BIA submission:
AI and IP
November 2020

About the BIA and IP Advisory Committee

Established over 25 years ago at the infancy of biotechnology, the BioIndustry Association (BIA) is the trade association for innovative life sciences in the UK representing approximately 200 SMEs and larger life science companies as well as over 100 firms and associations that support and service the sector. Our goal is to secure the UK's position as a global hub and as the best location for innovative research and commercialisation, enabling our world-leading research base to deliver healthcare solutions that can truly make a difference to people's lives. We promote an ecosystem that enables innovative life science companies to start and grow successfully and sustainably.

Our members include:

• Start-ups, biotechnology and innovative life science companies

• Pharmaceutical and technological companies

• Universities, research centres, tech transfer offices, incubators and accelerators

• A wide range of life science service providers: investors, lawyers, IP consultants, and communication agencies

The BIA's IP Advisory Committee is composed of leading life sciences lawyers and patent attorneys working in private practice or in-house within the BIA's membership. Further information can be found on the BIA website.[1]

Introduction

This submission addresses the questions in the call for views on patents and also makes comments on database rights relevant to the call for views on copyright and related rights.

There are a number of forms of AI inventions, and no doubt more will arise, but it is helpful to try to categorise them since, as each category develops, each will raise its own legal and patent issues that need to be addressed. The Intellectual Property Owner's Association submission to the USPTO's call for views on patenting AI inventions identified 4 categories of such (potential) inventions (as set out below). In this response, the BIA has sought to adopt and paraphrase these categories for the purposes of illustrating the issues that may arise under UK law in relation to each. The IPOA were explicit in their views as to how each category of AI invention should be viewed according to the current US patent legislation – the BIA IPAC's summary is not intended to be definitive, merely illustrative of the different possible categories of AI-systems. Furthermore, patentable AI systems may employ and combine features from more than one of the following categories therefore the definitions are not intended to be restrictive or limited:

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[1] https://www.bioindustry.org/bia-membership/advisory-committees/intellectual-property-advisory-committee.html

1. "Core AI inventions": The inventive contributions of AI researchers or data scientists developing new AI systems or improving existing AI systems are <u>human</u> activities that can be assessed under existing UK patent law for inventorship and patentability in the same way that other computer implemented inventions are assessed. A person (such as an AI researcher or data scientist) who contributes to the design of an AI algorithm that is the subject matter of a patent application may be eligible to be a named inventor on the patent and the patent application may be assessed as suitable for patent protection provided it fulfils the criteria for patentable subject matter.

2. "Application-Specific AI inventions": Inventors integrating AI components into larger systems can also be assessed under existing UK patent law for inventorship and patentability because their efforts may involve a patentable contribution which applies AI techniques to a new problem. This might involve performing "weighting adaptations," "structuring the data" used by an AI algorithm, or running an AI algorithm on data and obtaining technical results. Such a person may be eligible as a named inventor, sole or jointly, on a patent application provided they are an actual deviser of the invention in question.

3. "AI Generated inventions": Like other forms of technology, AI is a tool that can help human operators through the research and development process to create new products ranging from simple objects such as furniture to complex structural proteins for biopharmaceutical applications. The process of using AI to solve a problem may be technically and intellectually challenging due to the decisions involved in selecting the appropriate AI model, setting up the AI model, selecting and pre-processing suitable training data, training the system, etc. As above, specific activities (e.g., weighting adaptations; structuring the data on which an algorithm runs; and running an algorithm on the data and obtaining results) are illustrative human activities that could justify eligibility of a contribution as an inventor of an AI related invention. Nevertheless, for AI Generated inventions it is the output of the AI system that is the focus of the patent application, rather than the system itself or the manner in which the system generated the output.

4. "Artificial General Intelligence" (AGI) – describes an AI system that can arrive at a desired result based on a general description of the problem or solve problems across disciplines independently. AGI in this form does not currently exist[2].

Response to call for views on patents

Question 1. What role can/does the patent system play in encouraging the development and use of AI technologies?

AI technology has the potential to make important innovative contributions across many areas of technology, especially R&D in life sciences. The patent system is designed to incentivise investment in innovation. AI inventions (in whatever form) can and do benefit from patent protection. Developing useful AI technology, in common with all technological advances, requires significant investment which should be adequately protected to encourage further innovation and investment.

Patent protection for AI inventions can be challenging (according to the traditional hurdles required for patentability prescribed by UK and EPC patent law), enforcement of granted patent rights could be problematic (particularly with respect to obtaining evidence of infringement from within a 'black

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[2] The IPOA comments that "*even if technology sufficiently advances to accomplish a task with little human intervention, it can also be evaluated under existing law. One could view the human invoking AI to solve a problem like a manager giving an assignment to a subordinate*".

box' system[3]) and AI systems are heavily dependent on data, which is itself a valuable asset in raw, pre-AI-processed or post-AI-processed form. Legal protection for data in the form of a database right has become commercially unimportant as a form of enforceable protection (see separate submission on Database Rights at the end of this document). The reason for this is that the way AI developers cleanse, transform, aggregate, and build models from data for AI systems means that protecting the structure (database protection through copyright) or effort involved in maintaining and updating a database (*sui generis* database right protection) is less relevant.

Drug discovery is a key area in which AI related patent protection is likely to become increasingly important. Developing AI technology to discover and develop new medicines or identify new therapeutic applications for existing drugs requires significant investment. Traditional biopharma industry business models rely on patent protection of novel therapeutic molecules and for the identification and development of novel targets or disease states. AI technology will drive the identification of novel therapeutics and other patient-focussed applications. AI technology will increase the speed, efficiency, and accuracy of the drug discovery process and it will reduce patient-safety risks and drug discovery costs. Without AI technology, investment will continue according to the traditional approaches and timescales and consequentially innovation and the delivery of useful results is likely to be slower. Core AI inventions and Application Specific AI inventions should continue to be assessed for patentability on the same terms as other computer based technological advances, the protection of which should not be watered-down. Whereas, AI Generated inventions (and in the future AGI inventions) could be better assessed on the same basis as human-conceived inventions and patents granted where the statutory criteria are fulfilled.

Question 2. Can current AI systems devise inventions? Particularly:

A) **to what extent is AI a tool for human inventors to use?**

Currently, AI is primarily a tool for human inventors to use. As with other novel and inventive technological development, such tools should be adequately protected by the patent system provided they qualify for protection.

What is new and challenging about AI technology is that the technology may have the capacity to produce new and patentable subject matter itself (see above for AI Generated inventions and AGI in the future). This raises a question about whether an AI system's contribution to inventorship can and should be acknowledged (see below at Q3).

B) **could the AI developer, the user of the AI, or the person who constructs the datasets on which AI is trained, claim inventorship?**

According to current UK patent legislation[4], a patent may only be granted to the inventor(s) (subject to their agreement to contract out or through a provision of law) who are the "actual deviser(s)" of

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[3] The black box problem in AI is that the way an AI system may arrive at a solution or output is unknown to the creator/programmer. *"…for the first time, computers are no longer merely executing detailed pre-written instructions but are capable of arriving at dynamic solutions to problems based on patterns in data that humans may not even be able to perceive…"* Bathaee, Y [2018] Harvard Journal of Law & Technology Vol 31, 2, Spring 2018. https://jolt.law.harvard.edu/assets/articlePDFs/v31/The-Artificial-Intelligence-Black-Box-and-the-Failure-of-Intent-and-Causation-Yavar-Bathaee.pdf

[4] S.7(2) Patents Act 1977

the invention. The question of inventorship is a question of substance not form and when inventorship is challenged the legal position is resolved by adducing evidence of the facts leading to the invention. There is no logical or policy basis for changing this well settled approach and to do so would alter the equilibrium of the patent system more generally. Therefore, if the AI developer, the user of the AI, or the person who constructs the datasets on which AI is trained is, in fact, an **actual deviser** of **the invention** then they should be entitled to be named as an inventor. That is, in accordance with the current law, only those that produce or contribute to an invention as actual devisers can be recognised as inventors or joint-inventors.

C) **are there situations when a human inventor cannot be identified?**

Whilst there is a legal requirement for the inventor to be the actual deviser, it is conceivable that as AI technology advances, the need for human input (through conscious decision making and guided selection – (Application-Specific AI inventions and AI Generated Inventions as defined above) is relatively less significant than the contribution of the AI system to the inventive advance. In such cases it is possible that, but for the contribution coming from an AI system (which does not of course have the legal status of a natural person), the contribution of the human would not qualify that person as an actual deviser according to the legal test of inventorship.

Further, whilst it is likely that there will almost always be an opportunity to identify a human to name as an inventor through some nexus with the AI system[5], whether that person is the 'actual deviser' according to the statutory test is a question of fact. It is conceivable that in some situations an AI system could be the 'actual deviser' in preference to the arbitrarily identified human, perhaps named purely for the purposes of making the application.

The dilemma is illustrated by the comment from the IPOA at footnote 1: "*even if technology sufficiently advances to accomplish a task with little human intervention, it can also be evaluated under existing law. One could view the human invoking AI to solve a problem like a manager giving an assignment to a subordinate*". However, this approach presupposes that the manager would necessarily be entitled to be named inventor over, or in addition to, the subordinate; whereas according to s.7 Patents Act 1977, if the actual deviser of **the invention** was the subordinate then they would be the inventor under the current law, irrespective of their place in the corporate hierarchy. If the manager was not an actual deviser then they would not be entitled to be named inventor, irrespective of their position. In summary, requiring a human who is not the actual deviser to be named as inventor in order to allow a patent application to proceed appears contrary to s.7 Patents Act 1977.

Question 3. Should patent law allow AI to be identified as the sole or joint inventor?

If an AI system is in fact the actual deviser of the invention, in principle it seems appropriate that the patent law should allow such an AI system to be identified as a sole or joint inventor[6].

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[5] For example, the designers and or programmers of the AI system – of which there may be many tens if not hundreds of individuals.

[6] The issue of inventorship is separate to ownership. For the avoidance of doubt there is no suggestion in this call for the BIA's views that the law should allow AI systems to be owners of any patent or application.

There would be no need, just as there is no need today, to separate out contributions between named inventors, but it should remain important to accurately recognise all contributions where inventive.

However, this is a policy decision that would require a change to the s.7 Patents Act 1977 requirement that an inventor be a 'person'[7]. Or a change to the s.7 Patents Act 1977 requirement that only the actual deviser of an invention can be named as inventor. However, on the latter, as stated above at Q2(b), there does not appear to be any logical or policy basis for changing this well settled approach. Any modification to the definition of 'person' according to s.7 should be strictly limited to AI systems in the context of this issue, to avoid any unintended widening of the concept to other non-human inventors.

A patent system that allows the naming of an AI system as sole or joint inventor[8] avoids the need for applicants to engage in a legal fiction in circumstances where, in fact, no human contributed to the invention. Whereas if the patent system is not capable of recognising an AI system as inventor, a human inventor must be notionally identified. Otherwise, on current required formalities, any application would fail. There are also further potential ramifications of this legal fiction if third party challenges are made on inventorship and entitlement. For example, what happens if inventorship is successfully challenged (under s.13(3) Patents Act, any person may challenge the naming of an inventor) and the human inventor has to be removed but the AI system that devised the invention is not able to be named as inventor?

By recognising an AI contribution to inventorship of a patent application, all inventive contributions to the invention can be identified. A patent system that does not allow such identification will be a system that encourages applicants to obfuscate as to the true inventor and the inventive contribution. In the interests of transparency, accuracy and the disclosure and development of AI technology, AI contributions should be reflected on the record.

Contributions (either sole or joint) to the invention are currently most likely to come from AI Generated Inventions. These are the AI systems currently being applied to drug discovery endeavours in the life sciences sector and for which patent protection (i.e. of novel drug molecules, the novel application of existing drugs to new disease states etc.) is critically important.

However, there are strict requirements in some jurisdictions for the correct inventor to be identified, to formally assign the patent to their employer, and where failure to do so potentially renders the claims invalid. In the latest release of China's Draft Revised Patent Examination Guidelines (10 November 2020), the guidelines were amended to specifically exclude AI as an inventor[9]. This approach mirrors the USPTO petition decision denying DABUS to be listed as an inventor[10], and the IPOA also had little appetite to change the status quo on this issue. A tension will be created where one patent system recognises an AI inventor (because it is in fact the actual deviser according to the applicant) and another patent system that does not recognise non-natural

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[7] See discussion of Mr Justice Marcus Smith in *Thaler v Comptroller-General of Patents* [2020] EWHC 2412 (Pat)

[8] There is no reason why the AI system has to be given a name (i.e. DABUS as per *Thaler v Comptroller-General of Patents* [2020] EWHC 2412 (Pat).

[9] Chinese National Intellectual Property Administration, Notice on the Public Consultation on the Draft Amendments to the Guidelines for Patent Examination (Second Draft for the Solicitation of Comments) https://www.cnipa.gov.cn/art/2020/11/10/art_75_154712.html.

[10] United States Patent and Trademark Office, U.S. Patent Application No.: 16/524,350 "Devices and Methods for Attracting Enhanced Attention", Decision on Petition..

persons as inventors (and so requires a person to be arbitrarily nominated even where the applicant does not, as a matter of record in another jurisdiction, regard that nominated person as the actual deviser). Absent an internationally harmonised approach, problems complying with the formalities of international patent applications arise.

Question 4. As AI technology develops further and becomes more 'intelligent' and better trained on larger data sets, human input is likely to be reduced, making it increasingly difficult to identify a human inventor as the actual deviser. Consequently, this question is likely to become increasingly less academic and should be addressed sooner rather than later.If AI cannot be credited as inventor, will this discourage future inventions being protected by patents? Would this impact on innovation developed using AI? Would there be an impact if inventions were kept confidential rather than made public through the patent system?

One of the goals of the patent system is to facilitate innovation through public disclosure of invention. The *quid pro quo* for disclosure by the patentee is a limited exclusive right. If, as a matter of form or substance, a patent for an AI related 'invention' is unobtainable, the 'invention' may not be disclosed as protection by way of confidentiality and trade secrets is relied on instead. However, in biopharma, patents are usually very important, in particular for SME to secure the investment needed to continue to exist and invest in the research and development needed to achieve a specific healthcare goal. Although it may be said that investors should be more realistic in this regard, in such a field, it can be appreciated that an SME's confidential know how and trade secrets may not provide the same confidence to invest as compared to filed and/or granted patents.

Notwithstanding this, in respect of, *inter alia*, the application of AI to drug discovery, the development of therapeutics and medical devices, and the identification of novel diseases for treatment from large patient data sets etc. - no matter what the AI related 'invention' (which may or may not be disclosed depending on the likelihood of obtaining patent protection as a matter of form or substance), to get to market, any novel therapeutic or medical device will be subject to regulatory required testing and disclosure of the product characteristics in the regulatory file.

Question 5. Is there a moral case for recognising AI as an inventor in a patent?

If humans are required to be named as an inventor when in fact they have not contributed inventively, a moral issue arises: 'actual' or 'true' human inventorship would be undermined by deemed or pseudo-inventorship of those 'inventors' nominated on AI invention patents.

Attribution as 'inventor' for merely pressing a button or by virtue of ownership of an AI system when no contribution to the technical inventive advance as actual deviser had in fact been made would devalue the contributions of 'actual' or 'true' human inventors in the field.

Notwithstanding this, if a person uses an off the shelf AI system and/or presses a button to create a downstream invention through use of that AI system, then there could still be an inventive human contribution depending on the factual circumstances. For example, if they chose the particular algorithm from thousands of others using scientific reasoning that is not obvious, then they might be regarded as the inventor for having exercised inventiveness in combining the task at hand with that particular algorithm. In contrast, if the combination can be made simply by trial and error from a limited number of obvious choices, pressing a button may indeed not be enough to contribute to

the invention as an actual deviser. As always, this assessment should remain a question of fact and can be judged by the existing patent law.

Question 6. If AI was named as sole or joint inventor of a patented invention, who or what should be entitled to own the patent?

The starting point in relation to ownership of a patent is to identify who came up with the inventive concept (the actual devisor(s) of the invention) as discussed above in connection with Q2. The person or people identified is/are entitled to be named as the inventor(s) and is/are primarily granted ownership of the patent (subject to their agreement to contract out or through a provision of law). Currently, only natural or legal persons can apply for patents or transfer to another the right to apply for a patent and ownership of an AI system is not sufficient to give rise to the right to apply for a patent for an invention. Therefore, if an AI system could be named as a sole or joint inventor (rather than this being limited as it currently is), there then follows an issue with the ability to apply for a patent in any event. However, as already stated, BIA does not suggest that the law should allow AI systems to be owners of any patent or application.

Under s.9(3) of the Copyright, Designs and Patents Act, where no human author can be identified for a computer-generated work, the person who made the arrangements necessary for the creation of the work will be considered the author of the work. There is also a similar provision under the Registered Designs Act.   Also, companies can apply for patents since by virtue of s.39 Patents Act 1977, ownership of patents arising in the course of their employees' employment, belong to the employer.

In light of these provisions, it seems entirely feasible and appropriate, by way of a suitably crafted provision, to provide for AI inventions arising from an AI system to be deemed to be owned by the 'employer' (as a corporate legal entity commissioning the AI task) or by natural persons (as human controllers of the AI system). Such a provision, in combination with a limited change to s.7 of the Patents Act to allow for an AI system to be an inventor, are proposed to address these issues brought to the fore by the Thaler/DABUS test cases.

AI systems can be licensed by AI owners to third parties. AI licensees and licensors should be free to agree where ownership should flow according to commercial agreements. In the same way as (absent agreement to the contrary) ownership of IP rights flow to an independent contractor contracted to perform a specific task, the default position in law should be that the licensor of the AI system should own its output.

Question 7. Does current law or practice cause problems for the grant of patents for AI inventions in the UK?

AI related patents can already be obtained as "Computer Implemented Inventions" ("CIIs") provided that they fulfil the requirements of the EPC/UK Patent law and that they demonstrate the required technical effect for patentability.

AI patent applications for Core AI Inventions and Application-Specific AI Inventions are not, and should not, be treated differently to other computer-based patent applications at the EPO and national patent offices. If a traditional computer-based invention is judged not to qualify for patent

protection, for example falling foul of the exclusions of Article 52(2) and (3) EPC, forbidding patenting of a computer program "as such", then protection is still available through copyright in the code, or through trade secrets protection. Patents employing AI technology (Core AI Inventions and Application-Specific AI Inventions) should continue to be judged on the same basis as other computer-orientated technological advances where there is freedom to rely on the most appropriate IP protections depending on the nature of the system.

The key issue for patent offices internationally is to seek to align to a more harmonised standard for the patentability of CIIs – in particular if the UK is perceived as a less favourable jurisdiction for CIIs then this is likely to discourage AI research and development in the UK. This will be particularly important after Brexit to retain and encourage investment in AI technology in the UK.

Question 8. Could there be patentability issues in the future as AI technology develops?

Possible future patentability issues include:

- As the use of AI systems increases in a particular industry it will be more likely to be used by real-life researchers. Consequently, AI will become one of the standard tools available to the notional ordinary skilled person for the purposes of assessing inventive step. The benchmark level of the knowledge and capacity of the ordinary skilled person increases as AI systems process data outside of narrow disciplines and ever greater bodies of art are accessible or considered common general knowledge. As a result, the threshold for the knowledge of the skilled person increases with the advancement of AI technology and the inventive step hurdle rises. As with all developments in technology there will be a period of overlap, with some adopting AI systems earlier than others. An issue then arises where an inventor that has not yet adopted the use of AI systems is benchmarked against an ordinary skilled person that is held to have AI at their disposal and is at a disadvantage.
- The flooding of the patent system by AI Generated inventions as AI systems become more sophisticated, process more data and derive previously unidentified patentable insights at a faster rate.
- Resource-rich companies (e.g. big tech and big pharma companies) could monopolise technology and patent landscapes with patent thickets around core inventive AI advances.

However, the natural counterbalances to these possible issues, inherent in the current patent system, are:

- Patent law is naturally flexible. The benchmark level of knowledge and capacity of the ordinary skilled person evolves alongside industry practice. The move towards the use of AI systems will be akin to the move from paper publications to the use of digital databases in the scientific community.
- As today's AI technology becomes a commodity, the threshold of the knowledge and capacity of the ordinary skilled person aligns and it is not possible to obtain patent protection for inventions created by technology that everyone has access to. However, new advances in technology will be able to produce different types of invention which will continue to be patentable until that technology becomes commodity.
- The cost of filing and maintaining patents still provides an effective barrier to flooding the system. Weak patents that have little commercial utility are unlikely to be maintained for their full term.

Question 9. How difficult is it to secure patent protection for AI inventions because of the list of excluded categories in UK law? Where should the line be drawn here to best stimulate AI innovation?

The list of excluded categories in UK patent law does not itself pose a problem. The list mirrors that of the EPC. Nevertheless, how the exclusions are implemented in UK law causes a variation in approach between different technical fields. For example, AI performing image classification will not normally be caught by the exemptions, whereas AI performing classification of a text document will often be caught by the exemptions. The implementation of the exclusions by the UK IPO will often cause variations between the UK IPO and EPO. To stimulate AI innovation, the approach of the UK IPO needs to be harmonised with the EPO. Requiring an EPO filing as opposed to a direct UK filing for certain subject matter just to allow the applicant to protect in the UK is not a good platform upon which to stimulate AI innovation in the UK.

Furthermore, the current view that the UKIPO takes of the "technicality" of AI, and in particular machine learning, often represents a problem for the protection of Core AI inventions. Because the UKIPO (as well as the EPO) do not see machine learning as such as a technical field with many possible applications, but rather as abstract mathematical methods, Core AI inventions are currently not protectable by patent in the UK (although they could still attract some narrower protection for specific technical applications). The problem is that Core AI inventions typically find wide applications in many areas, so that protection for only a limited application is not commensurate with the potential value and contribution of Core AI inventions. As a result, innovation in this area may be kept confidential to the world at large as industry actors will prefer to keep Core AI advances secret rather than to disseminate the innovation in a patent of limited scope. Fundamental advances in an AI field that would be beneficial in a wide range of applications therefore risk not being disseminated to the detriment of the public.

AI and machine learning are widely applicable enabling technologies in the same way as advances in general purpose computing have been. Core AI innovations are more likely to become protectable when AI becomes recognised as a technology, in line with its real-world applications, rather than merely abstract mathematics and therefore excluded subject matter.

Such an approach of treating AI as a technological field in itself would not be ground-breaking, as it is the approach taken by the UKIPO (and also the EPO) in relation to cryptography, which is seen as a widely applicable technology (applicable to secure computer network communications, secure stored data, authentication of data, proofs of origin, etc.) and not an abstract mathematical method per se. There is a close analogy between how the mathematical machinery of cryptography is used in reality as an enabling technology in many fields and the applications of AI and machine learning today. Treating fundamental computer technologies, like cryptography and AI, consistently across the board as technical fields rather than abstract mathematics would enable the protection of Core AI inventions to encourage further investment in research and development as well as public dissemination of technological advances to the public in this important and widely applicable area of technology.

Question 10. Do restrictions on the availability of patent rights cause problems for ethical oversight of AI inventions?

The issue of ethical oversight is an issue of proper regulation of the uses of and applications of new technology by governments, companies and individuals. Such regulation must scrutinise the practical applications of technology (AI or otherwise) for anti-social or malign purposes. For example, use of facial recognition to characterise people on the basis of likely criminal tendencies[11] etc. This is not something that should fall on the shoulders of a patent regime. In any event, s.1(3) Patents Act 1977 is a broadly applicable exclusion that can be used to filter out the most obviously unethical applications[12].

From the BIA's perspective, therapeutic applications of AI Generated inventions will be heavily regulated in any event and therefore there is already a strong check and balance in place in respect of ethical and regulatory oversight.

Question 11. Does the requirement for a patent to provide enough detail to allow a skilled person to perform an invention pose problems for AI inventions?

Disclosure in the patent specification must be sufficient for the skilled addressee to work the end result of the claimed invention based on the patent disclosure and their common general knowledge. The patent specification must contain sufficient information to enable the invention to be worked across the scope of its claims. This hurdle should remain consistent across all inventions.

If AI contributes to or identifies an invention output (e.g. a novel drug molecule identified by an AI Generated invention) and the patent specification provides sufficient information to produce the output (the novel molecule) based on common general knowledge and the disclosure of the patent, there is no additional need to disclose the precise details of the AI system that led to the identification of the novel molecule. In such circumstances, there should be no issue relating to the AI system that presents a problem in meeting the requirement for an enabling disclosure.

Conversely, if the claimed outputs incorporate particular AI systems (e.g. a method for in-silico design of a drug molecule which employs Core-AI inventions or Application-Specific AI inventions), then the invention will require such AI systems to be disclosed and enabled in the patent application, and/or that they must comprise part of the common general knowledge. Otherwise the patent will be insufficient.

Question 12. In the future could there be reasons for the law to provide sufficient detail of an AI invention for societal reasons that go beyond the current purposes of patent law?

Consequential regulation that governs these questions should be the focus of current and further regulatory law and not patent law.

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[11] "Automated Inference on Criminality using Face Images" Wu & Zhang https://arxiv.org/pdf/1611.04135v1.pdf

[12] "A patent shall not be granted for an invention the commercial exploitation of which would be contrary to public policy or morality."

Question 13. Does or will AI challenge the level of inventive step required to obtain a patent? If yes, can this challenge be accommodated by current patent law?

The inventive step requirement should be maintained. It is an essential indicator that a contribution is worthy of patent protection, regardless of the person or entity responsible for the inventive step. However, it might be that if AI inventorship is recognised, the bar of a person skilled in the art needs to be reconsidered. Arguably as AI systems become common-place the commodity AI systems become a CGK tool. This will not diminish a technical advance made through the development of a novel and more refined AI system. See response to Q8 – the patent system already has the flexibility to self-correct as technology advances[13].

Question 14. Should we extend the concept of "the person skilled in the art" to "the machine trained in the art"?

One area which will require review is the inventive step assessment, and in particular, whether the 'person skilled in the art' evaluation is fit for purpose in light of AI inventions. It may be that the test – from a perspective of no inventive skill or ingenuity and having common general knowledge of the field - needs to be redefined when AI has contributed to or generated the invention.
If AI can be an inventor, AI should also have the capacity to be benchmarked according to the level of the ordinary skilled person where such AI is commonly used in the field. Similarly, AI generated content should qualify as prior art so long as it is available in the same way as human generated prior art and made available to the public and free in equity and law to be used by the skilled person.

Question 15. Who is liable when AI infringes a patent, particularly when this action could not have been predicted by a human?

It seems appropriate that liability should be determined in the same way as suggested for ownership for original AI Generated and AI assisted inventions (assuming AI can be recognised as an inventor - see Q6 above). As such, liability should rest with the entity or person controlling the AI. It will be important to consider when the acts of infringement occur. For example, where an AI system identifies a novel drug candidate in its output that is already protected by a patent, an infringement will arise only when any of the normal prohibited acts are carried out (make, dispose of, offer to dispose of, use or import the product or keep it whether for disposal or otherwise)[14]. In this scenario, the AI system identified is not carrying out the infringing acts in any event.

Question 15. Could there be problems proving patent infringement by AI? If yes, can you estimate the size and the impacts of the problem?

In respect of AI Generated inventions there will be no increased difficulty of proving patent infringement since the AI is used in the process of reaching the invention but is not a component of the invention.

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[13] Although not within the scope of this call for views, some BIA members consider that a review of whether the patent system is the best way to protect drug products resulting from AI will be warranted in due course. The issues raised by AI-Generated inventions may indicate that rewarding the investment into discovering new therapeutics and encouraging further research is better achieved through a time-limited monopoly, maybe based on orphan drug protection or regulatory exclusivity, rather than trying to apply human concepts of 'invention' and 'inventiveness' to the complex processing of data by AI-systems.

[14] According to the acts of infringement as set out in s.60(1)(a)(b)(c) Patents Act 1977

In respect of Core-AI inventions and Application-Specific AI inventions there could, on the face of it, be an issue with respect to explaining the "black box" features of an AI system, for example proving infringement of a process patent by an AI system could be an issue. However, "black box" does not necessarily mean "we can't see or don't know how it works", rather it often means "it works in a way that can't easily be explained". For example, the AI system may stratify a patient population into groups to differentiate the patients, but our current knowledge of physiology might not be able to explain the endotypes that underlie the categorisation. Or, an AI system predicts fact X but our current knowledge cannot identify the exact data it used to reach that conclusion.

These factors will not be an issue if disclosure of the features of the accused systems can be given at the level of generality of the claims of the infringed patent.

The current procedural rules on disclosure in patent cases are likely to be adequate and flexible enough to flush out a sufficiently detailed understanding of the accused AI system such that the patentee can determine whether there is an arguable case on infringement.

If the integers of the patent claims are, on the face of it, present in the allegedly infringing product or process and there is an arguable case on infringement, disclosure in the form of a detailed product and process description will most likely be sought and ordered to reveal detail on the unknown features.

Database Rights (relevant to the call for views on copyright and related rights)

The output from an AI system is only as good as the quality and relevance of the data inputted, which is used for training, processing and from which new information and insights may arise. Data suitable for an AI system can be at various levels of processing: it can be a valuable asset in raw, pre-AI processed or post-AI processed form. Therefore, whilst it is important that the UK IP regime protects new and inventive AI technology to encourage continued investment for research and development of AI technology, equal consideration should be given to adequate protection of 'data' which is the food on which AI systems are fuelled.

In terms of IP protection, data can be protected by (i) contractual access to a confidential and proprietary data set (that can be licensed according to the principles of confidentiality and trade secrets) or (ii) by the narrower *sui generis* database right (protecting the **investment** in obtaining or verifying data within the database) or (iii) by an even narrower scope of copyright which protects the literal representation of data in a database as a copyright work.

Legal protection for data in the form of a database right has become commercially unimportant or irrelevant as a form of enforceable protection for AI developers. The reason for this is that the way AI developers cleanse, transform, aggregate, and build models from data for AI systems means than protecting the structure (database protection through copyright) or effort involved in maintaining and updating a database (*sui generis* database right protection) is less relevant.

When the database right[15] was incorporated from EU law into UK law there was uncertainty as to the precise scope of what features of 'a database' or 'data' *per se* would be protected. It has slowly been clarified through European case law. The CJEU has consistently driven the interpretation and scope of database rights to an increasingly narrow enforceable right. In *Fixtures Marketing v Organismos prognostikon agonon podosfairou (OPAP)*[16], the right was interpreted such that protection was limited to 'primary' producers of databases. If database production was only secondary to the main activity of an entity, the database is to be excluded from protection. In *Ryanair Ltd v PR Aviation BV*[17], the CJEU determined that mandatory rights of usage by users of databases were "not applicable to a database which is not protected […] by the *sui generis* right", and that contractual provisions should govern the use of such databases. This, in effect, made it preferable for database owners not to seek to fulfil the requirements of database protection and instead to rely on contractual protection. Given such narrow treatment of the right by the CJEU, it is no surprise that the European Commission later found that database rights have not yet materially stimulated the creation and maintenance of databases or stimulated meaningful investment in a European database industry.[18]

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[15] Copyright and Rights in Databases Regulations 1997 (the "Regulations"), which implemented into UK law the provisions of European Directive 96/9/EC on the legal protection of databases.

[16] *Fixtures Marketing v Organismos prognostikon agonon podosfairou (OPAP)* (Case C-444/02) [2005] ECDR 3.

[17] *Ryanair Ltd v PR Aviation BV* (Case C-30/14) [2014] ECLI:EU:C:2015:10.

[18] European Commission. Commission Staff Working Document: Evaluation of Directive 96/9/EC on the legal protection of databases (25 April 2018); European Commission, DG Internal Market and Services Working Paper: First Evaluation of Directive 96/9/EC on the Legal Protection of Databases (12 December 2005).

As the UK prepares to leave the EU, an opportunity arises for new legislation to support strategically important areas such as the life sciences sector and AI technology. Database law (alongside SPC law) could be freed from the uncertainties of CJEU interpretation and is then open to reform and clarification at a national level such that an appropriate level of clearly defined protection can be achieved to encourage investment in the UK.

As data has different attributes depending on the context in which it is used, the focus may need to move from the value of the data itself towards the value of the outcome that can be achieved with the data. These considerations can be addressed by way of modernising commercial models/terms under which protected data is licensed (following the Tech sector). However a first step may be to improve protections in place to protect databases and the data within them.