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To: The United States Patent and Trademark Office
By email to myriad-mayo_2014@uspto.gov

Dear Sirs,

You have invited comments on the Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products (Guidance) published by the USPTO on March 4, 2014.

Isis Innovation Ltd, UCL Business PLC, Imperial Innovations Group PLC and Cambridge Enterprise Ltd are the technology transfer offices for the University of Oxford, University College London, Imperial College London and the University of Cambridge respectively. Our institutions are world class research universities based in the UK, and we are active users of the worldwide patent system.

Between us we file ca. 250 priority patent applications per year based on University technologies, and we routinely file in the US when our applications reach PCT national phase, filing over 900 US patent applications during the last 5 years.

A substantial proportion of these applications would be affected by this guidance. For example, researchers in our Universities are very active in areas such as medical diagnostics, personalised medicines, biomarkers and genetic analysis for stratification of patient groups, novel therapeutics, antibodies, vaccines, antisense DNA and siRNA.

Isis Innovation Ltd, UCL Business PLC, Imperial Innovations Group PLC and Cambridge Enterprise Ltd, like many other University applicants in the US and elsewhere, seek to maximise societal impact from University science and technology, using the established technology transfer mechanisms of patenting and licensing. To achieve this in the University environment requires careful use of limited financial resources for patent prosecution and maintenance.

We are seriously concerned about the uncertainty created by the differences between the specifics of the case law and the breadth of the USPTO's Guidance. Following the Guidance, it is difficult to determine the patentability of a new technology, even with advice from our US qualified patent attorneys, thus the applicant with technology in these fields has to invest in patenting in the hope of obtaining a patent, but with no real means of assessing the chance of success. In addition, the financial uncertainty that arises from prolonged examination will impact significantly on our

budgeting processes and may lead to fewer patent filings globally by Universities and small businesses.

We fully support arguments put forward by others that the Guidance will discourage investment in the life science industries, and takes the US further away from patent harmonisation with other jurisdictions. In particular we reference an extremely thorough article submitted by Paul Cole, and refer to the several examples contained therein. These all highlight areas of potential concern for Higher Education Institutions such as the Universities for whom we work, whose societal impact is potentially threatened by an inability to protect their inventions across the full breadth of science. We refer especially to the current increase in research in biomarkers for diagnosis of disease, and genetic analysis in personalised medicine – areas where there is a lot of research at the above mentioned institutions – and for which there is a need to extract and purify/amplify a natural product in order to do something useful with it (see examples B2 and C of the P Cole paper).

We respectfully urge the USPTO to limit the Guidance to implementing the specific conclusions of the Supreme Court and to avoid an overly broad interpretation of the decision of the court into fields beyond those subjects of the specific cases. In order to ensure certainty for the user of the USPTO, we would ask that the uncertainty between the Guidance and the case law is resolved as soon as possible.

Yours sincerely,

Isis Innovation Ltd, UCL Business PLC, Imperial Innovations Group plc and Cambridge Enterprise Ltd