ABPI Submission to the IPO on Artificial Intelligence and Intellectual Property: Copyright and Patents

January 2022

About the ABPI

The ABPI exists to make the UK the best place in the world to research, develop and use new medicines and vaccines. We represent companies of all sizes who invest in discovering the medicines of the future.

Our members supply cutting edge treatments that improve and save the lives of millions of people. We work in partnership with Government and the NHS so patients can get new treatments faster and the NHS can plan how much it spends on medicines.

Every day, we partner with organisations in the life sciences community and beyond to transform lives across the UK.

For more information, please contact [redacted]

Introduction

In 2020, the pharmaceutical industry invested £5 billion into R&D in the UK: the leading sector for overall investment and representing almost one-fifth of R&D spending across all sectors.[1] Correspondingly, the sector also employs 129,900 people, providing highly skilled jobs and contributing a turnover of £61.3 billion in 2020 to the UK economy – driving productivity, spurring knowledge creation and facilitating research to deliver innovative medicines to patients.[2]

Although perhaps in its infancy, the use of artificial intelligence (AI) in life science innovation is important and growing. It is being used, for example, to increase knowledge of diseases and help identify candidate products to treat them, for the early detection and diagnosis of disease, or patient monitoring in real-world settings. Its potential to further contribute to innovation across the life sciences sector and the whole life sciences lifecycle, from research through to patient treatment, is enormous.

The ABPI believes the government's approach to AI and intellectual property (IP) needs to meet three objectives:

1. Unlock the opportunities presented by AI to further the UK's ambition to become a science superpower, by stimulating innovation and creativity, which ultimately translates into faster and more advanced discovery and development of pioneering therapies for patients, as well as benefitting the UK economy.

2. Account for the international direction of travel of this topic by working with like-minded countries to ensure that the UK's IP framework for AI technologies does not substantially differentiate to the detriment of UK innovation, and is strategically aligned where

[1] **Business enterprise research and development, UK: 2020.** Office for National Statistics (November 2021).
[2] **Bioscience and health technology sector statistics 2020.** Office for Life Sciences (December 2021).

necessary. This will ensure that the UK remains competitive with other countries/legal jurisdictions in terms of AI access and investment.

3. Recognise the importance of maintaining a strong IP framework for the UK's innovative, R&D-intensive sectors. As such, any changes made as an output of this consultation exercise must not undermine IP rights, but provide an appropriate balance for rights holders to exercise these rights, support their business models and encourage the development/uptake of AI across the UK.

Section A

Copyright – computer generated works

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Copyright – text and data mining (TDM)

Introductory remarks

Life sciences research is becoming increasingly interdisciplinary, with a combination of data science, AI and cutting-edge engineering techniques revolutionising the R&D process. TDM offers distinct value and drives important aspects of medicines discovery and development, through maximising the ability to use text and data deriving from research to empower further R&D and R&D investment decisions.[3]

Recognising the strategic importance of TDM for the UK's leadership in AI, the government's approach must balance the incentives for those to create the copyright works (such as published articles and databases) and the interests of those wishing to use the copyright works for TDM, and provide clarity for both rights holders and those who would like to lawfully access text and data for mining purposes.

Q6. *If you license works for TDM, or purchase such licences, can you provide information on the costs and benefits of these? For example, availability, pricing, whether additional services are included or available, number and types of works covered by the licence. Please also consider the benefits that TDM provide to you and your colleagues.*

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Q7. *Is there a specific approach the government should adopt in relation to licensing?*

At present in the UK, the limited copyright exception for TDM only applies to non-commercial research. This means that negotiating licenses is a pre-condition of TDM activities undertaken by commercial life science researchers, to ensure that they have lawful access to the work to be mined.

Although the ABPI fully supports the need to safeguard the interests of rights holders, it is also important for the UK's approach to TDM for commercial research to redress any current imbalances and/or unnecessary uncertainty in the framework for both rights holders and those

[3] **The role of data science and text mining in the search for new therapies.** pharmaphorum (April 2021).

who would like to lawfully access text and data for mining purposes, and does not fall behind competitive economies.

As further elaborated upon in our answer to question 8 below, we believe there is an opportunity for the government to adopt a different approach to the UK's copyright exception for TDM, which addresses imbalances in the current system and offers clarity for rights holders and those wanting to engage in TDM activities.

Q8. *Please rank the options in order of preference (most to least preferred) and explain why.*

Our preferred option is to adopt a TDM exception for any use, with a rights holder opt-out (Option 3) and agree that the exception should cover both copyright works and those protected by the database right.

TDM is already used to deliver great benefits to researchers working in the private sector and within public-private partnerships across the broader research ecosystem, and consequently, this positively impacts patients, publishers and the UK economy. However, the UK has barriers to TDM not present in competitor economies, and an extended and appropriately crafted TDM exception with an opt-out for rights holders would enable UK innovators to have more straightforward access to textual information, data and databases: to incentivise the undertaking of increased TDM activities in the UK research environment, while preserving the interests of copyright holders.

The benefits of the UK moving to this model are as follows:

1. **Aligns the approach to commercial and non-commercial research, removing uncertainty for public-private collaborations:** for the UK to become the best place in the world for life sciences research and innovation, including in AI, it requires the fostering of a collaborative research culture, where individuals and institutions have the resources, opportunities, and incentives to deepen the current knowledge base and perpetuate an ever-deeper exchange of ideas between the commercial sector and the non-commercial sector (including academia). This stimulates innovation and creativity, which ultimately translates into faster and more advanced discovery and development of pioneering therapies for patients, as well as contributing to the UK economy.

   Over recent years, biopharmaceutical companies have increasingly been engaging in cross industry-academia and industry-public collaboration and engagement. These public-private partnerships (PPPs) play a key role in the broader research and innovation ecosystem, and support long-term, multi-party partnerships that can tackle strategic health system challenges, requiring the pooling of knowledge and resources to devise solutions that bring considerable health benefits.

   Such partnerships may involve one or more parties requiring access to information for TDM purposes. At present, there is an unclear delimitation between non-commercial and commercial research under the existing exception, which may involve public sector research organisations and private biopharmaceutical companies, as to whether or not they are 'commercial' in terms of intended output. This creates constraints for the real-world application and use of TDM to the fullest extent (legally permitted) within PPPs.

2. **The narrow scope of the government's non-commercial research exception places the UK at a competitive disadvantage:** other jurisdictions, such as the European Union (EU), the United States, Japan and Singapore, have opted to broaden copyright exceptions to include commercial research activities. This makes the use of TDM for commercial research easier to undertake in other countries that are competing with the UK for AI investment, adversely impacting the international competitiveness of the UK. We believe that moving to this model would create a level playing field on TDM with other jurisdictions and provide a more conducive environment for TDM and uptake of AI technologies in the UK.

3. **Provides a balanced approach for both rights holders and TDM users:** as noted above, we acknowledge the need to safeguard the interests of copyright and database right owners in order to provide incentives to create copyright works and databases, so suggest that a rights holder should retain the ability to opt out if they do not want their text/data used in mining activities under the exception. We would also emphasise that an extension of the copyright exception should not affect other IP rights held by the rights owner in respect of the work (e.g., confidentiality).

   Correspondingly, rights holders should be given an option to opt out in an appropriate and clear manner, such as the use of a machine readable opt-out for publicly available works. This is important to build and bolster trust, and clarity, in the legal framework underpinning TDM for **all** users and rights holders.

Brief comment on the other policy options proposed (<u>please note that these have not been ranked in order of preference</u>):

- **Option 0 – Make no legal change:** for the reasons we have listed above, the ABPI believes that maintaining the status quo would leave the UK at a competitive disadvantage to other countries which already have more TDM-friendly copyright legislations, and a new approach would benefit the UK's international standing as a leader in AI.
- **Option 1 – Improve licensing environment for TDM**: although steps to improve the licensing environment to benefit both rights holders and users should be carefully considered in addition to a change in the TDM exception, this option alone would not result in an aligned approach for commercial and non-commercial research and would fail to deal with issues faced when TDM is used as part of PPPs. Furthermore, it would see the UK as taking a different direction to other jurisdictions, impacting the competitiveness of the UK in this space.
- **Option 2 – Extend the existing TDM exception to cover commercial research:** although we fundamentally support this option, we believe the restriction to 'research' purposes, rather than 'any use', could result in missed opportunities for those who would like to undertake TDM activities in order to capitalise on the innovative output which it could provide across a range of sectors and interests.[4]

[4] As captured on page 25 of the IPO Impact Assessment, in assessing the potential benefits of Option 3 for TDM users. **Consultation stage impact assessment on Artificial Intelligence and Intellectual Property.** Intellectual Property Office (October 2021).

- **Option 4 – Adopt a TDM exception for any use, which does not allow rights holders to opt out:** the ABPI recognises the foundational role IP rights play in promoting and protecting innovation. For this reason, **this is our least preferred option** as this measure would disproportionately affect rights holders, undermine incentives to create copyright works and databases, and threaten the integrity of an IP framework intended to be balanced and fit for purpose in an increasingly digital and data-driven world.

Q9. *If you have experience of the EU exception with opt out for rights holders, how has this affected you?*

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Q10. *How would any of the exception options positively or negatively affect you? Please quantify this if possible.*

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Patents

Introductory remarks

Patents are a mechanism vital to enabling the development of cutting-edge medicines and sustaining future innovation. Developing medicines and vaccines is a uniquely high-risk, capital-intensive, and time-consuming process. For every 10,000 compounds that are tested, only one or two will successfully pass all stages of R&D and clinical trials to become marketable medicines.[5]

The complex and risky process of developing medicines and vaccines is supported by the incentive of knowing that successful innovation will not be reproduced by others within a time-limited period. IP protection enables life science companies to sustainably invest in the high-risk, uncertain and lengthy process of medicines and vaccines development. Without it, companies fuelled by research and innovation are vulnerable to unlawful competition from copycat products, and costs in the form of others "free-riding" on the costly and high-risk investments that lead to medical innovation, which challenge the business model and financial viability of the wider industry.

AI inventorship

Before addressing the questions under this sub-section of the consultation, we wish to make some important preliminary remarks.

Our guiding tenets whilst exploring the proposed policy options are as follows:

1. **AI-devised[6] inventions should be patentable, notwithstanding the role of the AI.** Patentability of such inventions should be based on the established substantive patent tests of: novelty, inventive step, sufficiency of disclosure, and being capable of industrial application irrespective of whether an AI was used to arrive at the invention or whether it should be designated as inventor in the patent application. For innovators, clarity and

[5] **Drug development: the journey of a medicine from lab to shelf**. The Pharmaceutical Journal (May 2015).
[6] As per the IPO's definition within the Impact Assessment for this consultation.

confidence in the ability to patent AI-devised inventions means that at a foundational level, a secure route is provided that will continue to incentivise the development of these inventions for life science innovators.

Contemplating an appropriate and capable legal mechanism pertaining to AI inventorship involves complex practical issues which need to be considered in such a way as not to undermine the core policy objective, and account for the likely evolution of this technology in the future. Retaining the need to identify a human inventor in patent applications makes successful patenting of AI-devised inventions more likely. The benefits of allowing grant are, as is the case with other technologies, that patents provide incentives to invent, develop, and bring inventions to market and to disclose the invention – thus promoting further innovation. The patent system has a solid history of proving these benefits.

At present, there are inventions in which AI has assisted human contributors, who can be identified as inventors, allowing patents to be granted. However, we could see autonomously AI-devised inventions in the (near) future, pointing to the need to future-proof the IP system to accommodate this technological evolution. Initiating a continued dialogue between the UK Government, stakeholders and international partners is very much welcome, and the ABPI commits to engaging on this topic as it develops.

As is the case with the development of all innovative medicines, if an AI system invented a compound, said compound would still need to go through the uncertain, lengthy and costly clinical studies required to prove safety and efficacy in sizeable cohorts of patients, before the product can be successfully brought to market. Further still, it is likely that there will be a significant risk of the compound failing to meet the required standards.[7] This means that even though AI-devised inventions may facilitate and accelerate identification of active compounds by replacing the activities currently carried out by human researchers, it is likely that the cost, time, and risk associated with seeking to bring a product to market will remain high, and still require adequate incentives to invest in practical development and commercialisation. Without the ability to patent the AI-devised invention, there will be little incentive to develop that invention or incur the financial, time-related and risk-based costs involved in creating the AI infrastructure and iteratively training AI systems, such as: data production and acquisition; investment into data pre-processing for AI systems; hardware, data storage, and energy expenses; and the necessary human capital (whether personnel or outsourced service providers). **That is why the ability to obtain patents will continue to remain so important.**

2. **AI-devised inventions should be patentable in the UK and in other countries:** ensuring that the UK approach to AI inventorship does not substantially differentiate from other leading jurisdictions to the detriment of UK innovation. In our highly globalised sector, the ability to obtain a patent in the UK alone is not likely to be a significant influence on decisions of whether to invest in development of AI-devised inventions. Investments in costly biopharmaceutical innovation can only be sustainable if they are commercially viable in multiple key markets. If a patent confers time-limited exclusive rights in the UK but the

[7] The attrition rate for compounds that enter pre-clinical Phase I studies in anticipation of reaching the stage of marketing authorisation application is approximated at around 90%. **Improving Translational Paradigms in Drug Discovery and Development.** Michael Williams (November 2021).

invention is not protected in other key global markets[8], the ability to patent in the UK alone will not be enough to realise the potential of AI for solving the nation's health challenges.

Therefore, **there is a real threat to cultivating investment into AI-devised innovation in our sector** if AI-devised inventions are not patentable in strategically important countries**.** In line with the objectives set out in its National AI Strategy, we encourage the UK Government to **take a lead in international discussions aimed at achieving that goal,** and continue to monitor the development of IP policy surrounding AI in other jurisdictions to ensure that prospective IP policies in the UK do not comparatively disadvantage domestic AI inventions.

Q11. *Please rank these options in order of preference (most to least preferred) and explain why.*

Q12. *Would the changes proposed under Options 1, 2 and 3 have any consequential effects on the patent system, for example on other patentability criteria?*

[For options 1 and 2]

Q13. *If UK patents were to protect AI-devised inventions, how should the inventor be identified, and who should be the patent owner? What effects does this have on incentivising and rewarding AI-devised inventions?*

Our preferred option is that which ensures that AI-devised inventions are patentable, is strategically aligned with the international direction of travel and can bring the benefits of AI to public health, society and the economy.

Assessing the feasibility of Policy Options 1, 2 and 3 (please note that at this stage, we are not in a position to indicate an order of preference for the proposed options set out in the consultation):

Option 1: "Inventor" expanded to include humans responsible for an AI system which devises inventions

For innovators, Option 1 – in principle – provides clarity as to the ability to seek patent protection for AI-devised inventions: which actively encourages and incentivises investment into the development of AI tools, algorithms, and machine learning models. Through this lens, the legal concept of personhood required for inventorship, as is the case under section 7 of the Patents Act[9], is not called into question or likely to be subject to legal challenge. Equally, an expanded categorisation for inventorship reflects the current state of progress in the AI space, where humans still have some responsibility for the AI systems under their management.

Should option 1 be selected, careful consideration will have to be given as to whether 'humans responsible for an AI system which devises inventions' is the appropriate test and whether

[8] For instance, within countries under the patent system of the **IP5**, the five largest intellectual property offices in the world: the European Patent Office (EPO), Japan Patent Office (JPO), Korean Intellectual Property Office (KIPO), the National Intellectual Property Administration of the People's Republic of China (CNIPA), and the United States Patent and Trademark Office (USPTO).

[9] **Right to apply for and obtain a patent and be mentioned as inventor: Section 7; Patents Act 1977 (c. 37)**. HM Government (July 1977).

guidance should be given as to what this means, rather than leaving it to the courts to decide when a dispute arises. Where the 'inventor' is specified to be certain persons, care is needed to ensure this does not result in someone having ownership rights (via inventorship) that was not actually involved in the activity leading to the invention (e.g., the owner/provider of the AI or of the used training data being named, without further involvement or oversight leading to the AI-devised invention).

Considerations should be given to whether the test in section 9(3) of the Copyright, Designs and Patents Act (CDPA) legislation addresses this by referring to "the person who undertakes the arrangements necessary for the creation"[10], would be more appropriate, making a distinction between the person(s) responsible for an AI system which devises the invention in question, and not 'inventions' more generally.

Option 2: Allow patent applications to identify AI as an inventor

Whilst we can understand why certain stakeholders might want to make clear where AI has devised an invention with minimal to no human input, **the potential ramifications of option 2 (including the distinction between 2(a) and 2(b)[11]), and allowing patent applications to identify AI as inventor, could have far-reaching implications for UK innovators.** As stated in the preamble, should the UK opt to choose a different direction of travel from other countries looking to build capabilities in the AI space, it could have a negative impact for investment on AI within the UK.

In considering the international state-of-play regarding AI inventorship, we note the recent decisions reached on the DABUS case in the United Kingdom[12] and at a European level, by the European Patent Office[13]. Similar conclusions were reached, which essentially rejected the applications made naming AI as inventor, and making the case-in-point that such inventions are not patentable – at least as present under UK law[14], and under the European Patent Convention (EPC).

The UK remains a member state of the European Patent Organisation, which operates on the basis of the EPC. Divergence from the EPC interpretation[13] that an inventor has to be a person with legal capacity, and not a machine such as AI, would present great difficulties for the UK's position within the European Patent Organisation. If the UK was to change its laws, this would also complicate how UK innovators file patents in Europe for AI-devised inventions, and might put UK membership of the EPC at risk.

Option 3: Protect AI-devised inventions through a new type of protection

At a time where life science companies active in the AI space are in the process of shaping their infrastructure for AI and introducing, training and testing its capacity, **it would be**

[10] **Authorship of work: Section 9; Copyright, Designs and Patents Act 1988 (c.48).** HM Government (November 1988).
[11] As identified in the consultation impact assessment, the further considerations for Option 2 are: **(a)** allow AI to be named as inventor and give ownership to humans responsible making the arrangements for the AI to devise the invention; OR **(b)** no requirement to name AI as the inventor, and give ownership to humans responsible making the arrangements for the AI to devise the invention.
[12] **Judgment of the Court of Appeal: Thaler v Comptroller General of Patents Trade Marks and Designs [2021] EWCA Civ 1374 (21 September 2021);** Case A3/2020/1851.
[13] **Decisions J 8/20 and J 9/20 of the European Patent Office Legal Board of Appeal** (December 2021).
[14] Referring to the Patents Act 1977.

premature to make sweeping legislative changes to the life sciences IP system and wider UK IP policy architecture – as proposed under option 3 and the introduction of a new *sui generis* right. Moreover, it is impossible to comment on this option without evidence of its need and some idea of the nature and scope of any such right.

Conclusion

The ABPI represents companies that base their business model on pursuing innovation, and **we share the ambition of the IPO to future-proof the UK IP framework to ensure IP is central to supporting life science innovation, through emerging technologies such as AI,** and enabling UK life science companies to flourish.

Several of the consultation questions that arise, if AI-devised inventions are to be patentable, relate to the legal mechanism(s) that should enable this ambition. The Impact Assessment[15] draws attention to possible problems that may arise, particularly for companies that file patents in various countries. These are very real problems and, in our view, require further consideration owing to the need for harmonised approaches in important global markets. Whilst we urge the government to take a measured but timely policy decision to make AI-devised inventions patentable, we believe that further detailed contemplation and consultation with key international partners should be undertaken. Action by the UK Government alone will not suffice to realise the potential benefit to patients and society of AI domestically, and on the global stage.

For options 1 and 2:

Q14. *In considering the differences between options 1 and 2, how important is it that the use of AI to devise inventions is transparent in the patent system?*

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Q15. *Would the UK adopting option 2 affect your global patent filing strategy, if so, how?*

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For option 3:

Q16. *What term and scope of protection should a new right offer?*

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Q17. *What should the criteria for grant of a new right be and why? Particularly should it: (a) Replicate the current requirements for a patent? (b) Set a different bar for inventive step? (c) Be an automatic or registered right?*

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General

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[15] **Consultation stage impact assessment on Artificial Intelligence and Intellectual Property.** Intellectual Property Office (October 2021).

Section B: Respondent information

A: *Please give your name (name of individual, business or organisation).*

[redacted] on behalf of The Association of the British Pharmaceutical Industry (ABPI).

B: *Are you responding as an individual, business or on behalf of an organisation?*

2) Organisation – see previous answer.

C: *If you are a responding on behalf of an organisation, please give a summary of who you represent.*

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D: *If you are an individual, are you?*

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E: *If you are responding on behalf of an organisation, are you?*

2) An industry body.

F: *If you are responding on behalf of a business or organisation, in which sector(s) do you operate? (choose all that apply)*

3) Manufacturing – Pharmaceutical products
16) Scientific and technical activities
21) Human health activities

G: *How many people work for your business or organisation across the UK as a whole? Please estimate if you are unsure.*

2) 10–49.

H: *The Intellectual Property Office may wish to contact you to discuss your response. Would you be happy to be contacted to discuss your response?*

Yes.

I: *If you are happy to be contacted by the Intellectual Property Office, please provide a contact email address.*

Please contact [redacted]

J: *Would you like an acknowledgement of receipt of your response?*

Yes.