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Biotechnology and AI

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ABSTRACT

Currently, the biotechnology industry relies heavily on data collection, filtration, analysis, and exchange. Biotechnology firms and numerous health agencies around the world maintain massive databases. Drug processing, chemical analysis of various chemicals, sequencing of RNA and DNA, enzyme studies, and other related biological processes need the strong help of computerised tools and applications to gain speed and minimise manual errors. Artificial Intelligence (AI) in biotechnology and related applications is critical for controlling biological processes, increasing drug development, managing supply chains, and managing the industry's data pool. Increased and improved predictability for both structured and unstructured data assists businesses in better managing their activities for increased efficiency and profitability. In terms of the Coronavirus pandemic, the world is currently facing an ongoing health emergency. Countries are on lockdown, economies are crashing, and all expectations are pinned on the biotechnology industry to develop a secure, successful vaccine in the shortest time possible.

Keywords: *Biotechnology, Artificial Intelligence, Privacy, Patentability, Negligence, Liability, Medical Innovation.*

I. INTRODUCTION

Artificial intelligence (AI) may seem futuristic, but it is already present in a variety of modern technologies. It provides voice and facial recognition capabilities to our mobile devices, for example. AI is now having an impact in biotechnology, where it is now used in many areas of drug production and exploration. Drug target recognition, drug screening, image screening, and predictive modelling are only a few of the AI applications in the biotech industry. Artificial intelligence is now being used to sift through scientific literature and keep track of clinical trial results.

The artificial intelligence (AI) sector has seen remarkable breakthroughs in recent years, thanks to the rapid growth of life sciences and information technology. Personal information recommendations, voice control, facial recognition, and other innovations have started to make

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everyday life more effective and convenient. Besides that, biotechnology has progressed to the first level of large-scale industrialization. The advent of a new technological and industrial revolution has been accelerated by biological technology advancement and business growth.

In terms of unveiling life laws, revolutionising the medical profession, creating new energy, reforming conventional manufacturing, and improving the climate, they have worked together to foster economic growth and social change. From concerns of responsibility if things go wrong to addressing the possibility of discriminatory consequences as a result of incorrect data, legal and regulatory hurdles must be addressed.

Companies will be keen to watch whether future changes to UK intellectual property laws to account for AI materialise and provide fresh incentives for investing in research into creative new uses, although compliance with data protection laws remains a key challenge for businesses trying to gain public confidence in the use of new technology such as AI. In addition, the integration of AI and biotechnology has the ability to significantly impact humanity's thought paradigm and lifestyle in the near future, as well as create a new perspective on human understanding.

In the future, artificial intelligence would almost certainly play a larger role in healthcare. Many people believe it will finally be able to detect illness, make correct diagnosis, and prescribe medication while preventing some of the errors that fallible humans make. This will help to improve healthcare, reduce costs, and free up money for other uses of the health system. In the future, artificial intelligence would almost certainly play a larger role in healthcare. Many people believe it will finally be able to detect illness, make correct diagnosis, and prescribe medication while preventing some of the errors that fallible humans make.

In the near future, we are likely to see the use of AI in a variety of regions. The first is radiology picture interpretation. Deep learning is a form of AI in which machines scan marked images and 'learn' to recognise features with the help of algorithms. They apply what they've learned to identify similar features in other pictures. There are early indications that this could aid in the diagnosis of cancer and other diseases.

(A) Healthcare, Artificial Intelligence (AI), and the Law

Clinical negligence law is currently unfit for a society where AI makes diagnosis and care decisions. Over the next 5 to 10 years, we can expect to see changes in medical practise, accompanied by changes in the legislation as it addresses some of the problems on a case-by-case basis.

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II. INTERNATIONAL REGULATION AND CONVENTION OF AI

(A) United Nations Law and Policy

1. UNICRI and Centre for Artificial Intelligence and Robotics

The United Nations Interregional Crime and Justice Research Institute (UNICRI) founded an AI and robotics centre in early 2015 to "assist in focusing expertise on Artificial Intelligence (AI) in the UN in a single agency."[2] UNICRI "signed the host country agreement for the opening of its Centre for Artificial Intelligence and Robotics in The Hague, the Netherlands, in September 2017," with the help of the Municipality of The Hague and the Ministry of Foreign Affairs of the Netherlands.[3] "Understanding and addressing the threats and benefits of AI and robotics from the perspective of crime and security through awareness-raising, education, knowledge sharing, and stakeholder harmonisation," according to the centre.[4] The International Criminal Police Organization (INTERPOL), the International Telecommunications Union (ITU), the Institute of Electrical and Electronics Engineers (IEEE), the Foundation for Responsible Robotics, the World Economic Forum, the Centre for Future Intelligence, and others are among the organisations with which UNICRI collaborates.[5] The Centre's mission is to increase understanding of Artificial Intelligence and Robotics' risk-benefit duality through better collaboration, information gathering and dissemination, awareness-raising, and outreach programmes. The Hague, the Netherlands, will host the opening of the Centre. The key result of the above initiative will be that all stakeholders, including policymakers and government officials, will have a better understanding of both the risks and benefits of such innovations, and that they will begin a thoughtful and informed dialogue about these risks and possible solutions[6]

2. International Telecommunication Union

The ITU is the United Nations' specialised agency for information and communication technology, and it has become one of the most important UN forums for researching AI's effect. According to the ITU website, it "will provide a neutral forum for government, industry, and academia to develop a shared understanding of the capabilities of emerging AI technologies

[2] AI Policy – United Nations, FUTURE OF LIFE INSTITUTE, https://futureoflife.org/ai-policy-united-nations/), archived at https://perma.cc/9CZ2-ETNX.
[3] Centre on Artificial Intelligence and Robotics, UNICRI, http://www.unicri.it/topics/ai_robotics/centre/) archived at https://perma.cc/475Y-ZZ6N
[4] Id
[5] Id.
[6] The Hague, The Netherlands UNICRI Centre for Artificial Intelligence and Robotics, UNICRI, http://www.unicri.it/in_focus/on/UNICRI_Centre_Artificial_Robotics archived at https://perm a.cc/RCN7-92BL.

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and the resulting need for technological standardisation and certification."[7]

3. The Oviedo Convention: A European Legal Framework.

This instrument is important because it is the first comprehensive multilateral treaty dealing with biomedical human rights issues.

III. ISSUES RELATED TO PATENTEBILITY AND IPR

When it comes to computer-based technologies, applying for patent protection comes with certain risks. If the innovation is simply a way to enhance the performance of a device without binding it to a practical application, there is a good chance that the patent office will deny it because it is based on "ineligible subject matter." Mental processes (concepts conducted by the human mind), methods of coordinating human behaviour (such as basic economic concepts or handling interpersonal interactions), or mathematical relationships, formulas, or equations are examples of subject matter that is unavailable for patent protection. This last category is particularly critical for AI-based inventions.

In the United States, for example, a stand-alone algorithm is likely to be seen as nothing more than abstract mathematics and thus not qualified for patent protection. The basic instruments of science and technical work are mathematical calculations that can be done by the human mind, which are "free to all men and reserved exclusively to none." *Mayo Collaborative Servs. v. Prometheus Labs*[8]. To others, this constraint could seem ludicrous, as the human mind could be capable of performing the millions of calculations that a neural network can, even though there is no guarantee that a human mind will complete such calculations in a single lifetime. Allowing patents on simple calculations, on the other hand, would stifle scientific exploration and progress. As a result, an algorithm-based innovation must substantially advance a particular technological application in order to be qualified for patent protection, rather than simply using an algorithm to solve a problem. The patent application must detail how the alleged algorithm communicates with the computer's physical infrastructure, network infrastructure, or both, as well as the real-world problem that the invention solves.

Many jurisdictions around the world, including the European Patent Office (EPO) and Israel, demand that algorithms be tied to real-world solutions. The European Patent Office, for example, has released new guidelines stating that AI technologies must be applied to a particular area of technology. In this regard, patent offices are taking a more technical

[7]Artificial Intelligence, ITU, https://www.itu.int/en/ITU-T/AI/Pages/default.aspx, A
[8] Mayo Collaborative Servs. v. Prometheus Labs 566 U.S. 66 (2012)

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approach, treating AI components of an invention as if they were any other software component.

Because of the use of computer systems and algorithms, as well as the rapidly changing law surrounding subject matter eligibility, several AI patents face an uphill fight for patentability. The U.S. Patent and Trademark Office (USPTO) has made amendments to the legislation in order to remedy the numerous patent application rejections. In January 2019, the USPTO released Updated Patent Subject Matter Eligibility Guidance, and in October 2019, the USPTO issued Patent Eligibility Guidance Update, which provided explanations for the revised subject matter eligibility.

(A) Facial Detection Using a Neural Network

The innovation tries to solve the issue of incorrect facial recognition by using a larger training set of facial images and then retraining the algorithm on a new set of images to correct false positives. Example 39[9] of the USPTO's October 2019 Patent Eligibility Guidance Update shows a patent application for a method of training a neural network for facial recognition that is permissible.

The example claim recites "A computer-implemented method of training a neural network for facial detection comprising: [a set of digital images] training the neural network in a first stage using the first training set;[10] creating a second training set for a second stage of training comprising the first training set and digital non-facial images that are incorrectly detected as facial images after the first stage of training; and training the neural network in a second stage using the second training set."[11]

Despite the use of an algorithm, the USPTO finds that this argument is patent-eligible subject matter because "some of the limitations may be based on mathematical principles, but the mathematical concepts are not recited in the claims..." This demonstrates that when an innovation involves a neural network, the creative means of achieving the result, rather than the underlying mathematical principles, should be a key focus of the statements. The argument

[9] Example 39 is a hypothetical AI innovation titled "Method for Training a Neural Network for Facial Detection," which describes an invention for solving issues with older facial recognition methods that were unable to detect human faces in images with changes, distortions, and variations in scale and rotation of the face pattern in the picture.

[10] Terri Shieh-Newton, PhD, Marguerite McConihe, Patenting Considerations for Artificial Intelligence in Biotech and Synthetic Biology https://www.mintz.com/insights-center/viewpoints/2231/2020-01-30-patenting-considerations-artificial-intelligence-biotech

[11] UMBER AGGARWAL; KARTHIK KUMAR, PH.D. OVERCOMING SECTION 101 CHALLENGES AGAINST AR AND VR INVENTIONS HTTPS://WWW.FINNEGAN.COM/EN/INSIGHTS/BLOGS/PROSECUTION-FIRST/OVERCOMING-SECTION-101-CHALLENGES-AGAINST-AR-AND-VR-INVENTIONS.HTML

does not discuss any mathematical relationships, formulas, or calculations, despite the fact that it mentions the computer-implemented procedure.

(B) Patents on Deep Learning for Vaccine Development

"Epitope concentrating by variable effective antigen surface concentration," is an example of a deep learning invention.[12] "Compositions and methods for the generation of an antibody or immunogenic composition, such as a vaccine, by epitope focusing by variable effective antigen surface concentration," according to this invention.[13]

The invention, according to the disclosure and abstract, is heavily reliant on "in silico bioinformatics," which refers to scientific experiments or research conducted or generated using computer modelling or computer simulation for the science of collecting and analysing complex biological data. For example, neural networks could be used to create a map of a given antigen's protein surfaces or an in silico library of antigenic variations, according to the disclosure. One of the invention's steps is to build "a library of possible antigens for use in the immunogenic composition" "in silico," according to the abstract.

The decision in Alice Corp. v. CLS Bank International[14] by the United States Supreme Court cast doubt on the patentability of software-related innovations, which AI falls firmly within.

(C) Cancer Diagnosis Using Machine Learning

Via ML, researchers have made several important advances in the detection of various types of cancer. It can be difficult to patent these types of aggregated data innovations because inventions that simply present the results of gathering and analysing data without additional elements that specify a specific tool for the presentation or application of the data are likely to be considered "abstract ideas." Unpatentable subject matter includes abstract ideas and inventions that require mathematical manipulation of data without the inclusion of additional elements to complete the abstract concept.

The discovery in that case was a method of "connecting multiple genomic alterations such as copy number, DNA methylation, somatic mutations, mRNA expression, and microRNA expression" to establish a "integrated pathway study, intended to improve the precision and sensitivity of causal interpretations for broad sets of observations." The US Patent Trial and

[12] U.S. Patent No. 10,196,427

[13] Ryan N. Phelan, Marshall, Gerstein & Borun LLP, How To Patent An Artificial Intelligence (AI) Invention: Guidance From The U.S. Patent Office (USPTO) https://www.mondaq.com/unitedstates/patent/1051174/how-to-patent-an-artificial-intelligence-ai-invention-guidance-from-the-us-patent-office-uspto

[14] Alice Corp. v. CLS Bank International, 573 U.S. 208 (2014)

Appeal Board (PTAB) recently upheld an Examiner's decision that[15], which sought to use machine learning to modernise cancer care, failed subject matter eligibility.[16]

(D) Used Machine Learning to Build Long-Lasting Bioplastics

ML is being used by a slew of new protein engineering technology firms to create interesting sustainably sourced products. Arzeda, for example, is designing scratch-resistant computer screens for mobile phones using tulips, a renewable resource you would not expect.

The metabolic pathway responsible for the development of tulipalin, a natural molecule found in tulips, has been ported into industrial microbes by Arzeda. Arzeda is combining protein design, pathway design, HT screening, and strain construction with machine learning to build and develop designer fermentation strains for virtually any chemical.[17]

(E) Patenting Machine Learning Inventions: Key Takeaways

The USPTO guidelines and competitive ML-based patent applications have two main takeaways. Focus first on the conditions for achieving the desired result. The EPO guidelines, like the USPTO's specifications for ML patents, require a "inventive stage" and a "further technical impact." Second, when reciting complex mathematical equations in the argument language.[18]

Many techniques may be used to ensure the patentability of AI and ML innovations at the EPO, but two are particularly important:

(1) navigating Article 56 EPC's "inventive stage" requirement successfully[19] and

(2) overcoming the requirement of Article 52 paragraph 1 EPC for "further technical impact"[20].

Based on the could-would exam[21], the solution to the technical problem is not apparent.[22]

If the innovation has the ability to solve problems in other areas of technology, it is not taken into account in the study. Most AI and ML applications will hit this stumbling block, and this

[15] Application No. 13/417,188
[16] LEXIS 3052, *3 (PTAB April 19, 2018)
[17] Patent No. 10,025,900 issued to Arzeda in the United States.
[18] Article 56 of the EPC stipulates, and has stipulated for many years, that each invention must include an innovative phase that is not obvious to an individual skilled in the art in the particular field of technology.
[19] https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar56.html
[20] https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar52.html
[21] We ask if the skilled person could have arrived at the invention by adapting or changing the closest prior art, rather than whether he would have done so because the prior art incited him to do so in the hope of solving the objective technical issue, under the could-would test.
[22] ibid. In the third point, the question to be answered is whether there is any teaching in the prior art as a whole that would (not simply could, but would) have prompted the skilled individual, faced with the objective technical issue, to change or adapt the closest prior art while taking that teaching into account, thereby arriving at something that falls within the terms of the claims, and thus achieving what was claimed and thus achieving what the invention achieves.

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is where the practitioner's imagination comes into play.

IV. ISSUES RELATED TO JURISDICTION AND PRIVACY

Privacy and surveillance, bias and prejudice, and probably the deepest, most challenging philosophical subject of the day, the function of human judgement, are all key ethical concerns for society.[23]

Facial recognition systems provide a foretaste of the privacy concerns that will arise. Computer recognition of faces has advanced rapidly from fuzzy photos of cats[24] to rapid (though still imperfect) recognition of individual humans, thanks to rich databases of digital photographs available through social media, websites, driver's license registries, surveillance cameras, and other sources.

Facial recognition technology is being used in cities and airports throughout the United States. However, China's use of facial recognition as a method of authoritarian repression in Xinjiang[25] and elsewhere has sparked outrage and demands for a ban.

Face recognition has been banned in the cities of Oakland, Berkeley, and San Francisco in California, as well as Brookline, Cambridge, Northampton, and Somerville in Massachusetts, due to privacy concerns.[26] California, New Hampshire, and Oregon have also passed laws prohibiting the use of facial recognition technology in police body cameras.[27]

(A) An Examination of the Ethical Issues Raised By AI in Healthcare

- Informed consent to use,
- protection and accountability,
- algorithmic fairness and prejudices, and

[23] Pallone spoke at the House Subcommittee on Consumer Protection and Commerce's hearing on "Protecting Consumer Privacy in the Era of Big Data" on February 26, 2019. Senate Commerce, Science, and Transportation Committee hearing on "Policy Principles for a Federal Data Privacy Framework in the United States," February 27, 2019. See: Principles for Privacy Legislation, which was co-sponsored by prominent Democratic privacy leaders in the Senate and urged for putting the burden of maintaining privacy on firms that collect personal data:https://www.democrats.senate.gov/imo/media/doc/Final_CMTE%20Privacy%20Principles_11.14.19.pdf

[24] https:/web.stanford.edu/class/aerchive/cs/cs106a.1188/lectures/lecture26.pdf

[25] "One Month, 500,000 Face Scans: How China Is Using A.I. to Profile a Minority," New York Times, April 14, 2019. Paul Mozur, "One Month, 500,000 Face Scans: How China Is Using A.I. to Profile a Minority," New York Times, April 14, 2019.

[26] "Berkeley Bans Government Face Recognition Use, Joining Other Cities," Sara Merken, "Berkeley Bans Government Face Recognition Use, Joining Other Cities," Bloomberg Law, 16 Oct. 2019; "Brookline becomes the second Massachusetts community to ban facial recognition," writes Nikolas DeCosta-Klipa. 12 December 2019, Boston.com. "Cambridge Votes to Ban Face Surveillance Technology," Tori Bedford. WGBH, 13 January 2020

[27] "Inspecting Algorithms for Bias," MIT Technology Review, June 12, 2017. Matthias Spielkamp, "Inspecting Algorithms for Bias," MIT Technology Review, June 12, 2017. https://securitytoday.com/articles/2019/10/10/california-to-become-third-state-to-ban-facial-recognition-software-in-police-body-cameras.aspx

- data privacy

(B) Informed Consent to Use

The patient–clinician relationship will be transformed by health AI applications such as imaging, diagnostics, and surgery. But how will the use of AI to help with patient treatment interact with informed consent principles? Even though informed consent would be one of the most urgent challenges in interdisciplinary research, this is a pressing issue that has received insufficient attention in the ethical debate.[28] In the clinical AI space, it is necessary to investigate under what circumstances (if at all) the principles of informed consent should be applied. To what degree do clinicians have a duty to inform patients about the nuances of AI, such as the type(s) of machine learning (ML) used by the system, the types of data inputs, and the likelihood of biases or other flaws in the data used? In what conditions would a clinician have to inform a patient that AI is being used?

AI health apps and chatbots are also becoming more common, with applications ranging from diet advice to health evaluations to medication adherence assistance and data analysis from wearable sensors.[29] For bioethicists, such apps pose concerns regarding user agreements and their relationship to informed consent.

(C) Protection and Accountability

One of the most significant challenges for AI in healthcare is safety. IBM Watson for Oncology[30], for example, uses AI algorithms to assess information from patients' medical histories and assist clinicians in exploring cancer care choices for their patients.

The issue appears to be with Watson for Oncology's training: instead of using actual patient data, the programme was only equipped with a few "synthetic" cancer cases generated by doctors at Memorial Sloan Kettering (MSK) Cancer Centre[31]. According to MSK, errors have happened as a result of device testing, and therefore no incorrect treatment advice has been provided to a patient.[32]

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[28] I.G. Cohen, R. Amarasingham, A. Shah, B. Xie, and B. Lo. Use of advanced predictive analytics in health care raises legal and ethical considerations. Health Affairs, vol. 7, no. 7, pp. 1139–1147, 2014. http://dx.doi.org/10.1377/hlthaff.2014.0048

[29] The Nuffield Council on Bioethics is a non-profit organisation based in the United Kingdom. In healthcare and research, artificial intelligence (AI) is being used., http://nuffieldbioethics.org/wp-content/uploads/Artificial-Intelligence-AI-in-healthcare-and-research.pdf; 2018

[30]IBM is an American multinational corporation. Oncology with IBM Watson, https://www.ibm.com; 2020

[31]According to reports, Brown J. IBM Watson prescribed cancer therapies that were "unsafe and wrong." Gizmodo is a website dedicated to technology., https://gizmodo.com/ibm-watson-reportedly-recommended-cancer-treatments-tha-1827868882; 2018

[32]C. Ross and I. Swetlitz. Internal documents reveal that IBM's Watson supercomputer recommended cancer therapies that were "unsafe and inaccurate." STATUS, https://www.statnews.com/2018/07/25/ibm-watson-

The field has been tarnished by this real-life example. It also demonstrates how crucial it is for AIs to be both healthy and reliable. But how do we know AIs can keep their promises? Stakeholders, especially AI developers, must ensure two main things in order to fully realise AI's potential: (1) dataset reliability and validity, and (2) transparency.

To begin, the datasets used must be trustworthy and accurate. In this case, the adage "garbage in, garbage out" holds true. The AI would work better if it has better training data (labelled data). Furthermore, in order to produce reliable results, the algorithms must frequently be refined. Another major problem is data sharing: In cases where AI must be extremely confident (for example, self-driving cars), massive quantities of data would be required, necessitating further data sharing. However, in some cases (for example, a text-based narrow sentiment AI), less data is needed. In general, the amount of data needed is often dependent on the AI in question and its tasks.[33]

Second, some level of accountability must be maintained in the interests of patient safety and trust. Although in an ideal world, all data and algorithms will be available for public scrutiny, there might be reasonable concerns about protecting investment and intellectual property while still reducing cybersecurity danger. Auditing by a third party or by the government may be an option.

(D) Fairness and Biases in Algorithmic Computation

AI has the potential to transform healthcare not only in high-income countries, but even in low-income ones by democratising expertise, “globalising” healthcare, and bringing it to even the most remote locations[34]. Any ML system or human-trained algorithm, on the other hand, will only be as reliable, accurate, and equal as the data it is trained with. AI is therefore vulnerable to prejudices and, as a result, prejudice. As a result, it's critical that AI developers are aware of this risk and work to reduce prejudices at any point of the product development process. When determining (1) the ML technologies/procedures to use to train the algorithms and (2) what datasets (including considering their consistency and diversity) to use for the programming, they should consider the possibility of biases in particular. Several real-world examples have shown that algorithms can be biased, resulting in discrimination based on ethnic backgrounds,

recommended-unsafe-incorrect-treatments; 2018

[33] What is training data?, https://www.figure-eight.com/resources/what-is-training-data; 2020

[34] Supra Note 33.

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skin colour, or gender[353637383940]. Biases may also exist when it comes to other characteristics, such as age or disability. The reasons for such prejudices vary and can be complicated. They may arise as a result of the datasets themselves (which are not representative), how data scientists and machine learning systems select and analyse data, the context in which AI is used, and so on.[41]

Biased AI may, for example, lead to false diagnoses and make treatments ineffective for certain subpopulations, jeopardising their protection in the health sector, where phenotype- and sometimes genotype-related knowledge is involved. Consider AI-powered clinical decision support (CDS) software that assists clinicians in determining the appropriate care for skin cancer patients. The algorithm, on the other hand, was primarily developed with Caucasian patients in mind. As a result, subpopulations for which the training data was insufficient, such as African Americans, would likely receive less reliable or even incorrect recommendations from AI software.

(E) Data Privacy

The UK Information Commissioner's Office (ICO) ruled in July 2017 that the Royal Free NHS Foundation Trust had broken the UK Data Protection Act 1998 when it gave Google DeepMind personal data on approximately 1.6 million patients.[42], [43] The information was shared as part of the clinical safety testing of "Streams," an app designed to aid in the diagnosis and identification of acute kidney injury. Patients, on the other hand, were not adequately told about the test's data processing. Elizabeth Denham, the Information Commissioner, rightly pointed

[35] Artificial intelligence (AI) and global health: How might AI contribute to health in resource-poor settings? Wahl B., Cossy-Gantner A., Germann S., Schwalbe N.R. 10.1136/bmjgh-2018-000798. BMJ Glob Health. 2018;3:e000798. doi:10.1136/bmjgh-2018-000798.

[36]E. (short) It was discovered that Amazon's AI hiring tool was biassed against women. Silicon Republic is a publishing house based in California., https://www.siliconrepublic.com/careers/amazon-ai-hiring-tool-women-discrimination; 2018

[37]Discriminating algorithms: 5 times AI demonstrated prejudice, according to Cossins D. Scientist N, https://www.newscientist.com/article/2166207-discriminating-algorithms-5-times-ai-showed-prejudice; 2018

[38] Examples of racial and gender bias in AI systems, Fefegha A., https://medium.com/thoughts-and-reflections/racial-bias-and-gender-bias-examples-in-ai-systems-7211e4c166a1; 2018

[39]Z. Obermeyer, B. Powers, C. Vogeli, and S. Mullainathan Investigating racial prejudice in a population health management algorithm. Science is a branch of knowledge that is. 2019;366:447–453. doi: 10.1126/science.aax2342.

[40]The effects of gender and race bias on AI, Sharkey N. Policy on Humanitarian Law, https://blogs.icrc.org/law-and-policy/2018/08/28/impact-gender-race-bias-ai; 2018

[41] RFA0627721—provision of patient data to DeepMind under the ICO., https://ico.org.uk/media/2014353/undertaking-cover-letter-revised-04072017-to-first-person.pdf; 2017

[42] https://ico.org.uk/about-the-ico/news-and-events/news-and-blogs/2017/07/royal-free-google-deepmind-trial-failed-to-comply-with-data-protection-law; 2017

[43] The House of Lords is a chamber of parliament in the United Kingdom. Are We Ready, Willing, and Able to Implement Artificial Intelligence in the United Kingdom?,https://publications.parliament.uk/pa/ld201719/ldselect/ldai/100/100.pdf; 2018

out that "the price of creativity does not have to be the erosion of human rights."

Despite the fact that the Streams app does not use artificial intelligence, this real-life scenario has highlighted the risk of privacy violations when creating technical solutions. If patients and clinicians don't trust AIs, they won't be able to successfully integrate them into clinical practise. It is critical to provide patients with adequate information about the processing of their data and to encourage an open dialogue.[44] However, what about the data's ownership? Health data may be worth billions of dollars, and some research shows that the public is wary of corporations or the government profiting from patient data.

The latest case studies of ***Dinerstein v. Google[45] and Google and Ascension's[46] Project Nightingale*** indicate patient privacy issues in the sense of data sharing and AI use.

Beyond the issue of what data is collected, it is important to protect patients from uses outside of the doctor–patient relationship that may have a negative effect on them, such as health or other insurance costs, work prospects, or even personal relationships Any of this would necessitate strict anti-discrimination legislation, comparable to the genetic privacy regimes in place[47] However, some AI health applications, such as those that exchange patient data with family members and friends in addition to the doctor, pose new concerns[48]. Unlike doctors, who are bound by statutory or case-law-enforced confidentiality obligations, family members and associates are unlikely to be bound by those obligations.

(F) GDPR and Artificial Intelligence

Artificial intelligence (AI) advancements, according to some estimates, could enhance global GDP by 14% in 2030, or $15.7 trillion in absolute terms. Governments all over the world have been competing to assist AI development and adoption to profit from this economic boom.

However, how governments manage AI and the huge volumes of digitally recorded data on which AI relies may have an impact on its progress. The General Data Protection Regulation (GDPR) was introduced by the European Union (EU) in 2018 and has been dubbed "the world's toughest privacy and security law" (GDPR). The GDPR establishes a set of data protection rules and applies to all companies that "handle the personal data of EU citizens or residents" or

[44] A.J. London,Hastings Cent Rep. 2019;49(1):15–21. doi: 10.1002/hast.973.
[45] Dinerstein v. Google. No. 1:19-cv-04311; 2019.
[46] R. Copeland https://www.wsj.com/articles/google-s-secret-project-nightingale-gathers-personal-health-data-on-millions-of-americans-11573496790; 2019
[47] Gerke S., Minssen T., Yu H., Cohen I.G. Ethical and legal issues of ingestible electronic sensors. Nat Electron. 2019;2:329–334. doi: 10.1038/s41928-019-0290-6.
[48] Evaluating NFL player health and performance: legal and ethical considerations, Roberts J.L., Cohen I.G., Deubert C.R., Lynch H.F. 2017;165:227–314. Univ Pa Law Rev. 2017;165:227–314.

"offer goods or services to such people," regardless of where they are situated. Can encourage compliance, the GDPR empowers each EU member state's data protection authority—the "independent public authorities that supervise" GDPR implementation—to fine offenders up to 20 million euros, or 4% of the firm's worldwide annual turnover from the previous financial year.

V. MEDICAL NEGLIGENCE AND BIO INNOVATION

Artificial intelligence's development and application in health, aged care, and biotechnology are bringing new opportunities and benefits to health care professionals and customers. AI is already being applied in medical disciplines such as diagnostics, e-health[49], and evidence-based medicine, while the reliability of AI interrogation of free text data fields in medical records appears to be a work in progress. It's difficult to decipher a doctor's handwritten notes.

With the employment of AI in the health-care sector, a number of legal, regulatory, ethical, and social challenges have arisen.

(A) Ethical issues

A number of working groups have been formed to explore ethical problems related to the use of AI in healthcare.

Despite the fact that Australia is not a member of the EU, its medicinal goods legislation closely resembles that of the EU, but less so than that of the US.

Based on the fundamental values enshrined in the EU Treaties and the EU Charter of Fundamental Rights, the following declaration presented a set of basic principles and democratic conditions. These concepts, as well as our thoughts on them, are outlined below.

- **Human dignity** - Human dignity, defined as the acknowledgement of the fundamental human state of being worthy of respect, must not be infringed by "autonomous" procedures. It indicates that there must be (legal) restrictions on how people can be made to feel they are dealing with humans when they are actually interacting with algorithms and intelligent robots[50].

Commentary: Should we inform people that they are interacting with AI in a transparent manner?

[49] A. Esteva, B. Kuprel, R. A. Novoa, and others A. Esteva, B. Kuprel, R. A. Novoa, and others Deep neural networks are used to classify skin cancer at the level of a dermatologist. Nature, 542(7639), 115-118, 2017.
[50] Artificial neural networks in medical diagnostics. Amato F, López A, Pea-Méndez EM, Vahara P, Hampl A, Havel J. J Appl Biomed, vol. 11, no. 2, pp. 47-58, 2013.

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- **Autonomy** - The notion of autonomy indicates that humans have the freedom to choose their own standards. When it comes to delegating decisions and actions to humans, technology must respect their choices.

Commentary: What tasks should we entrust to machines? Surely, the best care comes from a personal touch, and people should be prioritised?

- **Responsibility** - Only build and utilise autonomous systems in ways that benefit the global social and environmental good. AI and robotics applications should not represent an unacceptable risk of harm to humans.

Commentary: This follows the idea of doing no damage.

- **Justice, equity and solidarity** - Global justice and fair access should be aided by AI[51].

Commentary: It's critical to ensure that everyone has equal access to AI's benefits, and that the technology's advantages aren't limited to those countries or those who can afford it.

- **Democracy** - Key decisions should be subject to democratic debate and public engagement.

Commentary: AI should be used in a way that is consistent with community expectations and standards.

- **Rule of law and accountability** - The rule of law, access to justice, right to redress, and the right to a fair trial should provide the required foundation for ensuring that human rights principles and possible AI-specific regulation are followed.

Commentary: In the event of negligence, suitable compensation should be provided.

- **Security, safety, bodily and mental integrity** - External safety for the environment and users, reliability and internal robustness (e.g. against hacking), and emotional safety in human-machine interaction are all aspects of autonomous systems' safety and security.

Commentary: Artificial intelligence in health care should be properly regulated to ensure its safety.

- **Data protection and privacy** - Autonomous systems must not infringe on the right to privacy of personal information, as well as other human rights, such as the right to live without being watched.

[51] ennett CC, Hauser K. A Markov decision process approach to artificial intelligence for modelling clinical decision-making. Artif Intell Med, vol. 57, no. 1, pp. 9-19, 2013.

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Commentary: The preservation of personal information and privacy is crucial.

- **Sustainability** - Artificial intelligence (AI) must be compatible with human responsibility in order to maintain humanity's and the environment's long-term viability.

(B) Duty of Care, Negligence and AI

It will be fascinating to see how negligence and duty of care laws react to this new technology. Who will be held responsible if a patient is injured as a result of the usage of AI? Who was the treating doctor who relied on the SaMD? What is the name of the algorithm's creator? Who is the software's programmer? When there is machine learning in a multi-layered fluid environment and the machine is influencing the output, proving causation might be difficult[52].

Artificial intelligence and machine-learning algorithms are at the heart of a slew of new technologies in the works. AI is quickly becoming the hottest new focus of the tech sector, from self-driving Teslas to in-home assistants like Amazon's Alexa or Google Home. Even outside Silicon Valley, the Berkman Klein Center at Harvard University and the MIT Media Lab are partnering on a $27 million fund to ensure that AI evolves in an ethical and socially acceptable manner. Health-care diagnostics and decision-making are one area where machine learning and artificial intelligence are expected to have a significant impact. Medicine "already does and increasingly will employ the combination of large-scale high-quality datasets with powerful predictive algorithms to uncover and leverage implicit, complicated relationships between numerous patient characteristics," writes Nicholson Price in his piece Black Box Medicine[53]. Doctors will be able to improve the precision and accuracy of their diagnosis and judgments as a result of these links, diagnosing and treating illnesses more effectively than ever before.

The use of AI to medical diagnosis and decision-making, as it develops, has the potential to drastically minimise medical errors and misdiagnoses — and potentially allow diagnosis based on physiological links we don't even know exist. "A large, rich dataset and machine learning techniques enable many predictions based on intricate relationships between patient features and expected treatment results without explicitly identifying or understanding those links," according to Price. Increased reliance on artificial intelligence and machine learning could complicate prospective malpractice lawsuits when doctors seek incorrect treatment as a result

[52] Artificial intelligence in psychological practise: current and future applications and implications, by DD Luxton. 332-339 in Prof Psychol Res Pr. 2014;45(5):332-339 in Prof Psychol Res Pr.
[53] Commun ACM. 2017;60(11):68-78. Riek LD. Healthcare robotics. Commun ACM. 2017;60(11):68-78.

of an algorithm error by moving elements of the decision-making process to an algorithm. In its most basic form, the United States' medical malpractice regime is a professional tort system that holds physicians accountable when the care they deliver to patients deviates from accepted norms to the point of carelessness or recklessness. The system has grown around the concept of the physician as a trusted expert, and it is often assumed that the diagnosing or treating physician is solely responsible for her decisions — and consequently for any negligent or irresponsible treatment provided.

But who is to blame if a doctor follows an AI diagnostic tool's advice and offers incorrect care? It seems unfair to continue to blame the physician if the algorithm has a greater accuracy rate than the average clinician, as many will shortly[54]. Following the algorithm's recommendation would always be the statistically best option, thus it's difficult to claim that a physician would be negligent in doing so, even if the algorithm turns out to be incorrect and the doctor harms a patient. Traditional malpractice conceptions of physician negligence and recklessness may become more difficult to apply as algorithms improve and doctors use them more for diagnosis and decision-making.

Is this anything that we should be concerned about? Medical malpractice laws exist to safeguard patients, and as algorithms play a larger role in medical decision-making, they will become less effective at policing diagnosis and treatment decisions. However, there is grounds to suppose that this could be beneficial.

Medical malpractice liability generates incentives that may not assist individual patients but are detrimental to the health-care system as a whole. For starters, it's uncertain if medical malpractice rules protect patients. According to a new study conducted by Northwestern University researchers, severe malpractice liability regulations are not always associated with improved patient outcomes.

Second, and more importantly, employing AI and machine-learning algorithms to relieve physicians of malpractice liability may benefit the health-care system as a whole by reducing the still-unsolved problem of excessive expenditure on care. Increased malpractice liability for physicians has the unintended consequence of encouraging physicians to practise defensive medicine. Risk-averse physicians often order considerably more diagnostic tests and treatments than a patient's condition merits in order to avoid future litigation. This is an extremely common occurrence. 73 percent of private-sector physicians acknowledged to practising defensive

[54] Artificial Intelligence in Behavioral and Mental Health Care, Luxton DD. Elsevier Academic Press, San Diego, CA, 2016.

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medicine in a 2010 Gallup study. To put that sum in context, it is more than the United Kingdom spends on health care each year. When it comes to bending the cost curve and making the health-care system more sustainable in the United States, reducing the amount of money wasted on unneeded care will be a key goal. While removing culpability from doctors by relying on diagnosis and decision-making algorithms would not completely eliminate the problem of defensive medicine, it will reduce the impact of one of its key drivers in specific clinical contexts.

Artificially intelligent health-care devices are no longer a science fantasy concept. Dr. AI, an AI-powered consumer-facing diagnostic app that patients can download onto their phones. As these algorithms become more common and better, doctors will be able to rely on their improved accuracy and precision, and the resulting reduction in malpractice liability will allow them to avoid ordering every possible test or treatment. Those who pioneered health-care artificial intelligence may not have set out to solve the problem of defensive medicine, but they may have found one[55].

What standard of care should be legally required when AI is utilised is a legal question. What criteria should be used to determine whether or not detrimental results should result in damages?

The law currently assumes that doctors, not machines, make choices. They are in charge of diagnosing and treating patients. Because humans are fallible, things go wrong. They operate based on limited knowledge, their thinking is skewed by cognitive bias, they must make decisions, and they will inevitably make mistakes.

All of this is understood by the courts. They distinguish between decisions that are reasonable, even if they are incorrect, and those that no rational doctor should make. The former can be excused. The latter has been deemed 'negligent.' The Bolam test is a legal test that determines this distinction. AI-based decisions do not fit into this paradigm.

The Bolam test also believes that medical questions can have multiple valid answers. As a result, practise may differ between responsible doctors who hold opposing viewpoints. When this happens, the courts don't decide between competing ways as long as they pass a logical test.

Shouldn't the law need a higher standard if AI has the capacity to make better decisions than human doctors, based on access to a significant amount of data and free of cognitive bias? The

[55] Invisible Women: Exposing Data Bias in a Man-Centric World, published in 2019.

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Bolam test will be useless in this situation. It will be difficult to justify not employing AI if it is both available and proved to be more trustworthy than other methods of decision-making.

Will there be a legal obligation to use AI?

Will there be a legal obligation to employ AI if it becomes the gold standard?

The answer could be influenced by a variety of circumstances.

Then there's the issue of AI's dependability. We have not yet reached the stage where AI beats humans, but we may not be far away, according to recent studies.

Second, there's the question of how far AI will become commonplace in our hospitals for specific procedures. There will come a moment when the outcomes would be so compelling that no respectable physician would refuse to employ it[56]. In other words, if AI isn't used, the Bolam test will fail. Professional groups are likely to issue recommendations on the use of AI, and regulators such as the GMC will play a role at some stage.

Finally, there is the matter of cost. AI will not be cheap, even if it has the potential to save a lot of money. (For example, it may be able to identify people who are at risk for certain malignancies, enable effective screening, detect illnesses early, and lead to better treatment decisions.) All of these could help our health-care system save money by keeping people in jobs and lowering social-care costs.) The courts are already aware that hospitals' ability to offer high-quality care is limited by financial constraints. They do not criticise care where resources are just unavailable (although judicial review can be used to examine the legality of decisions made by public entities, such as how they all work).

Claims resulting from AI errors are anticipated to differ significantly from present clinical negligence claims. The errors we're looking into right now mostly involve human medical judgments or medical mishaps. The utilisation of and quality of data, software programmes, algorithms, and hardware configuration are more likely to be the source of AI mistakes. Investigating these issues will necessitate quite different abilities from lawyers as well as technological evidence rather than medical professionals[57]. We'll almost certainly need to request the help of our technology law colleagues, and we'll have to go to the Technology and Construction Court.

[56] Artif Intell Med. 2014;62(1):1-10. Luxton DD. Recommendations for the ethical use and design of artificial intelligent care providers.
[57] Artificial intelligence in medicine. Ann R Coll Surg Engl. 2004;86(5):334-338. Ramesh AN, Kambhampati C, Monson JRT, Drew PJ.

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Machine learning necessitates the usage of massive data sets. That data is particularly sensitive in the medical field. 'To anonymize the information obtained over the course of your treatment and use it to promote research and enhance care for others,' states the NHS Constitution for England. Maintaining data privacy and secrecy, on the other hand, would be difficult, especially given the massive datasets required for machine learning.

VI. CONCLUSION

In the future years, we will undoubtedly witness advancements in the application of AI, and AI may potentially change the face of medical treatment and decision-making. At the same time, it raises several legal issues. Our current legal system presumes human doctors make decisions and allows for the possibility of human error. The Bolam test presupposes that clinician exercising their judgement will, for good or evil, disagree on the optimum course of action. It also presupposes that doctor, not technology, are in charge of making decisions. For a world where AI and the data programmers, algorithm, and software designers behind it affect decisions, that foundation will need to be reshaped.

We will surely witness breakthroughs in the application of AI in the next years, and AI will surely revolutionize the face of medical treatment and decision-making. Simultaneously, it presents a variety of legal concerns. Our current legal system believes that decisions are made by human doctors, and it allows for the possibility of human error.

In the areas of cancer and diabetes, four of the five largest pharmaceutical and biotechnology companies are presently utilising AI solutions for chronic illness management. Initiatives to improve the patient and clinician experience of chronic illness treatment are smart business from an economic standpoint.

It's worth noting that nothing says "cool and fashionable" like putting "artificial intelligence" on a company's "about" page. While the AI startups we highlighted seemed to meet our criteria for AI competence (i.e., they hire people with advanced degrees and extensive experience in AI), it's safe to conclude that many drug discovery and biomedical firms will exploit the phrase for its sex appeal - even if they don't have a genuine focus on AI.

VII. RECOMMENDATION

- One option is to avoid using the technology in such situations. However, such a "solution" just serves to intensify current disparities. More consideration should be given to regulatory obligations and resource support to ensure that this technology

benefits not only people in high-income countries, but also those in low- and middle-income countries.

- For example, AI developers should be completely honest about the type of data they use and any software flaws (e.g., data bias).
- More therapies could be created, including genomes and proteomics, medicines and vaccines, and drug delivery systems.
- A thorough examination of whether traditional computational analysis and machine learning can compensate for insufficient loss and neglect should also be conducted.

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