Artificial Intelligence – How patent law in the U.S. and internationally will deal with the next frontier in medical technology

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I. Introduction
Artificial Intelligence (“AI”) is not just science fiction it is really happening and the most exciting opportunities for this technology are in medicine and medical technology. AI is already being used in many areas of medicine including in radiology where imaging platforms augmented with AI are able to identify accurately and repeatably the presence of structural abnormalities, tumours and other pathologies in tissue. AI is being used to assimilate massive amounts of medical research to provide an expert system tools to suggest to doctors possible treatments for their patients. AI is also being used to mine patient records to identify not only better treatments for patients but also to improve the standard and quality of healthcare delivery and to optimise the utilisation of scarce healthcare resources.

AI involves, at its core, computer implemented algorithms. As such, medical inventions incorporating AI will likely be developed by multidisciplinary teams of computer scientists and mathematicians who understand the AI and biotechnologists, physicians and pharmacists who understand human biology, medicine and pharmacology. The ability of researchers to capitalise on this work will depend on the extent to which patent systems around the world accommodate and afford monopoly protection for these technologies. Also, the extent to which these monopolies might be compromised by exemptions to patent infringement will have an impact on the returns available to investors in these areas of research.

This paper discusses the development of AI technologies and the recent explosion in start-ups and large technology companies taking an interest in developing AI technologies for medicine and considers how inventions resulting from this work will be treated by patent subject matter eligibility law in the U.S. and Internationally and the extent to which patent monopolies granted to such inventions might be constrained by research use exemptions.

As will become apparent from the foregoing, some jurisdictions such as the United States, Europe and Australia offer a very uncertain patent eligibility framework for inventions incorporating AI that might act as a disincentive to invest in research. As for jurisdictions such as China and Japan, a more liberal approach to patent subject matter eligibility provides greater certainty of patent protection for medical technologies including AI. Thankfully, some recent decisions of the courts in the United States seem to have reversed a trend towards patent ineligibility of most software related inventions by providing greater emphasis on the substance rather than the form in which an invention is claimed in a patent. Hopefully these recent authorities are consolidated by being followed in further decisions and that other less permissive jurisdictions take a similar approach of recognising the inherent technical character of software inventions such as AI inventions in various fields including in medicine.

II. What is Artificial Intelligence?
The term "artificial intelligence" encompasses a wide range of technologies enabling a machine to mimic “cognitive” functions that we normally associate with the human brain including "learning" and "problem solving".

Older AI technologies are typically logic or rule based systems that enable a machine to solve problems in a way that appears to exhibit some form of intelligence. Traditionally these systems, sometimes referred to as “expert systems”, comprise a knowledge base or library of information provided by experts and an inference engine and user interface. A user can input a query into the interface and the inference engine
consults the library and reports back with an answer. Such systems employ relatively models such as If-Then rules based models. These systems are heavily rule/logic based and work particularly well in areas that are also rule based such as engineering, mathematics and law.

However, AI includes a whole set of mathematical and statistical tools that have been developed to solve different problems in computer science. These include search and optimization methods such as genetic algorithms, which attempt to mimic the evolutionary process by which biological systems self-organize and adapt, fuzzy logic, which attempts to mimic the ability of the human brain to draw conclusions and generate responses based on incomplete or imprecise information, probabilistic methods such as Bayesian networks, classifiers and statistical learning methods such as neural networks which attempt to mimic the processing function of the human brain, k-nearest neighbour and decision trees to name but a few.

Since the 2000’s, artificial intelligence in medicine has mainly employed tools that are data driven rather than rule driven. Statistical modelling, data mining, machine learning and neural networks have taken on a greater significance in statistical domains such as medical diagnosis/prognosis and therapy selection. In very recent times, applications for data driven tools (i.e. data mining) have been identified and exploited in pharmaceutical development, imaging and diagnostics. \(^1\)

In very recent times, there has been keen interest in the field of machine learning and deep learning in particular. Deep learning is a class of machine learning algorithms that have a number of characteristics, namely:

- they use a cascade of many layers of non-linear processing units for feature extraction and transformation where each successive layers uses the output of a previous layer as the input;
- they are based on the unsupervised learning of multiple levels of features or representations of the data where higher level features are derived from lower level features to form a hierarchical representation.

One of the benefits of deep learning is the opportunities they create for unsupervised learning and hierarchical feature extraction with minimal intervention or supervision by a human.

**III. Recent Developments in AI in Medicine, Diagnostics and Bioinformatics**

In 2015, IBM launched Watson Health, a company whose objective is to partner with medical researchers to develop new technologies in health care. Partnerships have been established with the US Memorial Sloan-Kettering Cancer Center to improve access to current cancer data and the MD Anderson Center to develop its Oncology Expert Advisor.\(^2\) IBM has established collaborations with many other cancer research institutes to find new ways to treat disease using other information such as genomic data. Watson Health has partnered with Medtronic in the area of diabetes management and with Johnson & Johnson in the area of new drug development.

Google recently launched its new division DeepMind Health which has a similar model of partnering with medical researchers and healthcare providers. In particular, Google has partnered with the UK’s National Health Service (NHS) to integrate digital innovations, specifically with Moorfields Eye Hospital NHS Foundation Trust, to improve care for diabetic retinopathy and age-related macular degeneration (AMD). Its machine learning capabilities aim to speed the analysis of scans, which can take professional clinicians

\(^1\)AI Med – Artificial Intelligence in Medicine – Medical Intelligence and Innovation Institute – Opening Session – History of Artificial Intelligence in Medicine - 13 December 2016

\(^2\)Here’s how IBM Watson Health is Transforming the Health Care Industry – The Washington Post - 5 April 2016 Laura Lorenzetti
a long time. In addition, Google aims to gain access to and “mine” the medical records of about 1.6 million patients through this partnership which has caused some controversy. 3

There are also many examples of smaller artificial intelligence companies developing health care technologies in the fields of personalised health and personalised medicine, medical imaging and diagnostics where neural network algorithms that have been developed for image recognition applications outside of medicine and have been applied to medical imaging with the potential advantages of greater accuracy and faster analysis/diagnosis.

There have been great advances in the use of artificial intelligence in the field of medical imaging and diagnostics. Many of these technologies employ deep learning models, which are advanced training or learning models in which many thousands of medical images are analysed to develop a library of data to enable the model to identify relevant information from medical images e.g. tumours, cancerous cells, vascular structures, blood flow and other anatomical structures.

Enlitic is a small Silicon Valley based startup that uses deep learning to analyse radiographs as well as other imaging data such as CT and MRI. More recently Enlitic has released a medical natural language processing tool that can be used to comprehend medical texts and images to allow for the mining of historical pharmaceutical data for research, healthcare workflow optimization, drug discovery assistance, clinical study optimizations, and medical coding efficiencies.4 Enlitic claims their algorithms have outperformed radiologists in identifying benign or malignant lung cancer cells although the technology has not yet obtained FDA approval5

Numerous other companies are using deep learning platforms to analyse big data for drug discovery. For example, TwoXAR uses their DUMA Drug Discovery platform to evaluate large public and proprietary datasets to identify and rank high probability drug-disease matches. Atomwise uses their AtomNet deep learning technology to analyse thousands of molecules that might serve as drug candidates and predict their suitability for blocking the mechanism of a pathogen.

It is expected that AI will have a big impact on genetics, genomics, bioinformatics (i.e. the technologies for analysing and interpreting data including genetic information) and personalised medicine. The field development of personalised medicine is another area in which AI is having a big impact. There is great potential for AI algorithms to solve problems in personalised medicine such as accurate disease detection or prediction as well as the optimisation of treatment for individual patients based on information such as genotype (genetics) and phenotype (physical characteristics).

Canadian Start-up DeepGenomics is using deep learning technology to mine large data sets of genetic information and medical records to identify linkages between genetic mutations and disease. Deep Genomics is building an integrated computational system, the DG Engine, which can learn, predict and interpret how genetic variation, whether natural or therapeutic, alters crucial cellular processes in the context of disease.

Applications of robotics in surgical procedures are currently limited to human controlled devices such as the da Vinci system for laparoscopic surgery (i.e. prostatectomies and gynecologic procedures) which facilitates complex surgery using a minimally invasive approach. It is expected that there will be significant advancements in robotic surgical systems through the incorporation of advanced imaging and visualisation technologies and artificial intelligence.

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4 Enlitic Announces Deep Learning NLP Capabilities; Will Attend HIMSS 2017 To Meet with Partners and Stakeholders – PR Newswire – 13 February 2017
Surgeons and engineers at Children’s National Medical Center and Johns Hopkins have been working on a system called STAR (Smart Tissue Autonomous Robot). In 2016 this team was able to demonstrate a robot capable of semi-autonomous surgical procedures on soft tissue. What makes STAR unique is its ability to see soft tissue in real time and in 3-D to make adjustments during the surgical procedure.6

Verb Surgical, a joint venture between Alphabet and Johnson & Johnson, is working on an AI equipped surgical robot that they claim will be a major advancement over existing surgical robots such as the da Vinci system. Verb announced on 26 January 2017 that they have demonstrated their first digital surgery platform including all elements of the company's five technology pillars – robotics, visualization, advanced instrumentation, data analytics, and connectivity7. At this stage, there is no publicly available information about the prototype, however, the CEO of Verb, Scott Huennekens has stated that their work intends to provide an accessible Intuitive digital surgery solution incorporating robotics and advanced visualisation. Verb represents a commitment by Google and Johnson & Johnson to the development of robotic surgical tools that include advances in the combination of robotics and various artificial intelligence technologies, such as machine learning, to improve the outcomes of medical procedures.8

IV. How does Patent Law in the U.S. and Internationally Currently Deal with Artificial Intelligence Inventions?

AI involves, at its core, computer implemented algorithms so patents for inventions incorporating AI will likely have, as a relevant consideration, patent eligibility under 35 U.S.C. §101 and equivalent laws in other jurisdictions. Some of the applications of AI in medicine relate to diagnostic methods and the development of therapies that arise from discoveries about human physiology and pharmaceutical interactions. As such, the patentability of diagnostic methods, methods of medical treatment and natural phenomena or laws of nature can also be relevant.

In addition, research or experimental use exemptions to patent infringement, that are available in various forms around the world, will be a relevant consideration for the owners of patents for AI technologies and for commercial and academic researchers.

Some jurisdictions, notably the United States, Europe and Australia, have adopted patent eligibility positions that are uncertain or, at best complicated. The laws that apply in these jurisdictions have tended to focus on the form in which the invention is claimed in a patent rather than the substance of the invention. Recent decisions by U.S. courts seem to have reversed this trend through a focus on the substance of inventions. This recent trend could perhaps signal a recognition of the judiciary of the inherent technical character of software inventions, particularly in fields of technical endeavour.

V. Patent eligibility of abstract ideas and software in the U.S.

The decisions in Mayo, Myriad and Alice9 together enunciate the two step test for patent eligibility of an invention, namely: i) is the invention directed to a patent-ineligible concept, such as a law of nature, a natural phenomenon or an abstract idea; and if the answer to i) is yes, ii) do the claims define ‘something significantly more’ than the judicial exception.

Since Alice, any patent involving computer implementation of an abstract idea, such as an algorithm, would be at risk of a finding of patent ineligibility. Early post Alice decisions tended to have little difficulty in finding that algorithm patents were directed to an abstract idea thus requiring a consideration of whether the invention involves something significantly more.

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7 Press Release, Verb Surgical Delivers Digital Surgery Prototype Demonstration to Collaboration Partners, 26 January 2017
8 Scott Huennekens, Medical Innovation Summit, 24-26 October 2016, in Cleveland, Ohio
SmartGene Inc. v. Advanced Biological Laboratories SA\textsuperscript{10} considered an “expert system” invention, a relatively primitive form of AI. The invention consisted of a computer containing a library of knowledge of different treatment options and that was programmed with a set of expert rules for determining available treatment options in light of patient information entered into the system. The court concluded that the claimed invention did no more than describe an abstract, mental process engaged in routinely, either entirely within the physician’s mind, or potentially aided by other resources in the treatment of patients.\textsuperscript{11} The court cited with approval the decision in CyberSource Corp. v Retail Decisions, Inc.\textsuperscript{12} for the proposition that “section 101 did not embrace a process defined simply as using a computer to perform a series of mental steps that people, aware of each step, can and regularly do perform in their heads”.\textsuperscript{13} The court stated that section 101 excludes from patentability “mental processes” associated with, or as part of a category of “abstract ideas”, and also excludes processes that merely invoke generic computer implementation of such mental processes.

In more recent decisions, however, the pendulum has swung somewhat in favour of patent eligibility of software inventions. Since Enfish LLC v Microsoft\textsuperscript{14} the first step of the Mayo/Alice test has taken on a greater significance so that software inventions are not automatically considered to be directed to an abstract idea. In Enfish, the court concluded that the claimed invention, which was for an improved computer database model, was not directed to an abstract idea as it resulted in an improvement to computer technology.

In McRo, Inc. v. Bandai Namco Games America Inc.\textsuperscript{15} the court considered a computer implemented invention for generating automated lip-synchronization and associated facial expression for 3D animated characters. In finding the claimed invention to be patent eligible the Court reasoned that the invention was not merely an abstract idea under the first limb of the Mayo/Alice test as it related to a specific means or method that improves the relevant technology. In particular, the invention allowed computers to produce accurate and realistic lip synchronization and facial expressions in animated characters that previously could only be produced with some human input. The Court stated that processes that automate tasks that humans are capable of performing are patent eligible if properly claimed.

However, in BASCOM Global Internet Services, Inc. v. AT&T Mobility LLC\textsuperscript{16}, a computer implemented invention in the form of internet content filtering was considered to be an abstract idea and as such the second step of Mayo/Alice test required consideration. The court agreed that all of the claimed features of computer implementation, considered separately, were well known (i.e. generic). Nevertheless, the court went on to find that the claims contained significantly more than a mere abstract idea because the specific combination of features of the claimed invention, when considered as a whole, were not conventional or generic.\textsuperscript{17}

In McRo and BASCOM, the doctrine of pre-emption was significant in determining whether the invention was directed to an abstract idea.

\textsuperscript{10}No. 2013-1186, (Fed. Cir. Jan. 24, 2014)
\textsuperscript{11}SmartGene, Inc., 852 F. Supp. 2d at 45-46. at 55.
\textsuperscript{12}654 F.3d 1366, 1373 (Fed. Cir. 2011)
\textsuperscript{13}Id. at 7
\textsuperscript{14}Enfish, LLC v.Microsoft Corp., No. 15-1244 (Fed. Cir. May 12, 2016)
\textsuperscript{15}McRo, Inc. v. Bandai Namco Games America Inc. (Fed. Cir. 2016)
\textsuperscript{16}Bascom Global Internet Services, Inc. v. AT&T Mobility LLC (Fed. Cir. June 27, 2016)
\textsuperscript{17}USPTO- Memorandum, Recent Subject Matter Eligibility Decisions, 2 November 2016
VI. Patent eligibility of abstract ideas and software in:

A. Europe

The European Patent Convention (EPC)\textsuperscript{18} excludes from patentability discoveries, scientific theories and mathematical methods; schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers, “as such”\textsuperscript{19}.

Accordingly, under the European Patent Convention, computer programmes ‘as such’ are excluded from patentability, however, as long as there is some other technical subject matter defined in the claim then this exclusion can be avoided\textsuperscript{20}. In practice, this means that features incorporating technical computer implementation of software, such as a computer, computer network or any tangible technical element such as an AI equipped surgical robot system will pass this test.

However, in Europe, the inventive step consideration is most often responsible for tripping up computer implemented inventions. In this context, anything ‘non-technical’ is excluded from the assessment of inventive step, for example, an algorithm or steps carried out in a computer by software. Software, such an expert system in a less sophisticated AI system, a heuristic algorithm or even a machine learning algorithm, may be considered non-technical so that if the rest the claim is not inventive (i.e. is obvious) then the claim may fail to satisfy the inventive step requirement even if the combination of features of the invention may not be obvious. There is a qualification in that the software features might be considered technical if they interact with the technical subject matter to solve a technical problem\textsuperscript{21} however it difficult to discern how, in practice, this exception might be exploited.

Under European law, an AI invention, such as an expert system, that is directed towards making a diagnosis in a clinical context, is likely to be dismissed as failing to achieve a technical effect, the diagnosis being dismissed as non-technical. On the other hand, an AI invention that is applied in a technical field is likely to be patentable, provided that the features that make the invention work are novel and inventive. The bar to patent eligibility for software inventions, such as AI inventions, is perhaps higher in the EPO than anywhere else.

Patents defining computer implemented inventions such as AI should emphasise and claim the technical nature of the invention, and make clear and claim features of the technical problem that is purportedly solved by the invention. Emphasis should be given to how the technical aspects of the invention and its effects go beyond the normal functioning of a computer.

B. United Kingdom

The UK has a different approach than the EPO for handling exactly the same statutory exclusions. The UK treats the statutory exclusions and inventive step separately and requires that the contribution of the claimed invention be identified and the claim rejected as excluded from patentability if the contribution lies solely within the excluded subject matter. The contribution must also be technical in nature. UK practice does not allow features of the claim to be excluded from consideration of inventive step. The result is that the UK test for subject matter eligibility is a higher threshold than the EPO but the inventive step threshold is lower. Nevertheless, the end result in the UK and the EPO is more or less the same.

C. Japan

Japan has a relatively permissive regime with respect to patent eligibility of computer implemented inventions. There is no subject matter eligibility exclusion in Japan specifically directed to software. Section 2(1) of the Japanese Patents Act provides that an invention that is eligible for patent protection is one that is a “highly advanced creation of technical ideas utilizing the laws of nature”. Where the invention defines tangible components of computer implementation of a software invention then this is

\textsuperscript{18} European Patent Convention (EPC), Article 52, paragraph 2
\textsuperscript{19} Id Paragraph 3
\textsuperscript{20} EPO Decision T 154/04 of November 15, 2006, Reasons 12.
\textsuperscript{21} EPO Decision T 154/04, Reasons 5 (F)
enough to qualify for patent protection.\textsuperscript{22} A mathematical algorithm per se is not patent eligible in Japan but would be eligible if defined with reference to implementation by computer hardware.

Accordingly, the position in Japan is that computer implemented AI inventions are patent eligible and that relatively broad claims can be found to be patent eligible. Furthermore, relatively broad claims to methods of medical treatment, diagnostic methods as well as other methods will be patent eligible in Japan.

D. China

Computer implemented inventions in China are handled in a similar fashion as in Japan, with a similar emphasis on whether the invention has the requisite technical character. The Chinese national guidelines for examination\textsuperscript{23} specify a three-step test for patent eligibility of computer implemented inventions, namely that the invention must solve a technical problem, use technical means and achieve a technical effect. At the core of this test is the ‘technical effect’ requirement. Defining a software invention in terms of computer implementation is typically sufficient to satisfy patent eligibility in China. Accordingly, computer implemented AI inventions are patent eligible in China and relatively broad claims are permissible. Furthermore, relatively broad claims to methods of medical treatment, diagnostic methods as well as other methods will be patent eligible in China.

E. Australia

In Australia, patent eligibility is determined by an approach similar to the Mayo/Alice two step test. In the case of computer-implemented inventions the Australian Federal Court has emphasised that a technological innovation is patentable (as opposed to a business innovation)\textsuperscript{24} A mathematical algorithm per se is not patentable\textsuperscript{25} but may be so if implemented on a computer in a manner that produces some useful, material outcome such as an improvement in the functioning of the computer\textsuperscript{26} or some other useful result. Accordingly, the approach taken is that for a software or algorithm invention the software or algorithm itself does not render an invention patentable so for an invention to be eligible for a patent there must be something more than mere generic computer implementation.

VII. Patent eligibility of laws of nature, naturally occurring phenomena and methods of medical treatment in the U.S.

Some of the applications of AI in medicine such as imaging platforms, diagnostic methods and therapies derived from discoveries by AI facilitated or augmented genomics or informatics. Deep learning and other AI technologies are being employed to mine patient data, genomic data and other data-sets to make discoveries that can be used to improve therapies, identify drug candidates and make other discoveries. As such, the patentability of diagnostic methods, methods of medical treatment and natural phenomena or laws of nature can be relevant for this field of endeavour.

Methods of medical treatment have long been considered patent eligible in the U.S., however some doubt has been cast on this proposition since the decision in Mayo\textsuperscript{27} In Mayo, the court found that a method of optimizing a therapy was not patentable when that method simply relied upon a law of nature notwithstanding that the claimed invention included specific steps to be performed by a physician. The court found that the additional steps to be conducted by a physician were not enough to confer patentability on what was otherwise a claim to a naturally occurring phenomenon.

\textsuperscript{22} JPO Guidelines, Part III Chapter 1 Eligibility for Patent and Industrial Applicability
\textsuperscript{23} Guidelines of February 1, 2010, on Examination of Patents (promulgated by Order No. 55 of the State Intellectual Property Office (SIPO)
\textsuperscript{24} Commissioner of Patents v RPL Central Pty Ltd [2015] FCAFC 177 at 100, Research Affiliates, LLC v Commissioner of Patents [2014] FCAFC 150 at 93
\textsuperscript{25} Grant v Commissioner of Patents [2006] FCAFC 120
\textsuperscript{26} Re International Business Machines Corporation v Commissioner of Patents [1991] FCA 625
\textsuperscript{27} Mayo Collaborative Services Inc. v. Prometheus Laboratories Inc., 566 U.S., 132 S. Ct. 1289 (2012)
However, in Ariosa Diagnostics Inc. v. Sequenom Inc., the Federal Circuit seemed to open the door somewhat to patent eligibility for inventions derived from discoveries of naturally occurring phenomena, namely the existence of fetal DNA in maternal blood. In Sequenom the court found a claimed invention to a diagnostic method to be patent eligible as it did not pre-empt all uses for the discovery of fetal DNA in maternal blood that are outside the scope of the claims. The court explained that the doctrine of pre-emption may be an indicator of patent eligibility but is not determinative of the question.

In Rapid Litigation Management Ltd. v. Cellzdirect, Inc., the court considered claims to methods resulting from the discovery that liver cells could survive multiple freezing and thawing cycles. The Federal Circuit found that the claims were not merely directed to the discovery that hepatocytes are capable of surviving multiple freeze thaw cycles, but are instead directed to a new and useful laboratory technique for preserving hepatocytes. In its reasoning, the Federal Circuit stated that the claimed process, carried out by an artisan to achieve a new and useful end, is precisely the type of claim that is eligible for patent protection.

The Federal Circuit made a point of distinguishing the discovery underlying the invention from the claimed invention itself, which was directed to a method of preserving liver cells. The Court stated that were the patentee not to prevail then “no one could ever get a patent on any other innovative method that acts on something that is naturally occurring, simply because of the nature of the underlying subject matter. Section 101 is not so narrow.”

The decisions in Sequenom and Cellzdirect are positive for companies engaged in the development of diagnostic and personalised treatment technologies derived from discoveries made possible by the use of deep learning and other forms of AI. From McRo and Bascom we can assume that the doctrine of pre-emption is a significant factor in determining whether an invention satisfies the first or the second step of the Mayo/Alice test. In particular, by asking the question whether the abstract idea or the naturally occurring phenomena, as claimed, pre-empts all uses of the abstract idea. Accordingly, careful and conservative claim drafting is required to avoid lack of patent eligibility pursuant to the pre-emption doctrine.

The U.S. Patent System deals with surgical or other methods of medical treatment performed by a physician by denying a remedy for infringement of a medical or surgical method by a medical practitioner. This raises an interesting question as to whether a remedy could be obtained for infringement of a patent for an autonomous surgical robot or a personalised medicine system incorporating AI that substitute the role of the physician in diagnosing and administering a treatment or conducting surgery on a patient. Presumably, any tool for treatment or surgery would be considered not to fall within this exception, however, there may come a time in the future where human involvement in a diagnosis, procedure or treatment is non-existent such that

VIII. Patent eligibility of laws of nature, naturally occurring phenomena and methods of medical treatment in:

A. Europe

Article 53(c) EPC sets out exceptions to patentability in the field of medicine, including “methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body”. However, claims can generally be drafted so that they are directed to allowable in vitro methods or to non-medical uses, first or second medical uses drafted as purpose limited product claims.

28 Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015)
29 Rapid Litigation Management Ltd. v. Cellzdirect, Inc. (Fed. Cir. July 5, 2016)
30 Id at 1350
31 35 U.S.C. § 287(c)
Accordingly, there might be a question as to whether medical imaging platforms incorporating AI to assist in the diagnosis of disease or autonomous surgical robots that perform procedures on the human body and other personalised medicine technologies incorporating AI are eligible for patent protection in Europe.

Methods that have been considered not to be excluded diagnostic methods include a method of imaging an artery in a patient using magnetic resonance imaging, a method of detecting regional variations in oxygen uptake from the lungs and a method of determining ear temperature. A method that has been considered an excluded diagnostic method includes a method for determining lung function by measuring changes in the nitrogen monoxide content of exhaled air as it was to be considered to make a diagnosis of impaired lung function. An invention for the diagnoses of a predisposition for breast cancer by looking for a mutation in the BRCA1 gene in a tissue sample carried out in vitro was found to be patentable.

Accordingly, AI based diagnostic tools, AI equipped surgical robots or AI equipped personalised medicine platforms ought not to be considered to fall within one of the statutory exceptions to patent ability in Europe as long as at least one technical step is carried out separately from the body, for example by an AI algorithm executed on a computer. Careful drafting should ensure that a diagnostic method claim avoids exclusion under Article 53(c) EPC.

B. Japan
Like in Europe, Japan excludes methods of medical treatment of the human body and surgical methods from patentability. However, as in Europe, in most cases in vitro diagnostic procedures don’t fall within this exclusion and are, therefore, patentable. So, providing all steps are conducted in vitro, or on a sample which isn’t returned to the body, then such claims are allowable.

C. China
China excludes from patentability methods of medical treatment but this does not include methods of diagnosis, devices, instruments or the like. Accordingly, there is scope to obtain patent protection for in vitro diagnostic tests.

D. Australia
Unlike in most other jurisdictions, Australia does permit patentability of methods of medical treatment and therapies. As such, Australia permits patents for diagnostic tests.

With respect to the patentability of inventions based on discoveries by AI technology such as deep learning systems employed to mine patient data, genomic data and other data-sets, the Australian cases on laws of nature and naturally occurring phenomena could be a relevant for this field of endeavour.

In the decision of D’Arcy v Myriad Genetics Inc. the Australian High Court found that the isolated nucleic acid sequence coding for the BRCA-1 protein was not patent eligible subject matter. The High Court found that the substance of the invention was the information encoded in the isolated DNA sequence and since this was naturally occurring and was discerned through known techniques there was no subject matter eligible for patent protection. What was hitherto considered patent eligible subject matter in Australia, namely the isolated form of a nucleic acid, was no longer to be considered as such.

The discovery of information as a piece of abstract information without any means of practical application of the discovery has long been considered patent ineligible. However, broad claims that, in

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32 EPO Decision T663/024  
33 EPO Decision T990/035  
34 EPO Decision T1555/062  
35 EPO Decision T125/026  
36 EPO Decision T666/058  
38 Article 25(3) of the Chinese Patent Law  
39 Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd (2013) 253 CLR 284
substance, are directed towards the discernment of naturally occurring information such as genetic information or other biological interactions, through known scientific techniques such as deep learning and other AI technologies, could be of doubtful validity in view of Myriad.

Nevertheless, claims to diagnostics methods that are based on the discovery of naturally occurring phenomena are certainly patentable in Australia.

IX. What can we learn from the recent cases on patent eligibility with respect to the patentability of inventions including or derived from AI?

In the U.S., Enfish and McRo might be relied upon in favour of patent eligibility if an AI invention serves to improve the performance of a computer system within a medical device or technology. For example, it might be argued that specific applications of machine learning techniques such as deep learning and unsupervised learning in data mining, genomics and bioinformatics are patent eligible on the grounds that they involve improvements in the performance of a computer. To bolster the patentability of the invention, other features related to the application of AI that improve the speed of data analysis (e.g. parallel computing or other statistical or mathematical techniques), or the classification of data or how the computer interacts with other components such as the Internet or a network, should also be disclosed and claimed.

Enfish and McRo might also be relied upon in favour of patent eligibility of medical imaging systems and robotic surgery systems that incorporate AI on the basis that such inventions do not merely involve an abstract idea under the first limb of the Mayo/Alice test. It might be argued that such technologies are patent eligible if they result in improvements in technology by providing more accurate diagnoses such as the identification of cancerous cells or tumours in a medical image or more accurate excision of tumours or repair of damaged tissue in the case of AI controlled surgical robots. Such inventions, it could be argued, automate tasks that humans are capable of performing and are thus patent eligible if properly claimed. In any event, robotic systems are perhaps less likely to fall foul of Section 101 simply due to the fact that, by virtue of their robotic implementation, they involve something more than an abstract idea and generic computer implementation.

Furthermore, following the authorities of Enfish and McRo, claims to inventions incorporating AI should ideally be drafted to cover the specific application of the AI technology and not be cast so broadly as to pre-empt all other applications so as to avoid a finding that the invention involves an abstract idea. The focus of the claims should be on the specific means or method that improves the relevant technology and not simply the result or effect, which is the abstract idea.\footnote{McRO, Inc. v. Bandai Namco Games America Inc. (Fed. Cir. 2016) at 23}

Should an invention incorporating AI be considered to involve an abstract idea, if the claims are targeted towards a specific solution to a specific problem in a specific setting, then they’re more likely to be considered to involve something significantly more than the mere abstract idea and to satisfy the second step of the Mayo/Alice test for section 101 eligibility. The breadth of the claims and whether they are likely to pre-empt the use of the abstract idea for other purposes is a relevant consideration.

The above considerations are also applicable in Australia which takes a similarly approach to the U.S. in terms of patent eligibility of software inventions.

For European patent, a more narrow approach to claim drafting ought to be adopted such that patent claims should include a specific technical problem and substantial technical means for solving the problem in addition to any abstract software or AI algorithm component of the invention.

Japan and China have a relatively liberal approach to software patents such as might incorporate AI technology meaning that broader patent claims might be obtainable in those jurisdictions.

\footnote{National Research Development Corporation v Commissioner of Patents (1959) 102 CLR 252}
As for diagnostic methods, methods of medical treatment or surgical methods that might be derived from discoveries made with the benefit of AI technology or that may themselves incorporate AI technology, the U.S. take a relatively permissive approach to the allowability of such inventions. Other jurisdictions such as in Europe, Japan and China specifically exclude such inventions from patentability yet there are ways of circumventing these exclusions, particularly in the case of diagnostic methods as long as the methods are conducted in vitro.

X. Research/Experimental Use Exemptions and AI
The patent laws of many countries provide a research or experimental use exemption to patent infringement. One aspect of this exemption is what is commonly referred to as the Bolar exemption named after the decision in Roche Products, Inc. Appellant, v. Bolar Pharmaceutical Co., Inc.\(^{42}\) The Bolar exemption provides safe harbour for activities that are conducted for the purpose of obtaining regulatory approval of generic pharmaceuticals during the term of the patent. The general idea behind the Bolar type of research use exemptions is to enable generic pharmaceuticals and medical devices requiring regulatory approval to enter the market at the end of the term of a patent without delay.

The Bolar type exemption is also available in some jurisdictions for medical devices that also require regulatory approval. Also, some jurisdictions offer other forms of research use exemption which are generally intended to enable basic research by academic scientists.

Research use exemption provisions can be relevant to the application of AI in medicine such as the application of AI in: i) post market surveillance activities which may be required by regulation; ii) medical devices for which regulatory approval may or may not be required; iii) research tools which may be used to study pharmaceuticals or to identify new pharmaceuticals or therapies; and iv) surgical methods and methods of medical treatment.

The Bolar type of exemption seems less likely to be of concern to the patentee of AI technology, at least until the end of the patent term draws near. Of most significance, perhaps, to a patentee of AI technology is the extent of any exemptions to patent infringement for the use of patented AI technology as a research tool or for academic and arguably non-commercial purposes.

XI. Research/Experimental Use Exemptions in the USA
In the United States, research and experiment activities undertaken for obtaining regulatory approval are exempt from patent infringement. It is generally accepted that the research exemption is available for research and experiment on patented pharmaceuticals (Hatch-Waxman research use exemption is provided in 35 U.S.C. § 271(e)(1)). In general, experimentation with medical devices for the purposes of obtaining regulatory approval is also exempt from patent infringement (Eli Lilly and Company v. Medtronic, Inc., 496 U.S. 661 (1990)).

What is not so clear is whether the research use exemption would extend to AI technologies or tools employed in medical research more broadly and, if so, what are the limits to such an exemption.

The Federal Circuit in Proveris Scientific Corp. v. Innovasystems Inc.\(^{43}\) refused to exempt the sale of research tools from patent infringement. The defendant sold an infringing optical spray analyzer device to biopharmaceutical companies who used the device in experiments necessary for regulatory approval of therapeutics.

In Integra v Merck\(^{44}\) the Federal Circuit held that the use of a patented peptide in experiments to identify the best drug candidate for future clinical testing did not fall within the research use exemption. This

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\(^{43}\) Proveris Scientific Corp. v. Innovasystems, Inc., No. 07-1428 (Fed. Cir. Aug. 5, 2008)

\(^{44}\) Integra v Merck 331 F.3d 860 (Fed. Cir. 2003)
decision made it clear that tools for early-stage drug development are not protected by the research use exemption.

Accordingly, it is safe to assume that AI tools used for new pharmaceutical development would not be exempt from infringement by virtue of the safe harbour provisions.

Furthermore, in Classen Immunotherapies, Inc. v. Biogen IDEC and Momenta Pharma., Inc. v. Teva Pharma. USA Inc. (Momenta II), the Federal Circuit put to rest that post market approval activities would generally not be exempt from infringement.

Accordingly, the authorities suggest that research tools employing AI, such as deep learning tools used for the purpose of identifying new pharmaceuticals, will not be exempted from infringement under 35 U.S.C. § 271(e)(1). In addition, it is doubtful that pre or post market use of AI based research or analysis tools would be granted safe harbour despite their being used in for the satisfaction of regulatory approvals or requirements.

XII. Research/Experimental Use Exemptions Internationally

A. Europe, Germany, France

Patent infringement in Europe is dealt with on a country-by-country basis. Most European national patent laws have a research use exemption based on the Bolar exemption directive set out in Article 10(6) of Directive 2001/83/EC.

The German Patents Act sets out a bolar exemption as well as a seemingly broad experimental use exemption in Section 11 that includes acts done for experimental purposes relating to the subject matter of the invention. The German exemption covers experiments conducted with a commercial motivation, allows research for existing and new indications, and does not restrict clinical trials for regulatory approval.

The French Patents Act provides an experimental use exemption that extends to "acts performed on an experimental basis and which relate to the object of the patented invention". This provision has been interpreted as a Bolar type exemption, thus including experiments performed on a drug for the purpose of seeking regulatory approval of new applications of a drug.

However, the German and French experimental use exemptions are quite narrow and do not extend to research tools meaning that AI based research tool patents should be enforceable regardless of whether they are used for academic research or for commercial purposes or for pre or post market purposes. As such, AI technologies used for basic research in genomics and bioinformatics (e.g. data mining technologies) are likely to fall outside the research use exemption.

B. United Kingdom

The United Kingdom Patents Act provides exemptions from patent infringement for research done for experimental purposes. This exclusion has been construed narrowly to include only non-commercial purposes. However, recent amendments to the Act mean it now includes experimental use for regulatory approval of generic as well as novel (non-generic) pharmaceuticals. There is a suggestion, as yet untested, that the amended legislation may have broadened the exemption to encompass research tools

45 Classen Immunotherapies, Inc. v. Biogen IDEC (659 F.3d 1057) (Fed. Cir. 2011)
48 Article L.613-5
49 Welcome Foundation Limited vs. Parexel International and upheld on Appeal (Court of Appeal of Paris; January 27, 1999)
50 Section 60(5)(b) United Kingdom Patents Act
51 The Legislative Reform (Patents) Order 2014
52 Ibid Section 60(6D) and 60(6E)
which could involve AI technology as long as it is used for the purpose of obtaining regulatory approval of a therapy.\textsuperscript{53}

C. Japan and China

Japanese Patent law \textsuperscript{54} provides that patent rights shall not be effective against the working of the patented invention for experimental or research purposes. The Japanese Patent Law has no specific “Bolar exception” but it does allow for clinical trials and other research for generic and non-generic pharmaceuticals under the experimental use exemption\textsuperscript{55}.

Chinese Patent Law provides a research use exemption and an exemption for use of an invention for regulatory approval of pharmaceuticals\textsuperscript{56}. These provisions have not been extensively judicially tested, however, some guidance has been provided suggesting that research tools may not be encompassed within the exception\textsuperscript{57}.

D. Australia

Australia provides a Bolar type exemption for pre-market approval of pharmaceuticals\textsuperscript{58} and non-pharmaceutical inventions (e.g. Medical devices)\textsuperscript{59} for the purposes of regulatory approval. Australia also provides a broader experimental use exemption for various academic and non-academic purposes such as: (a) determining the properties of the invention; (b) determining the scope of a claim relating to the invention; (c) improving or modifying the invention; (d) determining the validity of the patent or of a claim relating to the invention; (e) determining whether the patent for the invention would be, or has been, infringed by the doing of an act\textsuperscript{60}. Accordingly, Australia has relatively well defined experimental use exemptions, however, the exemption does not extend to research tools.

XIII. In what ways could research use exemptions curtail the monopolies of patentees of inventions including or derived from AI?

Most countries offer a Bolar type of exemption for experimental use of patented pharmaceuticals or medical devices for the purposes of regulatory approval. However, these types of exemptions aren’t obviously relevant to technologies including AI except, perhaps, for medical devices nearing the end of their patent term.

Where the question of post market use of patented technologies has been judicially considered, courts have tended to find such uses to be excluded from safe harbour. As such, the adoption of patented AI technology for post market research in relation to medical devices of pharmaceuticals, even if for the dominant purpose of satisfying regulatory requirements, will not be exempt from patent infringement in any of the jurisdictions discussed above.

Perhaps of most concern would be any research use exemptions that might apply to research tools that might incorporate AI technology, such as deep learning platforms for the identification of molecules that might serve as drug candidates for subsequent development into pharmaceuticals. Most jurisdictions exclude research tools from their research use exemptions, except perhaps for the United Kingdom where there appears to be some doubt.

\textsuperscript{53} Matthew Spencer and Naomi Stevens, Insights: A broader research exemption from patent infringement in the UK, www.boult.com/bulletins, 25 June 2014
\textsuperscript{54} Article 69.1
\textsuperscript{55} Ono Pharmaceuticals Co Ltd v Kyoto Pharmaceutical Industries Ltd (1999)
\textsuperscript{56} Article 69
\textsuperscript{57} Beijing Higher People's Court (2013) "Guidelines for Judgment of Patent Infringement"
\textsuperscript{58} Section 119A of the Patents Act 1990
\textsuperscript{59} Ibid Section 119B
\textsuperscript{60} Ibid Section 119C