BRIEFING NOTE

from the Chartered Institute of Patent Attorneys (CIPA)

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THE NAGOYA PROTOCOL: NEW LAWS THAT MAY DAMAGE PUBLIC HEALTH AND UK SCIENCE

SUMMARY

CIPA is concerned about the damaging effect that EU implementation of the Nagoya Protocol to the Convention on Biological Diversity may have - on UK science in general and particularly on important biological research that may be conducted in the public interest, whether in the UK or elsewhere in the EU. CIPA calls on the UK Government to adopt the recommendations set out on page 2 of this paper.

BACKGROUND

- The Nagoya Protocol codifies the right of all countries to control research on non-human genetic resources found within their borders.
- The Protocol came into effect on October 12, 2014, expanding upon the principles found in the Convention on Biological Diversity (CBD,1993) to the effect that all research on genetic resources (including DNA and chemicals naturally produced within organisms) requires ‘prior informed consent’ and ‘mutually agreed terms’ from the 'country of origin'.
- Nagoya also obliges countries housing users of genetic resources ('user countries') to respect laws of the 'country of origin'. Future research on genetic resources will therefore be regulated by the laws (if any) of 'countries of origin'; as well as the laws of 'user countries'.
- The EU has implemented these requirements through Regulation 511/14. The intention of this Regulation is to ensure lawful use of genetic resources in accordance with the Protocol – a reasonable objective. However, the obligations it imposes are unclear and onerous. Further, two major countries, the USA and China, have not signed the Nagoya Protocol and may never do so.

KEY CONSIDERATIONS

- The central problem is that genetic resources - whether they are animals, leaves or microbes - do not carry a label indicating their origin nor whether they are subject to conditions of use. Those wishing to conduct research on such material will need to determine these facts for every sample they work on in order to comply with the Regulation. In addition, documentary evidence of each of these facts will need to be obtained and kept for 20 years. Worse, in cases of existing or impending public health emergencies, the Regulation requires that if the necessary formalities are not agreed within three months of research starting, the research must stop. This is ridiculous. In other than the very simplest cases, the formalities will almost inevitably take over three months. That essential life-saving research should be halted in such circumstances is quite unacceptable. The research being done to produce an Ebola vaccine has already taken more than three months and must continue. This short and arbitrary limit must be removed as soon as practicable..
- The Regulation requires Member States to impose weighty penalties for failure to comply. It is therefore vital that, before obligations on users come into effect in October 2015, those aspects of the Regulation that are unclear are clarified and detailed guidance issued as to

how to comply. No penalties should be imposed on a user who inadvertently or unwittingly breaches the law. New criminal offences are not required.

POTENTIAL CONSEQUENCES

- The Regulation applies only to research and development undertaken in the EU. If it remains unclear how to comply, or compliance is overly burdensome, or inadvertent breach is made a criminal offence, this will deter academia and companies of all sizes from embarking on cutting-edge research. Notably, the USA has not joined Nagoya or ratified the Convention and seems unlikely to do so. There is an obvious risk that important UK research will migrate, be abandoned or not be started at all. Were this to happen on a large scale, **the damage to UK science and UK business would be incalculable**.
- The negotiation of the required agreements for benefit-sharing will always take time and effort and may sometimes prove impossible. This could cause delays or prevent research altogether - including research to improve treatments for endemic diseases in developing countries and outbreaks which, like Ebola, could develop into a pandemic.
- Another example: suppose a batch of lettuces imported from South America were associated with consumer illness. The supermarket and the health authorities would need to research immediately whether pathogenic microbes were the cause. They would only be able to do so with appropriate consents from the country of origin of the pathogens - which may not be clear. Delaying or preventing such research would be unacceptable to the public, to the supermarket and to other retailers importing produce from that country.
- Any research on materials whose origin is not fully documented may prove too risky to undertake. Nagoya and the CBD aim to encourage research on biodiversity, but the Protocol, at least as implemented in the EU, seems as likely to discourage such research as to promote it.

RECOMMENDATIONS FOR GOVERNMENT

1. The Government in conjunction with the EU Commission, should produce clear official guidance, with examples, as to what companies and researchers should do to comply with the Regulation, especially regarding due diligence. Detailed consultation should take place with the user community, whose concerns must be adequately addressed, so that all involved may prepare fully to meet their new obligations under the Regulation.
2. Criminal sanctions for breach of the Regulation in the UK are disproportionate and unnecessary. If imposed at all, they should only be for flagrant and deliberate violations of the Regulation. There should be no criminal penalty for inadvertent or unintentional breaches.
3. As soon as the time is ripe, the Government should seek:
    a. first, to amend the Regulation to allow EU states to extend when necessary the three months time-limit on unsanctioned research vital for public health
    b. in the longer term, to adjust the Protocol so that provider countries lose their power of veto over such necessary research.

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Weblinks:

Convention on Biological Diversity - Nagoya Protocol - EU Regulation 0511/14