

The Executive Secretary  
Secretariat of the Convention on Biological Diversity  
United Nations Environment Programme  
413 Saint-Jacques Street, Suite 800,  
Montreal, QC, H2Y 1N9,  
Canada

By Email to: [secretariat@cbd.int](mailto:secretariat@cbd.int)

31 May 2019

Dear Executive Secretary

### **Digital Sequence Information on Genetic Resources: Submission of views**

We provide a submission of views pursuant to Decision 14/20, paragraph 9, of the fourteenth meeting of the Conference of the Parties to the Convention on Biological Diversity and Decision NP-3/12 of the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol on Access and Benefit-Sharing.

### **About the Chartered Institute of Patent Attorneys (CIPA)**

CIPA was founded in 1882 and was incorporated in the United Kingdom 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).

CIPA 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.

### **The Convention on Biological Diversity and the Nagoya Protocol**

The Convention on Biological Diversity (the "CBD") established three objectives: the conservation of biodiversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources (Art. 1 CBD).

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the CBD (the "NP") implemented and further specified Article 15 of the CBD, on access to genetic resources. The NP set up international rules governing access to genetic resources and associated traditional knowledge, and benefit sharing as well as user compliance measures. Benefit-sharing under the NP is based on so-called mutually agreed terms (MAT), which are contractual agreements concluded between a provider of genetic resources or traditional knowledge associated with genetic resources, and a natural or legal person accessing the genetic resource and/or associated traditional knowledge for the utilisation thereof (a "user").

**CIPA**  
The Chartered Institute of Patent Attorneys

2<sup>nd</sup> Floor, Halton House  
20-23 Holborn  
London EC1N 2JD  
T: 020 7405 9450  
F: 020 7430 0471  
E: [mail@cipa.org.uk](mailto:mail@cipa.org.uk)  
W: [cipa.org.uk](http://cipa.org.uk)

PATENTS  
TRADE MARKS  
DESIGNS  
COPYRIGHT



The key terms used in the CBD and, particularly in Article 2 of the NP, are as follows:

- **“Genetic resources”** means genetic material of actual or potential value.
- **“Utilisation of genetic resources”** means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the CBD.
- **“Biotechnology”** means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.
- **“Derivative”** means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

#### **DSI does not fall within the definition of ‘genetic resources’ as defined in the CBD and NP**

The terminology used to describe DSI in the context of the CBD and NP is always in relation to information on a genetic resource. Hence, by definition DSI on genetic resources cannot be considered to be comprised within the genetic resource itself. By analogy, the information about a chemical element as presented in the periodic table is not considered to constitute a part of the element itself. Rather, information on a chemical element is simply a description of the properties that the element exhibits in nature. This is no different to DSI which, in its broadest form, may simply represent a description of properties of a physical material which happens to be a genetic resource. Clearly it is wrong to suggest that a digitised sequence of letters that are biology shorthand for a nucleic acid sequence of a genetic resource somehow imbue and embody the chemical and genetic properties of that physical material to the extent that they are inherent within the definition of that physical resource. DSI is simply an abstraction that is representative and informative about a physical material, the genetic resource, but it is not the resource itself.

Any proposal to extend the concept of a ‘genetic resource’ to encompass DSI on that resource is an attempt to extend the terms of the CBD and NP beyond the originally intended and agreed scope of physical materials as articulated in Article 2 of the NP *inter alia*. To extend the CBD and NP into the realm of information control represents a clear departure from the original intentions and aims of the CBD. This presents multiple challenges to wider aspects of society and international relations that is beyond the remit of the *ad hoc* technical expert group (AHTEG) to analyse fully within the time span available.

If a genuine need is shown to exist for DSI to be controlled by a convention similar to the CBD so that it may achieve the three primary objectives, we believe that this should be the subject of an entirely new protocol. It is our view that it is inappropriate to contort the currently accepted definition of ‘genetic resources’ within the CBD and NP to such an extent that the integrity of the CBD and NP as a whole is compromised.

#### **DSI does not constitute “Traditional knowledge associated with genetic resources”**

“Traditional knowledge associated with genetic resources” is defined in the NP as traditional knowledge held by an indigenous or local community that is relevant for the utilisation of genetic resources and that is described in the mutually agreed terms applying to the utilisation of genetic resources. As such, DSI cannot be considered as constituting a form of traditional knowledge. If DSI were to be considered to be traditional knowledge presumably DSI generated in a laboratory would belong to the investigators in the laboratory and so, presumably, in many cases to their employer.

## **Imposition of benefit-sharing arrangements from commercial and non-commercial use of DSI on genetic resources would have a profound effect on freedom of thought and freedom of research**

Article 5 of the NP specifies that an intention of the CBD is to ensure that benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources. Free sharing of information, such as DSI, represents a fundamental benefit in its own right. Indeed, the free dissemination of DSI arising from physical genetic resources that have been subject ABS on MAT represents in its own right the very manifestation of the objectives of Article 5.

Article 17 of the CBD requires that Parties shall facilitate the exchange of information, from all publicly available sources, relevant to the conservation and sustainable use of biological diversity, taking into account the special needs of developing countries. The CBD, therefore, explicitly promotes the exchange of information, of which DSI is one type.

Parties, other Governments, indigenous peoples and local communities are the fundamental beneficiaries of a world where free and unfettered use of DSI allows for the production of new medicines, improved crops, new materials, biohazard monitoring and bio-vigilance to name but a few.

It is practically impossible to divide commercial from non-commercial use of DSI. The gap between the academic and private sectors is not clear cut. A great many of the world's major academic institutions from a great many countries are some of the largest holders of patented technologies. These intellectual property estates are a vital source of income to support fundamental basic research that benefits all of humanity. Hindering the public-funded sector from the ability to leverage their research base for commercial objectives, through the imposition of additional regulatory burdens such as ABS for DSI, could lead to catastrophic loss of interest in, and of vital funding streams for, that research.

Imposing a regime of benefit-sharing on MAT for DSI could result in either widespread non-compliance or, more worryingly, a mass movement of important research away from DSI on genetic resources that are subject to NP regulatory burdens. CIPA has been informed from other major stakeholders in the life science industry that such movement away from research on physical genetic resources subject to ABS is already occurring. In at least one example that we are aware of, following due diligence one major biotech company, which had previously been researching on "out of NP scope" material, opted not to pursue a similar research programme on material that was "in NP scope" due to a lack of clarity of the administrative process in the country of origin. If the definition of genetic resources is extended to include DSI it is likely to introduce multiple further parties from whom MAT and PIC will have to be obtained so increasing the difficulties. We fear that this movement could accelerate significantly. Preventing or reducing the sustainable utilisation of important genetic resources and the transfer of technology is contrary to the objectives of the CBD. It cannot be the intention of the CBD to frustrate beneficial research and transfers.

Widespread non-compliance with expanded scope of the NP to include DSI, could lead towards criminalisation of legitimate commercial and non-commercial research in countries that are Party to the NP. Once again, this could lead to outcomes that are fundamentally in contravention with the objectives of the CBD, most notably the conservation of biodiversity, and the sustainable use of its components. Hence, imposition of MAT for DSI could frustrate the three primary objectives of the Convention: the conservation of biodiversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.

The CBD recognises that some measures, policies or practices induce behaviour that is harmful for biodiversity, often as unanticipated side effects to policies designed to attain other objectives. Such unintended consequences are referred to in the CBD as 'perverse' incentives. Whilst the CBD clearly views subsidies that promote overproduction or consumption of resources as perverse incentives, it is important to recognise that

denial of free access to DSI and implementation of tariffs or controls on the use of information could also have a perverse effect on biodiversity and sustainable use of genetic resources.

**Imposition of benefit-sharing arrangements on use of DSI could restrict access to information for the purpose of conservation of biological diversity and the sustainable use of its components**

An unintended consequence of the proposals to include DSI within the remit of the NP could be to limit access to DSI for researchers around the world. The vast majority of biotechnology occurs within commercial and non-commercial R&D facilities within those Parties, or other Governments (such as the United States of America), that have developed advanced economies. For decades these advanced economies have utilised genetic resources, in the process of which they create and will continue to create DSI that could fall within a proposed remit of the NP.

Imposing a regime of benefit-sharing on MAT for DSI could result in advanced economies electing to control free access to DSI originating within their biotechnology industries and research facilities. In this way, the NP might serve to empower advanced economies to the detriment of conservation of biological diversity and the sustainable use of its components. In particular, loss of access to DSI might serve to impoverish developing nations, indigenous peoples and local communities by depriving them of the free access to the use of DSI they currently enjoy. Hence, an unintended consequence of extending the NP to cover use of DSI might be to hand the advanced economies yet a further mechanism to exert advantage over developing nations.

At present the benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization that is vested in the DSI created by these advanced economies is generally shared by all Parties that can access them online. In effect, DSI is by-and-large considered an open resource. This benefit is available to communities in all Parties to the NP and beyond, including indigenous peoples and local communities.

Article 16 of the CBD recognises that access to, and transfer of, technology among Parties are essential elements for the attainment of the objectives of the CBD. It is apparent that creating a regime that allows advanced economies to control access to DSI until MAT have been agreed will be disadvantageous to developing nations who have limited resources available.

It is not clear from any proposals so far put forward whether ABS resulting from the use of DSI would be allocated directly to the objectives of the CBD or would remain within the remit of the originator country. Allowing nations to control the use and exploitation of DSI, under the umbrella of the CBD, risks affording a sovereign moral right to the developed nations to levy the rest of the world for the use of DSI. This use might be in the form of the information itself, or more worryingly in the form of products, perhaps even medicines. This cannot possibly be to the benefit of the developing world or its indigenous communities.

It is our position that any measures taken under the CBD that restrict the use and exploitation of DSI will correspondingly reduce the dissemination of knowledge, contrary to the aims of the CBD.

DSI should not be included within the remit of the CBD or Nagoya, and nor should a convention be introduced which attempts to impose similar controls on DSI.

We at CIPA respectfully endorse these views.