CBD and Nagoya Protocol -
Possible extension to include Digital Sequence Information (DSI)

Comments of the Chartered Institute of Patent Attorneys (CIPA)

CIPA is the professional body of UK patent attorneys (see endnote).

The Convention on Biological Diversity (CBD) has three fundamental objectives:

to preserve genetic resources (GR);
to promote their sustainable use;
to share equitably the benefits that result.

Each of these objectives is important, and commands respect. They are to be implemented, as far as possible, in a mutually supportive manner. But they may sometimes conflict. To ensure fair sharing of benefits, it may be necessary to impose restrictions on use. The balance can be delicate, and not always easy to achieve. The Nagoya Protocol is concerned with the third objective, and care is needed to ensure that it is not implemented in a way which unduly detracts from the first and second. Any proposal to extend the scope of the CBD and Protocol must be carefully examined to ensure balance.

As patent attorneys, we at CIPA are particularly interested in the second objective: promoting sustainable uses of GRs. Many such uses will be new. To develop new uses, patent protection may be needed: both to help fund the research and development necessary to introduce these new uses, and to generate cash benefits that can be shared with the countries of origin of the resources.

The Nagoya Protocol is relatively recent (having been implemented in the EU, for example, only since October 2014). It may be too early to say that it is working satisfactorily, in a fully balanced way. If so, it is premature to think of extending the scope of the Protocol.

A difficulty that is already arising with application of the Protocol is assigning GRs to their 'country of origin'. Where samples are collected *in situ*, the 'country of origin' is clear However, the Protocol applies to all (non-human) genetic resources, not just those few that have recently been collected *in situ*. It is frequently difficult confidently to assign 'countries of origin' to GRs that have not been collected *in situ*. The resulting uncertainty can be a strong disincentive to doing research, in case this may (for lack of the permission that the Protocol requires) prove to be illegal. We fear that too often this results in useful research not being done. In consequence, potential new uses of GRs are not being discovered or developed, and the second objective of the CBD is being thwarted. It seem to us that the first priority is to refine the working of Nagoya so that the laudable aim of sharing benefits does not inhibit the, at least equally important, task of discovering and extending uses of GR.

Accordingly **we suggest** that any amendment or extension of the CBD or Nagoya should be postponed until there is confidence that the current system is meeting its three objectives in a balanced manner. Progress might be reviewed in 10 years' time.

Problems with the new proposal:

1. It is unclear how it could work. Controlling use of published information is both difficult and generally considered illiberal. Similar restrictions currently exist in few national laws. The closest available analogy is the monopoly given by a patent of invention. However, this is not absolute, but qualified in many vital respects. Patent rights are granted by specific countries, for limited periods (usually, twenty years) and generally after examination for novelty. What may not be done is delimited carefully by statements of claim - and typically prevents only commercial use of the defined information, allowing full freedom for research on and with it. Who owns the rights, and can give permission to use them, is normally clear. Few if any of these limitations, it seems, will apply to DSI rights. Rather these will apply automatically, in perpetuity, in all member nations of the Nagoya

protocol. That will not encourage further members to join the Protocol - it might even result in some member states choosing to leave the Protocol or even the CBD altogether.

2. It is argued in some quarters that the CBD already covers information - that information is included within the term 'genetic material' in the definition of 'genetic resources' (CBD, Article 2). On the contrary, 'information' is clearly not 'material' - rather it is immaterial. The CBD has never been interpreted as introducing a right over information as such If the newly proposed interpretation were correct, then it would in fact be unnecessary to amend the CBD. Only slightly more plausible is the argument that the CBD as a matter of justice should have covered information as well as physical samples. However it clearly did not do so, and the proposal now to add it represents a major and almost certainly undesirable change in scope.

3. Various practical difficulties with any proposed 'information' right are noted in the draft paper. For example, is there a certain minimum length below which a sequence will not receive protection? Below a certain minimum number of bases (8? 15?), DNA sequences cannot (or will not) be unique - and many functional sequences of much greater length are not unique, but are found in more than one, dometimes many different, organisms. Also, how much difference will be required to distinguish two sequences - one protected and one not? Will this be done by sequence similarity (and if so, how much will be needed?) or by similarity of function, or by some combination of the two? (again, how?).

4. Some of the difficulties under 3. might be partly resolved by a 'copyright' approach - that is to say, by considering rights to arise only where the 'infringer' was shown to have seen (and, therefore, assumed to have copied) the earlier disclosure. That would still leave open the question of how much similarity, and of what kind, should be considered in judging the extent of the right given by the earlier disclosure.

In summary, it is difficult to see how a DSI right, that potentially exists in perpetuity, could be sensibly and equitably enforced, even if it were considered in principle desirable.

We note, however, that many respondents to the consultation share our doubts whether the right, even if practical, is on balance desirable. For example, the European Union submission says:".. *the EU and its Member States are concerned that disproportionate restrictions on sequencing of the genetic resources and the publication of DSI could result in a slowing down of research progress on a global scale due to decreased accessibility of information. Any such restrictions may also result in a reduction in research on biodiversity*.. ". The UK Natural History Museum (joined by two UK Botanic Gardens, Kew and Edinburgh) states;"*Our unequivocal view is that sharing DSI without hindrance is overwhelmingly beneficial.* ". The Wellcome Trust, with the Sanger Institute, say: "*We strongly disagree with the proposal to include digital sequence information (DSI) in the scope of the Convention on Biological Diversity (CBD) and the Nagoya Protocol. We agree fully that countries should share equitably in the benefits of research and development activities to which they contribute and which utilise sovereign genetic resources, but consider that the inclusion of DSI would fail to achieve this goal, and* ***do far more harm than good***."(emphasis added).

We at CIPA respectfully endorse these views.

End Note: The Chartered Institute of Patent Attorneys ((CIPA)

. CIPA was founded in in 1882 and was incorporated in the UK by Royal Charter in 1891. It represents virtually all the 2000 or so registered patent attorneys in the UK, whether employed in industry or serving the general public. Total membership is over 3,200 and includes trainee patent attorneys, and other professionals with an interest in intellectual property (patents, trade marks, designs and copyright). It became, by the UK egal Services Act 2007, the official regulator of the patent attorney profession in UK, its regulatory functions being carried out completely independently of the membership. Members advise clients on a wide range of intellectual property matters, representing all types of enterprise both large and small in drafting, filing, prosecuting and enforcing patent rights throughout the world. Members are well placed to advise inventors who use genetic resources of their responsibilities under the Nagoya Protocol.

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