تأثير استخدام الذكاء الاصطناعي على شركات الأدوية

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الملخص

تحقق غالبا شركات الأدوية أرباحا عن طريق الأدوية الحاصلة على براءة اختراع، وتسوغ شركات الأدوية ارتفاع تكاليف الأدوية بسبب تكلفة التجارب السريرية والمخبرية التي باءت بالفشل، والتي يتم تعويض خسائرها برفع أسعار الأدوية التي تطرحها هذه الشركات في الأسواق. يسعى هذا البحث لربط العلاقة بين الذكاء الاصطناعي وشركات الأدوية والكشف عن الدور الذي سيلعبه الذكاء الاصطناعي في اتاحه المزيد من العقاقير من خلال خفض تكاليفها. يتاول هذا البحث أيضا العقبات التي تواجهها شركات الأدوية نتيجه استخدام الذكاء الاصطناعي في اكتشافات الأدوية، مثل ملكية الأدوية والحصول على براءة اختراع . وخلص هذا البحث الى تغيير التشريعات وتعديل الاتفاقيات المتعلقة بالجوانب التجارية لحقوق الملكية الفكرية (TRIPS) للسماح بالتقدم التكنولوجي مثل الاعتراف بالذكاء الاصطناعي كمبتكر للأدوية وبهذه الابتكارات كبراءات اختراع، من أجل اتاحه الوصول للمزيد من العقاقير ذات التكلفة المعقولة. ويوصي هذا البحث باستخدام شركات الأدوية الذكاء الاصول على براءة الماماح بالتقدم التكنولوجي مثل الاعتراف بالذكاء الاصطناعي كمبتكر للأدوية وبهذه الابتكارات كبراءات اختراع، من أجل اتاحه الماماح بالتقدم التكنولوجي مثل الاعتراف بالذكاء الاصطناعي كمبتكر للأدوية وبهذه الابتكارات كبراءات اختراع، من أجل اتاحه الوصول للمزيد من العقاقير ذات التكلفة المعقولة. ويوصي هذا البحث باستخدام شركات الادوية الذكاء الاصطناعي لتحسين طرق اكتشاف الادوية الجديدة. اما المنهجية المتبعة في هذا البحث فلي مزج بين منهجية البحث القانوني والتحليل المقارن.

الكلمات الدالة: الذكاء الاصطناعي، الأدوية، شركات الأدوية، (TRIPS) تربس.

The Impact of Using Artificial Intelligence in Pharmaceutical Companies

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Abstract

Pharmaceutical companies generate profits, predominantly, through patented medication. Pharmaceutical companies justify the high costs of medication by offsetting the costs, of tested and failed clinical trials, onto medicines that make it on the market. This paper links the relationship between Artificial Intelligence (AI), pharmaceutical companies and the role that AI will play in increasing access to medicines by decreasing costs of medicines. This article also considers the hurdles that pharmaceutical companies will face, such as ownership and patentability of drugs, as a result of using AI in drug discoveries. This paper concludes and recommends a change in legislation and an amendment of the Trade Related Aspect of Intellectual Property Rights (TRIPS) to allow for technological advancements such as AI to become recognised as inventors and for AI generated inventions to be patentable in order increase access to affordable medicines as well as utilising AI in pharmaceutical companies to enhance the method of new drug discovery. The methodology utilised in this paper is a hybrid approach between doctrinal legal research methodology and comparative analysis.

Keywords: Artificial Intelligence, access to medicine, pharmaceutical companies, TRIPS.

1. Introduction

Since Artificial Intelligence (AI) was first mentioned in the 1950s, the number of filed AI-related inventions has reached up to 340,000 in 2018.¹ It is now being called the 4th industrial revolution.² Machine learning, in particular, is the dominant technique cited in one third of all identified AI inventions.³

AI includes a wide range of services and there is no 'agreed definition' of what constitutes AI. This means that there is no list of situations where AI might apply.⁴ There is consensus, however, that AI includes a form of neural networks and machine learning.⁵

There are many industries that are utilising AI and an area that is witnessing significant attention is healthcare⁶. The benefits of employing AI are evident by AI's ability to differentiate, for example, on a chest CT scan, between a Covid-19 diagnosis and between community acquired pneumonia.⁷ Further, the pharmaceutical industry is also benefitting from AI as evidenced by companies such as Recursion, which utilises neural networks to analyse 'images of cells and learn how new drugs affect these cells'.⁸ Additionally, Bayer, has been using AI to diagnose rare illnesses and create new drugs.⁹ AI systems, undoubtedly, have an effect on pharmaceutical companies as they will improve and accelerate the process of developing drugs and will recognise patterns of targeted patients.¹⁰

² Lord Kitchin, UKIPO - WIPO conference, keynote speech, Lord Kitchin, Justice of the supreme court,18 June 2019 <<u>https://www.supremecourt.uk/docs/speech-190618.pdf</u>> accessed 7 December 2022, para 1.

³ ibid at para 1.

⁴ Economics, research and evidence team at the intellectual property office, "Artificial intelligence a worldwide overview of AI patents and patenting by the UK AI sector", ISBN 978-1-910790-61-8, June 2019, 5.

⁵ M. Lupu, 'Artificial intelligence and intellectual property' (2018) 53 World Patent Information.
 ⁶ Nasri Ali Falah Aldweikat, 'Tort Liability for Damages of Artificial Intelligence Robots in The Jordanian Civil Law', Al-Zaytoonah University of Jordan Journal for Legal studies, Volume (3), Issue (3), 2022, p.5
 ⁷ Li, Qin and other, 'Artificial Intelligence distinguishes COVID-19 from community acquired pneumonia on chest CT', Radiology 2020 < <u>https://doi.org/10.1148/radiol.2020200905</u>>

⁸ C. Metz, 'Making New Drugs With a Dose of Artificial Intelligence', The New York Times (San Francisco, Feb 2019) < <u>https://www.nytimes.com/2019/02/05/technology/artificial-intelligence-drug-research-deepmind.html</u> > accessed 7 December 2022, para 23. See also Recursion Pharmaceuticals, 'Recursion Pharmaceuticals Raises \$13M to Discover New Drugs Using Artificial Intelligence' 17 October 2016 Biotech Business Week, 110. ISSN 1543687X.

¹⁰ C. Taylor, 'AI meets IP' (PharmaTimes, April 2018)

<<u>http://www.pharmatimes.com/magazine/2018/may_2018/ai_and_ip</u> > accessed 7 December 2022, para 1. See also K K Mak and M R Pichika, 'Artificial intelligence in drug development: present status and future

¹ WIPO, 'WIPO's first "technology trends" study probes artificial intelligence: IBM and Microsoft are leaders amid recent global upsurge in AI inventive activity', Geneva, (31 January 2019, PR/2019/827) < <u>https://www.wipo.int/pressroom/en/articles/2019/article_0001.html></u> accessed 7 December 2022; World Intellectual Property Organisation, Technology Trends 2019: Artificial intelligence (1st edn, Geneva WIPO, 2019).

⁹ N Martin, 'Artificial Intelligence Is Being Used To Diagnose Disease And Design New Drugs', Forbes (30 September 2019) <<u>https://www.forbes.com/sites/nicolemartin1/2019/09/30/artificial-intelligence-is-being-used-to-diagnose-disease-and-design-new-drugs/#37f5e5ae44db</u> > accessed 7 December 2022. See also M. Devoy, 'Artificial intelligence – Technology-driven disease prediction to advance patient care', Bayer Pharmaceuticals < <u>http://pharma.bayer.com/en/innovation-partnering/artificial-intelligence-technology-driven-disease-prediction-to-advance-patient-care/</u> > accessed 7 December 2022.

Moreover, patent offices worldwide have been utilising AI technology, and AI systems are assisting patent offices in the tasks of patent classification and data analysis. For example, Morocco's Industrial and Commercial Property Office (OMPIC) employs Orbite Intelligence, which is 'a commercially available AI-powered patent analytics tool'; this tool searches global patent applications by 'technical domain or keywords and aids in identifying the 'state of the art and the precedence of patents'.¹ OMPIC also employs AI-assisted Optical Character Recognition (OCR) technology that has extended to the processing of patent documents.²

The preceding AI processes have reduced the costs associated with manual data entry³ and thus improved data quality. Moreover, Australia's patent auto classification tool employs 'developed software/machine learning' for patent classifications to 'build sophisticated hierarchy classification models to analyse the contents of each patent case'.⁴ This information is grouped, and then sent to examiners.

Volume, quality and cost of generating information are important factors for utilising AI generated systems.⁵ AI initiatives have also been used by patent offices to reduce administration costs of patents.⁶

The focus of this article is on pharmaceuticals overcoming hurdles in order to be transparent when utilising AI for drug discovery and patenting these drugs to increase access to medicines.

2. The effect of AI technology on increasing access to medicines

It is estimated that approximately 40 pharmaceutical companies, to date, are using and experimenting with AI technology.⁷ Pharmaceutical companies use AI to discover new drugs and employing AI means that pharmaceutical companies will be able to discover new drugs more efficiently. New drug discovery will be based on clinical data, hypotheses and scientific papers which will be fed into AI machines. AI machines will then process the information through deep learning techniques to produce 'the most promising hypotheses'.⁸

prospects'(2019)24 (3) Drug Discovery Today. This article explains the subdivisions which exist in AI that include machine learning, learning without being programmed, and deep learning, where neural networks adapt an learn from experimental data.

¹ For more initiatives see WIPO, 'Index of AI initiatives in IP offices' <<u>https://www.wipo.int/about-ip/en/artificial_intelligence/search.jsp</u>> accessed 7 December 2022.

 $^{^2}$ ibid, para 35.

³ ibid, para 35.

⁴ Ibid, para 1.

⁵ WIPO, 'Artificial intelligence and intellectual property: an interview with Francis Gurry', WIPO Magazine, September 2018 <<u>https://www.wipo.int/wipo_magazine/en/2018/05/article_0001.html</u>>accessed 7 December 2022 at para 14.

⁶ For example Brazil, the European Patent Office, Finland, Germany, Japan, Singapore, the UK, the US and WIPO use AI generated systems for patent classifications.WIPO's index of AI initiatives in IP offices < <u>https://www.wipo.int/about-ip/en/artificial_intelligence/search.jsp></u> accessed 7 December 2022.

⁷ S. Smith, '43 pharma companies using artificial intelligence in drug discovery', BenchSci, last updated 2 June 2020 <<u>https://blog.benchsci.com/pharma-companies-using-artificial-intelligence-in-drug-discovery</u> >accessed 7 December 2022.

⁸ World Intellectual Property Organisation, Technology Trends 2019: Artificial intelligence (1st edn, Geneva WIPO, 2019),149; see also Hu, K., Jin, J., Zheng, F. *et al.* 'Overview of behavior recognition based on deep learning'. *Artif Intell Rev* **56**, 1833–1865 (2023). <u>https://doi.org/10.1007/s10462-022-10210-8</u>.

Different institutions are using AI to find drugs which relate to specific diseases. For example, Predictive Oncology, a US pharmaceutical company, applies AI by analysing large data sets of patient drug treatment in ovarian cancer to produce additional sequential data derived from tumour samples to reach new drug development.¹ Similarly, Pepticom, a Jerusalem-based pharmaceutical company, is using AI to accelerate peptide/insulin-based discoveries of drugs.²

When a process such as discovering new drugs becomes a swifter process the other processes, such as the pre-clinical, clinical trial process with its three phases and the regulatory and manufacturing process, also become more efficient.³ AI could even contribute to revolutionising the clinical trial three phase model, as we know it, to forego the pre-clinical process altogether.⁴

AI applications will be able to predict what molecules will bind best with others. This means that there will be less or even minimal failures in clinical trials and a more streamlined and efficient drug development process ⁵. For example, 'Recursion' uses AI to recognise known indications of various known drugs which in turn decreases the amount of time spent on failed clinical trials.⁶

Utilising the assistance of AI means that it will become cheaper to produce new drugs, and therefore, easier to predict the costs and future costs of newly developed drugs. Companies utilise AI technology through using deep learning processes and feeding data from scientific sources such as patents, scientific papers, discoveries and clinical trials to build a reliable base of knowledge.⁷ For example, Benevolent AI, a UK based pharmaceutical company, describes the journey that, data to medicine, takes place in their vision statement which states that a hypothesis for an underlying condition is formulated before a series of testing is conducted to endorse the hypothesis. Once a hypothesis is validated another process commences which

⁴ ibid, 578.

¹ Predictive Oncology, 'Predictive oncology featured in publication discussing the impact of artificial intelligence on cancer treatment' Globe Newswire (New York, 6 November 2019) <<u>http://investors.predictive-oncology.com/news-release/news-release-details/predictive-oncology-featured-publication-discussing-impact</u> > accessed 7 December 2022 at para 5.

² See Pepticom's website <<u>http://www.pepticom.com/</u> > accessed 7 December 2022.

³ S. Harrer, P Shah, B Antony, J Hu, "Artificial Intelligence for Clinical Trial Design" (2019) 40 (8) Trends in Pharmacological Science 577-591.

⁵ D. L. Labovitz et al, 'Using artificial intelligence to reduce the risk of nonadherence in patients on anticoagulation therapy' (2017) 48 (5) Stroke 1416-1419; F Jiang, Y Jiang, H Zhi et al,

[&]quot;Artificial intelligence in healthcare: past, present and future" (2017) 2 Stroke and Vascular Neurology 230-243; N Fleming, "How artificial intelligence is changing drug discovery" (2018) 557 Nature 55-57; (as cited in K K Mak and M R Pichika, "Artificial intelligence in drug development: present status and future prospects" (2019) 24 (3) Drug Discovery Today at 774.

 ⁶ Recursion Pharmaceutical's website < <u>https://recursionpharma.com/></u> accessed 7 December 2022.
 ⁷ Verdict AI, 'A critical impact: How AI could transform healthcare', Verdict AI's website <<u>http://verdict-ai.nridigital.com/issue-one/a critical impact how ai could transform healthcare></u> accessed 7 December 2022.

comprises of designing and developing compounds which are targeted towards the most likely group of patients to benefit from that medicine.¹

Another company by the name of *Atomwise* takes the data to medicine journey further, by explaining that their technology is based on a statistical approach which extrapolates data matches and measurements from thousands of protein structures, to reach accurate predictions on the binding of small molecules and proteins.²

Furthermore, *Atomwise's* deep convolutional neural network, AtomNet, for example 'screens more than 100 million compounds each day' ³; this allowed *Atomwise* to analyse the technology which reduces Ebola's effectivity in one day rather than months and years.⁴ Similarly, Insilico Medicine aims to complete the drug discovery process within 46 days.⁵

The above processes evidently reduce the discovery time, and thus the costs of discovering new medicines. This means that pharmaceutical companies will not need to offset the costs of R&D onto patented drugs to recoup the costs of R&D and failed clinical trials. For example, the International Federation of Pharmaceutical Manufacturers (IFPMA) state 'On average, only 1 in 5 of our products ever get back their direct R&D investments. Intellectual property rights, whether patents, copyrights, trademarks, or trade secrets, help innovators to recover the sunk costs of research that did not make it to the market'.⁶ The prices of patented drugs, therefore, should reflect the decrease of discovery time.

3. The hurdles that pharmaceutical companies will face as a result of utilising AI in drug discoveries

3.1 Separating ownership and inventorship

Separating ownership and inventorship⁷ is essential when considering whether AI machines can become inventors. The ownership of monopoly rights to an AI patent is an issue which has not been fully considered by the courts.⁸

¹ Benevolent AI, "Our vision", Benevolent AI website <<u>https://benevolent.ai/our-vision></u> accessed 7 December 2022.

² Atomwise's website at para 1 <t <u>https://www.atomwise.com/our-technology/></u> accessed 15 December 2019. See also The Medical Futurist, "Top Companies Using A.I. In Drug Discovery And Development" 17 September 2019, The Medical Futurist < <u>https://medicalfuturist.com/top-companies-using-a-i-in-drug-discovery-and-development/</u> >accessed 15 December 2019.

³ The Medical Futurist, 'Top Companies Using A.I. In Drug Discovery And Development' (The Medical Futurist, 17 September 2019) < <u>https://medicalfuturist.com/top-companies-using-a-i-in-drug-discovery-and-development/</u> accessed 7 December 2022 at para 7.

⁴ ibid, para 7.

⁵ ibid, para 8. See also Insilico Medicine's website < <u>https://insilico.com/#rec41711523></u> accessed 7 December 2022.

⁶ IFPMA, 'Discovering medicines and vaccines' (2019) International Federation of Pharmaceutical Manufacturers & Associations < <u>http://www.ifpma.org/subtopics/ip-2/?parentid=258</u> > accessed 7 December 2022 at para 1.

⁷ S Y Tull and P E Miller, "Patenting Artificial intelligence: issues of obviousness, inventorship, and patent eligibility" (2018) 1 RAIL 313.

⁸ M. Curzon, 'AI in drug development: who's the inventor?' (Lexology, June 2019) <<u>https://www.lexology.com/library/detail.aspx?g=4bd8371b-e31a-4fe1-8d03-914c6bfc0e80</u>> accessed 7 December 2022.

Patent offices are currently being tested through Dabus. Dabus is an AI computer ¹ and the inventor of two patents.² The group behind Dabus filed patent applications in various countries including USPTO, UKIPO and EPO³. UKIPO has decided not to grant Dabus's application⁴, similarly USPTO and EPO's legal board of appeal have followed suit and rejected the application to name Dabus as an inventor.⁵ Applications are now pending in other countries and it remains to be seen whether Dabus, an AI machine, will be named as an inventor. Intellectual property offices of the UK, EU and US initially had varying responses but the legislators' conclusions were similar and stressed on the importance of the inventor being a natural person.

Perhaps a solution to the inventorship issue is to separate it from ownership. Designating AI inventors or the algorithm owner, or computer's owner as first owners could be a solution.⁶ In this instance, the computer's owner and the AI inventors could be employed by the pharmaceutical company and, therefore, the inventios may be assigned to pharmaceutical companies under the terms of the inventors' employment contracts.

Another solution could be to not list an inventor's name if a drug is developed by AI.⁷The courts and patent system could be tailored to allow considerations such as innovation and economics take precedence over listing an inventor's name.⁸

More to that effect the law could be amended to allow for an inventor not to be named. There are many jurisdictions that do not require an inventor to be named. For example, Bahrain's patent law grants patents to the inventor or the rights acquirer or partners of an invention and stipulates that 'the name of the inventor shall be mentioned in the patent **unless the same requires in writing not to do so [Emphasis added]**'.⁹

The example above relates to relatively new patent laws that have been implemented. Taking a step back to find out why the naming of the inventor has been listed could be beneficial. This requires a look back at the Travaux préparatoires ¹⁰ which, according to the EPO decision, refers to an inventor being a natural person.¹¹ The decision takes into account

¹ The Artificial Inventor Project is the group associated with Dabus. V Hudgins, "Some IP attorneys welcome our inventive robot overlords', 7 August 2019 < <u>https://www.law.com/legaltechnews/2019/08/07/some-ip-attorneys-welcome-our-inventive-robot-</u>

<u>overlords/?utm_source=email&utm_medium=enl&utm_campaign=skilledintheart&utm_content=20190827&utm_term=law</u> > accessed 7 December 2022.

² The patents relate to a food container which ensures food's safety and a rhythmic flickering lamp to be used in emergency situations. L Kelion, "AI system 'should be recognised as inventor', 1 August 2019 BBC < <u>https://www.bbc.co.uk/news/technology-49191645></u> accessed 7 December 2022.

³ Patents and Applications, <u>Patents and Applications – The Artificial Inventor Project</u>

⁴ Patent decision (O/741/19) (ipo.gov.uk)

⁵ <u>Register Plus PDF viewer (epo.org)</u>; <u>16524350</u> <u>22apr2020.pdf (uspto.gov)</u>

⁶ ibid.

⁷ World Economic Forum.

⁸ R. Abbott, Hal the inventor: big data and its use by artificial intelligence in: Sugimoto CR, Ekbia HR, Mattioli M (eds.), Big Data is Not a Monolith 14 187-198 MIT Press.

⁹ S. 11 of Bahrain's Law No. 1 of 2004 on Patents and Utility Models.

¹⁰ Travaux préparatoires, document IV/4860/61-F page 64 in specific.

¹¹ EPO decision: In Re EP 18 275 163 / In Re 18 275 174, II paras 24 and 25 fn5.

the legislative history of the Travaux préparatoires which in turn confirms the legislator's understanding that an inventor can only be a natural person.¹

This suggestion is not to be regarded as concealing an AI invention and naming a natural person instead.² The author contends that this paper calls for transparency and therefore concealing the involvement of AI to obtain patents should be discouraged. Naming the inventor is a fundamental principle of patent law and going against this is an offence in some jurisdictions, and is misleading to the public.³

3.2 AI as a separate legal entity

The UK's stance on AI authorship has undergone some confusion which has been caused by the UK's Copyright, Designs and Patents Act 1988 that allows for the authorship of computergenerated works. ⁴This means that the work is not generated by a human author.⁵ However, UKIPO updated its formalities manual in October 2019 to specifically state that an AI Inventor is not recognised as an acceptable inventor as this does not identify a person as is required by the law and a failure to identify a person results in the application being withdrawn⁶.

The UK's stance was tested through Dabus and the Formalities Manual, above stated, was brought into the attention of H. Jones, where he advised that he would determine each case in accordance with the requirements of the law and rules and that if his findings contravene the Formalities manual, then the practice will need to change.⁷

The law in question in the UK is the Patents Act 1977 at s.7, s. 13 and Rule 10 of the Patents Rules 2007.⁸ The UK's Patents Act 1977 at s.7(3) defines an inventor as 'the actual deviser of

⁷ UK Decision not to Grant: In Re GB1816909.4 / GB1818161.0, para 6.

⁸ The UK's Patents Act 1977 at s.7(2) states:

¹ EPO decision : In Re EP 18 275 163 / In Re 18 275 174, II para 25 fn 5 refers to the following preparatory documents : document BR/169 e/72 ett/AV/prk, point 31; first preliminary draft of a convention establishing a European system for the grant of patents (1970), Article 15(1); Minutes of the Munich Diplomatic Conference for setting up of a European system for the grant of patents, Munich 10 September to 5 October 1973, point 2039, document BR/84 e71 nan/KM/prk, point 11; document 4488/IV/62-F, Article 157(1); document IV/3858/61-F, Article 70; Vorentwurf eines Abkommens uber ein europaisches Patentrecht ausgearbeitet von der Arbeitsgruppe "Patente" (1962.

² Dr. Kollner has commented on the UKIPO's amended s. 3.05 in its formalities manual by saying 'It will simply bring applicants to lie about the contributions to the invention. They will conceal the AI contribution to the invention and just name a natural person.' Dennemeyer & Associates, 'Can Artificial Intelligence Systems Patent Their Inventions?' (Dennemeyer & Associates ,2 June 2020) <<u>https://blog.dennemeyer.com/can-artificial-intelligence-systems-patent-their-inventions</u> >accessed 7 December 2022.

³ EPO decision: In Re EP 18 275 163 / In Re 18 275 174, I -para 12/18

⁴ Copyright, Designs and Patents Act 1988 at s.178.

⁵ ibid.

⁶ Ch.3 sub section 3.05 < <u>https://www.gov.uk/guidance/formalities-manual-online-version/chapter-3-the-inventor accessed 8 December 2019> accessed 7 December 2022</u>.

⁷⁽²⁾ A patent for an invention may be granted

⁽a) primarily to the inventor or joint inventors;

the invention', and s. 13 is concerned with the right of the inventor to be mentioned in any granted patents and the right to be mentioned in any published application.¹

Moreover, the Patents Act 1977 at s.13 states:

(2) Unless he has already given the Patent Office the information hereinafter mentioned, an applicant for a patent shall within the prescribed period file with the Patent Office a statement -

(a) identifying the person or persons whom he believes to be the inventor or inventors; and

(b) where the applicant is not the sole inventor or the applicants are not the joint inventors, indicating the derivation of his or their right to be granted the patent; and, if he fails to do so, the application shall be taken to be withdrawn.²

The UK's decision not to grant Dabus's application concluded that AI is not a person. Furthermore, H. Jones concluded that even if this is incorrect a satisfactory derivation of right has not been established. The EPO's decision was also affixed on the point that the inventor does not meet the requirements laid down in Article 81 and Rule 19(1) of the EPC from the outset and before the oral proceedings³. The EPO further reiterated that Dabus does not meet the formal requirements under the aforementioned article and rule.⁴ EPO's Article 81 and Rule 19(1) refer to satisfying a full designation of the inventor's full address, full name and any given names and where the inventor is not the applicant then a statement indicating the origin to the European patent and the signature of the applicant or his representative.⁵

Moreover, the EPO decision stated that the legal framework of the EPC provides for natural, legal persons and bodies equivalent to legal persons⁶ in reference to Article 58 EPC. Furthermore, in the context of inventorship reference is made only to natural persons. This indicates a clear legislative understanding that the inventor is a natural person.⁷ The EPO in this instance refers to Europe's legislation in protecting the natural person's right to a name⁸ and Article 4(1) Regulation (EU) 2016/679.

- ⁶ EPO decision: In Re EP 18 275 163 / In Re 18 275 174, II para 23.
- ⁷ ibid.

⁽b) in preference to the foregoing, to any person or persons who, by virtue of any enactment or rule of law, or any foreign law or treaty or international convention, or by virtue of an enforceable term of any agreement entered into with the inventor before the making of the invention, was or were at the time of the making of the invention entitled to the whole of the property in it (other than equitable interests) in the United Kingdom;

⁽c) in any event, to the successor or successors in title of any person or persons mentioned in paragraph (a) or (b) above or any person so mentioned and the successor or successors in title of another person so mentioned; and to no other person

¹ S.13 (a) of the UK's Patent Act 1977

 $^{^{2}}$ S.13 (a) of the UK's Patent Act 1977

³ EPO decision: In Re EP 18 275 163 / In Re 18 275 174, I para 16/18.

⁴ Ibid, II para 19, 20 & 21.

⁵ In Re EP 18 275 163 / In Re 18 275 174 at I para 8/18. See also Rule 41(2)(c) and Rule 19(1) EPC.

⁸ EPO decision: In Re EP 18 275 163 / In Re 18 275 174, II para 22 refers to s.12 of Germany's BGB, Article 57(2)(4), Article 6 (1) of the Italian Civil Code, Article 2.20(1) Civil Code of the republic of Lithuania

The USPTO has also referred to its statutes which provides that an inventor refers to an individual¹. Moreover, the USPTO concluded to interpret the statutes which states: '[w]hoever invents or discovers any new useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent...' to indicate a natural person based on the 'Merriam-Webster's Collegiate Dictionary', the pronouns used in 35 U.S.C. s115 and Univ. of Utah v. Max-Planck-Gesellschaft zur Forderung der Wissenschaften E.V.²

There are serious contemplations whether AI should be regarded as a legal entity which could be, for example, subject for punishment. Scholars such as Abbott, lead the way in considering whether AI could be awarded legal entity status.³Although Abbott concluded that AI should not be subject to punishment giving a legal entity status to AI is imperative when considering patents.

The author contends that AI machines cannot be regarded as humans, however, they should not be relegated to mere machines. Pharmaceutical companies seeking to produce AI-generated drugs should champion establishing AI as a separate legal entity. This does not mean that AI should be given human status⁴. This means that AI will be placed in a separate category because we can no longer treat AI machines as simply computers and we cannot upgrade them to human status.

3.3 Innovation

The are many reasons why patent offices may be hesitant to grant patents to AI generated products. For example, there is a genuine fear that AI inventions may supress human innovation and that AI products should not be patentable because they would stifle human intelligence and R&D sectors.⁵

This was highlighted by H. Jones in his final observations when deciding not to grant Dabus the invention. More specifically, H. Jones highlighted that the fundamental purpose of patents is to increase the prospect of innovation through time specific monopolies granted in exchange of public discourse.⁶ The argument that recognising a machine as the inventor will, therefore, not assist in dissemination of information to the public.

¹ 35 U.S.C. 100 (f)(g); US Petition Decision: In Re: 16/524,350.

² 35 U.S.C. 101; US Petition Decision: In Re: 16/524,350 4, para 3; Merriam-Webster's Collegiate Dictionary (10th ed. 2001).

³ See for example R Abbott, A. F. Sarch, "Punishing artificial intelligence: legal fiction or science fiction" (2019) SSRN Electronic Journal, DOI: 10.2139/ssrn.3327485 and R Abbott, "Hal the inventor: big data and its use by artificial intelligence" in: Sugimoto CR, Ekbia HR, Mattioli M (eds.), Big Data is Not a Monolith 14 187-198 MIT Press.

⁴ R Y Yampolskiy, "Could an artificial intelligence be considered a person under the law?", 5 October 2018 The Conversation < <u>https://theconversation.com/could-an-artificial-intelligence-be-considered-a-person-under-the-law-102865</u> >accessed 14 December 2019.

⁵ World Economic Forum, 'Artificial intelligence collides with Patent Law' (April 2018, White Paper, REF 160418 - case 00048540)

<<u>http://www3.weforum.org/docs/WEF 48540 WP End of Innovation Protecting Patent Law.pdf</u> accessed 7 December 2022.

⁶ UK Decision not to Grant: In Re GB1816909.4 / GB1818161.0, para 28.

However, patenting AI-generated products does not necessarily and conclusively lead to a decrease in innovation because the incentive to innovate is derived from humans.¹ The legislators need to recognise that is always a man behind the machine. It may be worthwhile to provide a fixed term test trial to realise the potentials of AI generated medications especially in improving the public's health.

Additionally, the fear that AI inventions will halt innovation could be overcome by establishing a higher degree test for AI products by raising patentability standards such as non-obviousness.² Similarly, an assessment of the degree of human involvement may be relevant as patentability criteria.³

3.4 Contractual considerations

The result of increased reliance on AI systems is that data, that fuels⁴ AI systems, will become more valuable. Covenants may need to be produced within contracts to prevent datasets being exploited.⁵ This includes costs for all parties involved in the AI process.

The parties need to determine patent assignment upfront, for example will it be the pharmaceutical companies supplying the data, the AI collaborators, the party which identifies that a discovery of a new drug has been made. For instance, in the case of Dabus the inventor presented as an assignee.⁶

Agreeing patent ownership serves is a practical solution to sidestep issues that involved costs and more importantly ownership.

3.5 Patenting AI generated drugs

Patenting of drugs, which were developed through AI, is an issue that has been subject to continuous scrutiny. This is because AI produced medication is developed by a machine. A machine consists of algorithms, mathematical equations and abstract ideas which are not patentable in many, especially developed, countries.

¹ R. Abbott, 'AI-generated Works', (Video, Practical Law- Thomson Reuters, 26 February 2020) < <u>https://uk.practicallaw.thomsonreuters.com/w-024-</u>

^{2125?}comp=pluk&__lrTS=20200304163017626&transitionType=Default&contextData=(sc.Default)&firstPage =true&bhcp=1&OWSessionId=fe4977e01763499791b9568dfa4edd2e&skipAnonymous=true> accessed 7 December 2022.

² S. Yanisky-Ravid and X Liu, 'When artificial intelligence systems produce inventions: the 3a era and an alternative model for patent law' [1 March 2017] Cardozo L. Rev.

³ E. Fraser, 'Computers as Inventors – Legal and Policy Implications of Artificial Intelligence on Patent Law' (2016) 13 (3) SCRIPTed .

⁴ Taylor 2018, para 4.

⁵ ibid, para 4.

⁶ EPO decision: In Re EP 18 275 163 / In Re 18 275 174, I para 5/18.

Additionally, if pharmaceutical companies are utilising the assistance of machines to produce drugs, then the criteria for patenting such as non-obviousness ¹, as outlined by the Trade Related aspects of Intellectual Property Rights (TRIPS), then is diminished.

The issue of whether AI produced medication is patentable, therefore, is questionable. Patent offices need to have finality and a clear approach towards AI generated inventions when there is a benefit to the public's health.

EPO has introduced measures to tackle patenting drugs which involve AI technology.² These guidelines provide that AI methods are to be treated the same way as mathematical methods. This means that in order for an AI invention to become patentable 'technical character' needs to be established.³ This could mean that patent applications will need to specify more detail regarding the involvement of AI. This will be explored further in the section below.

IPO, has also issued guidelines on patent applications which involve AI generated subject matter and how they will be examined.⁴ IPO concludes that that AI invention is eligible to patent if a known task or technical process is performed by the AI invention⁵. This means that whilst AI generated inventions will not be patentable, inventions which utilise technical elements will be subject to patentability.

The US has evolved its concept of patentable subject matter as seen in the US's supreme court decisions in the Mayo vs Prometheus Laboratories⁶, Alice vs CLS Bank International⁷ and Blue Spike, LLC vs Google Inc⁸. The culmination of these cases resulted in the two step test where courts determine if the patent claim relates to an abstract idea and if it does then step two will apply where an inventive concept will render the invention patent-eligible⁹. These tests have been said to offer little or no guidance in respect of determining if an AI invention is patentable,¹⁰however it will be interesting to see how the US could decide whether an AI invention is in fact an abstract idea since it was developed by a machine.

 $\underline{https://www.sonovate.com/quickview/50-hottest-uk-ai-companies/> accessed 7 December 2022 .$

⁵ IPO, Examining patent applications relating to artificial intelligence (AI) inventions: The Guidance, published 22 September 2022, <u>Examining patent applications relating to artificial intelligence (AI) inventions: The Guidance - GOV.UK (www.gov.uk)</u>; A guide for AI- based UK companies <

https://www.sonovate.com/quickview/50-hottest-uk-ai-companies/> accessed 7 December 2022 .

10 ibid.

¹ Taylor 2018 at para 2.

²Article 3.3.1 European Patent Office <<u>https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_3_3_1.htm</u>> accessed 7 December 2022.

³ Lord Kitchin keynote speech (n6) at para 16.

⁴ IPO, Examining patent applications relating to artificial intelligence (AI) inventions: The Guidance, published 22 September 2022, <u>Examining patent applications relating to artificial intelligence (AI) inventions: The</u> <u>Guidance - GOV.UK (www.gov.uk)</u>; A guide for AI- based UK companies <

⁶ Mayo Collaborative Services V. Prometheus Laboratories, Inc. 566 U.S., 132 S.CT. 1289 (2012).

⁷ Alice Corp. v. CLS Bank Int'l, 134 S.Ct. 2347, 2355 (2014).

⁸ Blue Spike, LLC v. Google Inc., No. 14-CV01650-YGR, 2015 U.S. Dist. LEXIS 119382.

⁹ K Osenga, "Institutional design for innovation: a radical proposal for addressing sec. 101 patent-eligible subject matter" (2019) 68 Am U L Rev 1191.

The USPTO has recently asked for guidance regarding this issue and therefore there may be a willingness to change its position in the future.¹ Moreover, USPTO has, recently, issued revised guidelines to deal with inventions involving AI². The USPTO recommends that applications state whether a patent will need a judicial exception to ensure that patenting AI inventions follow a streamlined and uniform process. The USPTO's guidelines, however, have been criticised for being 'guidelines' rather than laws. ³Similarly, the Canadian government introduced two practice notices in March 2013 to give guidance regarding AI or computer implemented inventions.⁴

4. Amending legislation: WTO's TRIPS

The EPO's judgement states that patentability requirements are laid down solely by articles 52 and 57 of the EPC, ' in line with the TRIPS Agreement and the Strasbourg Agreement'.⁵ If the requirements regarding patentability criteria could be amended in TRIPS then perhaps patent offices will follow suits.

The two relevant Articles in TRIPS are Article 7 and Article 27(1). Article 7 sets out the objectives of TRIPS as follows:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Prima facie, this seems a self-explanatory statement that will assist all countries' policy makers and pharmaceutical companies; however, it is ambiguous how these objectives may be implemented within any one country. This ambiguity is observed in many Free Trade

² USPTO, "Subject Matter Eligibility", USPTO < <u>https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility></u> accessed 7 December 2022; L Leong, "Artificial intelligence and blockchain: US patent office weighs in' 26 February 2019,Oyen Wiggs < <u>https://patentable.com/artificial-intelligence-and-blockchain-us-patent-office-weighs-in/?utm_source=Mondaq&utm_medium=syndication&utm_campaign=View-Original</u> > accessed 7 December 2022.

³ R White, "Medical AI: Can patent law keep up with the trajectory of innovation?" Watermark April 30 2019 < <u>https://www.watermark.com.au/medical-ai-can-patent-law-keep-up-with-the-trajectory-of-innovation/</u> accessed 7 December 2022.

⁴ Examination Practice Respecting Purposive Construction—PN2013-02, Gov't Can. (Mar. 8, 2013) < <u>https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03626.html > accessed 7 December 2022.</u>

; Examination Practice Respecting Computer-Implemented Inventions—PN 2013-03, Gov't Can. (Mar. 8, 2013) <<u>https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03627.html> accessed 7 December 2022</u>. See S Esmaili, "Patenting artificial intelligence inventions In Canada" (October 2019) 24 Gowling WLG < ">https://gowlingwlg.com/en/insights-resources/articles/2019/patenting-artificial-intelligence-inventions/#footnote-8-referrer>">https://gowlingwlg.com/en/insights-resources/articles/2019/patenting-artificial-intelligence-inventions/#footnote-8-referrer>">https://gowlingwlg.com/en/insights-resources/articles/2019/patenting-artificial-intelligence-inventions/#footnote-8-referrer>">https://gowlingwlg.com/en/insights-resources/articles/2019/patenting-artificial-intelligence-inventions/#footnote-8-referrer>">https://gowlingwlg.com/en/insights-resources/articles/2019/patenting-artificial-intelligence-inventions/#footnote-8-referrer>">https://gowlingwlg.com/en/insights-resources/articles/2019/patenting-artificial-intelligence-inventions/#footnote-8-referrer>">https://gowlingwlg.com/en/insights-resources/articles/2019/patenting-artificial-intelligence-inventions/#footnote-8-referrer>">https://gowlingwlg.com/en/insights-resources/articles/2019/patenting-artificial-intelligence-inventions/#footnote-8-referrer>">https://gowlingwlg.com/en/insights-resources/articles/2019/patenting-artificial-intelligence-inventions/#footnote-8-referrer>">https://gowlingwlg.com/en/insights-resources/articles/2019/patenting-artificial-intelligence-inventions/#footnote-8-referrer>">https://gowlingwlg.com/en/insights-resources/articles/2019/patenting-artificial-intelligence-inventions/#footnote-8-referrer>">https://gowlingwlg.com/en/insights-resources/articles/2019/patenting-artificial-intelligence-inventions/#footnote-8-referrer>">https://gowlingwlg.com/en/insights-8/

¹ USPTO's initiatives <<u>https://www.uspto.gov/initiatives/artificial-intelligence</u>> accessed 7 December 2022.

⁵ EPO decision: In Re EP 18 275 163 / In Re 18 275 174, I para 11/18.

Agreements such as the Bahrain US Free Trade Agreement (BUSFTA) which makes no mention of promoting technological innovation between Bahrain and US, nor of the transfer and dissemination of technology. Another example is the Jordan US Free Trade Agreement (JUSFTA) which refers to a desire to 'foster creativity and innovation';¹ however, and similar to BUSFTA, there is no mention of encouraging technological knowledge in the manner described above.

If Article 7 is interpreted to the effect of providing technological advancements into each country's national policies, then this article can grant countries additional policy space and greater access to medicines by allowing for the promotion of technological innovation. This could encompass new and innovative ways of dealing with patents, such as Artificial Intelligence tools, that have become increasingly popular when dealing with intellectual property.²

The utilisation of AI in IP is an evolving area from which developing countries could benefit. AI systems affect outputs, meaning that policymakers will be able to 'achieve better quality and reduce administration costs'.³ Member countries could utilise AI in its simplest form. For example, WIPO has invented a tool for instant patent translation designed especially for patent documents.⁴ Use of this tool is free of charge, meaning that there are no cost implications for countries that utilise it.

Countries which are in the process of acceding to TRIPS, such as Sudan, might benefit the most from this tool. This is because they are in the process of amending their patent laws, and will therefore need an accurate tool to draft these laws; moreover, use of the tool will reduce translation and outsourcing costs.⁵

As mentioned previously, pharmaceutical companies utilising the assistance of machines to produce drugs means that the criteria for patenting such as inventive step or non-obviousness⁶, as outlined by TRIPS's Article $27(1)^7$, is diminished. TRIPS at Article 27(1) states that 'Patents shall be available for any invention, whether product or process, in all fields of technology, provided that it is new, involves an inventive step and is capable of industrial

⁴ WIPO Translate <<u>https://www.wipo.int/patentscope/en/wipo-translate/</u>> accessed 7 December 2022. WIPO has also invented a universal tool that will aid in identifying trademark designs and image searches; however, trademarks are outside the scope of this research.

⁵ A. Supertramp, 'How IP Offices Use Artificial Intelligence' (WIPR, 22 May 2019)
 https://www.worldipreview.com/contributed-article/how-ip-offices-use-artificial-intelligence> accessed 7 December 2022.
 ⁶ Taylor 2018, para 2.

⁷ Article 27(1) of TRIPS

¹ JUSFTA's preamble.

² WIPO, 'Artificial intelligence and intellectual property: an interview with Francis Gurry' (WIPO Magazine, September 2018) < <u>https://www.wipo.int/wipo_magazine/en/2018/05/article_0001.html</u>>

accessed 7 December 2022.

³ 'WIPO, 'Artificial intelligence and intellectual property: an interview with Francis Gurry' (WIPO Magazine, September 2018) para 14 <<u>https://www.wipo.int/wipo_magazine/en/2018/05/article_0001.html</u>> accessed 7 December 2022.

application'.¹ TRIPS also lists exceptions that countries may include in their national legislation. This article contains considerable flexibility, as it provides a clear definition of what constitutes patentable subject matter and lists three identifiable criteria.

The WTO recognises that AI is one of the technologies which will have an impact on future trade.² This means that more specific AI-patenting discussions should come into focus. The WTO is aware of the impact that AI can have in relation to access to medicine and therefore amending TRIPS, in line with achieving the greatest access to medicine through AI products, should be on its next agenda. Arguments when considering AI should now be steered towards benefiting rather than pointing out the negative implications of AI. Helpfully, amending TRIPS is feasible as evidenced by the amendment which took effect on 23 January 2017.³

More specifically, pharmaceutical companies have the power to influence WTO members⁴ to introduce amendments to TRIPS's Article 27(1) to address computer-generated inventions. The influences of pharmaceutical companies on lobbying the WTO are beyond the scope of this paper.

Changing the current legislation is the most straightforward solution as highlighted in UKIPO's decision, as H. Jones stated that this is a possibility by stating that the current system does not cover such inventions and that technology and times have moved on.⁵

Additionally, another method to ensure the patentability of AI products is to detail the use of AI in the patent applications. The purpose of this is to highlight the usefulness of the AI product and the impact that this will have on access to health. The detailed use of AI, therefore, should be 'transformative' and not merely an extension of 'human endeavour'.⁶ Perhaps TRIPS, at Article 29 which currently requires an applicant to 'disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art...', could be amended to include more guidance on disclosing more information regarding computer generated inventions.⁷

¹ TRIPS Article 27

² WTO, "World trade report 2018: the future of world trade: How digital technologies are transforming global commerce", <<u>https://www.wto.org/english/res_e/publications_e/world_trade_report18_e.pdf></u> accessed 7 December 2022.

³ WTO, "Amendment of the TRIPS agreement"

<https://www.wto.org/english/tratop e/trips e/amendment e.htm>.

⁴ Pharmaceutical companies' influence can be traced back to the GATT negotiations. B Baker and T Avafia, "The evolution of IPRS from humble beginnings to the modern day TRIPS-plus era: implications for treatment access." (7-9 July 2011) Working Paper prepared for the Third Meeting of the Technical Advisory Group of the Global Commission on HIV and the Law <<u>http://bibliobase.sermais.pt:8008/BiblioNET/upload/PDF/0583.pdf</u> >accessed 15 December 2019 at 9. See also P Drahos, 'Who owns the knowledge economy: political organizing behind TRIPS' (2004) 32 The Corner House: Briefing < <u>http://www.thecornerhoUse.org.uk/resource/whoowns-knowledge-economy</u> > accessed 15 December 2019.

⁵ UK Decision not to grant: In Re GB1816909.4 / GB1818161.0, para 29.

⁶ R. White, 'Medical AI: Can patent law keep up with the trajectory of innovation?', (Watermark, 30 April 2019) < <u>https://www.watermark.com.au/medical-ai-can-patent-law-keep-up-with-the-trajectory-of-innovation/></u> accessed 7 December 2022 at para 13.

5. Conclusion

This article highlights the benefits of AI and discusses the concerns that may prevent pharmaceutical companies from investing in AI technology. It also recommends that pharmaceutical companies utilise AI to increase access to medicine by improving and speeding up new drug discovery. This, in turn, will yield cheaper and affordable patented medications, fewer or no delays in producing generic drugs, and improve transparency in costs.

Pharmaceutical companies may be dissuaded from utilising AI because patenting of drugs which involve AI technology is an issue. Intellectual property offices are considering computer generated technologies and guidelines have been introduced, for example by UKIPO and USPTO, to address this area. The author states that patent offices should reconsider their guidelines so that they can increase transparency where AI developed drugs and where AI technology has been used.

The author makes recommendations to deal with patenting AI drugs which include agreeing costs upfront with the parties, as well as clarifying ownership and inventorship issues. Further recommendations include that in order for pharmaceutical companies to argue for the use of AI generated products, then it will need to exert its existing influence on developed countries to allow for computer generated inventions within the definition of TRIPS, and particularly, in line with TRIPS's Article 7 and 27(1). The author urges pharmaceutical companies to influence policymakers in developed countries and members of WTO to amend Article 27(1) of TRIPS to include criteria to patent and regulate AI-generated products. The author further argues that WTO's dialogue should be geared towards shifting the perception of how AI could benefit humankind and increase access to medicines. Pharmaceutical companies should also champion establishing AI as a separate legal entity as there should be an emphasis on what is being generated and how it would benefit public health.

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