BIA submission: Artificial Intelligence and IP - copyright and patents

January 2022

UK BioIndustry Association

This consultation was submitted to the UK Intellectual Property Office (UKIPO) via email in response to its consultation on AI and IP, covering copyright in works made by AI; text and data mining using copyright material; and patents for inventions devised by AI. All text below in bold is copied verbatim from UKIPO's consultation response form.

Summary

In this response, the BioIndustry Association (BIA) sets out its rationale for favouring:

- No change to the status quo regarding legal changes to **computer generated works (CGW**) (Ranking of options: 0 > 2 > 1).
- A **text and data mining (TDM)** exception that allows mining of both copyright works and databases, for both non-commercial and commercial use, rather than attempting to adjust the definition of "non-commercial use". Access to larger, better quality and more diversified datasets is key to developing new healthcare solutions with the power of AI and to reducing the potential problems with bias in AI systems. However, data holders should still be free to put express limitations on the use of their data and there should be the ability for data holders to opt-out of TDM. (Ranking of options: 3 > 2 > 1 > 4 > 0).
- If an AI system is the actual deviser of an invention and the invention meets the various other criteria for **patentability**, then that invention should be afforded the same protection as a human conceived invention. AI contributions should be acknowledged on the record. The BIA does not support introducing a new ground for revocation under which anyone could challenge the validity of a patent on the basis that an inventor was an AI system, if that person themselves did not have a potential entitlement claim to the invention themselves. (Ranking of options: 2(b>a)[1] > 1 > 0 > 3)

While it is hoped that the UK would be among the first countries taking the lead on updating patent law to make sure it is fit for the AI world, the BIA is not proposing that it does this alone but in close consultation with other countries to achieve harmonisation where possible – most particularly with Europe. The BIA would encourage the UK IPO to actively engage with other countries/relevant bodies to consider the options regarding AI inventorship. The patent protection available for AI-devised inventions should be the same (in all respects) as that for inventions that are devised by other means. The BIA is not in favour of a new right.

[1] Option 2: Allow patent applications to allow AI as inventor and (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. (IPO (2021) *AI and IP: copyright and patents*: https://www.gov.uk/government/consultations/artificial-intelligence-and-ip-copyright-and-patents/artificial-intelligence-and-intellectual-property-copyright-and-patents.)

Introduction and overview of AI & IP in the UK life sciences sector

The UK's R&D-intensive life sciences sector is universally recognised as world-leading, and it delivers great benefits to the economy, the health of the nation, and is key to the Government's net-zero agenda. This is a growing sector of the future that poses a unique opportunity. The UK life sciences industry employs 268,000 people across the UK. There are 6,330 life sciences businesses, 85% of which are SMEs, and combined they generate a turnover of £88.9bn.[2] From improving patients' lives through new treatments and digital healthcare, to the development of environmentally sustainable technologies, such as biological fossil fuel substitutes and biodegradable bioplastics, the sector's deep understanding of biology is helping to address humankind's greatest challenges.

AI technology has the potential to revolutionise the healthcare industry and many other biology-based technology sectors. It is becoming increasingly important in the mission of speeding up the development timeline for much-needed medicines, medical devices and diagnostics, lowering the costs of R&D in the sector, selecting those patients who will benefit most from the treatment and making diagnostics more accurate.

Pharmaceutical and biotech companies have always relied heavily on patent protection for novel molecules and new uses of existing molecules. Increasingly, these are being identified and developed with the aid of AI. Drug discovery is a key area in which protection for AI related inventions is becoming increasingly important. Without AI technology, investment in R&D will continue according to the traditional approaches. AI technology should increase the speed, efficiency, and accuracy of the drug discovery process and reduce patient safety risks and drug discovery costs – without it, innovation and timescales are likely to be slower and much more expensive.

AI technology has the potential to make important innovative contributions across many areas of technology, especially R&D in life sciences. Adequately protecting AI systems, and their outputs, through IP rights will encourage further innovation and investment in those systems.

Section A

Copyright – computer generated works (CGW)

Question 1: Do you currently rely on the computer-generated works provision? If so, please provide details of the types of works, the value of any rights you license and how the provision benefits your business. What approach do you take in territories that do not offer copyright protection for computer-generated works?

The life sciences sector is typically concerned with computer-generated data and databases. Highly valuable proprietary datasets are created using AI from aggregating, cleansing, processing and analysing existing, usually human-generated data – however, the outputs tend to be unstructured data, more often than copyrightable works. The life sciences sector tends not to rely heavily on the CGW works provision, in contrast to some other industries.

[2] OLS (2021), *Bioscience and health technology sector statistics 2020*: https://www.gov.uk/government/statistics/bioscience-and-health-technology-sector-statistics-2020

Question 2: Please rank these options in order of preference (most to least preferred) and explain why.

Rank: 0 > 2 > 1.

From the life sciences sector perspective, the BIA does not see a compelling reason to change the status quo. The test for who is the author of a CGW (namely "the person by whom the arrangements necessary for the creation of the work are undertaken") could be adopted as a more general principle in relation to AI-generated works and inventions (i.e., AI generated IP) and would provide for a more consistent approach. Please see the answer to Question 18 on patents.

Question 3: If we introduce a related right for computer-generated works, as per option 2, what scope and term of protection do you think it should have? Please explain how you think this scope and term is justified in terms of encouraging investment in AI-generated works and technology.

Intentionally blank.

Question 4: What are your views of the implications the policy options and of AI technology for the designs system?

The BIA favours the current approach adopted by UK legislation on registered and unregistered designs – namely that, for designs generated by a computer, the author is considered to be "the person who made the arrangements necessary for the creation of the design". Designs of medical devices, for instance, should be and continue to be protected even if generated by AI rather than by a human.

Question 5: For each option, what are your views on the risk that AI generated works may be falsely attributed to a person?

Intentionally blank.

Copyright – text and data mining (TDM)

Question 6: If you license works for TDM, or purchase such licences, can you provide information on the costs and benefits of these? For example, availability, price-point, whether additional services are included or available, number and types of works covered by the licence etc.

AI companies operating in the Life Sciences sector draw on data and copyright works from a diverse range of resources, both public and private. However, much of the most valuable dataset/works lies in the hands of private companies – including scientific, technical, and medical (STM) publishers of journals for example, some of whom hold works/data that is either difficult or impossible to obtain elsewhere. Negotiating licences with such publishers is often difficult and time-consuming and is becoming increasingly expensive, with multiple layers of different types of access and numerous restrictions around use (and sometimes attaching significant strings to any outputs that a company generates from the use of the publishers' content). Additional fees are

usually required for TDM access, in contrast to access for traditional human viewing (and in some cases TDM access is not granted at all).

While many users in the Life Sciences sector access and read these resources in the traditional way, TDM is becoming of increasing interest and TDM is therefore set to rise. Many of these publishers see AI companies as a threat to their business model - there is a fearing that in the future their customers will go to the AI companies for the information instead.

Question 7: Is there a specific approach the government should adopt in relation to licensing?

The current TDM exception (which was the first introduced in the EU) is restricted to "non-commercial use", which is a narrow exception in practice and therefore does not allow commercial organisations to mine text and data as part of its R&D activities and then commercialise the outputs, even if the outputs do not include the text and raw data that has been mined.

On the understanding that the majority of AI and machine learning expertise lies in the commercial sector and given how valuable it is overall to foster R&D for new therapies and diagnostics through the secondary use of data, the BIA would welcome a TDM exception that allows mining of both copyright works and databases, for both non-commercial and commercial use, rather than attempting to adjust the definition of "non-commercial use". Access to larger, better quality and more diversified datasets is key to developing new healthcare solutions with the power of AI and to reducing the potential problems with bias in AI systems, which is an issue with AI systems that have been trained on more limited amounts of information.

As a general principle, if a user is given lawful access to a database or other works, the rights should be the same whether that information is read by a human or a machine – to put it another way, the "right to read is the right to mine".

Nevertheless, it is crucial to strike the right balance. Datasets and databases are the lifeblood of AI systems and so it is vital to incentivise investment in the generation, building and sharing of good quality datasets. The data holders/publishers need assurance that the user will not use the datasets in competition, and that they will be able to make an appropriate return on their investment. On this basis, the BIA considers that:

- data holders should still be free to put express limitations on the use of their data – e.g., grant access for commercial purposes (or particular commercial purposes only), or non-commercial purposes – with the default position being that a commercial licence should carry with it a licence to mine for commercial purposes (or for the particular commercial purposes that have been expressly permitted) and a non-commercial licence includes a licence to mine for academic purposes … and so on; and
- there should be an ability for data holders to opt-out of TDM.

It is worth highlighting that many datasets being used in the life sciences industry include patient data and so it is crucial that any TDM exception does not cut across or diminish any rights of privacy.

The position outlined above would not necessarily address the initial issues raised in this section – i.e., those around the challenges and the expense of negotiating data licences with STM publishers. Therefore, even though the BIA does not favour Option 1 as such, it is supportive of the proposals in Option 1 to find ways to facilitate the licensing of data on fair and clear terms – by developing model licences for commercial data sharing and associated best practice guidance. These will be very valuable to help standardise and simplify the process and reduce the negotiation costs for less complex arrangements.

Question 8: Please rank the options in order of preference (most to least preferred) and explain why.

Rank: 3 > 2 > 1 > 4 > 0.

The BIA recognises that, with Option 4, it is quite possible that data holders will simply opt-out – thereby defeating the efforts and ambition to make more resources available to develop, train and enhance AI and machine learning technologies. However, if users are given automatic rights to mine for commercial purposes (whether for research or more general commercial purposes) without an ability for the data holder to opt-out, the BIA anticipates that there is a real risk that this will stifle the investment in the creation of datasets and databases and data holders will have more concerns about sharing their data.

Option 3 seems to strike a balance, albeit not a perfect one. It would in any event unlock various data resources and make them available for use in cases where the ability to mine is currently in doubt and where the data holder does not positively object.

Question 9: If you have experience of the EU exception with opt out for rights holders, how has this affected you?

Intentionally blank.

Question 10: How would any of the exception options positively or negatively affect you? Please quantify this if possible.

Option 1 – the BIA favours legislative change but as noted above, it also endorses the development of model licensing terms, codes of practice, etc. in any event, as there can be no downside to that.

Options 2 and 4 – these could achieve the objective of making more data available for mining, although STM publishers would not necessarily provide their data any more cheaply. However, these options would appear to run the risk of being too draconian for all data holders (i.e., there is no opt-out) and having a resultant negative effect on data sharing.

Option 3 – all data holder organisations would need to be well briefed and prepared for the opt-outs before any such system was introduced. The guidance and mechanisms for opt-out would need to be clear, simple, and inexpensive to implement, otherwise academic institutions and SMEs in particular are likely to be disadvantaged.

Patents

Question 11: Please rank these options in order of preference (most to least preferred) and explain why?

Rank: 2(b>a) > 1 > 0 > 3

Option 0 – The BIA notes that a number of stakeholders who responded to the Government's "Call for Views on Artificial Intelligence and Intellectual Property" (the results of which were published in March 2021)[3] thought that the current law was sufficient to deal with AI inventions, at least in the short term. The BIA recognises the concerns expressed, for example, as regards legislating prematurely, being out of step with key economies, patent thickets and more broadly, known unknowns and even unknown unknowns. However, in the view of the BIA, this should be balanced against the key public policy consideration of making sure that there is continued incentive for future developments for the benefit of mankind, such as a cure for cancer.

In addition, the BIA considers it important that the law should stay abreast of technological developments and, where possible, that the UK takes a proactive stance rather than a reactive stance on this matter. The UK IPO is well respected and should be leading (whether by example or in committee) to bring consensus on how to tackle the AI issues, rather than responding reactively or implementing short term fixes. This does not mean that the BIA would not want the UK IPO to align with other key economies on this issue where possible (see the answer below on Question 15).

As the use of AI increases, the more important it becomes to establish to what extent AI generated inventions are eligible for patent protection – otherwise the legal uncertainty will continue to grow as applicants perhaps somewhat arbitrarily name humans as inventors for the purposes of securing patents and then become exposed to subsequent validity challenges (because a human had been incorrectly named as an inventor) and therefore take on unnecessary business risk.

Options 1 and 2: Overall, the BIA view is that if an AI system is the actual deviser of an invention and the invention meets the various other criteria for patentability (novelty, inventive step, etc. – on which see further below), then that invention should be afforded the same protection as a human-conceived invention, rather than a watered-down version. The reasons for this are outlined in the answers to Question 18 below. Although both Option 1 and Option 2 would allow AI-generated inventions to be patented, overall, the preference is for Option 2 (b)[4], as it does not hide the true inventor and its/their inventive contribution. In the interests of transparency, accuracy and the disclosure and development of AI technology, AI contributions should be acknowledged on the record. Please also see the answers to Question 15 in relation to the impact that this may have on patent filings internationally.

Option 3 - Please see the answers to Questions 16 and 17 below for the reasons why Option 3 is the least preferred.

Regardless of what Option is adopted, the BIA does not support introducing a new ground for revocation under which anyone could challenge the validity of a patent on the basis that an inventor was an AI system, if that person themselves did not have a potential entitlement claim to the invention themselves.

[3] IPO (2020) *Artificial intelligence and intellectual property: call for views*: https://www.gov.uk/government/consultations/artificial-intelligence-and-intellectual-property-call-for-views.

[4] Option 2 (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."

Question 12: Would the changes proposed under Options 1, 2 and 3 have any consequential effects on the patent system, for example on other patentability criteria?

The BIA considers that the UK patent law is sufficiently well-equipped and flexible to deal with AI-assisted and AI-generated inventions and the changes proposed in accordance with the favoured Options 2/1 above should not affect that.

The current inventive step requirement should continue to be applied in the same way, regardless of whether a person or an AI system has been responsible for the inventive step. As the use of AI becomes more common, the benchmark level of the knowledge and capacity of the ordinary skilled person will increase. As with all developments in technology, there will be a period of transition - with some adopting AI systems earlier than others. An issue then potentially 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 so could be at a disadvantage). However, as indicated above, the BIA considers that the current patent law is flexible enough to deal with this. As today's AI technology becomes a commodity, the threshold of the knowledge and capacity of the ordinary skilled person aligns and the bar for inventive step in this context may change. Nevertheless, new advances in technology will be able to produce different types of invention which should continue to be patentable until that technology becomes a commodity. The move towards the use of AI systems may be considered to be akin to the move from paper publications to the use of digital databases in the scientific community.

In relation to novelty, again the BIA considers the current regime can accommodate AI-generated content - which 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.

For options 1 and 2:

Question 13: 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?

Identification of the inventor
In the interests of transparency (see answer to Question 11 above), the BIA's preference is for the AI system that devised the invention (rather than any human) to be identified as the inventor (or as co-inventor depending on the circumstances). However, the BIA does not consider there is a need to try to name or precisely specify the AI system responsible when completing a patent application, particularly as the technology will likely change and evolve very quickly.

Who should be the patent owner?
The starting point in relation to ownership of a patent is to identify who came up with the inventive concept (the actual deviser(s) of the invention). If the actual deviser is an AI system then, although the BIA proposes that the AI system should be recognised as an inventor, it is not suggested that the law should allow an AI system to be the owner of the patent itself. The BIA notes that one route is to adopt a test similar to s.9(3) of the Copyright,

Designs and Patents Act (CPDA)[5] for computer generated works with no human author (and the similar provision that exists in the Registered Designs Act (RDA)[6]) – i.e., that the owner of an AI-generated invention should be the person who made the arrangements necessary for the AI to devise the invention.

Reference is also made to the BIA's response to the UK IPO's 2020 call for views on AI and IP[7], where the BIA suggested the possibility 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) 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. This approach – i.e., one that gives ownership to the person or entity controlling/commissioning the AI task – aligns with the Option 2 proposal of the owner being "the person who makes the arrangements for the AI to devise the invention" (and also aligns with the provisions referred to in the CPDA and RDA above). In applying this employer/employee analogy, possible scenarios would include, for example, situations where AI developer/owner itself is the patent owner because it controls the tasks that the AI system is asked to perform, and situations where a licensee of an AI system is the patent owner in cases where the AI system has been licensed out and the licensee controls what work the AI system is required to carry out.

There should be a default position (such as is proposed above), in the absence of any agreement to the contrary. However, that should not stop: (a) a user of the AI being the owner of an invention/patent if in truth that user was the one who was responsible for the inventive concept (e.g. the one that came up with the inputs or parameters for the AI or trained the AI or who recognised the applications of the outputs or who trained the AI); or (b) parties agreeing different ownership rights by contract (those involved in developing, licensing and using AI systems should be free to agree how ownership should flow).

It is acknowledged that there may be difficulties in identifying an owner where an AI system's component parts include e.g., hardware, proprietary software, open-source software etc.

What effects does this have on incentivising and rewarding AI-devised inventions?
The BIA considers that the above would incentivise AI-devised inventions (and the development of AI systems that can devise such inventions), which is important in the healthcare sector (as well as other industries) for the reasons outlined in answer to Question 18 below (and Question 11 above).

Question 14: 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?

Please see answer to Question 11 – disclosure is a fundamental tenet of the patent system and therefore transparency in respect of patented inventions, not just in terms of the claims or how a skilled person in the art can work the invention, but also how they were devised should follow. This will also be important with respect to assessing inventive step in the future.

[5] IPO (2021) *Copyright, Designs and Patents Act 1988*: https://www.gov.uk/government/publications/copyright-acts-and-related-laws.
[6] IPO (2021) *Registered Designs Act 1949*: https://www.gov.uk/government/publications/registered-designs-act-and-rules.
[7] BIA (2020). *BIA submission to the IPO consultation on AI and IP*: https://www.bioindustry.org/resource-listing/bia-submission-to-the-ipo-consultation-on-ai-and-ip-pdf.html.

Question 15: Would the UK adopting option 2 affect your global patent filing strategy, if so, how?

The BIA is concerned that, by naming a human arbitrarily as an inventor just because they were involved in making the arrangements for the AI to devise the invention, when that human was not personally responsible for contributing to the inventive concept, creates a risk of that patent being challenged in various jurisdictions (e.g., the US) for incorrectly naming a human as the inventor.

If those jurisdictions truly do not afford patent protection to AI-generated inventions (putting aside any formalities for the moment), then the applicant should not be able to secure patent protection in those countries in any event.

However, the BIA is also concerned with the difficulties that will arise if an AI system is identified as the true inventor on a UK patent but cannot be named on its foreign counterpart patent applications in other countries whose patenting laws are different (but nevertheless do not rule out protection for AI-generated inventions).

Therefore, while it is hoped that the UK would be among the first countries taking the lead on updating patent law to make sure it is fit for the AI world, the BIA is not proposing that it does this alone but in close consultation with other countries to achieve harmonisation where possible – most particularly with Europe. It is anticipated that given the UK's participation in the European Patent Convention (EPC) and the importance of remaining in this system, it would become very difficult to take a different approach to the EPC on this issue. It is also anticipated that Option 1 may be the direction that other jurisdictions (who are willing to recognise AI inventions) might tend towards and may therefore be considered to be the more pragmatic or "safe" option. However, the BIA would encourage the UK IPO to actively engage with other countries/relevant bodies to consider Options 1 and 2 properly.

For option 3:

Question 16: What term and scope of protection should a new right offer?

Intentionally blank.

Question 17: What should the criteria for grant of a new right be and why? Particularly should it: (1) Replicate the current requirements for a patent? (2) Set a different bar for inventive step? (3) Be an automatic or registered right?

The BIA is not in favour of a new right. The protection available for AI-devised inventions should be the same (in all respects) as that for inventions that are devised by other means.

Some of the key reasons for this are:

- it introduces an unnecessary layer of complexity;
- "downgrading" the protection for an invention (depending on purely whether it was devised by a human or machine) will likely act as disincentive to use AI in the development of new technologies (for example, making Biotech and Pharmaceutical companies nervous about using AI in drug discovery). This would

have a negative impact on advancements in healthcare (as well as other industries). In turn, the market for developing AI technologies would be held back;

- the Life Sciences sector already faces long lead-times and great challenges in bringing products to market, with high regulatory hurdles and heavy investment to ensure drugs and devices are safe and effective. Therefore, shortening any protection would not give organisations in the sector enough time (if any) to recoup their investment and also support further innovation; and

- introducing a right which is automatic (as opposed to a right that goes through a registration process and a substantive examination) increases the uncertainty and risk of developing and putting a medicine or medical device on the market on the basis of such protection.

General

Question 18: What role does the IP system play in the decision of firms to invest in AI?

AI technology has the potential to make important innovative contributions across many areas of technology, especially R&D in life sciences. Developing useful AI technology, in common with all technological advances, requires significant investment. AI systems, and their outputs, should be adequately protected by IP rights to encourage further innovation and investment in those systems.

In biopharma, patents are usually very important, in particular for SMEs, so they can secure the investment needed to continue in business and invest in the R&D 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 investors as compared to filed and/or granted patents.

Drug discovery is a key area in which protection for AI related inventions is becoming increasingly important. Developing AI systems to discover and develop new medicines, or identify new therapeutic applications for existing drugs, still requires significant investment. Also, crucially, pharmaceutical and biotech companies have always relied heavily on patent protection for novel molecules and new uses of existing molecules. Increasingly these are being identified and developed with the aid of AI. A significant amount of time and vast resources are invested in developing a drug, testing it and bringing it to market. If, for example, a molecule could not benefit from patent protection because it had been devised by AI, then the risks for the companies involved in taking that invention forward would be too great. Without AI technology, investment in R&D will continue according to the traditional approaches. AI technology should increase the speed, efficiency, and accuracy of the drug discovery process and reduce patient safety risks and drug discovery costs – without it, innovation and timescales are likely to be slower and much more expensive. Please also see the answer to Question 20.

In the BIA's November 2020 response[8], it was also noted that some BIA members thought that there should also be a review of whether the patent system is the best way to protect therapeutics resulting from AI. The issues

[8] BIA (2020). *BIA submission to the IPO consultation on AI and IP*: https://www.bioindustry.org/resource-listing/bia-submission-to-the-ipo-consultation-on-ai-and-ip-pdf.html.

raised by AI-devised inventions may suggest that rewarding the investment into discovering new therapeutics and encouraging further research is better achieved through a time-limited regulatory based monopoly.

Question 19: Does the first mover advantage and winner-take-all effect prevail in industries adopting AI? How would this affect the impact of the policy options proposed on innovation and competition?

The BIA notes the comments in the UK IPO's impact assessment, raising concerns about the possibility of a small number of dominant players (with access to the best AI technology and training data) potentially filing large volumes of patents for AI generated inventions, resulting in a winner-takes-all effect whereby they monopolise technology and patent landscapes with patent thickets around a wide range of inventions, making it difficult for new entrants to penetrate the market. Whilst resource rich companies (such as big tech and big pharma companies) will undoubtedly take advantage of a patent system that allows AI devised inventions to be patented, 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. More generally the examination and grant process and procedures of certain bodies could be considered to be a key piece in the ability of some patentees to create patent thickets, rather than that being an issue with AI itself.

It is important not to deny SMEs and start-ups the ability to secure patents for AI-devised inventions which may struggle to attract investment without such protection - such companies make up the majority of BIA members. Reference is made to the answer in Question 11 and the overriding public policy consideration of providing the incentive necessary for innovation for the greater good.

Question 20: How does AI adoption by firms affect the economy? Does the use of AI in R&D lead to a higher productivity?

AI technology has the potential to revolutionise the healthcare industry. It is becoming increasingly important in the mission of speeding up the development timeline for much-needed medicines, medical devices and diagnostics, lowering the costs of R&D in the sector (e.g. by identifying unsuitable treatments more rapidly – in other words "fail fast and early"), selecting those patients who will benefit most from the treatment (thus reducing patient safety risks and also avoiding conducting costly and time-consuming clinical trials unnecessarily on those who are unlikely to respond to treatment) and making diagnostics more accurate – to name just some of the key benefits. This comes at a time when the Life Sciences industry is having to combat: (a) rising costs of R&D generally, including the additional costs associated with advanced therapies (such as cell and gene therapies) and precision medicine; and (b) pressure from health authorities, governments and the public to make healthcare more affordable.

Question 21: Do the proposed policy options have an impact on civil society organisations? If so, what types of impacts?

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Section B: Respondent Information

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

UK BioIndustry Association (BIA)

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

2) Organisation – UK BioIndustry Association

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

The BIA[9] is the trade association for innovative life sciences in the UK. 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 over 460 members include:

- Start-ups, biotechnology and innovative life science companies
- Large pharmaceutical and technology companies
- Universities, research centres, tech transfer offices, incubators and accelerators
- A wide range of life science service providers: investors, lawyers, IP consultants, and communications agencies

D: If you are an individual, are you?

Intentionally blank.

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
23) Other activities – *life sciences, pharmaceutical sciences and biotechnology R&D?*

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

[9] BIA (2021), *UK BioIndustry Association*: https://www.bioindustry.org/.

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 Linda Bedenik, Policy and Public Affairs Manager, lbedenik@bioindustry.org.

J: Would you like an acknowledgement of receipt of your response? Yes/No

Yes.

Contact

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