PATENTING PRACTICE: A FOCUS ON MEDICAL METHODS OF TREATMENT

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SUMMARY

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The thesis explores the case of medical methods of treatment and their patentability or lack thereof, depending on the jurisdiction. Consider medical devices, pharmaceuticals and biotechnology: these are all theoretically patentable (if the requirements are met, of course, and after much debate and controversy in many cases), and this presumably controls the market and aids in the protection of the public through the creation of products that are carefully designed and produced. Medical methods of treatment, however, are afforded no such protection in approximately 80 countries, including those governed by the European Patent Convention (EPC), which raises the question: how can a novel method or treatment be used for the well-being of the public, if these novelties cannot be adequately disseminated via the patent system? For a number of reasons, methods of medical treatment have historically been excluded from patent protection in many jurisdictions. Two fundamental questions thus act as justification for the chosen research topic, firstly, why this is so, and secondly, should it be so?

The jurisdictions examined are the countries signatory to the European Patent Convention, contrasted with the USA and Australia, in an effort to create a legislative comparative analysis with the hope of illuminating the issue from a variety of perspectives, since legal systems are created and coloured by the social systems that surround them. These three jurisdictions are considered here with the aim of illuminating international comparisons between the countries bound by the EPC and two large common law jurisdictions where patenting medical methods of treatment is permitted, at least in theory if not always in practice, and with whom the EPC countries may often share some convergence in the sense of legal culture. The aim of the comparative analysis is to generate further clarity regarding why methods of medical treatment are legislated for differently in the aforementioned jurisdictions and from there to consider the validity – or indeed invalidity – of patenting medical treatment methods on the basis of the cases and legislation discussed.

Keywords: patenting, medical methods of treatment, comparative law, international law

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Part I

Introduction to the Research Question

> *"The insurmountable problem, from a public policy viewpoint, of drawing a logical distinction which would justify allowing patentability for a product for treating the human body, but deny patentability for a method of treatment".*[1]

Concerns regarding to what extent creators and inventors in the life sciences, such as medicine and biotechnology, should be capable of obtaining property protection for their intellectual efforts frequently come to the fore, with opinions oscillating between extensive protection with lengthy intellectual property rights, and no protection at all. The first supposition predominantly arises from the perspective that medical and biotech creators should be equally as entitled to intellectual property protection as those in other fields, since presumably their creative efforts are correspondingly valid; moreover this particular field can frequently cost a great deal more that many others in terms of development (both financially and in a time-consuming regulatory sense),[2] and creativity would be stunted without the incentive of property rights and possible financial reward. The other end of the pendulum swing has ethical edges, however, and opponents can maintain either a) that these sciences exist first and foremost to serve the needs of people and animals; by protecting valuable inventions in these fields, fair and equal access for all to e.g. the latest and more effective treatment for illness, is hampered, sometimes to the extent that access is

[1] *Bristol-Myers Squibb Co v F H Faulding & Co. Ltd,* 2000, as stated by the Australian Federal Court
[2] See e.g. Mayfield (2016), p. 1

unattainable, or b) the type of patent sought is too contrary to human morality, e.g. embryonic stem cell research and patents.[3] Thus, instead of these possible restrictions, the ethical argument can support the idea that all information and discoveries in medicine should pass freely throughout the community, or that the manner in which the subject matter of the patent is created is too controversial to support.

What the moral argument often overlooks, however, is that without incentive, the will to create can be dulled. Put simply, intellectual property rights serve to provide that incentive to create, by protecting valuable inventions and offering potential financial reward. Without the possibility of patents in medicine for instance, access to e.g. effective care could be reduced, ostensibly causing those in need to suffer unnecessarily. If creators of intellectual property in other fields can differentiate themselves from their competitors, then why not those in the life sciences? As always, the law purports to create a balance somewhere between these competing interests, while the debate continues regarding the relative success of the legislators in drafting suitable laws and the judiciary in applying them. In the words of Leon Kass: "…the contract formed by the patent law brings together, in stressful if fertile union, certain contradictory, or at least inhospitable, partners and principles: self-interest and common good; monopoly and liberty; the ownership of ideas and the shareability or publicity of speech and thought."[4]

Wider context aside, this paper endeavours to discuss specifically the case of medical methods of treatment and their patentability or lack thereof, depending on the jurisdiction. Consider medical devices, pharmaceuticals and biotechnology: these are all theoretically patentable (if the requirements are met, of course, and after much debate and controversy in many cases), and this presumably controls the market and helps protect the public by creating

[3] See e.g. Stazi (2015), p 120.
[4] Cass, L (1981), p 580

products that are carefully designed and produced. Medical methods, however, are afforded no such protection in approximately 80 countries,[5] including those governed by the European Patent Convention (EPC), which raises the question: how can a novel method or treatment be used for the well-being of the public, if these novelties cannot be adequately disseminated via the patent system? For a number of reasons methods of medical treatment have historically been excluded from patent protection in many jurisdictions. Two fundamental questions thus act as justification for the chosen research topic, firstly, why this is so, and secondly, should it be so?

Medical methods are viewed as falling into three separate categories: surgical, diagnostic, and therapeutic, and the extent to which they are patentable depends upon the jurisdiction. This thesis seeks to explore some of the history behind the inclusions to and exclusions from patentability for these methods, in the hope of providing some context and justification for the patentability of medical methods of treatment. For example, methods of medical treatment are excluded under Article 53 (c) of the European Patent Convention: "methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body;"[6], and it has usually been understood, at least before the EPO's revision of the EPC in 2000 (hitherto this exclusion was contained in Article 52(4) of the EPC 1973), that this was on the grounds of medical methods' not being susceptible of industrial application.[7] As the EPO have stated in their proposal from 2000 prior to the EPC's revision: "It is undesirable to uphold this fiction [lack of industrial application] since methods of treatment and diagnostic methods are excluded from patentability in the interests of public health."[8] So here we have a clear instance of their being excluded for one reason, which was then revised as being for an entirely different reason. This is not all, however, since a further explanation was then given for the intent behind Article 53(c), which reveals an insight into the EPO's

[5] Rastogi (2014), p 1
[6] EPC, art 53(c)
[7] EPC (1973), art 52(4)
[8] OJ EPO (2007), p 50

mindset regarding the reason for this article's existence, or at the very least, the EPO's reason: "it must be borne in mind that the intention of art. 53(c) is only to free from restraint non-commercial and non-industrial activities."[9] Thus, once again, another justification was declared for the excluding medical methods from patent protection.

Aside from industrial applicability and commercial/industrial activities, arguments have included angles such as whether allowing a patent would cause a conflict of interest (i.e. that for instance a doctor would choose his or her patented method over a more suitable one),[10] or whether it would interfere with the flow of information owing to the lengthy patent process. The issue may then either be constrained by medical law, by patent law, by historical precedent, or by various combinations of all three. These developments will be considered in terms of how justifiable they are against the lack of intellectual property protection under the EPC for medical method inventors.

Focus and methodology

The jurisdictions to be examined will be the countries signatory to the European Patent Convention in contrast with the USA and Australia, in an effort to create a legislative comparative analysis in the hope of illuminating the issue from a variety of perspectives, since legal systems are created and coloured by the social systems that surround them, for instance, a particular jurisdiction's societal view of morality can differ widely from another's. As Jaakko Husa states: "In comparative methodology a matter is merely a technical problem only very rarely. The mental challenge of comparison comes from the difference in legal cultures – diversity and hybridity present their own challenges."[11] These three jurisdictions are considered here in the hope of drawing international comparisons between the countries bound by the EPC and two large common

[9] EPO, Guidelines for examination, Part G, 4.2.1
[10] Meier (1997), p 265
[11] Husa (2015), p 15

law jurisdictions where patenting medical methods of treatment is permitted, at least in theory if not always in practice, and with whom the EPC countries may often share some convergence in the sense of legal culture. Regarding the concept of legal culture, it can be said that in many ways the laws of these jurisdictions and the codification thereof are sometimes quite alike, at least in terms of the topic at hand, but the end results can vary considerably.

The aforementioned medical treatment methods - therapeutic, diagnostic, and surgical - will be examined in order to identify how they are defined in the three jurisdictions under examination, as well as issues such as possible limitations that would influence any exclusions, and also consider what factors the courts have considered when interpreting the laws in terms of the patent claims brought before them. The comparative models involved include historical considerations, e.g. Chapter 3 examines the unfolding of the legislation surrounding the patentability of these methods via judiciary decisions, with some direct comparison between different cases and jurisdictions as relevant. This is examined in light of the differences between the methods themselves and how those differences are interpreted, as well the justifications for the exclusions, be they based on ethical considerations, lack of industrial application, or some other reason. The overall aim of the comparative analysis is to generate further clarity regarding why methods of medical treatment are legislated for differently in the aforementioned jurisdictions and from there to consider the validity – or indeed invalidity – of patenting medical treatment methods on the basis of the cases and legislation discussed.

This thesis will also consider other issues that to a lesser extent affect the discussion, such as how excluding patent protection for methods of medical treatment could also be applicable to pharmaceuticals; indeed, arguing against one while supporting the other might be criticised for failing to take into the account the considerable overlap between the two. Where is the distinction and can it be adequately determined and thereby justified? While examining the arguments against patent protection for methods of medical treatment, this thesis will attempt to highlight, where necessary and possible, the differences

between these two areas of invention. Other aspects of the discussion will include comparative angles such as law and ethics/morality, and the advancement of medicine in general, since the development of artificial intelligence and personalised medicine in the realm of medical treatment, for instance, are worth examining in terms of future possible trends in patenting.

1 Patents in general, medical patents, and development in the medical field

1.1 General patent requirements: A Legislative overview by jurisdiction

Upon the creation of an invention, the creator can choose to patent that invention. Patents are time-limited rights that exist to protect inventions, or to put it another way, it can be described as a negative right that protects the rights of the creator in relation to that invention regarding distribution and usage, since it excludes others from selling, using or making copies[12], hence the use of the term 'negative right'. Such protection is designed to function as a type of price paid by society to encourage innovation and creativity. Among all intellectual property rights, patents offer the most significant protection to their holders,

[12] Frankel et al (2016), p 89

meaning they are highly sought-after, although the process of obtaining a patent is more challenging, than e.g. copyright, since any claim must be examined by the relevant patent office.[13] For the purposes of the comparative discussions that will take place below, at the time of writing, the three jurisdictions under discussion in this paper are signatories to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement). This agreement came into force in 1995 and all the members of the World Trade Organisation are signatories to it. The pertinent section pertaining to the subject at hand is article 27, which outlines the three criteria for obtaining a patent for an invention, namely that the invention must be novel, it must have what is referred to as an inventive step and it must be industrially applicable[14]. These three criteria are interpreted, worded and legislated for somewhat differently in the three jurisdictions under discussion and the criteria will be examined in following sections in terms of their similarities and differences.

Patenting in the European Patent Convention Community: overview

Founded in 1978, the European Patent Convention is a multinational treaty to which 38 nations are signatories (this includes all the member states of the European Union and all non-members are also European countries). The purpose of the treaty was to create an office where European patents claims could be examined, thus creating the existence of a common standard for member states, and, once granted a patent, the holder is entitled to rights throughout all the member states that are the identical to the national patent rights normally granted within each state. The length of a standard patent term in Europe under the EPC is twenty years from the filing date. Since the vast

[13] Waelde et al (2013), p 365
[14] TRIPS, art. 27(1), in section 5

majority of member states that are signatories to the convention are also members of the World Trade Organisation, the provisions of the Paris Convention and the TRIPS agreement that are relevant to patenting have been included in the convention.[15]

For a patent claim to be valid, there must be an invention, which is the essential subject matter for patent eligibility, thus distinguishing that which is patentable from unpatentable. In the provisions of the European Patent Convention, the concept of invention is mostly defined in negative terms, i.e. by describing what an invention is not.[16] Creations not viewed as inventions include methods and theories, as well as, for example, sets of rules for carrying out particular activities, such as games, or operating computer programmes. Rule 43 of the Convention provides that the invention must be defined in technical terms[17], i.e. that it possesses some kind of technical features that relate to a problem of a technical nature.[18]

This is provided in Article 52(1) EPC as inventions from any field that are "new, involve an inventive step, and are susceptible of industrial application"[19]; i.e. these three steps from the test for patentability, and these concepts will be outlined and discussed further in their relevant sections below.

Patenting in the USA: overview

The first US Patent Act came into force in 1790 and went through many revisions and iterations before becoming codified in the United States Code.[20] Published for the first time in 1926, this Code is comprised of a collection of the

[15] See e.g. EPC, art. 87.
[16] See EPC, art. 52(2)
[17] EPC, Case Law of the Boards of Appeal. 9.1.1 Technical character of an invention
[18] EPC, Rule 43 (Form and content of claims), 1(a)
[19] EPC, Art. 52(1)
[20] See United States Code info at govinfo.gov/app/collection/uscode

laws of the USA by subject. Title 35 concerns patents. Article 1, section 8 of the US Constitution states that power is invested in the United States Congress to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[21]

While the patents are mostly overseen by the US Code Title 35,[22] the USA is also a common law country, meaning that the decisions made by the federal court play an important role in litigation with regard to patent cases, given that its jurisdiction in infringement cases is exclusive, and the decisions and constitutional interpretations can be binding on state courts. Only the United States Court of Appeals for the Federal Circuit hears appellate cases in claims relating to patents.[23] With regard to the examination and granting of patents, the USPTO (the US Patent Office, part of the Department of Commerce) is responsible for the administration side of patenting, as well as officiating patent challenges between parties. For a "inventions patentable"[24] to be granted by the USPTO, there are four requirements that form the test for patentability: the invention should consist of statutory subject matter; it should be new; it must be useful; and finally the invention must be non-obvious (see below for further discussion on these steps). Regarding the types of patent, three general types exist, namely utility patents, plant patents and design patents.[25] As these names suggest, the utility patents constitute the most common type of patent, and the purpose is to seek protection over the invention's essential concept. Design patents, however, serve the function of protecting other aspects of product, namely those involving appearance ad aesthetics. These kinds of patents are often sought for consumer products, and, unlike utility patents, which are granted 20 years protection, design patents are allowed 15 years, but are considered easier to obtain.[26] In line with its name, a plant patent can

[21] United States Constitution, Art 1, S.8 (8)
[22] 35 U.S. Code Title 35 - Patents
[23] Murphy et al (2015), p.5
[24] 35 U.S.C. § 101
[25] Murphy et al (2015), p. 5
[26] For a practical guide to inventions and patents in the USA; eee Tidwell et al (2017), pp 391-98

be sought when an inventor has both discovered/invented and reproduced asexually "any distinct and new variety of plant."[27]

Patenting in Australia: overview

Given Australia's shared history with the United Kingdom, it is not surprising that the two jurisdictions share a similar approach to patenting and Australia originally based much of its legislation upon the UK Patents Act of 1883. The Australian Commonwealth Parliament was founded in 1901, upon which law-making power was granted to that parliament via Section 51[28] of the new Australian Constitution.[29] Included in this power was that of making laws relating to intellectual property, which was then legislated for in the provisions of the Patents Act 1903. This Act has undergone several amendments and was redrafted in 1952 and again in 1990, which is the current version under which patents are legislated for in Australia. Alongside the Patents Act 1990, the Patents Regulations 1991 was enacted to serve as a regulatory complement to the Patents Act. The administration of patent rights is the responsibility of the government authority IP Australia.[30] The ACIP (Advisory Council on Intellectual Property) is a government appointed independent

[27] See United States Patent and Trademark Office, 'General information concerning patents' at 'Plant Patents'

[28] The Australian Constitution, Part V 'Powers of the Parliament¨', section 51 'Legislative powers of the Parliament', xviii.

[29] Australia became a federated nation at this time, before which it had been comprised of a collection of colonies, each of which had its own legislation.

[30] See ipaustralia.gov.au

council that advises the relevant government ministers (e.g. Industry) on policy issues relating to intellectual property.[31]

Section 18 of the Patents Act provides that for an invention to be protected by patent, there are five key requirements that must be satisfied: the manner of manufacture is in line with the meaning of the Statute of Monopolies 1623, s. 6; the invention must be novel; the invention must include an inventive step (these two criteria - novelty and inventive step - are listed separately but within the same subsection, as opposed to the other three requirements, which are provided discretely under section 1);[32] it must be useful; and finally the invention must not have been used in Australia in secret prior to the priority date (see the relevant sections below for further discussion).

1.1.2 EPC

EPC: Novelty & the inventive step

"An invention shall be considered to be new if it does not form part of the state of the art."[33] On receipt of a patent application, the patent office in question must examine the state of the art in the relevant field in order to determine if the invention's technical features are completely new. The purpose of this step is in an effort to eliminate patent claims with regard to material that had already received a patent, referred to as 'prior art'[34], regardless of whether or not that patent has expired. Moreover, it also serves to prohibit the grant of a patent to subject matter that is already known to the public, i.e. if the invention is something that has already been used, albeit without patent in the relevant field,

[31] Advisory Council on Intellectual Property (2015), Review of the Innovation Patent System
[32] Patents Act 1990, sect 18 (1)
[33] EPC, Art. 54(1)
[34] EPO, Guide for Applicants 2017: How to get a European Patent, II Basic Principles: Novelty, under B: Patentability

the novelty criterion renders it unpatentable, thus protecting those prior users. This process can be substantially more difficult in fields like biotechnology and medicine, owing to the depth of knowledge required and the extent and volume of the research and literature already in existence. The state of the art, synonymous with 'prior art' mentioned above, according to the EPO, "comprises everything made available to the world by means of a written or oral description, by use, or in any other way, before the date of filing or priority."[35] It follows that without novelty[36], inventiveness cannot be shown.

"An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art."[37] For this step to be fulfilled, a person skilled in the relevant field is considered as a benchmark for the purposes of determining whether or not the invention would have been obvious to an individual with the requisite knowledge. The concept of such a person is not defined in the EPC, but rather in case law arising from the Board of Appeal and various European courts.[38] While technically fictional, the purpose is to elucidate what such a skilled person would know and whether they could have developed the same result based on their own knowledge. This should serve to show if the invention, as with novelty, is inventive with regard to the technical features therein.[39]

The concepts of novelty and inventive step serve different legal functions, with the concept of non-obviousness in the inventive step helping to show the difference between the two, i.e. that what is new must also not be obvious. To portray this distinction using a very simple example, if a brush is resigned with a different shape, let's say for the sake of some ergonomic effect, if it can be

[35] Ibid. See also EPC, Art. 54(2).
[36] Novelty should be global in scale, i.e. new throughout the world, as shown in C-428/08 *Monsanto Technology LLS v Cefetra BB and Others* [2010], in para 45.
[37] EPC, Art. 56
[38] EPO, 3. Person skilled in the art, under Chapter IV: Inventive step in G: Patentability
[39] For a case concerning the knowledge required to ascertain the existence of an inventive step, see T 32/81 (Cleaning apparatus for a conveyor belt) of 5.3.1982

shown that such a shaped brush hitherto did not exist, then it is novel. If, however, a person knowledgeable in the art of brushes could not reasonably come to the same design, then it is also inventive.

EPC: Industrial application

While the US Constitution speaks of the promotion of the 'useful arts', the equivalent concept within the EPC is perhaps phrased more conservatively, through the stipulation that the invention has to be of a 'technical character'.[40] As mentioned above, the word 'technical' here is used in reference to the invention's features, the problem (which the invention purports to solve) and its field. An invention's 'technical character', if adequately shown, thus serves to distinguish the activity from activities in aesthetic and performing arts, i.e. the arts that presumably are considered to lack the necessary technical character, rendering them insusceptible of industrial application. Interestingly, despite the liberal use of the word 'technical' in the Guidelines, no actual definition is given in the Convention for what is precisely meant by the term. It can perhaps be presumed that such a definition is lacking from the EPC owing to the ever-evolving nature of technology, such that future technological advancements would suffer as a result of an express definition. This lack of meaningful definition, however, gives rise to a lack of legal certainty in patent considerations. Moreover, in the words of Bakels: "Exclusion of non-technical inventions is an indirect method to achieve a purpose. But, what actually is that purpose?"[41]

Put simply (lack of sufficient definition aside), for the EPC's final criterion to be met adequately, it fundamentally requires that the invention can be made and

[40] See the EPO's Guidelines for Examination, Part G 2, ii
[41] Bakels (2008), p 56

used in an industry[42]. In many instances, or at least in many industries, this concept was often readily met and could almost be viewed as a formality in the sense that most inventions traditionally have been physical things which served a technical purpose or solved a technical problem. The decision T 870/04 of the EPO Board of Appeal regarding a substance, however, made this step more demanding, on the grounds that the substance must also have a use that is profitable.[43] This revision would seem to serve a practical purpose, since what would be the point of going to such lengths (financial and otherwise) to obtain a patent if the invention itself would prove to be economically worthless? In any case, because of this physical or tangible feature of industrial applicability, it has been here that the stumbling blocks for life sciences industries such as medicine have often occurred. This stems partly from the reasoning that many inventions in this field are more abstract in nature, or intangible, thus their use in the field is harder to define or display, meaning such inventions have not lent themselves easily to proof of industrial application. This will be examined in more detail in the chapter below.

1.1.3 USA

USA: statutory invention

> *"Inventions patentable: Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title*."[44]

[42] EPC, Art. 57

[43] "Merely because a substance could be produced in some ways does not necessarily mean that the requirements of Article 57 EPC are fulfilled, unless there is also some profitable use for which the substance can be employed." EPO T 870/04 (BDP1 Phosphatase/MAX PLANCK) of 11.5.2005, no. 4 under Reasons for the Decision.

[44] 35 U.S.C. § 101

There are four statutory categories of invention under US patent law: machine, useful process, manufacture, and composition of matter; any invention that does not fall within at least one of these categories cannot be patentable. Conversely, if an invention should partly fall outside of all four categories, even though it partly lies within at least one of them, it will be rejected under §101.[45] These four terms are given brief - yet what appear to be clear - definitions on the face of things (case law may indeed tell another story), with a machine described as "a concrete thing consisting of parts", while a 'process' constitutes an act, "or series of steps."[46] For the manufacture requirement to be fulfilled, the invention must be made from materials whether prepared or raw such that they thereafter have new properties or forms. Regarding the fulfilment of the 'composition of matter' patent category: as the name implies, the invention must involve the combination of at least two substances, regardless of their physical matter or whether they are mechanical or chemical in substance. The categories of invention that are expressly excluded from patentability have been created through case law by the Supreme Court; abstract ideas, physical phenomena, and laws of nature.[47] Interestingly, since the US Code does not specify categories that should be excluded, it is the opinion of Oppenheimer that the Court has exceeded its mandate in expressly denying patentability to these three categories, potentially harming development in e.g. the fields of biotech and software, and he goes so far as to say that the withdrawal of such protection hampers the progress in these areas; taking away the right to protection removes the inventor's willingness to reveal and share his/her invention.[48]

[45] See cases e.g. *Digitech Image Technologies* and *In re Ferguson* for examples of non-statutory examples of (unsuccessful) patent claims.
[46] 35 U.S.C. § 101
[47] Oppenheimer (2012), p 4 and USPTO, 'General information concerning patents' at 'What can be patented'.
[48] Ibid. p 5

USA: non-obviousness and novelty

Despite the commonly quoted Supreme Court phrase claiming: “anything under the sun made by man”[49] is patentable,[50] the reality is decidedly more restrained. As with the EPC, once usefulness can be established, the prior art is taken into consideration when examining patent eligibility, since knowledge of what has come before is necessary in determining the newness or novelty of the invention being inspected. In order for this to take place, the invention is considered in light of the concepts of novelty, as well as non-obviousness. These concepts sound similar, meaning it might be easy to confuse or conflate the two, but they do in fact serve different functions in examining patent eligibility and are located in different areas of the code: § 102 and § 103, respectively. If the prior art is considered to have anticipated the invention, it will be ineligible for patenting. Involved in this process is the precise definition of the nature of the invention, after which it is compared to the relevant prior art in that field, a process akin to that in Europe.

The novelty requirement in § 102 of the Patent Code denies patentability if the invention can be shown to exist in the prior art. There are three steps involved in defeating novelty; the invention or reference to the invention must have existed for at least a year before the date of filing, each individual element of the proposed invention must be evident in this reference of prior art, and finally the reference must enable a person skilled in the art to create the invention without unreasonable effort, thus the invention can be said to have been anticipated and novelty is defeated.[51]

[49] *Diamond v Chakrabarty*, 447 U.S. 303 (1980)
[50] 35 U.S.C. 103: Conditions for Patentability; Non-Obvious Subject Matter
[51] Seymore (2011), p 923

Thus, it can be determined that the existence of an inventive step (see above) is also evident in U.S patent law, but it is generally referred to as non-obviousness. In order to show non-obviousness in a patent claim, the patentee should be able to demonstrate that the elements combined to produce the invention in its entirety would not have been reasonably expected by others skilled in the art. According to Mueller & Brean, non-obviousness is the most challenging requirement of US patent law: “An applicant for patent must take a “large step” forward, establishing that its [the patent’s] advance would not have been obvious”.[52] It follows that this process is highly subjective, and must be determined case-by-case, as with the other jurisdictions discussed here.

1.1.4 AUSTRALIA

Australia: manner of manufacture within s 6 of the Statute of Monopolies 1623

Section 6 of the Statute of Monopolies is concerned with what is patentable and exclusions therefrom, and it excludes patents for inventions that are contrary to law, that might hurt trade, or that are viewed as ‘generally inconvenient’.[53] Needless to say, the fact that the statute was written a considerable time ago makes this provision of Australian patent law quite fascinating in terms of its longevity and persistence in regulating modern patent applications.

[52] Mueller et al (2009), p 424
[53] Statute of Monopolies 1623, s. 6

A landmark case in Australia became the benchmark for defining what constitutes falling within this meaning of manner of manufacture in terms of patentability, namely *National Research Development Corporation v Commissioner of Patents* (NRDC).[54] Prior to this case, the classes that had developed over time as to what constituted patentable inventions in terms of the manner of their manufacture were clear in theory, e.g. ideas and natural principles were excluded, but no consistent reasoning existed that justified the exclusion of certain types and classes of inventions from patent eligibility, such as horticultural methods and methods of medical treatment.[55] In a previous case, Re GEC's Application, Justice Morton created a definition of what might constitute a manner of manufacture, in which there were three possibilities: the process or method must result in either a 'vendible' product, a vendible product that is improved or restored by the method/process, or lastly a preservative effect upon a vendible product.[56] It was the position of the High Court in NRDC that the Justice Morton's formula, particularly the terms 'vendible' and 'product' required a broad interpretation. The High Court thus held that the horticultural method in question was patentable, despite it being a horticultural method that would hitherto have been excluded, since the court claimed that the word 'manufacture' was troublesome in its application, and gave rise to the impression that only something tangible would be patentable.[57] This decision to grant a broad interpretation to the concept of a vendible product such that it need not be a palpable object meant that the way was opened for the potential patentability of other methods and processes, such as those involving medical treatment.

[54] *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252; (1961) RPC 134; 1A IPR 63

[55] Monotti (2006), p 461

[56] *G.E.C.'s Application* (1943) 60 RPC 1

[57] To the Court's mind, asking whether a proposed invention was a manner of manufacture led to this erroneous view of a patentable invention as purely tangible. In their view, the correct question should be: "Is this a proper subject of letters patent according to the principles which have been developed for the application of s .6. of the Statute of Monopolies?", in NRDC, CLR 259.

Australia: novelty and the inventive step

Novelty is determined in Australian patent law through what is known as the reverse infringement test. This term refers to the process by which all relevant and publicly available information from the prior art concerning the proposed invention is shown clearly and unequivocally. If all the essential features of the invention are displayed in the prior art, for example in a patent application that was published at an earlier date, the invention will fail the novelty requirement. Failing this requirement is tied to whether or not the prior art information was publicly available, whether through an act or collection or acts, or through documentation.[58] Cases concerning public availability have ruled, for instance, that the language of the prior art is immaterial, i.e. if documentation exists in another language but with regard to the same product, it is enough that person skilled in the art would understand it such that the novelty requirement would not be fulfilled.[59]

The provision regarding the inventive step and how it is phrased in Australia's Patents Act seems a little more cumbersome than in the EPC or the US, since (similarly to the other jurisdictions under discussion here) it stipulates the necessity of the comparison with the prior art, and whether or not it is obvious to a person skilled in the art, but it also states that this must be in line with the "common general knowledge as it existed (whether in or out of the patent area) before the priority date".[60] In fact, it has been the opinion of commenters that the inventive step standard is too low,[61] and Australia amended the law in 2012 via the Intellectual Property Laws Amendment (Raising the Bar) Act. This

[58] Australian Law Reform Commission (2010), 6. Patentability of Genetic Materials and Technologies - Novelty

[59] See *Dennison Manufacturing Co v Monarch Manufacturing Systems Inc* (1983) 66 ALR 265

[60] Patents Act 1990, s 7, Inventive step (2) and (3)

[61] See for instance, the *Emperor Sports* case, wherein an inventor of a type of strip that can torn off during Australian rules football passed the test for inventiveness, despite the existence of an identical product in American football, since the court determined that the person skilled in the art could not have been expected to have known this.

intention behind this act was to bring Australian patent law more in line with jurisdictions such as the US and Europe, and it included updates such as that the general common knowledge should be of a worldwide nature, rather than limited merely to Australia.[62]

For the time being, at least, thus worthy of mention here, Australia currently still has a form of patent available known as an 'innovation patent'. This type of patent serves a second-tier function, in that it has been available for inventions that may not necessarily meet the criteria for being sufficiently inventive but are nevertheless innovative enough to warrant some kind of patent protection (a term of 8 years). The chief difference rests on the innovative patent system's lack of requirement for an inventive step.[63] These will no longer be available as of August 2021, since the system was repealed by the Intellectual Property Laws Amendments (Productivity Commission Response Part 2 and Other Measures) Bill 2019; apparently, according to IP Australia these patents were not aiding SMEs in the world of intellectual property as initially hoped, owing to larger companies building patent thickets to diminish competition.[64]

1.2 Patenting in Biotech & Medicine, and Medical Advancement

Thus far, for introductory purposes, the discussion has focussed on patenting and patent legislation in the three selected jurisdictions at a general level. This

[62] For more details on these legislative changes, see for example IP Australia's summary: *Intellectual Property Reform in Australia* (2013), p 3
[63] ALRC (2010) 5. Domestic Legal Framework – Types of Patents
[64] IP Australia (2020) Phase out of the innovation patent, https://www.ipaustralia.gov.au/patents/applying-patent/innovation-patent-application-process/phase-out-innovation-patent

section is intended to provide some brief broader context to the discussion at hand in this paper, through the examination and discussion of patenting processes in other life science fields, namely biotechnology and medical devices. The purpose is to demonstrate briefly the ways in which the fields share similarities and draw attention to some questions regarding the express exclusion of medical methods of treatment from patentability by the EPC, when other fields of innovation bear striking resemblances. The section will then take a short look at advancements in the medical field and how the world of patenting might be affected.

Comparing medical treatment methods with pharmaceutical product patentability

Perhaps one the most central concerns regarding patenting medical methods of treatment involves the issue of supply. Once the method is patented it means that there is a form of direct control regarding its supply. Of course, the situation is to all intents and purposes identical to that of pharmaceuticals and medical devices, since the patent holders could theoretically limit supply or charge exorbitant prices, but it is not feasible that it would be in the patent holder's interests to behave in such a manner. Thus, as with e.g. medical devices or drugs, a doctor holding a method patent could, at least in theory, restrict the licensing of the method, thus stunting its dissemination and availability in the wider medical community, but again, this is not in the inventor's interests, not to mention the fact of how it would not be in keeping with the public good. It

could be arguable that the situation might be a cause for greater concern in cases involving medical treatment, since drugs can be manufactured, sold, and distributed. If licenses are withheld for some reason, i.e. that the patent holder is unable to make theme widely available, then a reasonable solution might be compulsory licensing and/or collective rights agencies. Of course, this is a mere theory, and would need further examination in terms of effects on dissemination and the public good.

1.3 Considering medical advancement

For many of us, understanding what is truly meant by artificial intelligence is beyond our grasp without extensive research; perhaps this situation is further hindered by the fact that it is difficult to locate any one perfect definition of what artificial intelligence actually is. Despite this difficulty an attempt needs to be made for the purposes of this paper, so as a starting point we could say that when we talk about 'artificial intelligence' (AI), we are referring to systems and objects that are designed to imitate human intelligence in some way, but without the biology. The term AI have several synonyms, such as deep learning, machine learning and neural networks (a sub-set of machine learning), but terminology notwithstanding these systems are generally built using algorithms; a set of clear instructions to be carried out by the machine, whence it learns from previous results and tries to predict future results based on that learning.[65] This type of intelligence includes the design of systems like artificial neural networks, i.e. machines designed to learn and make decisions autonomously, so-called as a result of their design based on the human nervous system, and one of its chief benefits is the ability to process huge amounts of data rapidly.

Interesting and exciting questions have come to the fore regarding AI and intellectual property rights, such as whether or not an AI can be considered an

[65] Tsang et al (2017), p 1

‘inventor’ and also issues regarding the inventive step and how the position of the ‘person skilled in the art’ might change when the invention in question comes from an AI, some of which have been at least briefly mentioned by the EPO in the summary of the Patenting Artificial Intelligence Conference from May 2018, wherein it is stated: “The skilled person was aware of concepts and terminology used in the field of the application and had the means for routine work and experimentation, which could include AI tools if their use was common in the filed in question.”[66] This statement served to demonstrate the EPO’s belief that such a person skilled in the art would also have knowledge of the relevant AI in the field and use it as necessary to determine the existence of an inventive step. Of course, this is a very brief and introductory statement, but it at least indicates the acceptance of the use of AI in the course of an examination by a person skilled in the art.

The exciting questions notwithstanding, for the present at least, the creation and development of artificial intelligence is ostensibly to serve as an aid to human intelligence across a variety of fields and has been shown to bring significant advances to medical research and treatment; the medical field has seen the level of interest and usage of AI rise substantially over the past three decades or so. As with other fields and industries interested in the use of AI, big data and machine learning are of particular interest to medicine, given the possibilities for improving medical research and patient care, for example by improving the field of diagnostics. Artificial neural networks, for instance, form a very significant part of the type of AI used in medicine, given their “ability to classify and recognise patterns accurately has attracted researchers to apply them in solving many clinical problems”.[67] These types of networks can be used in processing images in radiology, for example, as well assisting physicians in diagnostics and dosage.[68] The importance and potential of AI in medicine and healthcare is worthy of mention, since it shows great possibilities, for instance,

[66] EPO (2018), Patenting Artificial Intelligence Conference Summary, p 5
[67] Ramesh et al. (2004), p 335
[68] Ibid

for improving data collection and processing; at present maybe one of its chief benefits is this ability to process huge amounts of data, since machine learning's rapid processing of such data can improve areas like diagnostics and prognosis, as well as more mundane tasks, such a patient record filing. Such developments help increase accuracy in medicine, resulting in fewer errors, and also help to save medical practitioners and their staff from time-consuming tasks that detract from time spent on research or with their patients. Even the European Patent Office (EPO) has referred to AI as the 4th industrial revolution, thus its significance should not be underplayed.[69]

2 The Categories of medical methods of treatment in depth

The following chapter will analyse the three categories of methods of medical treatment in more detail, drawing on case law from the three jurisdictions in an effort to compare and contrast how these categories are understood and the legislation that as built around them through case law. By categories is meant the three fields of medical method invention, that is surgical, therapeutic and diagnostic, and not e.g. pharmaceuticals or medical devices. The three methods will be discussed in separate sections, with statute and case law from each jurisdiction interspersed through each.

From a European perspective, this discussion will take shape in light of the decisions of the TBA (Technical Board of Appeal) in their dealings with the cases that have come before them. Some pertinent claims brought before the

[69] EPO, December 2017

Board of Patent Appeals in the US and the Federal Court of Australia will hopefully serve to highlight some of the ways these categories are judged in terms of patent claims, with the intention being to display similarities and differences between the jurisdiction where they are expressly excluded in statute (countries signatory to the EPC) and those in which they are not (USA and Australia).

2.1 Surgical Methods of Treatment

A surgical method of treatment concerns acts or interventions of a physical nature on a body that is either human or animal, usually with the intention of maintaining or improving the health thereof. Case law, however, has shown that the interpretation and conceptualisation of what is precisely meant by surgery and a method of treatment by surgery, and thus what is excluded and what can be patented. For instance, it is generally the case that if a surgical method has a more cosmetic purpose, such as hair removal, it is not excluded from patentability. Such methods are viewed as not having any curative purpose or genuine invasive step.[70] Some cases have determined that the involvement of a professional and associated expertise in the procedure as well as having a step that amounts to a physical intervention of a substantial nature amounts to a method of treatment by surgery.[71]

Article 53(c) of the EPC states that patents shall not be granted for: “methods for treatment of the human or animal body by surgery…”. It stands to reason that when attempting to delineate the extent and breadth of what is excluded, a solid definition of what constitutes a method of treatment by surgery would certainly be useful; as one would imagine such a definition is to be expected. A definition of surgery in the Guidelines for Examination is outlined at 4.2.1.1. with

[70] EPO; Guidelines for Examination, Part G: Patentability, Chapter II: Inventions, section 4.2.1.1: Surgery

[71] Of course it should be noted that other surgical methods exist for treatment in a negative way, such as e.g. insect sterilisation (an example given by XXXX)

the case G 1/07 (*MEDI-PHYSICS*) being the sole case cited. Needless to say, the Guidelines are careful to state that each potential surgical treatment method patent claim must be assessed case by case, but that in general, a definition "of the term "treatment by surgery" must cover the kind of interventions which constitute the core of the medical profession's activities".[72] Moreover, aside from the cosmetic treatments mentioned above, inventions that involve no significant health risk and wherein the intervention is minor shall not be included in the scope of 53(c). This is claimed in the Guidelines as a 'narrower' interpretation of the article, which nevertheless serves to protect the interests of those in the medical profession. The difficulty with this definition is thus determining, for example, just how narrow the "narrower understanding of the exclusion" is, for which we must turn to the case law of the TBA.

If the definition, or the understanding there of, is overly broad, more exclusions from patentability would appear than would not be perhaps justifiable or perhaps contrary to the spirit of the provision. An overly narrow interpretation, however, could permit the patenting of treatments by surgery that the legislation was drafted to prevent. The legal question of a balance of interests must again be struck here; if the EPC excludes methods of treatments by surgery so as to ensure that veterinary surgeons and physicians are not unduly burdened by the existence of excessive patents in their field, the narrowness of the understanding must be still be such that creativity and development are possible.

An interesting question is how these interpretations apply to the other methods, i.e. whether or not they are equal in their understanding, such that neither diagnostic methods that are practiced on the human or animal body nor therapeutic methods are afforded greater scope for patentability or restricted either through broader or narrower interpretations of the article. These kinds of

[72] Ibid.

questions and considerations that arise from the Guidelines mean that a consistent approach by the TBA would help to further clarify both the spirit behind the provision and the length and breadth of its interpretation. According to Eddy Ventose: “The TBAs have not been able to delineate the scope of the exclusion with any measure of consistency.”[73]

The case of T 182/90 (*SEE-SHELL/Blood flow*) saw the TBA dissect the then article 52(4) into several pieces, in order to examine and define the meanings of the terms therein before deciding the scope of the exclusion.[74] In so doing, the Board endeavoured to illustrate what is meant by the terms ‘treatment’, ‘surgery’ and ‘treatment by surgery’, before determining the intent of the exclusion and making a judgment based on that conclusion. According to the Board in *Blood flow*, ‘treatment’ as a concept encompasses many possibilities, of which some can be patentable, since the term is apparently not restricted to methods which serve a strictly therapeutic function.[75] This is intriguing, since if one reads the article 53(c) ‘as is’, the exclusion applies to treatment methods by surgery *or* therapy, which raises the question of the relationship between the three words. Are surgery and therapy mutually exclusive? But should all treatments not automatically serve a therapeutic purpose? The wording of the article suggests not, otherwise why explicitly prohibit treatment by therapy. The TBA, in the meantime, appear to have disagreed with this reading in the case of Blood flow, since they draw a distinction between types of treatment, since a medical method: “may also include treatments for other, non-curative purposes such as cosmetic treatment, the termination of pregnancy, castration, sterilisation, artificial insemination, embryo transplants…”[76] The Board also disagreed with the Guidelines by (admittedly rather tentatively) disputing the statement that surgery should define the treatment’s nature rather than its purpose.

[73] Ventose (2011), p 124.
[74] T 0182/90 (Blood flow) of 30.7.1993
[75] Ibid, s. 2.2
[76] Ibid

In the case of *MEDI-PHYSICS*,[77] the belief that exclusions for treatments of a surgical nature could be limited to surgeries that took place for therapeutic purposes was not possible, since it was their view that surely it would already be excluded by default as a result of the exclusion of methods of treatment by therapy from patentability. It is from this case that treatment by surgery was given some more clarity by the EBA, owing to the TBA referring questions to the Enlarged Board. MEDI-PHYSICS concerned an imaging method, and it was denied patentability owing to the presence of an invasive step, which required the skill of a trained professional. Although the method itself was not precisely aimed at the maintenance of life or health, the EBA held that it was not necessary for a method of surgery to have a therapeutic purpose. This case is discussed further in Chapter 3.

2.2 Therapeutic Methods of Treatment

With regard to therapeutic methods of medical treatment, this section will consider and discuss this exclusion in terms of its core definitions and whether or not these have been consistently applied. Possible solutions to any such inconsistencies regarding methods of treatment (on humans or animals) found in the TBAs' decisions will also be analysed.

By way of introduction, a method of treatment by therapy is usually defined as a treatment that serves the purpose of either eliminating, relieving, curing, or reducing disease symptoms, or lessens/eliminates the chances of contracting disorders or diseases. From this we can determine that a therapeutic method is one that serves to provide relief for pain and discomfort. Cases have also shown that a treatment for prophylactic purposes (e.g. methods for preventing

[77] G 01/07 (MEDI-PHYSICS) of 15.2.2010

potential illness or maintaining good health) are also methods of treatment by therapy. As such, in accordance with the decisions of the TBA and EBA (many of which for some reason seem to concern pigs), should a claim display even one step or feature that would constitute a method of treatment by therapy, it is excluded by default from patentability.

In Europe, a narrow interpretation of the exclusion from patentability of methods of medical treatment is expected, which means that it does not include treatment methods that are not of a therapeutic nature. This means that the word 'therapy' is expected to be precisely defined, with that definition adhered to. According to the TBA in the of *SALMINEN/Pigs III*, the word 'therapy' includes: "any non-surgical treatment which is designed to cure, alleviate, remove or lessen the symptom of, or prevent or reduce the possibility of contracting any malfunction in the human body".[78] The case concerned an invention to prevent the suffocation of piglets by blowing air whenever the sow stood up. In this instance the Board determined that the mere prevention of accidents could not constitute a therapeutic method: "the invention is concerned with prevention accidents, analogous to a method of preventing a worker from trapping his hand in machinery".[79]

Furthermore, the TBA goes on to state that a therapeutic method: "relates to the treatment of a disease in general or to a curative treatment in the narrow sense, as well as the alleviation of the symptoms of pain and suffering".[80] Thus the term 'therapy' was not intended to signify only diseases and their cures, but any particular treatment that is for curing, reducing or completely removing symptoms of illness in human or animals, as well as treatments developed to prevent the contraction of illnesses and their associated symptoms.

[78] T 0058/87 of 24.11.1988 at 2.1
[79] T 0058/87 of 24.11.1988, at 2.3
[80] Ibid

It was also earlier in *Pigs II* that the TBA pondered methods of medical treatment by therapy that serve to maintain or restore the health of humans or animals and came to the conclusion that a method is not excluded if there is no direct effort to restore or maintain health, which renders the treatment unmedical and the exclusion does not apply. The Board determined that this was a prophylactic treatment and thus came within the scope of the word 'therapy' in Art. 53(c). Therefore, if the purpose of the method is in any way preventative or curative, it will be excluded as a medical method. The case of *Dysmenorrhoea* from the same year drew some interesting conclusions when it determined that the treatment of pain, whether from a disease or from a normal functioning of the human body resulted in the treatment method being considered as a medical one: "Irrespective of the origin of pain, discomfort or incapacity, its relief, by the administration of an appropriate agent, is to be construed as "therapy" or "therapeutic use" in the sense of Article 52(4)."[81]

According to the TBA, as stated in the case T 0592/98, the reasoning behind Article 52(4) in EPC 1973 was "to prevent any obstacle to the freedom to choose the best medical treatment to be applied to a patient and to avoid any delay in the application of such medical treatment".[82] It was the Board's view that treatment patents would amount to stumbling blocks that could prevent swift treatment in a timely manner, thus infringing on the rights of the patient. The Board do not outline what would cause such delays, although it is to be presumed that if a treatment is patented, the e.g. physician seeking to use it in the course of patient treatment would need to seek permission first in order to do so, leading to a possible delay in providing it, which is not in the best interests of public health.

[81] T 0081/84
[82] T 0592/98 of 5.10.2001, at *Reasons for the Decision*, 2.

Products and devices used in medical methods of treatment

The second sentence to Article 53(c) EPC provides that the exclusion from patent protection of methods of medical treatment shall not apply to products, substances or compositions for use in any of the medical methods. It is self-evident that the prohibition on patenting methods of medical treatments would not prevent the patentability of products, including substances or compositions, even if they are used in such excluded methods, since otherwise it would be difficult to medical products or devices in general. Where, however, a claim covers the actual use of a device in the treatment of a patient, it becomes necessary to determine whether or not that device is patentable, notwithstanding the exclusion of methods of treatment by therapy from patent protection. Arguably, the exclusion for methods of medical treatment begins to bite when the claim is for a device 'when used' in a method of medical treatment such as by therapy, surgery or of diagnosis. This means that while patent protection is available for medical devices, they cannot derive novelty from the way they are intended to be used in the excluded method of treatment. These claims are, therefore, not excluded from patent protection by virtue of Article 53(c) EPC.

Speaking of devices, if a device is used in treatment it can have a large bearing on whether or not the use of that device indicates if method is actually a method of medical treatment. In order to determine whether or not the method falls within the exclusion, the degree to which the device is used in its connection to an animal or human is examined, such that a very profound connection or functional link would render the device as an extension of the treatment, meaning it would fall within the exclusion. In the case of *Flow measurement* for instance, a flow rate measurement device measured liquid in small amounts passing through a tube, which in turn administered insulin using an implanted pump. The measurement method thus determined how well the pump was

working. It was the decision of the TBA that no functional link between the flow measurement and the insulin pump existed, since: “the fact that…a drug is also passing into the body generally with a therapeutic effect, is not sufficient on its own…to justify a finding that the flow timing is therapeutic.”[83] It would seem that the Board’s decision is based on the idea that the measurement device itself did not have any influence on the insulin administration, thus it produced no therapeutic effect, i.e. the body was not affected in any way by the workings of the device.

That said, implantable devices fall on both sides of the fence regarding patentability, for instance if a method to operate a pacer controls cardiac function, then it is a therapeutic method of treatment. The case of *TELECTRONICS,* in which a method to adjust a pacemaker’s rate for optimal performance while someone is exercising, the TBA were of the view that the functional link did exist in this instance, since the method had a therapeutic effect on the body by causing the pacemaker to adjust its rate. Thus the claim was excluded, since it “defined a method for treatment of the human body by therapy.”[84]

The above explanations regarding the definition of medical methods of treatment by therapy notwithstanding, there are still areas that could be further defined. Some questions that could arise include: issues including the human or animal body, such as if there are or should be differences in how the methods are considered with regard to whether they are performed on a human or an animal; if a cosmetic treatment has some therapeutic purpose can be eligible;

[83] T 0245/87 (Flow measurement) of 25.9.1987, at 3.2.1
[84] T 0082/93 (Telectronics) of 15.05.1995

if there can be a clearer dividing line between devices used for therapy and methods of therapeutic treatment.

2.3. Diagnostic Methods of Treatment

Christina Gates describes diagnosis as: "the determination of the nature of a medical or veterinary medical condition intended to identify or uncover a pathology."[85] With regard to medical diagnostic methods, Article 53(c) EPC also excludes '*diagnostic methods* practised on the human or animal body' from patent protection. A method to obtain a diagnosis is a little different from other methods, since a diagnosis is not in and of itself a treatment, so to speak. Nevertheless, its exclusion is also evident in the 'methods of medical treatment exclusion' found in Article 53(c). With the increasing complexity and technical sophistication associated with medical treatments, and by extension diagnostic methods, in this technologically advanced age, the EPO view it as important that this exclusion in Article 53(c) EPC is not interpreted in a way that would serve to suffocate appropriate research and development in this vital and essential area.[86] The new age of technological advancement in the medical field, using genetic testing and gene therapy, would not be sustainable if an appropriate balance is not struck when interpreting the exclusion.

Arising from the case of *CYGNUS/Diagnostic method*, the EBA further defined what is meant by a diagnostic method for future reference in cases where exclusions from patentability should be applied regarding methods to be

[85] Gates (2014)
[86] G 0001/04 (Diagnostic methods) of 16.12.2005, Reasons for the opinion, 4

practised on humans or animals. The Board determined that a diagnostic method includes 4 discrete steps: i) data gathering & examination; (ii) comparison of the data with more normal values; (iii) recording possible significant deviations; and (iv) showing that the deviation is part of a certain clinical picture.[87] In order to be considered as a diagnostic method, and thus patent ineligible, the claim must display all four of the aforementioned steps. Moreover, for exclusion of that method to occur, there must be one technical step that is practised on the animal or human body.[88] As a result of these steps from *CYGNUS*, it has perhaps become somewhat clearer for the Technical Boards to determine when a patent application should be accepted or rejected depending on whether or not a method can be established as being diagnostic in nature.

The case of *BRUKER/Non-invasive measurement* meant that the TBA had to consider the scope of the exclusion of diagnostic methods from patent protection, and came to a number of important conclusions.[89] The claim concerned local magnetic resonance for the non-invasive determination of chemical and/or physical conditions inside a living human or animal body. After examining the legislative history of the exclusion, the TBA concluded that the purpose of Article 52(4) EPC (in force at that time) was for the purpose of shielding doctors from unwanted legislative obstructions in the course of their practice, thus for similar reasons to the other methods of treatment discussed above. Since what constituted a 'diagnostic method' needed to be first delineated by the Board before proceeding further in their judgement, it was in this case that the definition of diagnostic methods in terms of patent exclusion was outlined as: "the only diagnostic methods to be excluded from patent protection are those whose results immediately make it possible to decide on a

[87] By clinical picture is meant the overall picture of all the information that is relevant to a disorder or disease, or a patient's state of health.
[88] G 0001/04, Conclusion, 4: "Article 52(¤) EPC does not require a specific type and intensity of interaction with the human or animal body; a preceding step of a technical nature thus satisfies the criterion "practised on the human or animal body."
[89] T 0385/86 (Non-invasive measurement) of 25.9.1987

particular course of medical treatment."[90] A method that does not allow a physician to make a decision immediately, but rather requires further e.g. analysis and/or tests is not by itself a diagnostic method. Thus a method that gives interim results, i.e. further steps that would need to be taken in order to reach a conclusion regarding the course of treatment, would not be not considered a diagnostic method as per Article 52(4).

Having considered the issues with regard to what is meant by diagnostic method, the Board proceeded to examine the case in terms of methods of diagnosis that are only carried out and are only capable of being carried out by a qualified doctor and whether such methods would be unpatentable, and finally to what extent does the phase 'practised on the human or animal body' apply and what are its limitations. Regarding the second question, the Board came to the conclusion that a diagnostic method is susceptible of industrial application if a technician can use it to the desired effect, even without any special medical knowledge or expertise.[91]

The EPO, in its decisions regarding diagnostic methods in G 01/04 made some significant decisions. As mentioned above, the diagnostic method of treatment under examination must contain all four of the steps devised by the Board in order to be excluded. It was the Board's determination that the provision under article 53(c) should be construed narrowly, since the article does not refer to steps of any kind, or any other broader features, thus "in order to be excluded from patentability, the method is to include all the steps relating to it".[92] Thus if the data-gathering step or diagnosis step is omitted, the method is not a diagnostic one.

[90] T 0385/86 (non-invasive measurement) of 25.9.1987, headnote
[91] Ibid, Reasons for the Decision, 3.5.2
[92] G 1/04: 349-50

As Sterckx and Cockbain phrased it with regard to the four steps: “the insistence on the inclusion of the (mental) act of diagnosis raised the problem of how such a step could be practiced on the patient’s body.”[93] As an act of the mind, the deductive phase cannot of itself have a practical physical application to a body. This conundrum was answered in the Board’s decision regarding ‘practised on the human body’, in that only the steps that had a technical nature needed to practiced on the body, or that the body at least be somewhere nearby. This may seem a little on the convenient side, but the Board supported their decision by stating that other steps may: “*include method steps such as comparing data collected in the examination phase… These activities are predominantly of a non-technical nature and…are not normally practiced on the human or animal body*.”[94] Of course, a potential patentee might try to avoid the exclusion by omitting the technical steps from the claim, but would be in any event excluded from patentability owing to the mental act of diagnosis or deduction being just that, a mental act, such acts being patent ineligible under article 52(2) EPC: “schemes, rules and methods for performing mental acts”. Thus, in order to become patent eligible, a method of this nature would need to display steps of a technical character not practiced on the body.

Finally, the Board further clarified some other aspects regarding possible methods of diagnosis for instance with regard to steps performed in vitro in a laboratory, such methods would include DNA microarrays and are not practiced on the human body directly. These kinds of genetic diagnostic methods are thus not excluded, at least not in principle, since the steps are of a technical nature. “*In respect of diagnostic methods it already follows that the various method steps of a technical nature relating to such a method are basically meant to be performed on the…body, suggesting an interaction with the latter, rather than in vitro*.”[95]

[93] Sterckx et al (2015), p 155
[94] G 1/04, Reasons for the opinion, 6.4.1
[95] G 001/04, Reasons for the opinion, 6.4.4

PART II

The function of Part II is first to trace some of the history (chapter 3) of medical methods of treatment in terms of patentability in the three selected jurisdictions (Europe, USA & Australia), followed by a critical discussion of the commonly cited pros and cons (chapter 4).

3 Tracing the history of patenting medical methods of treatment

3.1 EUROPE (EPC)

Of course, European-wide laws do not share the same extensive history with individual countries in terms of longevity (Australia and the USA will be discussed in the sections below), since the EPO (European Patent Office) was established by the EPC (European Patent Convention) in 1973. The purpose of its founding was to create a European body that would process the granting of patent claims, in the sense that while inventors could seek national patents as before, the option now existed to seek a patent directly from the EPO, which, if successful, could be granted in all states that form the EPC's Members, of which there are 38 at the present time. As stated in Article 1 of the EPC: "A

system of law, common to the Contracting States, for the grant of patents for invention is hereby established."[96]

With regard to medical methods of treatment, the original provision precluding them from patentability was contained in EPC Article 52(4). Section 1 of the same Article states: "European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step."[97] Following on from this, Section 4 provides (Art. 54):

> "Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods."[98]

Thus as can be seen, medical methods of treatment were denied patentability under the guise of lack of industrial application. The second sentence is presumably intended to clarify that this exemption does not stretch to materials etc used when performing a method. EPC 2000 entered into force in December 2007, and with this new edition of the convention, Article 52(4) of the original convention was replaced by Article 53(c). Essentially, what is excluded in terms of content remained unaffected, all that was actually altered was the reasoning and legal justification warranting the exclusion of medical methods of treatment from patentability. In their explanatory comments, the EPC 2000 drafters indicated that the alteration would not more than likely not have any effect on the interpretation of the prohibition in practice when it came to judging the inventions brought before the EPO.[99] Whereas hitherto the legal justification was based on the concept of a medical method as lacking any industrial

[96] European Patent Convention, 1973, art. 1. The revised EPC 2000 (art. 1) states: "A system of law, common to the Contracting States, for the grant of patents for invention is established by this Convention."
[97] EPC, 1973, Art. 52(1)
[98] EPC 1973, Art 52(4)
[99] '[a] change in the EPO's current practice regarding these inventions is not envisaged' as a result (The Basic Proposal for the Revision of the European Patent Convention, 13 October 2000, Article 53 EPC, Explanatory Remarks, at para. 3).

application, this reasoning was rather conspicuously left absent from Article 53(c). It seems therefore that while the justification was removed, the judicial approach under Article 53(c) would remain similar to that of Article 52(4). The exclusions under 53(c) and the changes in interpretation and justification will be discussed further below.

Exclusions from patentability under Article 53 EPC

As mentioned above, a number of exclusions exist in European law, denying patentability to certain types of subject matter, the relevant provisions of which are contained in Article 53 EPC. Article 53(a) prohibits patents on inventions that would be contrary to the *ordre public*, i.e. subject matter that would run afoul of public opinion, owing to the sensitive nature of the content involved.[100] Article 53(b) excludes the patenting of varieties of plants or animals or the "essentially biological processes for the production or plants or animals"[101], from which we can deduce that no process that occurs or can occur in nature should be patentable. From a European perspective, it is Article 53(c) of the European Patent Convention (EPC) that is addresses the subject matter under discussion, since it prohibits patentability 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"[102], and moreover "this provision shall not apply to products, in particular substances or compositions, for use in any of these methods."[103] On the face of it, therefore, it appears that a medical method in itself may not seek a patent, but any products used in the course (at least, any newly invented ones) of that method might be patentable. A review

[100] EPC, Art 53(a)
[101] EPC, Art 53(b)
[102] EPC, Art. 53(c)
[103] Ibid.

and discussion of the unpatentability of medical method will take place in the next chapter.

Article 53(c) EPC: exclusion of surgical, therapeutic and diagnostic methods

The discussion here will examine medical methods as discussed above and how they are categorised in law, along with the EPO guidelines for medical methods and the limitations to these exclusions.

The EPC was revised in 2000 and this exclusionary provision had hitherto formed part of Article 52 of EPC 1973.[104] Its relocation to Article 53(c) was "so as to make it a stand-alone policy exclusion rather than an exclusion grounded in the requirement for susceptibility of industrial application."[105] This raises the question: why was this? If medical methods cannot have industrial application, why then was a separate provision deemed necessary to address this? According to the EPO, this fascinating change was a result of the recognition of the complete "legal fiction" that medical methods are not susceptible of industrial application.[106] The correct reason, so to speak, given by the EPO for the existence of this exclusion is that such methods are excluded from patentability for reasons of public health. In the words of the 2000 proposal: "It is undesirable to uphold this fiction [lack of industrial application] since methods of treatment and diagnostic methods are excluded from patentability in the interests of public health."[107] It could be claimed that the wording of Article 52(4) of EPC 73 gives rise to the suggestion that the methods could in fact be

[104] EPC 73, Art. 52(4)
[105] Pila et al. (2016), p 122
[106] EPO, 1.1. Amendments made to Article 53 EPC as part of the EPC 2000 revision, in Case Law of the Boards of Appeal
[107] MR/2/00, p 45

susceptible of industrial application, a view which is supported with a note from Case T 182/90, wherein the court stated that such methods cannot be granted patents because of the article 52(4): “irrespective of whether or not these methods are, in fact, susceptible of industrial application”[108], which does suggest a certain frustration on the part of the court regarding the sweeping nature of the provision. In light of this change or update in reasoning regarding the unpatentability of these methods, the EPO has provided guidelines and opinions addressing the limitations of these exceptions, discussed here in section 3.3.

Worthy of mention here is a little more historical context, specifically with regard to UK law. In Justine Pila’s article on invention requirements, she examines the course of the exclusionary provisions in the UK, starting with the Statute of Monopolies 1623. Patents were originally intended only for manufacturing, i.e. for what was referred to as the industrial arts, and further refined to mean the manufacturing arts, excluding such items as business plans.[109] What is of significance is Pila’s assertion: “Equally uncertain…was the status of methods of medical treatment. While accepted as inherently unpatentable, the reason was unclear.”[110] This suggests that medical treatments have traditionally been excluded from patentability for purposes ill-defined or even unknown. While further research into the history and development of this exclusion would undoubtedly be very intriguing, it remains outside the scope of the present discussion.

That said, this type of context nevertheless serves as useful insight into how policy changes over time, i.e. the history of medical methods excluded because of lack of industrial art advancement or some other reason stands in quite stark contrast with the modern view of exclusions to protect physicians and others from claims of patent infringement. If it can be said that patentability exclusions for medical methods and treatments have been justified resulting (perhaps) from their not being part of the manufacturing arts, subsequently progressing

[108] Case T 182/90, Blood Flow/See-Shell, point 2.1. in supra note 10, 88
[109] Pila, in Arezzo et al (2011), p 65
[110] Ibid.

to the so-called fiction regarding their lack of industrial applicability and currently to their lack of admissibility owing to concerns for public health, it is interesting to consider future directions such a policy might take, especially in light of advances in medical methods in recent decades.

EPO Guidelines and opinions regarding exclusions of surgical, therapeutic and diagnostic methods

In the original drafts of the EPC, there was no mention of methods of treatment by surgery, and this exclusion was not expanded to include them until 1969, with the broadening of the exclusion to surgical methods. THe next two years saw the wording change to 'methods for treatment of the human [or animal] body by surgery', an alteration that seemed to serve no other purpose than the cosmetic.

The limitations to exclusions in Article 53(c) appear drafted so as to support and define the decidedly vague and brief explanation of "the interests of public health" in the EPC revision of 2000. The fundamental reasoning behind the exclusions concern methods that involve acts upon a human or animal, i.e. "to be excluded from patentability, a treatment or diagnostic method must actually be carried out on the living human or animal body".[111] Methods performed on the dead ones, by contrast, do no fall within the remit of Article 53(c). The parameters are then further defined, for example: should fluid or tissue be removed from living creatures, any suitably inventive method or treatment carried out on those samples is potentially patentable, provided their subsequent return to the subject does not feature in the process.[112]

[111] EPO, 4.2 Surgery, therapy and diagnostic methods in G ii Guidelines for Examination
[112] Ibid

In the original drafts of the EPC, there was no mention of methods of treatment by surgery, and this exclusion was not expanded to include them until 1969. For surgical treatments and methods, the EPO advise that exclusions from patentability be assessed case by case, with one of the overarching criteria for exclusion arising from particularly invasive forms of surgery, wherein there is a significant risk to the patient, whereas smaller operations on non-critical body parts e.g. tattooing and piercing are not excluded from patentability. One argument for excluding surgical methods is that many methods of operating are decidedly similar and require specific knowledge and education on the part of the surgeon, meaning that patents are not possible given a method's potential widespread use. It was the *Re Medi-Physics* case that served to illuminate the Board of Appeal's efforts to achieve this more middle-of-the-road approach to these exclusions. This case concerned a method that included the injection of what is known as a contrast agent into a patient's heart as part of a MRI (magnetic resonance imaging) process. It was the view of the court that this method could not be eligible for patentability as it fell under the definition of treatment by surgery and was thus excluded under Article 53(c). [113] Thus the Board did not hold the view that treatment by surgery needed to be therapeutic in nature, but could include other types of body treatment. Furthermore, at 58 in the same case the Board believed the exclusion too restrictive owing to the advancement in various cosmetic procedures, such as piercing and tattooing, since they are non-invasive and not technically medical, even though they can be considered in a surgical light.[114] Notably, the Board recognised the ever-changing nature of technology and thus refused to give any all-encompassing definition of 'treatment by surgery',[115] perhaps showing a certain amount of foresight into the rapid development of technology in the medical field.

By therapy is generally meant methods for curing or preventing illness and disease in humans or animals, defined in T24/91 as "any treatment which is

[113] G 001/07 (Treatment by surgery/MEDI-PHYSICS), 2010
[114] Ibid, 58
[115] Ibid, 63

designed to cure, alleviate, remove or lessen the symptoms of, or prevent or reduce the possibility of contracting any disorder or malfunction of the animal body'.[116] As with surgical methods, certain cosmetic treatments that can considered to have a therapeutic effect are not excluded under article 53(c). Regarding an apparatus used in therapy, in order to determine that apparatus's validity for a patent, it must be shown that a functional link does not exist between the steps involved in the method and the effect on the body. This might appear somewhat confusing, but the case included in the Limitations provides a useful distinction, namely the Flow Measurement case T 245/87, which concerned a monitoring system for a device for drug administration. It was the view of the Court that because the apparatus was concerned only with measuring the function of the drug delivery device, the steps were purely technical and had no link to the therapeutic effects of the device itself.[117]

In assessing patent exclusions for diagnostics methods, the EPO have devised a four-step system to determine a lack of patentability, namely i) examination, ii) comparison of data gathered, iii) the finding of any significant deviation, and iv) the deduction or decision phase.[118] These aforementioned steps should be carried out on a living body, the standard rule for which is that a body must be present for the steps, regardless of the level of interaction with the medical practitioner. These steps aim to match the standard diagnostic process, and all of these steps must be met for exclusion. One rule of thumb could be that if the method steps are sufficiently technical and do not of themselves form a diagnosis, but instead assist in an eventual diagnosis, such a method may be patentable.

[116] T 24/91 *Thompson/Cornea* [1996] EPO 19
[117] T 0245/87 (Flow measurement) of 25.9.1987, 3.1
[118] EPO, Guidelines for Examination, 4.2.1.3: Diagnostic methods. See also G 1/04 Diagnostic methods (16.12.2005), at 5.

Crucially, an explanation is given for the intent behind Article 53(c), which reveals an insight into the EPO's mindset regarding the reason for this article's existence, or at the very least, their reason: "it must be borne in mind that the intention of art. 53(c) is only to free from restraint non-commercial and non-industrial activities."[119] As mentioned above, this statement has clearly been viewed as too broad by the Courts in cases such as *Re Medi-Physics* and was revised to include only invasive and/or risky methods or treatments. The EPO guideline nevertheless naturally suggests that e.g. physicians and medical practitioners going about their work of treating, diagnosing, or operating on live subjects will not need to fear potential claims for patent infringement when they are endeavouring to execute the ordinary business of their profession. This is evidently in line with public health policy, since any medical practitioner afraid to do their job as effectively as possible as a result of possible threats of litigation is certainly not in the public interest. What is notable in the EPO's explanation, however, is the use of the terms "non-commercial and non-industrial". Is it to be inferred that potential commercial or industrial methods or treatments are in fact capable of patentability, even if they involve acts on living subjects? The answer to that question is, needless to say: it depends, for example if, as in the *Eisai* case G 0005/83, a second medical indication is found for "specified new and inventive therapeutic application"[120] then a patent claim may be valid.

How strict is the exclusion under 53(c)?

It is interesting to examine some of the challenges brought to the Board by parties opposed to the patent in question. As mentioned above, article 53(a) of the EPC excludes patentability on the grounds of the invention being contrary to morality or pubic order, for instance if an invention was so repugnant to

[119] EPO, Guidelines for Examination, 4.2.1: Limitations of exception under Art. 53(c)
[120] G 0005/83 (Second medical indication) of 5.12.1984, p 14

society, as was contested in the *Relaxin* case, which involved the codifying of the female pregnancy hormone of the same name, i.e. the inventors wished to patent human genetic material,[121] the objections were all overturned by the board. The objections included various concerns, the most of dramatic of which was perhaps that patenting human genes "amounts to a form of modern slavery since it involves the dismemberment of women and their piecemeal sale to commercial enterprises". Aside from these more outlandish challenges, other concerns included the lack of inventive step and the lack of novelty.

In the case of *Mutation/University of Utah*, (which was the second of three cases), the defendants had created a method for diagnosing possible predispositions to mammary gland and ovarian cancer, which the appellants argued should not have been eligible for patenting under article 53(a), owing to it giving rise to ethical issues, and also under article 53(c), since in their view it constituted a method for diagnosis of the human body. The Technical Board, however, held that the exclusion only applies (as per the decision in G 01/04) to methods practised on the human or animal body, and since the method is question is performed on a tissue sample, the appeal on that count must fail.

Regarding the potential socio-economic and ethical consequences that might occur (e.g. that patients would become dependent on the patent holder, and this would not be in line with human dignity), the Board followed the decision in T 1213/05, that the appeal was against the possible exploitation of the patent and not of the invention, meaning that the objection did not fall within article 53(a).[122] This is an interesting decision, since the Board (entirely legitimately) discounted the objection on a point of law. However, the appellants' concerns with the ordre public being threatened through the patent exploitation were dismissed by the Board as merely being part of the "exclusionary nature of the rights granted by a patent…[S]uch an objection applies to the exploitation of any patent."[123] This is certainly an intriguing viewpoint for the Board to take on

[121] T 0272/95 (Relaxin/HOWARD FLOREY INSTITUTE), see also EPO Official Journal, 1995, 388
[122] T 1213/05 (Breast and ovarian cancer/UNIVERSITY OF UTAH) of 27.9.2007, 53.
[123] Ibid

considerations regarding the ordre public, since it appears quite dismissive in terms of concerns regarding ethical considerations. The Board came to this opinion because of their belief that the objection, when 'reduced to its essence', amounted to the type of exploitation that could occur from any patent. Yet by only examining the essence of patent process and possible unfortunate outcomes resulting therefrom, does this not undermine the consideration of each patent application and objection on a case-by-case basis.

3.2. USA

Patent law in the USA grew from the U.S. Constitution, since the constitutional mandate was to encourage "the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writing sand discoveries."[124] The Patent Act (35 U.S. Code) regulates patenting the USA and the United States Patent and Trademark Office (USPTO) was established under that code, to which prospective inventors must apply. According to the Patent Act §101: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."[125] The word 'process' is defined in §100(b) as "process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."[126]

[124] U.S. Constitution, Art. 1, s. 8
[125] Patent Act (35 U.S. Code), §101
[126] Patent Act (35 U.S. Code) §100(b)

In terms of the present discussion, the patenting of medical methods of treatment is not prohibited under US patent law. That said, the issue has been in a state of uncertainty, and the fluctuations in case law over the past century have shown that medical methods have had a chequered reception regarding their patentability and the patents were infrequently granted until more recently. In fact, it was originally decided between the patent office and the medical profession that medical methods should be excluded from patentability, with the original medical Code of Ethics stating that for a doctor to hold a patent would be "derogatory to professional character".[127] The courts and the medical profession appeared to remain in agreement over this matter until 1954, when a landmark case, *Ex Parte Scherer*[128] overturned a decision in the earlier case of *Brinkerhoff*,[129] by permitting a claim to a patent for the use of a pressure jet to inject fluids into the body.[130] It wasn't perhaps until the case of *Diamond v Chakrabarty*[131] in 1980, which permitted a biotechnology patent, that the idea of patenting medical methods really began to take hold.

Thus patents for medical methods were rare, and did not begin to surface until the 1990s.[132] For instance, It would appear that the first instance that (famously) came to light in the US concerning medical method infringement was the case of *Pallin v Singer* in 1993.[133] The case centred on a claim by Dr Samuel Pallin that another doctor, Dr Jack Singer had infringed on a patented method for cataract surgery created (or at least patented) by Dr Pallin. The claimant alleged that the defendant performed the procedure more than 200 times in a year, as well as teaching the method to students. No license fees or royalties had been paid to Dr Pallin. The defendant claimed that he had been using the

[127] American Medical Association, Code of Medical Ethics §4 (1847)

[128] Ex Parte Scherer, 103 U.S.P.Q

[129] Ex Parte Brinkerhoff. The court stated: "the methods or modes of treatment of physicians of certain diseases are not patentable".
[130] Strandburg (2014), p 4
[131] *Diamond v Chakrabarty*, 477 U.S. 303
[132] Chartrand (1995)
[133] *Pallin v Singer* 36 USPQ 2d 1050 (1995)

cataract surgery method some time before Dr Pallin had filed for a patent, a claim that was supported by the testimony of the defence, as well as through the cross-examination of the claimant. The claimant lost the case, since the presiding judge, Judge Session, declared that the patent claims were invalid. Had the claim succeeded, Dr Pallin would have received a considerable income from royalty fees, given that approximately one million cataract removal surgeries are performed each year.[134] The controversy caused by this case led to the amendment of the patent code through the addition of § 287 to 35 U.S.C.: *"With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under § 271…the provisions of §§ 281, 283, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity."*[135] This frankly astonishing addition to the patent code was created in the interests of bringing tranquillity back to the medical realm, but rather than expressly prohibiting the right to patent a medical method of treatment, Congress instead chose to permit such methods, but render them utterly toothless. This issue will be discussed further later in the paper.

The decision in *Pallin* does not seem to have seriously affected the patenting of medical methods or litigation with regard to them, however, since in more current times, quite a significant number of cases have come before the US courts regarding methods of medical treatment. the *Mayo v Prometheus*[136] case created much criticism surrounding patents for medical methods of treatment, since once again, as in earlier cases, it was the Supreme Court's ruling that such a method should not be patentable. The controversy arose from critics declaring that such a ruling would have the effect of bringing chaos to the patenting world, especially since it would appear that the method in *Mayo*

[134] Findlaw Attorney Writers, 2017
[135] 35 U.S.C. § 287(c)(1) (Supp. II 1996).
[136] *Mayo Collaborative Services v. Prometheus Laboratories*, Inc., 566 U.S. 66 (2012)

would easily satisfy §101 of the 35 U.S.C.[137] The case a patented method that involved diagnostic kits for determining how well a patient could metabolise a medicine for gastrointestinal disorders. When *Prometheus* sued *Mayo* for producing and selling its own diagnostic kits, the Supreme court dismissed the rulings of the lower courts (apart from the District Court, which had come to the same conclusion) and held that the patents were ineligible, since they were based on a natural law and "the claimed processes are not patentable unless they have additional features…Doctors had been using these drugs for this purpose long before these patents existed."[138]

This controversial Supreme Court decision aside, in the Court of Appeals for the Federal Circuit (CAFC), there has generally been a more or less consistent policy regarding methods of treatment, in that it is not merely, for instance, a 'mental process' that would eliminate a method from patentability. It has usually been decided by the CAFC that a medical method of treatment can be capable of receiving a patent, whether or not a diagnostic step is involved.

In the case of *Classen Immunotherapies Inc*,[139], which is something of a landmark case, the CAFC determined whether or not a method for immunisation would be eligible for a patent. The facts of the case concerned immunising patients in accordance with two different immunisation timetables and observing which timetable had the lesser risk in terms of side effects, after which a patient would be immunised in accordance with the safer timetable. The act of deciding the safer schedule was not deemed patentable in and of itself, but the immunisation of a patient as a result of that decision was capable of receiving a patent. In other words, the decision was unanimous that immunizing two subject groups and comparing the results to determine the

[137] See, for instance, Gene Quinn's criticism of the ruling in IP Watchdog, 2017 https://www.ipwatchdog.com/2017/01/23/mayo-v-prometheus-lawless-decision-wreaking-havoc-patents/id=77438/

[138] *Mayo*, Syllabus, p 2

[139] *Classen Immunotherapies Inc. v Biogen IDEC* (Fed. Cir. 2011)

most appropriate schedule for further immunisations, while not applying that same schedule to a specific individual, was not patent eligible. The added step of providing a subject with immunisations as per the decided schedule, however, caused the panel majority to allow patent eligibility for the method. While the majority of the court allowed that - despite the presence of mental steps - a method of medical treatment is eligible for patenting, a dissenting judge thought the claims were "a monopoly over the scientific method itself."[140] It was Judge Moore's view that the claims principles were 'basic and abstract', to the extent that they should be rendered unpatentable.

Methods of diagnosis

This positive ruling continued in later cases, including *Endo Pharmaceuticals Inc*[141] and *National Alternatives International Inc.*[142] However, if a claim for a patent does not involve a medical method of treatment, and only has diagnostic steps or elements, the CAFC has routinely declared such claims ineligible, for instance in *PerkinElmer Inc v Intema Ltd*[143] and *Cleveland Clinic Foundation v True Health Diagnostics LLC*.[144] Some further examples are also evident where applications for patents for diagnostic methods of treatment were struck down by the Federal Circuit, including *Myriad* (by the Federal Circuit, before it went to the Supreme Court, *Roche Molecular Systems, Inc v Cepheid*,[145] and *Ariosa Diagnostics, Inc v. Sequenom, Inc*.[146] The facts are of course different in each of these, but in each one the method's result is diagnosis, not in the actual treatment of patients. Some of these cases will be discussed below.

[140] Classen, Moore, Circuit Judge, at 1076
[141] *Endo Pharmaceuticals Inc v Mallinckrodt LLC.,* 919 F.3d 1347 (2015)
[142] *National Alternatives International Inc v Creative Compounds LLC., Appeal no. 2018-1295*
[143] *PerkinElmer Inc v Intema Ltd*, No 11-1577 (Fed. Cir. 2012)
[144] *Cleveland Clinic Foundation v True Health Diagnostics LLC*, No 18-1218 (Fed. Cir. 2019)
[145] *Roche Molecular Systems, Inc. v Cepheid*, No. 17-1690 (Fed. Cir. 2018)
[146] *Ariosa Diagnostics, Inc. v. Sequenom, Inc*., 788 F.3d 1371 (Fed. Cir. 2015)

The case of *National Alternatives International Inc* concerned a patent infringement claim with regard to a method for the increase of anaerobic performance and capacity in humans through the administration of an amino acid selected from a group of three. The defendant was of the opinion that the patent was ineligible owing to it being the simple recognition of a natural principle, since it known which amino acids improve anaerobic ability. At first instance this defence was accepted and the patents were invalidated, but on appeal in the Federal Circuit, this ruling was overturned. It was their view that rather than being natural phenomena on which the claimant was attempting to capitalize, the claims were "an application of the law and new use of that product…[T]he use of the supplement to achieve a given result is not directed to a law of nature."[147] It would be difficult, in the Court's view, to ban medical treatment that is based on natural principles without banning a great many other methods of treatment.

The case of *Endo Pharmaceuticals Inc* was an infringement case concerning a pain treatment method for patients with renal problems. The patent itself involved the release of oxycodone (a pain-relief medication) in a controlled fashion in line with the measurements of creatine clearance in the patient, after which another lower dose would be given, a situation that would continue until the medicine dropped below a certain administration rate. This meant that the dosage rate of the painkiller was correlated with the patient's rate of creatine clearance, such that excessive dosages would be avoided, and the amount of the medicine administered would be tailored to the individual patient. This is a kind of personalized medicine, which has given rise to and may yet give rise to many new methods of medical treatment, since finding ways to prevent illness and treat patients according to their specific physiology and e.g. molecular profiling and lifestyle information, has been increasing in recent years.[148] As in

[147] *National Alternatives International Inc*, p. 20

[148] See e.g. *Council conclusions on personalized medicine for patients,* by the Council of the European Union (2015/C 421/03)

National Alternatives International, Inc, the court at first instance upheld the view that the patent was based on a mere law of nature, thus ineligible for patenting. Once again, the Federal Circuit chose to overturn this decision, stating that the method used a natural law in its application, but the method as whole concerned the treatment of pain, not the claiming of a law of nature.

A decision taken in the case of *INO Therapeutics v Praxair Distribution*, however, seems to signify a change in course.[149] This ruling therein could perhaps have significant ramifications for patenting medical methods in the US, if this decision is followed in future cases.

In *INO,* the invention involved the treatment of new-borns with hypoxia using nitric oxide. A possibly fatal side effect of this treatment is pulmonary edema, and the invention in this case established that if a new-born's left ventricle was not functioning normally, the risk of edema was greatly increased when nitric oxide was used as a treatment. Thus, the inventors were seeking a patent for a method of diagnosis using echocardiography to determine the presence of left ventricular dysfunction in a new-born with hypoxia.

As with e.g. *Classen* (discussed above) and the other similar cases, the patent in this case concerned a diagnostic step, the result of which led to a medical intervention. However, unlike the ruling in *Classen*, the court in *INO* ruled that the treatment methods were already known and that the left ventricular dysfunction diagnosis did not contribute significantly more in terms of how we perceive natural law. It seemed the majority of the court interpreted the invention in *INO* as having one distinctive difference to the earlier cases of e.g. *Classen* and *Endo*, since the diagnostic step in *INO* only determined whether

[149] *INO Therapeutics LLC v. Praxair Distribution Inc*, No 18-1019 (Fed. Cir. 2019)

treatment should be given or not, while the earlier inventions led to a definite administration of medical treatment, with the diagnostic step merely informing the level or form of the treatment. The reasoning of the court regarding why this invention was ineligible, as with cases like *Mayo*, included the determination that nitric oxide as a treatment was not new in any way, thus, "the patented method does not propose a new way of treating LVD patients."[150] Although the patentee argued that the claim in its entirety was new, the majority dismissed this approach, and declared "the focus of the invention is screening for a particular adverse condition that, once identified, requires iNO treatment be withheld."[151]

This is a clear difference with cases like *Endo*, since in that case the diagnostic step/test helped determine the correct dosage for the given treatment, rather than no treatment at all, as is sometimes the case with the *INO* method. It seems clear from this that the court believes an actual treatment should take place, rather than the withholding of one, in order to qualify as a medical method of treatment. That is, treatment in e.g. Endo, will occur in any event, which is not the case with *INO*.

From this, we can interpret the court's decision as being based on two factors, firstly that if the new-born does not suffer from left ventricular dysfunction, then the treatment cannot be included, since that form of treatment (nitric oxide in new-borns) is already known and in use. Secondly, if the new-born does in fact have left ventricular dysfunction, then it is very difficult to view the non-administration of nitric oxide as a treatment, since the very premise is not to provide that treatment at all. The court pointed out that by not treating a patient, it amounts to the same result as allowing the body's natural processes to take place: "the claim simply requires that the patient *not* be treated with INO. This is significant because a claim not to treat…risks monopolizing the natural

[150] *INO Therapeutics LLC,* p 10
[151] *INO Therapeutics LLC,* p 10

processes themselves."[152] The method in question is thus a law of nature and an instruction on how to follow it, at least in terms of the effect of nitric oxide on new-born infants.

It should be noted that the court was not in unanimous agreement, with Judge Newman dissenting. The judge disagreed with the notion of the invention as an application of a law of nature, since "it was designed by and is administered by humans"[153], and also stated that how physiology reacts to a human/medical intervention is how all medical treatments are created. It is also true (as Judge Newman also pointed out) that dividing patent claims into smaller pieces and considering only some of those parts in a patent claim case has been strongly discouraged by the Supreme Court. It was the Judge's opinion that to declare the *INO* claim ineligible was not in keeping with the previous rulings of the Supreme Court and the CAFC.

The current status of medical treatment patents in the US

At the present time, a case of some significance to the discussion here is under consideration by the Supreme Court, regarding whether or not to rule on it. *Hikma Pharmaceuticals USA, Inc.*,[154] is another case that concerns treatment through diagnosis to provide personalized medicine (the concept was briefly outlined above in Endo Pharmaceuticals) and concerns a genetic test for patients with schizophrenia in order to establish the patient's tolerance for a medicine called iloperidone. This genetic test could determine how well the patient could metabolise the medicine, since a low metabolic ability would increase risks of cardiac issues and complications. If such a genetic risk was

[152] Ibid
[153] *INO Therapeutics LLC*, p 2
[154] *Hikma Pharmaceuticals, Inc., v Vanda Pharmaceuticals, Inc*., F.3d 1117 (2018) NB: This case is often also referred to as *Vanda*, but in the current paper it remains *Hikma*, for the sake of clarity.

present in the patient, the dose of iloperidone would be below 12mg, thus vastly reducing the possibility of negative side effects. If absent, the dosage is set between 12 and 24mg per day.

It was the view of the Federal Circuit that this method is patent eligible, and compared it to the ruling in *Mayo*, wherein a patent was denied since the court believed it only followed a law of nature and tried to optimize treatments according to those observations. In *Hikma*, however, the court held that the difference lay in the fact that the method contained the step of administering the medicine based upon the genetic knowledge with the intent of altering the patient's condition. *Hikma* (and West-Ward pharmaceuticals International Limited, a subsidiary of Hikma) sought to file a petition for a writ of certiorari (a judicial review) with the Supreme Court, asking the Court to invalidate the patent on the grounds that it is merely a diagnostic method based on a natural law, since "patentees may circumvent § 101 by merely adding a simple treatment step that follows from the diagnosis."[155] The petition was denied in January 2020, with the Supreme Court permitting the Federal Court decision to stand.[156]

Thus, at the present time, the status of medical diagnostic methods of treatment in the US is somewhat uncertain. The refusal by the Supreme Court to accept the petition for certiorari can be viewed as somewhat unfortunate, since it would have presented a useful opportunity to address the alleged inconsistencies in the rulings between *Mayo* and *Hikma*.[157] Had the Supreme Court agreed to address the decision, it is entirely possible that personalized medicine and diagnostic method patents would be in some danger of becoming patent ineligible. It is certainly true that the issue has quite persuasive arguments on

[155] *West-Ward inc., & Hikma Inc., Application for an extension of time to file*, (2018) p 3
[156] 'Petition Denied', Supreme Court of the United States, at https://www.supremecourt.gov/search.aspx?filename=/docket/docketfiles/html/public/18-817.html

[157] See for instance, Chief Judge Prost's dissenting view in the Federal Circuit decision in *Hikma.*

each side. For instance, if a method of medical treatment that does not contain any diagnostic step is patent eligible, why should it be so that the addition of such a step would render it ineligible? On the other hand, it could be argued that medical diagnostic methods are of little use with no actual treatment, thus the addition of a treatment step to a diagnostic method (a method banned from patent eligibility in *Mayo*) to foster an eligible patent claim is questionable. What does this indicate for the future of medial methods of treatment in the US? As mentioned above, the current state of affairs is that while such patents are permitted, the possibility to seek remedies for infringement is prohibited, meaning that such patents are for the most part unenforceable.[158] In light of this, it could be possible that the banning of medical diagnostic methods will be extended to other methods at some point, although the decision by the Supreme Court not to allow the *Hikma* petition suggests that for the time being the current position of the courts in holding that such methods are not merely natural laws or mental processes is likely to remain in place.

3.3 Australia:

In Australia, there is now no express law prohibiting the patenting of medical methods of treatment. This is especially interesting given Australia's place in the Commonwealth, since originally Australia was bound by the Statute of Monopolies of 1623 (Section IV of which is quoted below), and as such would have followed UK precedent in patent matters, even though the UK laws

[158] 35 U.S.C. § 287(c) in 1997. § 287(c) eliminates remedies against physicians for infringement of many medical procedure patent claims.

contained no express prohibition until considerably later (Patents Act 1977[159]). In the UK[160], it was a case from 1914 that truly created a precedent for medical methods' non-patentability. The judge ruled that the patent sought was merely for a method of treatment, and had no element of manufacture, and thus it followed in common law England and Wales that the absence of manufacture precluded a medical method of treatment from patentability (this case is discussed further below).[161] Australia, however, gradually proceeded to acknowledge the right to patentability through case law. Patents for medical methods of treatment became eligible for patents in 1972.

As with patent law in England prior to the Patents Act of 1977, there is no prohibition in Australian law with regard to the patenting of methods of medical treatment, with the issue thus being left to the courts' determination. That said, at first there was some opposition to these methods of medical treatment being granted patents by either the Patent Court or the Australian courts, yet that time was short-lived, with both courts now generally appearing to support the patenting of these kinds of methods. Interestingly, the original preclusion of medical methods had little or nothing to do with ethics.

Before 1972 the patentability of methods of medical treatment was viewed by Australian courts as being a matter of what constitutes an 'invention', rather than a moral issue. The issue was reimagined after 1971 in moral terms and it is likely that there were several reasons for this, such as the idea that it might be permitted to grant patents for treatments that could have an impact on patients' lives, and perhaps an growing interest in natural sciences and morality, which would naturally impact how patenting in such areas would be

[159] See Section 4A (1) "A patent shall not be granted for the invention of; (a) a method of treatment of the human or animal body by surgery or therapy, or (b) a method of diagnosis practiced on the human or animal body."
[160] The brief inclusion of the UK in the discussion here is beneficial in aiding the understanding of the wider impact on the other jurisdictions under consideration, in particular with regard to Australia, which is still a Commonwealth country.
[161] *C & W's Application for a Patent*:31 RPC 235 (1914)

perceived. On the other hand, whether or not methods of medical treatment could be viewed as patentable has perhaps always had a pivotal position from the perspective of ethics and public interest with regard to patenting, since the concept of an invention and its applicability to a clearly moral or ethical issue is always fraught with difficulties regarding the patentability of such supposed inventions.

Justine Pila speaks of inherent patentability and states: “Inherent patentability under Australian law depends on the existence of an inherently patentable subject matter or, as such subject matter has traditionally been denoted, on the existence of an ‘invention’ within the meaning of contemporary patents legislation.”[162] The Patents Act 1990 defines the term *invention* in Schedule 1, and the definition has not altered in any substantial fashion from the original patent legislation. Schedule 1 states that an invention: “means any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies, and includes an alleged invention”. If we look at Section 6 of the *Statute of Monopolies 1623* (Eng) (‘*Statute of Monopolies*’) it states the following:

> *“Provided also, and be it declared and enacted, that any declaration, before-mentioned, shall not extend to any letters patents (b) and grants of privilege for the term of fourteen years or under, hereafter to be made, of the sole working or making of any manner of new manufactures within this realm (c) to the true and first inventor (d) and inventors of such manufactures, which others at the time of making such letters patents and grants shall not use (e), so as also they be not contrary to the law nor mischievous to the state by raising prices of commodities at home, or hurt of trade, or generally inconvenient (f): the same fourteen years to be accounted from the date of the first letters patents or grant of such privilege hereafter to be made, but that the same shall be of such force as they should be if this act had never been made, and of none other (g).” [163]*

[162] Pila (2001), in University of New South Wales Law Journal

[163] For the purists and the curious, the original text reads:

“Provided alsoe That any Declaracion before mencioned shall not extend to any tres Patents and Graunt of Privilege for the tearme of fowerteene yeares or under, hereafter to be made of the sole working or makinge of any manner of new Manufactures within this Realme, to the true and first Inventor and

It can therefore be seen that an invention in Australian law can encompass anything, once it is not unlawful, or mischievous, or 'generally inconvenient'. This last phrase is quite interesting, since the law itself does not make further comment regarding what is generally inconvenient and what the possible tests could be in establishing an invention's general inconvenience.

As we saw in the development of patent law in the USA, the granting of patents for 'any manner of manufacture' began to be defined in case law, with exclusions appearing for claims that were enabling a natural process in some way, or the claims were too abstract. The case of *Re Cooper's Application*[164] was the first case to depart from the UK norm of "any practical manifestation of an idea regardless of physical form",[165] since in the original case Mr Cooper was denied a patent for a new manner of folding newspapers (leaving blank spaces along the fold line, so the text would not be affected), since, according to the Comptroller in that case: "A Patent may be properly refused in any case in which no material product of a substantial character is realised or effected by the alleged invention, or in which the only material product is a printed sheet, or its equivalent, and the only alleged invention in an arrangement of words, or the like, upon such sheet."[166] The patent was granted on appeal, since it was determined that the invention was sound, owing to it being "a particular way of manufacturing a newspaper, and the alleged utility of his supposed invention is purely mechanical",[167] but what is interesting is how the Attorney-General agreed with the first part of the Comptroller's argument by saying "The subject with reference to which you must apply for a Patent must be one which results

*Inventors of such Manufactures, which others at the tyme of makinge such tres Patents and Graunts shall not use, soe as alsoe they be not contrary to the Lawe nor mischievous to the State, by raisinge prices of Commodities at home, or hurt of Trade, or generallie inconvenient; the said fourteene yeares to be **[X1**accomplished**]** from the date of the first tres Patents or Grant of such priviledge hereafter to be made, but that the same shall be of such force as they should be if this Act had never byn made, and of none other."* Statute of Monopolies 1623, s 6

[164] *Re Cooper's Application* (1901) 19 RPC 53

[165] Pila, (2001) in University of New South Wales Law Journal

[166] *In the Matter of Cooper's Application for a Patent*, Before the Attorney-General (1901), p 54

[167] Ibid.

in a material product of some substantial character."[168] This stipulation clearly departs from the UK concept of any combination of ideas that were new and useful, by instead stating the need for a material device or object.

Methods of Medical Treatment in Australia

It was in 1914 that the first case of a medical method being rejected for a patent came to light in Australia. *C & W's Application*[169]for patent involved a process wherein lead could be removed from the body. It was decided that this invention was lacking in commerciality as a product and so could not be an invention under patent legislation. The Solicitor General relied on s 6 of the Statue of Monopolies in determining his judgment, particularly the 'manner of new manufacture' using the exclusions therein ("'contrary to the law, or mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient') – and declared an invention to be "a machine or a process that can be used in making something that is, or may be, of commercial value".[170] It was also considered whether or not a human or animal body could be something improvable by a method such as the one in the case, but it was the Solicitor-General's determination that this had no relevance to manufacture

[168] Ibid.
[169] *C & W's Application* 31 RPC 235 (1914)
[170] Ibid

or trade. As a result, methods of medical treatment would be excluded from patentability as a general rule, which the Solicitor-General found acceptable.

In terms of legal justification, the decision in *C & W's Application* is an intriguing one. Declaring that the method had no relevance to trade seems unlikely, since, regardless of whether the method was medical one or not, such a method (if patented) could be licensed and subject to royalties, especially given that lead poisoning at the time was still quite common. As justifications go, this one seems unconvincing, since decided that such a method would have no commercial applicability is more than likely untrue. If this reasoning was thus used as means to exclude medial methods of treatment, the justification for this decision remains cloudy, since it is not at all clear how these methods are not relevant to manufacture or trade. When reading through the judgment, it is perhaps possible to infer that the Solicitor-General might have been uncomfortable with the idea of the commercialization of the human body, or perhaps also that the seeking of patents by doctors would somehow be contrary to the morality of their profession. That said, the Solicitor-General stated that morality was not a factor in considering the judgement by saying:

"*It has been urged, and I think quite rightly, that the question of humanity ought not to affect the decision in such a case as this ... Of course, it is well known that the medical profession do all in their power to discourage members of their body from obtaining protection for any discovery that has for its object the alleviation of human suffering, and it is impossible to speak too highly of such conduct, but it cannot affect my judgment in arriving at a conclusion upon the terms of the Section of the Act of Parliament, and I have altogether excluded such consideration from my mind."*[171]

[171] *C & W's Application* (1914) 31 RPC 235, p. 236

While this is a ringing statement denying any moral element in his decision-making, the fact remains that the justifications given for the exclusion are not entirely plausible in persuading a reader to accept his point of view. The fact remains that the Solicitor-General would have been aware of the provision in the UK Patents and Designs Act of 1907, which permitted the judiciary to 'refuse to grant a patent for an invention ... of which the use would, in his opinion, be contrary to law or morality'.[172] It is also true that the inclusion of a claim as being generally inconvenient in patent law as grounds for ineligibility would theoretically be a very broad brush for the courts to use in excluding an invention from patentability owing to it being contrary to a public policy.

As a result, the decision in *C & W's Application* can be considered a rather disappointing one, since it failed to address in any open way the public order issues at hand, such as that of morality in allowing doctors to have monopolies over their methods. This means that the idea that medical methods of treatment lacking a commercial product requirement was the overarching result of the case. The lack of inclusion of a discussion surrounding public policy concerns, as well as the failure to declare that there is no commercially justifiable reason to exclude medical methods from patentability left a lasting mark on patent law in Australia, with the effects being evident in subsequent cases of a similar nature.

The case of *Joos v The Commissioner of Patents* (1972) was another landmark case in the Australian courts regarding patenting medical methods of treatment. It involved a cosmetic treatment to improve the strength and elasticity of hair in an effort to prevent hair thinning and baldness. It was ruled that cosmetic methods of treatment were inherently patentable because they would have commercial viability and significance.[173] This certainly – at least on the surface – appears to be an opener into permitting patents for medical treatments, and

[172] Patents and Designs Act 1907 (UK) 7 Edw 7, c29 s 75
[173] *Joos v The Commissioner of Patents* (1972) HCA 38 & (1972) 126 CLR 611

the judge went onto define methods as being: “for medical treatment of human disease, malfunction, disability or incapacity of the human body or any other part of it“ and that their exclusions from patentability could only be justifiable on “public policy as being, in the language of the Statute of Monopolies, “generally inconvenient”.”[174] We can determine from this, unlike the decision in *C & W’s Application*, that medical methods are indeed inventions in line with the Statue, and would thus be patentable, save any public policy exclusions. This ruling undermined the decision in *C & W*, since it dismissed the notion that medical methods of treatment were not economic in nature. It also paved the way for providing a more genuine justification for the possible exclusion of medical methods from patent eligibility than was shown in *C & W’s Application*.

In 1994, the case of *Anaesthetic Supplies Pty Ltd v Rescare Ltd (Rescare)*[175] was brought before the Federal Court and the method concerned sleep apnoea (a snoring sickness with potentially serious side effects) and its treatment, in which there was both a device and a treatment. In this case at first instance,[176] it was ruled that such a method was not ‘generally inconvenient’ and that the method would be patent eligible. It was also the view of the judge (Gummow J) that it would be illogical to conclude that products for human treatment would be eligible for patents, but methods for treatment would not be.

The decision was appealed, and in the Full Court it was agreed (not unanimously) that Gummow J’s ruling had been correct in determining that under Australian patent law, medical methods of treatment were patent eligible.[177] Lockhart J and Wilcox J were in agreement for the most part that Australian law contained no provision that excluded medical treatment processes from patentability. Lockhart J also mentioned the Patent Act of 1990

[174] Ibid, p 622.
[175] *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1
[176] *Rescare Ltd V Anaesthetic Supplies P/L* (1992) FCA 811; 111 ALR 205; 25 IPR 119
[177] *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1

and made the observation that if it had been the desire of Parliament to deny patent eligibility to medical methods of treatment, the express provision would have been included there. Instead, section 18(2) states: ‘‘Human beings and biological processes for their generation, are not patentable inventions’’, with no mention of processes or methods. The third judge was in strong disagreement with the majority, claiming the ‘generally inconvenient’ provision from Section 6 of the Statue of Monopolies should be applicable here on grounds of incompatibility with public policy.

Subsequent to *Rescare*, granting of patents for methods of medical treatment were granted with more frequency. It wasn’t until the case of *Bristol Myers Squibb Co v F H Faulding & Co Ltd* in the mid ‘90s that the issue rose to light once more.[178] This case concerned two method patents for the administration of a cancer treatment drug known as Taxol. At first instance in the Federal Court the judge (Heerey J) concluded that the decision in Rescare was not binding as a *ratio decidendi*, but instead was merely an *obiter* statement (i.e. not a binding precedent in common law rules), and thus dismissed both patents as invalid on the grounds of their being generally inconvenient from the perspective of public policy.

This decision, however, was appealed, with the Full Court overturning Heerey J’s ruling in order to comply with the majority ruling in *Rescare*, with Lehane J stating on the issue of: “the insurmountable problem, from a public policy viewpoint, of drawing a logical distinction which would justify allowing patentability for a *product* for treating the human body, but deny patentability for a *method* of treatment.”[179] In terms of medical patents as whole, this line of reasoning would appear to be the most salient, since if medical methods are denied patent eligibility on grounds of morality or some other public policy, it

[178] *Bristol Myers Squibb Co v F H Faulding Co Ltd* (1998) FCA 860; 41 IPR 467
[179] *Bristol-Myers Squibb Co v FH Faulding & Co Ltd* (2000) 170 ALR 439, p 444

stands to reason that patenting drugs or medical devices would also be contrary to the *ordre public*.

Solidifying the patentability of medical methods in the Australian High Court

More recently, the case of *Apotex*[180] in 2013 seems to have given more certainty to the status of medical treatment methods in terms of their patentability. The case concerned a method of treatment by therapy, in which a method of administering a previously known medicine for the treatment for psoriasis as a subsequent use was patent eligible. Thus the 'manner of manufacture' decision in *NRDC* (see page 17 above), which is the only possible invalid ground brought by Apotex against Sanofi that was accepted as grounds for a case by the High Court was reinforced in this case. French CJ stated as follows: "The exclusion from patentability of methods of medical treatment represents an anomaly for which no clear and consistent foundation has been anunciated… [M]ethods of medical treatment…cannot today be conceived as "essentially non-economic.""[181]

With that said, the court raised the issue (but did not make a direct ruling) on the difference between such medical methods, i.e. one such as the case at hand, which involves the therapeutic use of an already-known medicine, and other methods e.g. physical methods of treatment used by healthcare professionals when treating patients. According to Kiefel and Crennan JJ: "To the extent that such activities or procedures involve 'a method or process', they

[180] *Apotex Pty Ltd v. Sanofi Aventis Australia Pty Ltd [2013] HCA 50*
[181] *Apotex,* at 50

are unlikely to be able to satisfy the NRDC Case test…they are not capable of being practically applied in commerce or industry."[182]

4 Reflections the reasons against patenting medical methods of treatment

4.1. Conflict of interest

A 'conflict of interest' is an oft-raised concern when it comes to patenting medical methods of treatment. The issue appears to stem primarily from the belief that if, for instance, a doctor should obtain a licence (for a fee) to perform a particular method to aid in his or her treatment of a patient, the inclination would be to favour that method to the possible exclusion of other methods. This reasoning supposes that the doctor's moral, ethical and/or professional judgement would be clouded by the cost of obtaining the licence, and he or she would thus feel (perhaps unwittingly) compelled to use that purchased method of treatment in order to obtain a return on the cost of the license. This is to say, the financial recompense in using the patented method could potentially interfere with the practitioner's ability to recommend the most suitable and effective treatment for the patient in his or her care. This issue could also be argued to the contrary, i.e. that a doctor might choose to decline the recommendation of the most suitable method of treatment so as to avoid paying for a licence to use it.[183] In fact, according to the TBA, the reasoning behind Article 52(4) in EPC 1973 was "to prevent any obstacle to the freedom to

[182] *Apotex*, at 286-7
[183] Meier, 2015, p 267.

choose the best medical treatment to be applied to a patient and to avoid any delay in the application of such medical treatment" and furthermore that '[s]uch obstacles or delays could arise if a medical treatment were the subject of an exclusive patent right'.

That said, it goes against a doctor's code of ethics not to act in the best interests of the patient, and a doctor's failure to inform said patient of all the treatments methods available to him or her would certainly be contrary to those ethics. Not only that, but the laws regarding medical malpractice would surely also serve to deter a physician from neglecting to inform a patient about a suitable medical method of treatment, or indeed by choosing to perform a method without sufficient reason.[184]

As we saw in the case of *Pallin*, a worthwhile suggestion might be to pay royalties, since it would eliminate any pressure on doctors to pay large license fees in advance, which would presumably go some way towards guaranteeing that the doctor provides his or her patients with the most suitable methods available. This would remove any pressure on doctors to recoup losses arising from the purchase of a license. Of course, Dr Pallin failed in his patent claim case, but that was more so on the grounds of absence of novelty, since the method was already in use elsewhere before he attempted to patent it (see section 3.2. above for a discussion of this case).

[184] See, for instance, the case of *Moore v Regents of University of California,* which concerned a patient's right to know the reasoning behind a doctor's decisions.

4.2 Restriction of Information

Owing to the lengthy patent system, the resulting patented method may take several years before it becomes available, meaning that the specifics regarding the invention's details will inevitably face some delay. Of course, it is a well-established fact in the medical world that information is disseminated through the publication, thus the fear is that if new methods are begin patented, it will affect this dissemination severely. Of course, because of this publication tradition, any prospective inventor must be careful not to publish details of the potentially patentable invention before filing for a patent, since such disclosure might serve to render the 'novelty' aspect of the invention invalid.

In respect of this, some in the medical community are of the opinion that patenting medical discoveries hinders information dissemination to the community at large.[185] However, the publication of a new medical process can take place with immediate effect, without hindering the patent process, provided the filing takes place within the allotted time limit. It is also possible to argue that investors might attempt to claim intellectual property rights over procedures developed and shared by others, an argument that also goes against the fundamental purpose of patenting. The argument overlooks the other requirements of novelty and the inventive step, not to mention the chance to challenge any claims with regard to patents. The patent system has been developed over the years to prevent situations like this one.

As mentioned above, it is already widely understood that the dissemination of ideas is vital for the progression of the medicine and the medical world in general. That said – the above concerns notwithstanding – by adopting the stance that patents would hurt the world of medical methods, one is ignoring the fact that the very fundamental purpose of patents is to improve the

[185] Wang (1995) at 40-42

dissemination of information, in accordance with the storehouse theory. It must also be remembered that when filing a for a patent, the invention must be fully and thoroughly described, which is not a requirement for a journal article. Furthermore, it is useful to keep in mind that there may also be delays with article and journal publications. “Patent Convention Treaty applications are required to be published 18 months after filing, and in some countries inventors are required to publish immediately after filing (EPC article 54(2)).”[186]

Moreover, if patents are not permitted or available, an inventor (e.g. a doctor) may choose to keep a method secret, a method that is far more damaging to the sharing of information than patenting.

4.3 Fear of infringement

A genuine concern raised by those who oppose the patenting of medical methods it the fear of infringing on another’s intellectual property in the course of their duties. There are, however, many different obstacles that lie before a doctor performing his or her duties. There are many deciding factors before a medical practitioner when faced with a patient, such as malpractice concerns, insurance and consent, long before the fact of patent considerations come to the fore.

There is also the existence of the doctrine of necessity, a doctrine that serves to protect doctors in an emergency should they use a patented method. This arguments against patenting medical methods of treatment because a medical professional will hesitate in an emergency situation do not hold much water, since patenting emergency procedures would seem decidedly unlikely, owing

[186] Mitnovetski et al (2004)

to the aforementioned doctrine of necessity which would render that claim null and void. As an aside, it is also true that such fear of infringement cannot necessarily exist in the US, for instance, since it is not possible to sue another physician for the use of your patent.[187]

4.4 Rising costs in healthcare

In many jurisdictions, the price of healthcare is already significant, and one concern is that medical method patents will force these prices to rise even higher. In light of the costs of drugs and medical devices however, this argument seems somewhat spurious, given the protection afforded to such products. It fails to address the central question: why can products and devices remain eligible for patenting, while methods cannot? It is also possible that such an investment in treatment would eventually reduce the overall cost of the healthcare costs, because of more efficacious treatment at an earlier stage in the treatment lifecycle. Wendy Yang, for instance, makes the argument: "[F]or procedures that would have been developed even if a patent were not available, society pays a price for a benefit it would have received without the grant of the patent monopoly."[188] This reasoning can give rise to some scepticism, since it seems to dispense with the idea of patents encouraging the incentive-to-innovate, but only when considering medical methods.

Those in support of medical procedure patents, on the other hand, claim that royalties can be merited where a significant amount of the funding for development has come from private parties, who have funded the research and development on the expectation or at least the possibility of profiting from any licence arising from the technology. Of course, it remains the case that much

[187] 35 U.S.C § 278(C)
[188] Yang(?), at 19.

of this funding is for the development of medicines and devices and not towards methods, thus any increase in cost would be decidedly small in comparison. The medical world is certainly quite a litigious one, but excluding methods of treatment from patentability on the grounds of possible cost increases would not seem to be the most convincing argument.

Part III

5. Further thoughts and conclusions

5.1 The future of medical methods of treatment patentability

This paper has examined the exclusion of medical methods and treatments from patent protection in the member states of the EPC, the inclusion thereof in the USA and Australia, along with some questions and insights into medical advancement such as AI and some of its possible repercussions for this patent law. While the law will always be somewhat lagging in terms of legislating for scientific progress, at present it appears as though the status quo is likely to remain i.e. that such creations, regardless of their level of innovation or inventiveness, will remain unpatentable, particularly if the method or treatment is risky or invasive. It will be interesting to observe the effect in law if (or perhaps rather when) the number of medical methods/treatments that employ AI (at least as part of the process) increases, whether the number of inventors seeking patents will rise accordingly, and what the reactions of the judiciary will be and whether or not their views on the present legislation might change. After all, if a medical method or treatment uses AI in some form, could it not be argued that it might be far less likely that e.g. other medical practitioners are using the same processes? Thus, its widespread use in the community might not be relevant at the time of invention, greatly reducing the fear of patent infringement as grounds for patent refusal.

Furthermore, another outcome to consider is that it is certainly possible that over time the advancement of AI in these areas of surgery, therapy and diagnostics will become so sophisticated that the risks associated with certain methods may reduce significantly, which may in turn lead to a redefinition of what is eligible for patent protection. The curious nature of the development of

the reasons for this provision also cannot be disregarded, and if the fundamental reason for the exclusion is indeed to protect patients, it is to be presumed that the law will update accordingly when such protection would no longer be required. Thus the current reasons for the exclusions themselves may yet become firstly a medical and thereafter a legal fiction.

5.2 AI and its (un)patentability in medical treatments and methods

Having discussed the nature of patent exclusions for medical methods and treatments, what implications (if any) will AI technology have for this area of patent law? One question surrounding the use of AI generally has concerned the nature of intellectual property law when the creator of the product warranting protection is not human. If we narrow the focus to areas of law discussed above, some questions that seem pertinent include: if the methods and treatments are excluded on the aforementioned grounds of public health, will it matter if the method is performed by an AI? If we are to deduce from this public policy argument that the crux of the issue lies in the fact that the method is performed on a human or animal, it may still prove very difficult to obtain such a patent. Linked to this notion is the statement in the EPO Guidelines that the exclusions do not depend on the person carrying out the method[189], so for instance if the executor of the process in not a person, does the law remain the same?

In light of this, it is useful to examine whether or not any such patents that concern artificial intelligence and medical methods or treatments might exist. One interesting patent award concerned a device for eye surgery. While we already know that devices are not excluded from patentability under art 53(c), the EPO expressly pointed out the difficulties with such patents, especially if they prove difficult to separate from the method: “For some inventions in medical technology, however, it is not easy to determine whether they encompass a medical method in the first place and it may also not be possible

[189] EPO, Guidelines for Examination, 4.2.1 Limitations of exception under Art. 53(c)

to draft a patent application on a device without having to relate to the method as such"[190], and imaging methods for surgeries were cited as a good example of this. So, while it might appear unfair that an eye device for eye surgery can receive a patent but imaging methods during surgeries cannot, the fundamental reasoning behind it must be borne in mind, namely keeping medical practitioners free of restraint in the course of their profession. The crux of the issue regarding this distinction between devices and methods perhaps can be attributed to the fact that a device is presumably far less likely to be invented by many different creators coincidentally, thus such an invention by one individual or company is unlikely to put other individuals at risk of infringement if that device is patented, a situation believed not to be true of medical methods and treatments.

Given this reasoning from the EPO that medical methods and treatments are generally not patentable on public health grounds, and the difficult and costly efforts involved in bringing methods into use, it is certain that those creating these inventions (or supervising an AI in creating them) will seek the assistance of the law in helping to protect their products or processes from unjust duplication or dissemination. But what if the law does not go far enough? Who knows how many invaluable medical methods are currently protected as confidential, i.e. trade secrets? This is understandable from the view of one who does not wish to disclose their creation for fear of not obtaining a patent and wants to maintain a competitive edge, but such a practice is hardly in line with the interests of public health policy. In the words of W Nicholson Price II: "While secrecy may be an effective intellectual property strategy, it runs headlong into the concerns raised…about safety, malpractice and regulation".[191] In the abovementioned summary of the EPO Patenting Artificial Intelligence Conference, this concern is addressed: "From the perspective of innovation for the benefit of society, there should be as much incentive as possible for

[190] EPO, 2013: Patents for a medical apparatus or for medical methods?
[191] Price, W (2017), p 12

innovators to disclose AI innovations – such as the algorithms and how they were trained – and not to choose the option of trade secrets."[192]

5.3 Final conclusions

This paper has investigated the patentability of medical methods of treatment in three jurisdictions: the countries signatory to the EPC, the USA, and Australia, in an effort to compare their varying approaches to the subject of the patentability of methods of medical treatment. The aim of the discussion was to highlight and compare the differences in approach to the issue that have been taken by the legislature in each location.

As outlined above, personalized medicine involves tailoring medical treatment to each patient on an individual level. The idea is to use the breakthroughs in scientific understanding to study an individual's genetic and molecular idiosyncrasies in order to better comprehend and identity the possible illnesses to which they may be genetically predisposed. Through this, it can gradually become easier to decipher which medicines will be best suited to each patient, and which medicines may be dangerous. This closing section will discuss the possible ramifications of patentability or its exclusion from patentability on this type of healthcare.

As discussed earlier regarding the current position of patentability in the USA, the *INO* case decision gives rise to many questions that presently remain unanswered regarding the future of medicine patents in terms of personalised medicine. Prior to *INO*, the earlier *Vanda* decision was a welcome clarification in the aftermath of the *Mayo* decision in terms of when it came to patenting medical methods. It brought a new and welcome certainty level to the subject matter eligibility questions since the *Mayo* case. In fact, UPSTO guidance in

[192] EPO, (2018) Patenting Artificial Intelligence Conference Summary, p 3

the wake of *Vanda* declare that “it is not necessary for method of treatment claims that practically apply natural relationships to include nonroutine or unconventional steps to be considered patent eligible under 35 U.S.C. § 101.”

As we saw in *Mayo*, patents that depend on interrelationships with laws of nature to create diagnostic tests were denied, since the Supreme Court held that these interrelationships were merely based on natural principles. This decision created much doubt regarding the patentability of a significant range of therapies and methods. “These include proteins, kinases, colony-stimulating factors (such as growth factors), peptides, antibodies, viruses, and venoms. It also means that advances in personalized medicine, which hold significant promise for curing an array of diseases, may no longer be patent-eligible.”[193] The decision of the Supreme Court not to consider the case of Hikma further, however, means that for the time being, such methods can be awarded patent status, while of course “because medical procedure patents constitute statutory subject matter, the legislation resorted to prohibiting patent owners from enforcing their right to collect damages for infringement.”[194] This decidedly strange ‘halfway house’ approach to the issue will hopefully be revisited by Congress in the near future, since the nullification of the right to recoup infringement damages undermines the very purpose of the patent system.

In Australia, after a chequered case law history, the issue of whether medical methods of treatment can be patentable was settled in the case of Apotex, although the question remains uncertain regarding methods that do not involve the subsequent use of medicines, but rather methods physically practised by healthcare professionals on their patients. In any case, IP Australia have stated that objections cannot be made to “methods of processes for the treatment, medical or otherwise, of the human body or part of it, only on the basis that the

[193] Dreyfuss et al (2018), Introduction
[194] Anderson (1999) p 121

human body is involved."[195] Moreover, the Australian Law Reform Commission does not hold the view that medical treatments methods involving genetic technology and material should be excluded, on that grounds that such an exclusion would hamper investment in "biotechnology, medical research and innovation in healthcare."[196] This is a statement that could be applied to many treatment methods outside of those concerning genetic technology, which seems to be the aim of the Australian legislature, at least for the present.

As for the EPC, it is the only jurisdiction of the three to have expressly excluded methods of medical treatment from patentability, an exclusion it shares with countries such as New Zealand and Canada. The discussion stemmed from the fact that the exact reasoning for this exclusion remained unclear, beginning with these methods being insusceptible of industrial application which was admitted as being a legal fiction. The case of *MEDI-PHYSICS* gave the EBA the opportunity to state what they believed to be the genuine intent behind the exclusion: "[T]he principle has been confirmed that medical and veterinary practitioners' freedom to use the best available treatments to the benefit of their patients uninhibited by any worry that some treatment might be covered by a patent is protected by excluding these activities from patentability."[197] While this is a relevant concern, it does little to alleviate the issue of incentive to innovate, which is perhaps hampered in the countries signatory to the EPC. In the interests of public health, the encouragement of research and development, as well as the controlled formulation and dissemination of new information, it would seem more fruitful for the EPC to allow methods of medical treatment the possibility of patentability on a case-by-case basis, rather than their express exclusion, whether that exclusion remains based on a 'legal fiction' or otherwise. As it stands, the words of Black CJ and Lehane J[198] in *Bristol-Myers Squibb* (quoted at the outset of this discussion) still ring true, since the sometimes contradictory actions of the legislature in their efforts to address this

[195] IP Australia (2002) (8.2.13.3)
[196] ALRC (2010), *Methods of medical treatment*, 7.41
[197] G 0001/07 (MEDI-PHYSICS) of 15.2.2010, at 3.2.3.2
[198] *Bristol-Myers Squibb Co* (2000)

issue mean that the logical distinction between permitting a patent for a product of treatment, but not for a method of treatment remains unclear.

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