



## **Making Open Data Real: A Public Consultation**

### **BIA Response**

#### **About the BIA**

Established in 1989, the BioIndustry Association (BIA) exists to encourage and promote a financially sound and thriving bioscience sector within the UK economy and concentrates its efforts on emerging enterprise and the related interests of companies with whom such enterprises trade. The BIA represents innovative healthcare-focused bioscience companies, including over ninety per cent of biotech medicines currently in clinical development in the UK. BIA members are at the forefront of innovative scientific developments targeting areas of unmet medical need and this innovation will lead to better outcomes for patients, to the development of the knowledge economy, and economic growth.

#### **The BIA Response**

The BIA would like to focus on one aspect of government transparency and welcomes the opportunity to raise it through this consultation response. The aims expressed within the consultation document are laudable and it is the BIA's view that a presumption in favour of transparency and openness should apply across government departments with secrecy preserved only in exceptional circumstances and for good reason.

The BIA's concern relates to the procedures and transparency surrounding the process of responding to references to the Court of Justice of the European Union (CJEU). Specifically, the lack of publication of the UK's response to such references requires review and should be changed. This consultation provides an opportunity to do so.

#### **Background**

The BIA represents and advises its member's interests in a number of areas of importance to the continued growth of the bioscience sector including issues of access to finance, health policy and regulation. One key pillar for the sector is the protection and stimulation of innovation through Intellectual Property Rights, predominantly in the form of patents.

Therefore, the IP framework and the UK government's approach to IP are of vital importance to the BIA and its members. As such, the BIA monitors and engages with ongoing IP matters with government and other external stakeholders. The BIA regularly responds to IP consultations, such as the Hargreaves Review and the consultation on the Research and Bolar exceptions most recently, and holds regular bilateral meetings with the UK Intellectual Property Office (IPO).

The BIA also closely follows cases before the Courts in the UK, Europe and beyond given the importance of case law to the IP framework. Where there are often opportunities during an ongoing case for interested parties to submit their views to the Court the BIA will often take that opportunity. In cases referred to the CJEU such an opportunity is provided through a process of notification to Member States. These often concern areas of great importance to BIA members such as, most recently, several References on Supplementary Protection Certificates and the patentability of stem cells in the *Brustle v Greenpeace* case.

### The CJEU notification process

On receipt of a Reference from a Court of a Member State, the CJEU invites parties to the Reference, Member States and the Commission to submit Written Observations. Subsequently, those same parties are invited to attend a short Oral Hearing, after which the Advocate-General publishes an Opinion and the Court will then give its Judgment.

As a Member State, the UK receives such References from the CJEU. Where the Reference relates to IP, the government will through the IPO, notify interested parties of the opportunity to submit their views on the Reference. If the Reference relates to an area of concern to the bioscience sector and its members, the BIA will often submit its views on what position it feels the UK should adopt. Similarly, other organisations with an interest will do the same.

We understand the IPO will collect these responses before making its recommendation on the position the UK should take with regards to the Reference, or indeed if the UK should make a Written Observation at all. We further understand the final decision on making a Written Observation and, if so, its content, rests with HM Treasury solicitors.

### Transparency

The IPO, and we understand other parts of Government, do not advise stakeholders, even those who have made submissions in relation to the Reference, whether:

1. the UK made any Written Observations to the CJEU on the Reference; or
2. if a Written Observation was made, what position the UK took.

As a matter of principle the BIA, and others within the IP field of whom the BIA is aware, regard this approach as lacking in transparency and openness on the government's part. The References concern interpretation of the principles of European Union law and therefore have a wide ranging effect throughout the Union. The lack of transparency is a matter of significant concern.

The BIA and others have raised this issue directly with the IPO and the Minister with responsibility for IP. In response, the practice of the CJEU in treating all Observations submitted to the Court as confidential is cited. As far as the BIA is aware, there are no provisions in any of the instruments governing procedure in the CJEU which render documents filed with the Court as confidential.

Furthermore, this position applies to both ongoing cases before the Court and completed proceedings. Interested stakeholders are therefore unable to obtain copies of Written Observations regarding a case which is completed to understand at that point the arguments put forward by third parties in the case.

The BIA's view is that the UK should not adopt the same position as the Court, which reduces openness and transparency in the Reference process, but should set an example. The lack of transparency also undermines the value of stakeholder engagement as it leaves the BIA unaware of the effect of its submission, unaware of whether the UK is adopting a position supportive of the UK bioscience industry, and unaware whether the UK has even made a Written Observation to the CJEU at all.

The BIA is keen to ensure that it engages effectively with government on such References to the CJEU. It is therefore important that interested parties are informed by the Government whether the UK has submitted Written Observations on any particular Reference and that

these Written Observations are made public. Stakeholders will then be able to see clearly what the Government's view is on a particular matter and will be able to act accordingly in future. The current situation results in the UK effectively not making public its policy position on aspects of IP principles that have critical importance to the bioscience sector.

The BIA is aware that the situation has led to a number of Freedom of Information requests for access to the Observations. Each FOI request is then determined on the individual case which leads to inconsistency with regards to openness and transparency of judicial proceedings. The BIA is also aware of action being taken further and referrals made to the Information Commissioner. This represents, in the BIA's view, another unnecessary, cumbersome and costly outcome of the current approach of the UK government to the publication of Written Observations.

This should be of direct relevance in regards to this consultation as in paragraph 3.2 of the Executive Summary it is stated that, *"better data actually means less but higher quality data, and more openness means fewer Freedom of Information Act requests for this data and less red-tape"*. The BIA certainly concurs and the above demonstrates how a move to more openness will reduce unnecessary FOI requests.

In other countries, such as Canada and the US, there is significantly more openness and transparency with regards Written Observations to ongoing court proceedings. For example, Amicus Briefs filed before the Supreme Court in the US, are made publicly available, including those of the US Government. As such, interested parties are clearly able to ascertain the approach taken by policymakers which allows for a more open and informed debate. In Canada, all Written Observations are placed online and are publicly available upon submission.

### Summary

This consultation provides an opportunity to review this specific issue and the BIA urges the UK government to take a lead in providing a more open and transparent process for CJEU References. Such an approach would allow for a more open and informed discussion on issues of crucial importance to the bioscience sector. References are of course made in a wide range of issues and improving transparency will also have a positive affect on various other sectors also who have an interest in CJEU cases. The BIA believes the public should be able to easily view the UK government's position on key issues and that this amendment to ensure greater openness and transparency is long overdue.