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CIPA comments on ABS Guidance and changes needed for the U.K.

About the Chartered Institute of Patent Attorneys (CIPA)

CIPA represents virtually all the 2,300 or so registered patent attorneys in the UK, whether employed in industry or private practice. Total membership is over 4,000 and includes trainee patent attorneys, judges, barristers and other professionals with an interest in protecting innovation through the use of intellectual property rights (patents, trade marks, designs and copyright).

CIPA members work on a wide range of intellectual property matters, both as external advisors and in house for innovative companies across a range of industries. All patent attorneys were scientists first. Patent attorneys working in the life sciences are qualified in areas such as chemistry and biological sciences (genetics, microbiology, animal cell culture, molecular biology, biochemistry, embryology, cell biology) and advise those using genetic resources, particularly those in drug development and pharmaceutical innovation, of their responsibilities under the CBD and the Nagoya Protocol

Backgound

In considering the guidance for those wishing to use genetic resources it should be kept clearly at the forefront of that consideration that:

CBD has three objectives:

To:

1. Conserve biodiversity;
2. Promote its sustainable use;
3. Share equitably the benefit arising from such use.

If there is no use, no benefits will arise and none of the objectives will be achieved.

It is also important to bear in mind some of the recitals to EU Regulation No. 511/ 2014 (the EU Regulation) on the compliance measures for users of genetic resources under the Nagoya Protocol which currently applies in the U.K.

> Recital 23: "The due diligence obligation should apply to all users irrespective of their size, including micro, small and medium-sized enterprises. This Regulation should offer a range of measures and tools *to enable micro, small and medium-sized enterprises to comply with their obligations at an affordable cost and with a high level of legal certainty*." [Emphasis added.]

Any measures and tools should be simple and cheap to use and their application should be clear and certain.

And Article 2.1.2 of EU Guidance Document (2016/C 313/01)

"The Regulation only applies to genetic resources from provider countries which have ratified the Nagoya Protocol and established applicable access measures" and

"One of the key ABS principles as stated in Article 15(2) of the CBD and further elaborated in Article 6(3) of the Nagoya Protocol is that Parties should facilitate access to genetic resources for environmentally sound uses by other Contracting Parties. For effective access and benefit-sharing, users need legal certainty and clarity when accessing genetic resources. *In accordance with Article 14(2) of the Nagoya Protocol, Parties are obliged to put their legislative, administrative or policy measures on ABS on the ABS Clearing-House*. This makes it easier for users and the competent authorities in jurisdictions where the genetic resources are utilised to get information on provider country rules. Accordingly, information on both elements, (a) whether a country is a Party to the Nagoya Protocol and (b) whether the country has access measures in place, can be searched on the ABS Clearing-House ….., the main mechanism under the Protocol for sharing information related to access and benefit-sharing, by searching the country profiles under https://absch.cbd.int/countries

In summary, with regard to the Regulation's geographic scope as regards the provenance of genetic resources, the combined effect of Article 2(1) and 2(4) is that *the Regulation only applies to genetic resources over which the countries exercise sovereign rights and where access and benefit-sharing measures have been established by a Party to the Protocol, with those measures applying to the specific genetic resource (or associated traditional knowledge) in question. When these criteria are not met, the Regulation does not apply.*"

[Emphasis added]

Thus far, the object appears to be to make it simple and straightforward for would be users of genetic resources, large and small, to discover whether or not Nagoya applies and, if it does apply, to put them in a position to know where to go to attempt to negotiate appropriate PIC and MAT. If the Party has not put the relevant information on the ABS Clearing House it has not complied with, and does not appear to be able to benefit from, the CBD and the Nagoya Protocol under EU law.

But reading further down EU Guidance Document (2016/C 313/01) it becomes clear that this apparently simple and straightforward approach is illusory. Article 3.2 states "If there is no information about applicable access and benefit-sharing measures on the Clearing House but there are reasons to believe that access legislation or regulatory requirements may nonetheless exist, and in other situations where the potential user considers that it might be useful, contact should be made directly with the provider country's National Focal Point (NFP) designated under the Protocol. If the existence of access measures is confirmed, the NFP should also be in a position to clarify what procedures are required to access genetic resources in the country in question. If despite reasonable attempts to obtain an answer from the NFP there is none, the (potential) users need to decide for themselves whether or not to access or utilise the genetic resources in question. The necessary steps in order to establish the applicability of the EU ABS Regulation are then considered to have been undertaken."

CIPA's comments

CIPA has considered EU Regulation 511/2014 of 16 April 2014 on compliance measures for users from the Nagoya Protocol; the ABS Guidance published by the EU in Regulation (EU) 2015/1866 of 13 October 2015; and Guidance Document 2016/C 313/01 of 27th August 2016. All are presently in

force in the U.K. CIPA has also considered The European Commission Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union (2021/C 13/01), which is under consideration.

CIPA's view is that all these documents are unnecessarily over prescriptive and over restrictive, and basically impractical. So much so that they are more likely to put people off attempting to do work on genetic material if they perceive there is even the slightest risk it could fall within scope. (CIPA understands anecdotally that major pharmaceutical companies in the U.K. have indeed abandoned possible lines of research on genetic material because of the uncertainty.)

It would be better to start again.

In the time available CIPA has limited itself to the problems posed by due diligence and by Article 8 of Regulation 511/ 2014, but these are merely the most extreme and egregious examples of the problems posed by the current law.

CIPA is also concerned at the penalties that may be imposed.

Due Diligence

One of the problems is the obligation of due diligence. The rules laid down by the current law and the OPSS require due diligence to be extensive and to be an on-going obligation. If the continuing obligation of due diligence is not complied with, or it subsequently transpires that despite reasonable efforts at the time research has been initiated, a party has not complied fully a party must abandon that research. So a party that has spent much time, money and effort in developing a product may be prevented from finalising it having started work after conducting due diligence satisfactorily. Such a situation is going to mitigate against any research on genetic resources being started.

The Nagoya Protocol provides at Article 13 that "Each Party shall designate a focal point on access and benefit sharing". Article 14 establishes a Clearing House and "each Party shall make available to the Access and Benefit-sharing Clearing-House any information required by this Protocol, as well as information required pursuant to the decisions taken by the Conference of the Parties serving as the meeting of the Parties to this Protocol." Both are obligations: "shall". They are obligatory.

CIPA believes that a party wishing to do research must search at the Clearing House. If there is relevant information there, the party must follow it up, get PIC and MAT as necessary and may then proceed with its research under the terms of those agreements. If there is no information, the Party to the Protocol has not complied with its obligations. The party wishing to do the research has complied with its obligations and should be free to continue and conclude its research and development and to commercialise any fruits of that work.

A Due Diligence Declaration would be made after completing PIC and MAT; or after completing a search at the Clearing House. No further declaration would be needed.

Penalties

The current penalties include criminal penalties. Criminal penalties, and indeed penalties generally, are too severe save in the most egregious cases where there has been knowing and deliberate refusal to comply with the requirements. And such penalties should only be visited on those directly responsible for that refusal. Inadvertent breaches should not be penalised. Particular care must be taken to avoid a situation where a search at the Clearing House has been made, nothing has been found, work has been done, time and money have been spent and, hopefully, a successful product has been produced or is on its way to development and that work is then stopped. To run the risk of finding work, time and money has been wasted will deter research and development and risks damaging the commercialisation of a potentially valuable product to the detriment of all parties.

EU Regulation.

Further, the EU Regulation itself, EU Regulation No 511/2014, is overly prescriptive and extends obligations beyond those intended or envisioned within the CBD and Nagoya.

In particular under Article 8 research on a pathogen causing a present or imminent public health emergency of international concern must be halted if PIC and MAT is not obtained within three months of research starting. In many cases obtaining PIC and MAT during a global pandemic is likely to be impractical, if not impossible, so research on a pathogen must stop? In the case of covid any research to develop improved vaccines to provide boosters must be stopped if material has been obtained from samples derived from another country and the consent is not immediately available. How much of the current work on vaccines for the autumn should be stopped? How much work on future strains or variants of covid must be stopped? Indeed how much work in the EU to develop covid vaccines has not been carried out in accordance with the CBD and Nagoya? Must the EU; must the world; abandon many of the vaccines that have been developed? And must the developers be penalised; criminalised; for giving the World vaccines that it desperately wants and needs?

This three month time limit set by the Regulation is much stricter than the requirement in Nagoya, Article 8, that each Party shall "Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries"

Further a representative of the OPSS, Jane Collins, stated recently at the ABS Stakeholder Meeting on 22nd April 2021 that if PIC and MAT had not been obtained after the three months "the materials must be destroyed", which goes even further beyond the obligation in the Regulation that in such circumstances "utilisation shall be discontinued" and must discourage any research being started. This amounts to "gold plating" of the Regulation, something the U.K. Government has said in the past that it will avoid.

There is a need, therefore, for the U.K. Government to undertake a detailed reconsideration of the obligations of the EU Regulation particularly their impact on public health policy and the ability of researchers to create medicines that are so desperately needed during a health crisis. Simpler rules providing a straightforward, practical system which will encourage research and innovation and not hamper and stifle it, are needed.

Digital Sequence Information (D.S.I.)

Under the Convention on Biological Diversity, Article 2, "Genetic material means any material of plant, animal, microbial or other origin containing functional units of heredity". Anything which does not include "functional units of heredity" is not within the scope of the CBD or Nagoya.

CIPA's view is that D.S.I cannot be within the scope of the CBD or Nagoya. Any attempt to include D.S.I. within the CBD and Nagoya would require a new treaty and a new protocol.

CIPA's view also is that to include D.S.I. in the CBD and Nagoya (or any other instrument), and accordingly to impose the requirements of PIC and MAT on pure information is going to make any work on sequence information, and accordingly on genetic material, totally impractical. CIPA understands that much of the research to develop vaccines against covid relied on the publication of the sequence of the covid virus. Since the CBD and Nagoya do not extend to D.S.I. such research would have been lawfully carried out. But if PIC and MAT was needed to work on sequence listings it would not have been lawful and the development of vaccines would have been delayed, or possibly compromised.

CIPA strongly supports the U.K.'s unwillingness to include D.S.I. in either the CBD or Nagoya and its belief that the Nagoya Protocol is not the appropriate mechanism by which to do that.

CIPA also believes that there should be no extension of the CBD or Nagoya, for example to the open ocean, at least until the current system is shown to be working well and delivering the benefits of conserving biodiversity; promoting its sustainable use; and leading to an equitable sharing of the benefits arising from such use.

Appendix to CIPA comments on ABS Guidance and changes needed for the U.K.

The Problems with Nagoya.

Its lack of precision. "The Nagoya Protocol has been described as a "masterpiece in creative ambiguity" (ENB, 2010, p. 26), which has "left experts puzzled about what exactly has been agreed on for many critical issues, […] giving rise to a range of partially conflicting interpretations" (ICTSD, 2010)."

The problems it gives rise to:

1. "the concept of national ownership of genetic resources reached its appalling culmination in the announcement by the government of Indonesia invoking "viral sovereignty" in order to deny access to a new strain of avian influenza (H5N1) virus that was first detected in that country".
2. "The protocol has the potential to hamper disease monitoring, according to the London-based biomedical research charity the Wellcome Trust. Red tape could make it harder to quickly share samples across borders, which in turn could cripple efforts to monitor drug resistance in malaria, for example, or outbreaks of *Escherichia coli*."
3. The concern about the ability to develop 'flu vaccines among other things, either in time or at all.
4. "The new rules will also present challenges for synthetic biologists, who combine genetic code from many different organisms to create drugs or sensors. This could require dozens of ABS arrangements for a single product, says Tim Fell, chief executive of Synthace, a biotechnology company in London. Such bureaucracy could push European companies to countries — particularly the United States — that are not signatories, he adds."
5. "There is also uncertainty about the protocol's reach, particularly for genetic sequences. A possible interpretation of the rules is that anyone who uses sequence data would have to complete ABS paperwork."
6. "the Nagoya Protocol threatens future microbial research, potentially defeating its original purpose."

The ever widening scope claimed for it: "But this assumes that 'access' means physical access. Many people (like the writer) have assumed this – what else could it mean? But more recently it has become apparent that developing countries have another view. For them, access means legal access – access for purposes agreed by the country of origin. According to this view, the CBD has given 'countries of origin' legal rights over 'their' resources that follow them wherever they go." This appears to extend to digital sequence listings.

"*ex post* renegotiation [of terms] has the possibility to generate considerable risk" as to the terms awarded. [In circumstances where something outside the terms of the original MATs takes place, and particularly if that something is commercially very successful]

The potential penalties: "The BioIndustry Association also says that the threat of criminal charges for non-compliance — the UK government is considering jail terms of up to two years — could have a chilling effect on research."

The following comment in The Economist from the former Chairman of India's National Biodiversity Authority (NBA): "I preferred to step down than support Government's intentions to restrict

exchange of resources and saw the approval mechanism as a money spinner for country's exchequer. With working experience for about 20 years on issues of 'biopiracy' I strongly believe in a facilitative ABS mechanism to promote sustainable use of genetic resources and ensure countries do not stop future actions for agriculture for climate resistance and food security." [I believe this is correctly in context.]

The risk that research may be moved from Nagoya countries, and particularly the EU with its extreme regime, to other countries, particularly the U.S. which is a party to neither the CBD nor Nagoya. It also appears that a product developed and manufactured in the U.S. would be free to circulate without being caught by the CBD at all anywhere.

The fact that there is no problem to solve. "the Protocol makes sense only if you believe that such a thing as biopiracy exists to a non-negligible degree." and "Recently an anonymous commentator on the blog stated that this activity happens all the time. When I challenged to support this allegation then answer came there none."