Guidance document for the Pharmaceutical sector

(Commission Draft V1.0, 3 October 2016)

Comments from the Chartered Institute of Patent Attorneys (CIPA)

1. CIPA is grateful for the opportunity to comment on the draft guidance document for the Pharmaceutical sector.

2. CIPA is the United Kingdom professional body that represents over 2000 UK patent attorneys. Most of our UK patent attorney members are also European Patent Attorneys and play major roles in representing clients at the European Patent Office. We also have other members who are European Patent Attorneys while not fully qualified as UK patent attorneys, and associate members (solicitors and barristers) active in intellectual property litigation.

3. CIPA members frequently file patent applications on inventions related to genetic resources, many with medical uses. We regard it as part of our job to help ensure that the research involved in such inventions is in full accordance with the law. We also see it as our task to try to ensure that the law governing such research is interpreted and administered in a way that fulfils its objectives, as clearly and as simply as possible.

4. The sector-specific guidance on the Pharmaceutical sector is exceptionally important. Pharmaceutical research and development is vital to the economy of the European Union. Still more importantly, the work done by the sector provides new drugs to relieve suffering in diseases of all types, as well as vaccines against infections both old and new. This work is of benefit to the whole world community. It must not be impeded unnecessarily.

5. We have comments of two types, general and specific. The former relate to the interaction of the Nagoya Protocol with public health policy under EU regulation 511/14: the latter to the detailed proposals set forth in the draft Guidance. We consider the former first.

6. The Nagoya Protocol is a protocol to the Convention on Biological Diversity (CBD). The objectives of the CBD are three-fold (paraphrased):

   preservation of genetic resources (GR)

   wider (sustainable) use of GR

   fairer sharing of the benefits of such use.

   The Nagoya Protocol emphasises the third, seen as neglected. But this emphasis must not be allowed to prejudice the first two – in particular the second. Unnecessarily strict, complex or uncertain rules to ensure sharing benefits can easily inhibit wider use. All three objectives must be held in balance. Further, the Protocol must not be applied in such a way as to detract from other important policy goals, such as public health.

7. The Protocol recognises the need to take into account other policy goals. In Article 8 ('Special Considerations'), parties are required to take into account 'emergencies' that 'threaten or damage human, animal or plant health' and the need for 'expeditious access' - to GR and the benefits resulting – including 'affordable treatments for those in need, especially in developing countries' [Art. 8(b)]. Special treatment for GR for food and agriculture ('food security') is also proposed [Art. 8(c)].

8. However, with regard to public health at least, the provisions of Regulation 511/14 are totally unsuitable. Influenza pandemics are specifically excluded from the Regulation (see Recital 16) as covered by a special agreement (the 'PIP Framework'). Seasonal influenza strains are not. They (and other infectious agents – ebola? Zika virus?), are covered (if at all) by Article 4(8). This allows research on such agents to begin immediately, without permission from the source country. However, unless arrangements for use and benefit-sharing are finalised with the source country within **three months,** research must **stop**. How could a company start work to defeat a threat like Ebola, if there were a real risk that after three months' work, and before they had developed a useful product, they must stop? Some fear Article 4(8) means it may no longer be possible to prepare annual vaccines against seasonal influenza strains.

9. The provisions of Article 4(8) are barely credible. They take no account of practicalities. Infectious agents carry no stamp revealing their country of origin. Sometimes this is known, because it is where the sample has been collected. But then there is the problem of finding out who in the country of origin has the right to grant consent to the research. To help to find the answer, the CBD Secretariat has set up a website on which countries are to list 'focal points' to deal with such matters. Some countries have done so, others not yet. Even when 'focal points' are listed, early experience shows that replies to enquiries are often not received within three months (or at all). Perhaps this may improve with time. But even if prompt replies are received, three months is a quite inadequate period for negotiating an important agreement of this kind. It seems likely that if a serious public health emergency arises, the provisions of Article 4.8 will simply be ignored. That in itself indicates that Regulation 511/14, at least insofar as it applies to public health, is unfit for purpose, and must be amended.

10. Meanwhile, the draft Guidance is proposed to deal with the position under the Regulation in its current form. We have two general comments on this.

11. Firstly, 'guidance' should be (to the extent possible) clear and definite. To say (as the Guidance does, in several places) "it could be argued that" is not helpful. Users want to know what they may do. If officially advised that an action 'could be argued' to be illegal, they won't do it. The Regulation is after all backed by criminal sanctions, in some countries at least. If the Commission feels that the argument is unsound, and may be disregarded, it should say so. That would not prevent a court subsequently deciding differently. However, if in such a case an action were subsequently found to be illegal, the 'user' would be able to argue that following the Commission's advice constituted 'due diligence'.

12. Secondly (and related to the first point) what is to constitute 'due diligence' is not made sufficiently clear. Research into genetic resources is to be encouraged, by as wide a range of users as possible, including academic researchers and SMEs. Such smaller entities, in particular, need the clearest possible instructions as to how to fulfil the legal requirements, so that they can have the confidence to invest time and money in risky projects. We are told by SMEs that the draft guidance does not meet that standard. We have no doubt that universities, which are generally risk-averse, will be of the same mind.

13. We hope that the draft guidance will be reconsidered in the light of the above comments. We also hope (while recognising that this is beyond the scope of the present consultation) that the Commission will give prompt and serious consideration to considering how Regulation 511/14 might be amended to respect important public health goals.

Submitted on behalf of CIPA by CIPA's Life Sciences Committee 10 November 2016