STATEMENT OF GROUNDS

1. The BioIndustry Association ('BIA') applies for permission to intervene under Rule 26 of the Supreme Court Rules 2009 in the appeal in *Warner Lambert Company LLC* v *Generics (UK) Limited and others [2016] EWCA Civ 1006*. Permission is sought for intervention.

2. The BIA should be granted permission to intervene because the point of law at issue is of vital importance to companies in the biosciences field which make up its membership. The Appellant is a member of the BIA but neither of the Respondents are members. Members of the BIA include startups, small and medium-sized enterprises (SMEs) and established large companies. Given the diversity of its membership, the BIA cannot unequivocally support the position of either party in this appeal, and therefore offers an independent view of the way in which the outcome of this appeal will affect its members, and consequently the biosciences industry as a whole.

The BIA

3. The BIA is the trade association for innovative enterprises in the UK's bioscience sector. The BIA's mission is to promote the human health benefits of new bioscience technologies and to encourage the commercial success of the bioscience industry by focusing on emerging enterprises and the related interests of companies with whom such enterprises trade.

4. An independent analysis by PwC estimated that the UK life sciences sector contributed £30.4 billion to the economy in 2015 and supported 482,000 jobs[1]. Workforce productivity in the sector is twice the UK average, with Gross Value Added (GVA) per employee equalling £104,000. The activities of life science companies directly contributed £14.5 billion to the economy in 2015, with an additional £15.9 billion provided through the supply chain and employee spending. Within the sector, the UK has a vibrant community of bioscience SMEs that are developing innovative new medicines but do not currently have any products on the market. The UK has the strongest R&D pipeline among such companies in Europe, with 275 products in development.[2]

5. The BIA brings a broader, more rounded perspective to the issues beyond the respective positions of the Appellant and the Respondents. It is therefore eminently capable of making submissions in the public interest.

6. The biosciences sector is heavily dependent on patents: the significant investment required for the research and development of medicines is made possible by the commercial incentive provided by patent protection. Robust patent applications are also essential to persuade investors to finance the research. As a result, a key concern of members of the BIA is that there is clarity and certainty in patent law. A threshold test for plausibility that is uncertain or places an increased burden on bioscience companies to disclose data at an early stage in the research process could make it more difficult to obtain patents in the sector. Developments in the biosciences field require a great deal of research and the BIA is keen to ensure that a test for plausibility does not impact this sector more than others, leading to differing standards for patenting across sectors. Both outcomes would make it harder for UK bioscience companies to attract investment in their research and development programs.

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[1] PwC (2017), commissioned by ABPI, BIA, BIVDA and ABHI, The economic contribution of the UK life sciences industry: https://goo.gl/6sMhrB

[2] BIA (2017), Building something great: UK's Global Bioscience Cluster 2016: https://goo.gl/CyQyf6

The Issue of Plausibility

7. It has become increasingly common in patent cases to attack the validity of a patent on the grounds that the invention was not plausible. As the Honourable Mr Justice Birss put it in *Merck Sharp & Dohme Ltd v Ono Pharmaceutical Co* [2015] EWHC 2973 (Pat) at §133-137:

> "The term is not to be found in the legislation and … as an aspect of patent law is a fairly new point" and "it is worth reminding oneself that 'plausible' is not a term found in the relevant parts of either the EPC or the 1977 Patents Act. It has proved to be a useful concept in various factual situations but just because that has proved to be true in one case does not mean that everything said in that context applies in a very different context. There is no law of plausibility as such.'"

8. Notwithstanding Mr Justice Birss' note of caution, the test has developed into a "threshold test". It has been regularly applied as a preliminary, albeit low, threshold for insufficiency and obviousness (and the test appears to be the same in both contexts). It has also been considered as relevant to industrial applicability, novelty and enablement.

9. The test of whether an invention is plausible is one developed and applied by the EPO (in connection with its "problem – solution" approach to assessing inventive step) and it is not clear that the approach of the EPO and UK courts is consistent in the context of insufficiency. The need to show that an invention is "plausible" affects not only the ability of a bioscience company to defend a patent in litigation (which has a bearing on its value to investors) but also impacts strategy at the time of filing for patent protection. A bioscience company has to decide whether to file early and risk facing an allegation that the invention was not "plausible" at that stage, or delay filing until further tests are done at the risk of losing out on the patent protection to a competitor.

10. The concept of plausibility was considered by the Supreme Court in the context of industrial applicability in *Human Genome Sciences Inc v Eli Lilly and Company* [2011] UKSC 51. The Supreme Court noted the need for clarity, consistency and certainty in this area of the law and the importance of bioscience companies being able to decide at what stage to file for patent protection (see paragraphs 96-102). With regard to consistency, Lord Neuberger commented at paragraph 87 that it would take "very unusual facts" to justify departure from a consistent approach of the EPO towards an issue. It is submitted that a high plausibility threshold would make the UK's approach inconsistent with those of other jurisdictions, including the EPO.

11. In this sector, a large amount of costly research and development is needed to identify molecules and develop them to a stage where they can be of therapeutic value. As Lord Neuberger said in that case at paragraph 130 "Just as it would be undesirable to let someone have a monopoly over a particular biological molecule too early, because it risks closing down competition, so it would be wrong to set the hurdle for patentability too high".

12. It is respectfully suggested that, in the context of a test for industrial applicability, it makes sense to ask whether a patent provides a "plausible" invention or only "a vague and speculative indication of possible objectives".

13. In the context of sufficiency or obviousness, however, the impact of the test is of even greater significance. In this context, it has been adopted as a threshold test (see for example § 37 in *Conor Medsystems Incorporated v Angiotech Pharmaceuticals Incorporated* [2008] UKHL 49 and *Warner-Lambert* v *Generics* at §46 and §130), which must be satisfied before separately assessing inventive step and/or insufficiency. A finding of lack of plausibility in the context of obviousness or insufficiency can invalidate the patent independently of a finding based on the established statutory tests for

obviousness and insufficiency. This makes it an important hurdle. The BIA is concerned that the hurdle for validity is not set too high.

14. The facts of the *Warner Lambert* case are a demonstration of the impact of the test since the Court of Appeal held that the claim was not plausible across its whole scope at the time of filing, even though in fact the invention works across the whole scope of the claim. The risk of setting a high threshold test for plausibility is that it has the potential to lead to a different result than the statutory tests for validity.

The impact of the plausibility test in the biosciences sector

15. The point in issue is particularly relevant to patents and patent applications for inventions relating to novel molecules and new uses for known molecules, which are key sources of innovation in the sector. A large amount of research and development is necessary before a molecule can be deployed therapeutically or used in a new application.

16. An innovative bioscience company must try to identify the optimum point in the period between discovery and therapeutic deployment at which to apply for a patent to protect its invention. The identification of this point is of critical importance. It will depend on the nature and extent of information the company has by then accumulated about that molecule, its function and its application.

17. If patentees are required to disclose a substantial amount of information in the original patent application in the form of experimental data to make plausible any potential uses described, tests will need to be conducted which show that the molecule has one or more potential uses. This amount of information will not be available in the early stages of the research and development process because it requires substantial work. Although in vitro assays or animal studies may point to a potential therapeutic area, small clinical trials in patients are often used to refine the therapeutic indication to be studied in later trials. Therefore, such clinical work is likely to be necessary to satisfy the test for plausibility.

18. Companies are increasingly required to publish clinical data. This jeopardises patent protection. While this transparency is obviously desirable, a plausibility test that has the effect of pushing companies to do clinical trials earlier than might have otherwise been appropriate and file patent applications at a very early stage is undesirable.

19. If the application is filed early, there may be too little information for a patent office or a court to identify a plausible aspect of the disclosed invention and the patent or the relevant claim will be invalid. The company may be left with no patent protection, but would have disclosed its invention in the published patent application to competitors.

20. If the application is filed late, in such a competitive environment, where it is likely that several companies will be working in the same field of research, the risk is that a third party will already have filed a patent application covering the same or a similar invention. Consequently, the company may not be able to gain any patent protection for its work and the value of the expensive research and development project will be lost. It may also risk infringing that competitor's patents by continuing its research.

21. The Court's determination of the nature and extent of the information that must be disclosed in a patent specification for an invention to be valid is therefore of key importance to all bioscience companies seeking to identify the appropriate application date. It will affect whether the patent system achieves its principal goals, which are the same in the bioscience sector as they are in others. The BIA filed an intervention in the Supreme Court case *Human Genome Sciences Inc* v *Eli Lilly and Company* [2011] UK SC 51 concerning the plausibility test in the context of sufficiency, because that raised similar concerns about the need for clinical data.

22. As the Supreme Court observed in *HGS* v *Eli Lilly*: (page 31):

> *"It is worth remembering the purposes of the patent system, namely to provide a temporary monopoly as an incentive to innovation, while at the same time facilitating the early dissemination of any such innovation through an early application for a patent, and its subsequent publication. Although this is true in any sector, it has particular force in the pharmaceutical field, where even many of those who are sceptical about the value of intellectual property rights accept that there is a public interest in, and a commercial need for, patent protection."*

23. The most important factor that investors in the biosciences sector consider when deciding whether to invest is the nature and extent of a company's patent portfolio. There will be reluctance to invest in a company whose work is not covered by a patent application. It follows that if patentees are unable to file any applications at the early stages of the process, when a degree of informed prediction about therapeutic use is possible, they will find it more difficult to attract the necessary investment at this stage. Similarly, if companies cannot have confidence that their patents will be reasonably safe from concern because of the uncertainty about the requirements for the data to be included, investors will be wary. Inability to attract investment may put whole research projects in peril or prevent companies from even initiating the relevant trials.

24. This case therefore raises questions of principle affecting the functioning of the biosciences sector and the interests of the members of the BIA to an appreciable extent.

25. The BIA accepts that patent offices are faced with a balancing act. The purpose of a patent is not to reserve an unexplored field of research for the applicant nor to give the patentee unjustified control over others who are actively investigating in that area and who might eventually find ways actually to exploit it. The invention disclosed in a patent at an early stage must not be a vague indication of possible objectives that might or might not be achievable by carrying out further research.

26. Therefore the BIA requests the Supreme Court endeavours to strike a balance that neither unfairly penalises biotechnology companies in requiring an unwarranted level of information (e.g. data from clinical studies), in order to demonstrate plausibility of an invention nor permits applicants to unfairly foreclose areas of research through the filing of patent applications disclosing only vague indications of possible research objectives flowing from a discovery.

Conclusion

27. For the reasons set out above, the BIA respectfully requests that it be granted permission to intervene by written submission in this appeal so that the court may consider this statement.