belonging to the same family also narrows the scope of protection in a similar way. US6746691 (B2) defines the dissolution curve and profile of nicotinic acid, measured by in vitro tests. US6818229 (B1) defines the content of nicotinic acid in the blood. The narrow definition of the product in these claims gives the US product patents a more limited scope of protection than the European patent claims. The US method claims do not have the same limitation, and they therefore have a scope of protection more comparable to the European patent claims, which makes these more relevant for the purpose of comparison. This is also an example of how a new use method claim can have a wider scope of protection than a traditional product claim, due to the product claim being so narrowly defined.

Of the three US method claims, US7011848 (B1) has the broadest claim:

"A method of treating hyperlipidemia in a hyperlipidemic comprising dosing the hyperlipidemic with an effective antihyperlipidemic amount of nicotinic acid or compound metabolized to nicotinic acid by the body, once per day in the evening or at
night combined with pharmaceutically acceptable carriers, to produce a reduction in total and LDL cholesterol, triglycerides and Lp(a), with a significant increase in HDL cholesterol."

This is a new use method claim. When comparing the scope of protection between the US new use method claim and the European new use product claims, consideration must be given both to the difference in scope of protection between new use products and methods, and to the specific limitations in the claims. The European product claims are limited to certain groups of active compounds, and also have a negative limitation in order to distinguish the inventions from previously known formulations. It is difficult to determine how much these limitation mean in practice, and this must be determined concretely. With regards to the way that the invention is performed (the use limitations), there is no practical difference. The new dosage regime claimed by the European patent consists of administering the drug once a day in the evening or night. Similarly, the process step of the US method claim is administering the drug “once per day in the evening or at night”. The principle difference is thus in the difference of enforcing a product patent (against direct infringement) versus a method patent (against indirect infringement), as explained in 3.2.3 and in 4.2.3. As such, patents on the new use of a known composition generally have slightly stronger protection in Europe than in the US.

5.3.2 Genetic diagnostic testing
Genetic testing is the performance of medical tests that gather information about a person's genes and chromosomes, by identifying changes in chromosomes, genes or proteins. Diagnostic testing of genes is applied to identify or rule out specific genetic or chromosomal conditions. It is usually enforced in response to physical signs and symptoms that indicate a particular condition, in order to confirm a suspected diagnosis. Diagnostic testing can be performed at any point during the life of a person, even before birth. The results can be used to guide a person in making informed decisions about health care and management of a possible condition. There are great economic interests associated with genetic testing. The costs of genetic testing are significant. For instance, Myriad Genetics charges around $3,000 for genetic testing of two genes (to test for mutations associated with breast cancer).

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91 https://ghr.nlm.nih.gov/primer/testing/genetictesting
92 https://ghr.nlm.nih.gov/primer/testing/uses
Under EPC isolated biological material (which can be utilized for genetic testing) is patentable even if it has occurred previously in nature (EPC rule 27(a)), and an invention relating to gene sequences can be patented as long as the industrial application of the sequence is disclosed in the application and all other patentability criteria are fulfilled (EPC rule 29(3)). When it comes to diagnostic methods, as explained above in 3.1.3.1, in order to be exempt from patentability, diagnostic methods (as well as the other types of methods) must be “practiced on the human or animal body”. This criterion is not met by method steps carried out in vitro (in a laboratory). When performing genetic diagnostic testing human tissue is normally isolated from the human body and the samples are analyzed in vitro. Consequently, methods for genetic diagnostic testing are not covered by the medical method exclusion, and therefore patentable in Europe, given that no other exceptions apply.

In contrast, the US Supreme Court decided in Association for Molecular Pathology v. Myriad Genetics, Inc., 689 F. 3d 1303, that genes are not patentable in the US. The respondent Myriad discovered the precise location and sequence of two human genes (BRCA1 and BRAC2) that, if mutated, could substantially increase the risk of breast and ovarian cancer. This discovery enabled the genetic testing of women in order to establish their risk of developing cancer. Myriad obtained several patents based on this discovery. The question before the court was whether naturally occurring DNA could be patented simply because it was isolated from the rest of the human genome. The court also addressed the patentability of synthetically created DNA, known as complementary DNA (cDNA). The Court concluded that a naturally occurring DNA segment is a "product of nature" and isolating it does not make it eligible for patent. cDNA on the other hand is patent eligible as it is not naturally occurring. Myriad's patents were consequently not upheld.

This does not mean that genes always are excluded from patentability in the US, but the criteria are stricter and the scope more narrow for what is patentable, compared to Europe.

In this case, the only new element was the discovery of the precise location and the genetic sequence of the genes, that enabled the discoverer to isolate the genes (using a known method)

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95 G 1/04.
in order to perform genetic testing, applying known knowledge of the connection between the mutated genes and the risk of particular types of cancer. This is nothing more than applying laws of nature to a physical phenomenon.

In Europe, on the other hand, Myriad was granted three different BRCA1 patents; exclusive rights to the isolated BRCA1 gene (EP705902 (B1)), exclusive use of the gene in cancer diagnosis in general (EP699754 (B1)) and the right to 30 different mutations in the gene that are associated with an increased risk of cancer (EP705903 (B1)).96 Admittedly, following an appeal procedure97, the first patent was not upheld, and Myriad lost patent protection for the gene as such. However, this was not because naturally occurring genes cannot be patented, but a consequence of the failure to satisfy traditional criteria for obtaining patents, more specifically the novelty requirement. The originally filed patent applications contained errors in the description of the DNA sequence, and the correct DNA sequence was published before Myriad filed a correct application, describing the correct DNA sequence. The other two patents were severely limited following appeal procedures, and what remained was patent coverage of one single specific cancer mutation, and the detection of frame shift mutations in the gene. However, also in these cases, the reasons for limiting the patents consisted in failure to meet the traditional criteria for patents.98 To sum up, the situation under EPC still remains that genes are patentable even though the only inventive step lies in identifying and isolating the gene, in contrast to the US, where genes as such are not patentable because of the laws of nature exception. Thus, the patentability of genes for diagnostic purposes is more limited in the US than in Europe.

If the gene itself cannot be patented regardless because it is already known, a patent can only be given for a new use of the gene. This would typically be claimed in the form of an EPC 2000-claim in Europe, and as a new medical use method in the US. The difference in scope of protection will then be the same as seen above under 5.3.1. Such a new medical use patent would not have been subject to limited enforcement in the US, also since it is a biotechnological patent.

96 Mattson (2010).
97 T 1213/05
98 Mattson (2010).
5.3.3 Gene therapy

Gene therapy is therapy aimed at treating genetic deficiencies. It is still largely an experimental technique. The goal is that this technique can be used to treat a disorder by inserting a gene into the patient’s cells, thereby replacing traditional drugs or surgery. Several methods are being tested, such as replacing the mutated gene that causes the disease with a healthy copy of the gene, inactivating the mutated gene that isn’t functioning properly, and introducing a new gene into the body that can help fight the disease. Gene therapy is a promising treatment for several diseases, however it is still risky and currently researched in order to be safe and effective. At the moment it is only tested for treating otherwise incurable diseases. The treatment is for example being tested with regards to certain inherited disorders, specific types of cancers, some viral infections such as malaria and HIV, and various diseases caused by the body not producing important hormones or other proteins the way it is supposed to."Potentially successful gene therapy can lead to enormous medical progress in terms of cures for diseases that have never before been treatable, which also translates to extensive economic interests. There are high costs associated with gene therapy, both in terms of researching successful methods of performing it, and in applying the developed treatment. Gene therapy can cost as much as $1,000,000 for one single treatment."

In T 0800/99 (Cancer therapy/SIDNEY KIMMEL CANCER CENTER), the Technical Board of Appeals considered an application for patent on a method for gene therapy, comprising delivering wild-type therapy-sensitizing gene therapy (e.g. a therapy sensitizing protein or gene) in order to make cancer cells more susceptible to cancer therapy. The Examining Division had refused the application mainly because (the former) claims 1, 14 and 24 comprised "in vivo methods for increasing the effect of a cancer therapy i.e. methods of treatment of the human body which were not patentable pursuant to Art. 52(4) EPC". Claim 1 of the original application read as follows: "Method of increasing the effect of a cancer therapy comprising the steps of: delivering wild-type therapy-sensitizing gene activity to a tumor cell characterized by loss of said wild-type therapy-sensitizing gene activity, and subjecting said tumor cells to said cancer therapy" [emphasis added], and "Independent claim 14 related to the same method wherein the specific wild-type p53 gene was delivered to, and expressed in, the tumor cells."

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100 Aarons.
101 European application No. 95 918 867.3.
102 Decision made under EPC 1973, corresponds to Art. 53(c) of EPC 2000.
Independent claim 24 related to the same method wherein the wild-type p53 protein was delivered to the tumor cell." Claims 1 and 24 were deleted before the appellate procedure, and the new claim 1 corresponding to former claim 14 was "drafted as a claim to the use of the therapy-sensitizing p53 gene activity for the manufacture of a pharmaceutical composition. All other claims (claims 2 to 10) are dependent on claim 1. Thus, the objection under Art. 52(4) EPC does not apply any more. The invention is of the kind for which a patent may be granted providing the other requirements for patentability are fulfilled." [emphasis added] The redrafting of the claims changed the method from an unpatentable therapeutic method to a patentable Swiss-type claim, thereby avoiding the medical method exception. Inapplicable. Under the current rules, it could have been patented in the EPC 2000 form. However, the appeal was ultimately dismissed due to lack of inventive step.

Patent on the same invention was applied for in the US as a method; US2004072775 (A1) (Enhancing the sensitivity of tumor cells to therapies). The first claim is almost identical to the one that was denied in Europe: "1. Method of increasing the effect of a cancer therapy, comprising the steps of: delivering wild-type therapy-sensitizing gene activity to a tumor cell characterized by loss of said wild-type therapy-sensitizing gene activity, and subjecting said tumor cell to said cancer therapy." However, this patent was not granted in the US either. Based on the refusal document from the USPTO103, the reasons for this was not the subject matter being gene therapy, but rather lack of inventive step, as in Europe. Had it been patented, it would have been a new medical use patent and a biotechnology patent, which is not subject to limited enforcement.

Another example of a gene therapy invention is a patent involving a method for effectively bringing DNA molecules into the patient's cells by using electrical stimulation. This new medical use method was patented both in the US (US6261281 (B1)) and in Europe (EP1023107 (B1)). In Europe it was patented as a Swiss-type claim, and would have been patentable in the form of an EPC-2000 claim today. In the US, it was patented as a new use method.

Based on this, a gene therapy invention would typically have protection as a new use product patent in Europe, and as a new use method patent in the US. This means that methods for gene

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therapy would generally have better protection in Europe, due to the difference in enforcement seen in 5.3.1 and 5.3.2.

6 Conclusions
The comparison above lead to the following main findings:

As seen in 5.2.1, certain medical methods are completely excluded from patent protection in Europe. This applies to therapeutic, surgical or diagnostic methods performed on the body, that neither includes an inventive product nor a new medical use of a known product. These methods will always have better protection in the US, unless they are excluded there under other exceptions. The US laws of nature exception, cf. 5.2.2, has a wider scope than the European exception for discoveries, and can affect the patentability of medical methods if they are based on compositions found in nature or on application of scientific theories. This means that even though medical methods in the US are not subject to patentability restrictions as such, they can be excluded through other exceptions. In such cases a medical method can be patentable in Europe only, for example a natural gene applicable in genetic diagnostic testing. This shows that it is necessary to look at each individual medical method in a holistic perspective, including all rules that might apply and hinder patentability.

The level of protection for medical methods in the US, depends on whether it is fully enforceable or subject to limited enforcement. If the method constitutes a "medical activity", and is performed by a "medical practitioner", it is subject to limited enforcement, unless the medical practitioner is guilty of contributory infringement, which requires him to act in the capacity of distributor (or similar), as he cannot be held liable for contributory infringement by performing the tasks associated with his role as a medical practitioner. A medical method subject to limited enforcement can be enforced against other entities than the doctor or the hospital, such as manufacturers, importers or merchandisers of a product used in the method. These are only liable for inducing infringement or contributory infringement. As explained above, since this is typically the type of enforcement preferable for medical methods in the first place, the limited enforcement rule might not detract much of the practical value of medical method patents, and it can also explain why there are few cases regarding this rule.

In the case analyses, this impression of the limited enforcement rule's narrow scope is further substantiated, as it does not directly influence the scope of protection of the medical methods
in any of the three areas. New use patents are specifically excluded from the limitation, the patent application in relation to gene diagnostics was excluded from patentability in the US under the laws of nature exception, and the patents in relation to gene therapy were again new use patents unaffected by the limitation. Thus, in the US, other rules than the limited enforcement rule might have greater impact on the patentability and enforcement value of such patents.

Regarding new use patents, these are patentable in both jurisdictions, but the scope can be somewhat different due to the differences in type of claim; product versus method. This must be determined in the specific case based on an interpretation of the claims. A new use product does not have the same wide scope as a regular product patent, due to the restrictions in the claim with regard to the specific use. However, it usually still has a somewhat larger scope than a method patent. One must also keep in mind that the method patent can give cause for infringement action against indirect infringers producing or selling the product used in the method, regardless of whether the limited enforcement rule applies.

The overall conclusion is that neither jurisdiction inherently provides the strongest protection for medical methods, but that the level of protection varies. In some cases a medical method will have better protection in Europe, and in some cases it will have better protection in the US. It is a common misinterpretation that European law is more restrictive in this area.\textsuperscript{104} This must be determined based on a consideration of the rules presented above. Which jurisdiction better achieve the purpose behind the rules can also not be determined generally, but will vary from case to case. However, the presentation here focus mainly on the differences. In many cases the rules will have similar results. Even when the scope of protection is slightly different, such as for new use products and new use methods, the practical enforcement will often be similar. Even though looking at the rules initially can give the impression that they are very different, and maybe that the protection in the US is better, the results are not that different in most practical cases.

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