THE NAGOYA PROTOCOL AND SYNTHETIC BIOLOGY RESEARCH:
A Look at the Potential Impacts



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Synthetic BIOLOGY PROJECT

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The views expressed are the authors own and do not necessarily represent those of the Woodrow Wilson International Center for Scholars, University of Virginia School of Law, or Duke Law School.

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Professor Bagley's writings include: Margo A. Bagley, Ruth L. Okediji, and Jay A. Erstling, *International Patent Law and Policy* (West Publishing 2013); *Patent Law in Global Perspectives*, (Ruth L. Okediji & Margo A. Bagley, eds., Oxford University Press, forthcoming, 2014); *Pharmaceutical Data Exclusivity Protection*, book chapter in Drexl Josef and Nari Lee eds. '*Pharmaceutical Innovation, Competition and Patent Law: a Trilateral Perspective*,' (Edward Elgar Publishing, 2013); *The New Invention Creation Boundary in Patent Law*, (51 William & Mary L. Rev. 2009); *The Need for Speed (and Grace): Issues in a First-Inventor-To-File World*, 23 Berkeley Tech. L.J. (2008) (symposium issue); *Patents and Technology Commercialization: Issues and Opportunities*, book chapter in vol. 18, Advances in the Study of Entrepreneurship, Innovation and Economic Growth (Gary Libecap, ed., Elsevier Science and Technology Books 2007); *Academic Discourse and Proprietary Rights, Putting Patents in Their Proper Place*, 47 B.C.L. Rev. 1 (2006); Patent First, Ask Questions Later: Morality and Biotechnology in U.S. Patent Law, 45 William & Mary L. Rev. 1 (2004).

Arti K. Rai, Elvin R. Latty Professor, Duke Law School, co-Director, Duke Law Center for Innovation Policy, and Faculty Associate, Duke Institute for Genome Sciences and Policy, is an internationally recognized expert in intellectual property (IP) law, administrative law, and health policy. Rai has also taught at Harvard, Yale, and the University of Pennsylvania law schools. Rai's research on IP law and policy in biotechnology, pharmaceuticals, and software has been funded by NIH, the Kauffman Foundation, and the Woodrow Wilson Center. She has published numerous articles, essays, and book chapters on IP law, administrative law, and health policy. She recently received a 5-year grant from the NIH to examine genomics as information. Her publications have appeared in both peer-reviewed journals and law reviews, including Science, the New England Journal of Medicine, the Journal of Legal Studies, Nature Biotechnology, and the Columbia, Georgetown, and Northwestern law reviews. She is the editor of *Intellectual Property Law and Biotechnology: Critical Concepts* (Edward Elgar, 2011) and the co-author of a 2012 Kauffman Foundation monograph on cost-effective health care innovation.

From 2009-2010, Rai served as the Administrator of the Office of External Affairs at the U.S. Patent and Trademark Office (USPTO). As External Affairs Administrator, Rai led policy analysis of the patent reform legislation that ultimately became the America Invents Act and worked to establish the USPTO's Office of the Chief Economist. Prior to that time, she had served on President-Elect Obama's transition team reviewing the USPTO. Prior to entering academia, Rai clerked for the Honorable Marilyn Hall Patel of the U.S. District Court for the Northern District of California; was a litigation associate at Jenner & Block (doing patent litigation as well as other litigation); and was a litigator at the Federal Programs Branch of the U.S. Department of Justice's Civil Division.

Rai regularly testifies before Congress and relevant administrative bodies on IP law and policy issues and regularly advises federal agencies on IP policy issues raised by the research that they fund. She is a member of the National Advisory Council for Human Genome Research and of an Expert Advisory Council to the Defense Advanced Projects Research Agency (DARPA). Rai is a public member of the Administrative Conference of the United States, a member of the American Law Institute, and co-chair of the IP Committee of the Administrative Law Section of the ABA. Rai is currently a member of the Institute of Medicine Committee on Strategies for Responsible Sharing of Clinical Trial Data and has served on, or as a reviewer for, numerous National Academies of Science committees. In 2011, Rai won the World Technology Network Award for Law.

Glossary of Terms

Definitions from Article 2 of the Convention on Biological Diversity:

- "Biological diversity" means the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.
- "Biological resources" includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.
- "Biotechnology" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.
- "Country of origin of genetic resources" means the country which possesses those genetic resources in in-situ conditions.
- "Country providing genetic resources" means the country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country.
- "Domesticated or cultivated species" means species in which the evolutionary process has been influenced by humans to meet their needs.
- "Ecosystem" means a dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit.
- "Ex-situ conservation" means the conservation of components of biological diversity outside their natural habitats.
- "Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.
- "Genetic resources" means genetic material of actual or potential value (tangible and intangible).
- "Habitat" means the place or type of site where an organism or population naturally occurs.
- "In-situ conditions" means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.
- "In-situ conservation" means the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

- "Protected area" means a geographically defined area which is designated or regulated and managed to achieve specific conservation objectives.
- "Sustainable use" means the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations.

Definitions from Article 2 of the Nagoya Protocol:

- "Utilization 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 Convention;
- "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.

Acronyms

NP	Nagoya Protocol on Access and Benefit Sharing
CBD	Convention on Biological Diversity
DNA	Deoxyribonucleic acid
PIC	Prior Informed Consent
ABS	Access and Benefit Sharing
DOO	Disclosure of Origin
COP	Conference of the Parties
UN	United Nations
LMOs	Living Modified Organisms
TBD	To Be Determined
EU	European Union
NGO	Non-Governmental Organization
GR	Genetic Resource
TK	Traditional Knowledge
MATs	Mutually Agreed Terms
IP	Intellectual Property

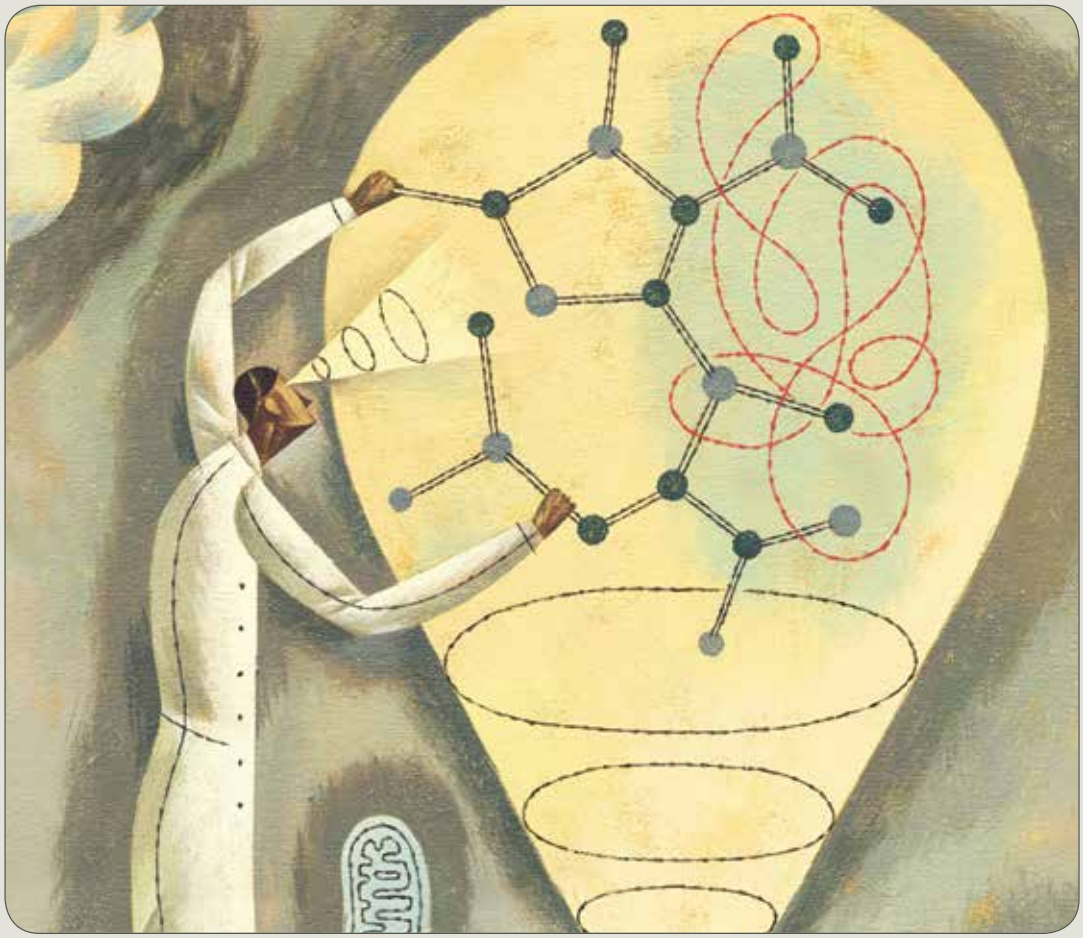
Executive Summary

This report assesses how implementation of the Nagoya Protocol on Access and Benefit Sharing (NP) to the Convention on Biological Diversity (CBD) may affect U.S. researchers working in the area of synthetic biology. It also analyzes selected provisions in CBD-related national legislation predating the NP that may be relevant for such researchers.

The report concludes that numerous questions remain unanswered, both with respect to the time period covered by CBD/NP and with respect to what sorts of genetic material are covered. Despite this uncertainty, and despite the fact that the U.S. is not a party to the CBD/NP, U.S. researchers would be well-advised to:

1. inquire into the origin of tangible genetic material that they use and, where applicable, to
2. ensure that such material was taken in compliance with the domestic law of a provider country

With respect to digital genetic information, determining origin is likely to be more difficult. Even so, provider countries may assert that such information falls within the scope of the CBD/NP.



Synthetic Biology and Genetic Resources

Synthetic biology aims to take genetic engineering to a new level. Whether this new level will ultimately be revolutionary or evolutionary remains to be seen. Revolutionary advances might allow full-scale application of engineering principles like standardization, decoupling of information from manufacture, and abstraction, with the result that well-characterized DNA parts could readily be assembled in many different ways to generate predictable outputs.[1] On the other hand, if current levels of unpredictability in biology continue to perplex researchers,[2] synthetic biology may be better understood as a suite of evolutionary advances in DNA synthesis and system modeling that allow more rapid design of new microbial systems.[3]

Regardless of how the technology develops in the future, synthetic biology research into improving DNA sequences (including not only full sequences that code for proteins but also sequences that have other functions) has already utilized significant quantities of tangible genetic material.[4] Additionally, the emergence of firms that can synthesize relatively long DNA sequences accurately has highlighted the central role of intangible genetic information.[5]

For purposes of compliance with the CBD/NP, one key question is whether particular genetic material and information represents "genetic resources." As shown in the glossary,[6] the CBD and NP define "genetic resources" to mean "genetic material of actual or potential value." Genetic material, in turn, means any material that contains "functional units of heredity."

Neither the CBD nor the NP defines "functional units of heredity."[7] Thus it is unclear whether all categories of DNA sequences are covered. In addition, important questions regarding the reach of the CBD/NP into intangible genetic information or so-called derivative products remain unanswered. We address these issues in the Implementation Issues Section. Before addressing these and other specific issues of implementation, however, we provide relevant historical and policy background on the CBD/NP, particularly with respect to the U.S. role.

Background on the Convention on Biological Diversity and the Nagoya Protocol

The CBD is designed to facilitate the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits generated by the use of genetic resources.[8] It establishes that genetic resources should be viewed not as the common heritage of mankind, freely available to all, but instead as the property of sovereigns who make access to them available under principles of prior informed consent (PIC) and access and benefit sharing (ABS).[9]

The CBD is an environmental treaty in the sense that it was driven by a desire to stem the uncontrolled depletion of flora and fauna diversity, largely in the global south. But the agreement was also designed to address concerns relating to "biopiracy." Biopiracy has been defined as "[t]he patenting of plants, genes, and other biological products that are indigenous to a foreign country without compensating the keepers of those resources and the holders of knowledge appropriated during ethnobiological research processes."[10] Compensation, in turn, would presumably provide an incentive for appropriate biodiversity conservation going forward.

The CBD has 193 members and went into effect in 1993. Its key principles include the following:

- States have sovereign control over biological resources within their borders and shall ensure conservation of same (Art. 3);
- States shall endeavor to create conditions to facilitate access on mutually agreed terms and subject to prior informed consent (Art. 15(2));
- There should be fair and equitable sharing of benefits of use of genetic resources with the providing party (Art. 15(7)); and
- Any wider application of traditional knowledge (TK) shall be with the approval and involvement of TK holders (Art. 8(j)).[11]

Although then-President Bill Clinton signed the CBD in 1993 on behalf of the United States, the treaty was never ratified by the U.S. Senate. Consequently, the United States is not a party to either the CBD or the NP. The U.S. is also opposed to CBD-implementing legislation in many countries which, for example, links ABS/PIC obligations with patent protection through a disclosure of origin requirement for genetic resources used in creating an invention. (See Box: U.S. Opposition to linking ABS/PIC) For example, as discussed later, the 2009 amendments to the Chinese Patent Act included provisions requiring patent applicants to disclose the country of origin of relevant genetic resources used in creating an invention and denying patent protection to inventions created with genetic resources obtained in violation of Chinese law.

In addition, for many years, a number of countries rich in genetic resources (so-called "provider countries") have been pressing in several multilateral fora for ABS/PIC treaty provisions and a new Disclosure of Origin (DOO) patentability requirement. Such efforts have generally been consistent with, and designed to give effect to, the CBD. Many of these countries also have created, or are in the process of creating, biodiversity legislation, first to comply with the CBD and more

recently to implement the NP after it comes into force. Most countries do not view treaty obligations as self-implementing; rather, they must be incorporated into domestic law by implementing legislation.[12]

Most countries embrace dualism. However, some dualist countries do allow treaties to have direct effect in national law on a case-by-case basis.[13] Implementing legislation often is also necessary because treaty terms may lack specificity regarding how obligations are to be met, leaving such details to individual countries to decide.

The Conference of the Parties (COP) is the governing body of the CBD and takes decisions at periodic meetings to advance implementation of the Convention. Its decisions include the promulgation of the Cartagena Protocol on Biosafety,[14] which went into effect in 2003, adoption of the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising from their Utilization in 2002[15] (See Appendix for full text of Bonn Guidelines) and, at its Tenth meeting in 2010 Nagoya, Japan, the Nagoya Protocol on Access and Benefit Sharing to the Convention on Biological Diversity ("NP"). The Bonn Guidelines and the NP were necessary because, while the CBD obligated Parties to facilitate access to their genetic resources, and to fairly and equitably share benefits arising from the utilization of genetic resources with provider countries, it provided almost no detail on how ABS should be accomplished in practice.[16] Consequently, provider countries had wide latitude in developing legislation to implement the CBD, creating a miasma of legal uncertainty for users faced with often burdensome rules for ABS/PIC that varied significantly by country. Over the eighteen years that elapsed between adoption of the CBD and adoption of the NP, the Parties studied and debated ways to move forward on this issue. Although the Bonn Guidelines were a helpful step in providing further specificity on ABS and PIC, they are not binding on Parties. The NP, as a binding agreement, is a logical step in the evolution of a detailed framework to reduce uncertainty and provide increased uniformity for both users and providers of genetic resources and associated TK.[17]

That said, whether the NP ultimately fulfills its goal of bringing greater certainty and uniformity will depend on how it is implemented and ultimately comes into effect. Although the NP was adopted in 2010, it will not formally come into effect until ninety days after the fiftieth instrument of ratification is deposited with the CBD.[18] Ninety-two countries signed the agreement, and twenty-six have ratified it at the time of this writing. Interestingly, some countries, such as China, that are parties to the CBD, did not sign the NP before the deadline for signatures passed. Nevertheless, such countries can still accede to the Protocol at a later date, and even countries not parties to the CBD can accede to the Protocol as long as they also become a contracting party to the CBD at the same time. In addition to ratifying the NP, member countries must enact legislation to implement the Agreement. It is expected that the Agreement will come into effect in 2014 at the earliest.

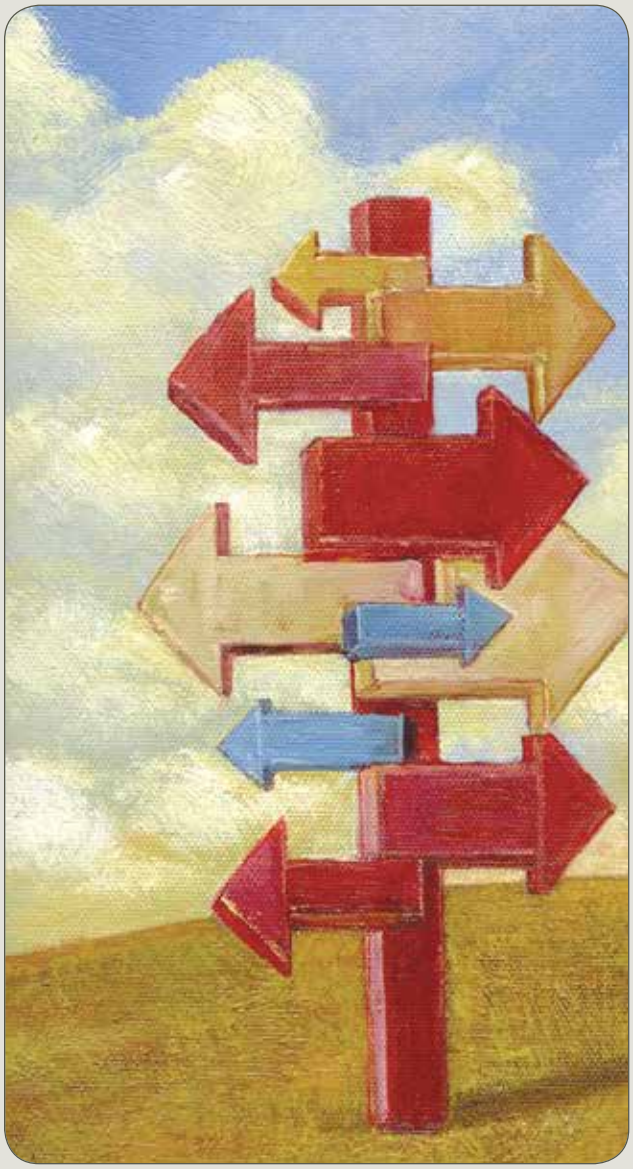
The NP has two main foci: access and user compliance. The access provisions give Parties significant leeway to decide whether they wish to regulate ABS and require PIC for their genetic resources. If a country decides to regulate ABS/PIC, it then must implement the rather detailed NP international access

standards, which build on and incorporate aspects of the Bonn Guidelines to create a framework for ABS/PIC. Regarding user-compliance, the NP requires all Parties to ensure that only legally acquired genetic resources and associated TK are utilized in their jurisdictions, to monitor user compliance via checkpoints (e.g., when receiving public funding), and allow for ABS contract disputes to be resolved in court. However, the NP allows a fair amount of Party discretion in choosing particular user-compliance implementing measures.[19]

The NP includes the following key provisions:

- It is applicable to genetic resources covered by CBD Article 15, to the benefits arising from the utilization of such resources, as well as to traditional knowledge associated with such resources and benefits arising from utilization of such knowledge (Art. 3).
- It incorporates the definitions provided in the CBD and additionally defines "derivatives" and "utilization of genetic resources" (Art. 2).
- It leaves to the discretion of the parties whether to regulate access to their genetic resources and associated traditional knowledge, and require prior informed consent and benefit sharing (ABS/PIC). However, any parties choosing to require PIC must implement, through binding legislation, the detailed access standards specified in the Protocol (Art. 6).
- It specifies that, consistent with CBD Art. 15, benefits arising from genetic resource utilization shall be shared in a fair and equitable way with the Providing Party and shall be upon mutually agreed terms (MAT) (Art. 5).
- It encourages countries to explore the need for and modalities of a global multilateral benefit sharing mechanism/fund to facilitate benefit sharing (Art. 10).
- It requires countries to designate national focal points for access and benefit sharing, so as to make information available to users, providers and the COP, on the procedures for obtaining PIC and complying with ABS requirements (Art. 13).
- It requires countries to designate one or more checkpoints to collect information from users of genetic resources when users claim, for example, an intellectual property right relating to a product developed from genetic resource utilization. It also provides for certain government-issued permits to serve as internationally recognized certificates of compliance;[20] evidence that covered genetic resources have been accessed in accordance with PIC/ABS on mutually agreed terms (Art. 17).
- Several of its Articles also deal with ABS and PIC obligations when traditional knowledge is used (e.g., Arts. 7 & 12).

Article 4 also explains how the NP relates to other existing and future treaties, noting that the NP does not affect Party rights and obligations in relation to other existing agreements, except when exercising those provisions would seriously damage or threaten biological diversity. It also states that although it is the instrument for implementing the ABS provisions of the CBD, it does not apply to Parties of other specialized international agreements with ABS provisions that are consistent with the objectives of the CBD and NP in respect of the specific genetic resource covered by the specialized instrument. Thus, for example, the sharing of genetic resources for food and agriculture is excluded from the NP, as such are covered by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).[21]



BOX 1

U.S. opposition to linking ABS/PIC obligations with patent protection through a disclosure of origin requirement for genetic resources used in creating an invention

A U.S. Group response to a 2010 AIPPI questionnaire on the "Requirement of Indicating the Source and/or Country of Origin of Genetic Resources and Traditional Knowledge in Patent Applications" sums up the Position of the United States on this issue:

While the United States has been monitoring the proposals that have been made in a variety of fora to allow or mandate that national patent legislation require the declaration of the source of genetic resources and traditional knowledge in patent applications as well as demands for sharing of benefits from the commercialization of products utilizing them, the US government, with the strong support of US companies, has taken the position that these initiatives are unwise and unnecessary.*

A separate document explains reasons for the U.S. position:

We further note that there appears to be a presumption by the proponents, without empirical evidence, that an invention related to a genetic resource is automatically based upon illegal access or misappropriation absent concrete evidence to the contrary. However. . . many genetic resources are indeed commercially sold, legally obtained, and independently researched and developed into inventions. Even within publicly accessible international and national gene banks, there are many resources where the country of origin is unknown. Even assuming arguendo, that new disclosure requirements could achieve the purported goals, new patent disclosure requirements would be unworkable given the absence of knowledge of country of origin for numerous publicly available resources. However. . . such new disclosure requirements create legal uncertainty and increased burdens on the patent system, as well as negative effects on benefit sharing, but will not prevent the purported acts of misappropriation or bad patents. These objectives must be accomplished through national ABS systems upon access to the material initially. These examples lead to the conclusion that new patent disclosure requirements will not achieve the desired objectives and that incorporation of such requirements in the patent system would stifle innovation and undermine the patent system.**

There are no pending bills or discussions that would suggest that legislation will be introduced on these issues within the United States. It should also be noted that the United States is not a party to the Convention on Biological Diversity [CBD], and no pending legislation exists that would alter that status.

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*International Association for the Protection of Intellectual Property (AIPPI), Questionnaire February 2010: Special Committees Q 94—WTO/TRIPS and Q166—Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore on the Requirement of Indicating the Source and/or Country of Origin of Genetic Resources and Traditional Knowledge in Patent Applications: Communication from the US Group (Apr. 7, 2010).

**Council for Trade-Related Aspects of Intellectual Property Rights, Communication by the United States, Article 27.3(b), Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore, IP/C/W/469, para. 37 (Mar. 13, 2006). See also Jonathan Carr, *Agreements That Divide: TRIPS vs. CBD and Proposals for Mandatory Disclosure of Source and Origin of Genetic Resources in Patent Applications*, 18 J. Transnat'l L. & Policy 131, 144 (2008) (discussing U.S. opposition to proposed TRIPS disclosure of origin amendments). Nevertheless, regulations are apparently in place for U.S. government agencies to comply with CBD and Protocol requirements when engaging in commercial and noncommercial scientific research. See Geoff Burton, *Implementation of the Nagoya Protocol in JUSCANZ Countries: The Unlikely Lot*, p. 311, in The 2010 Nagoya Protocol on Access and Benefit-Sharing in Perspective: Implications for International Law and Implementation Challenges, Elisa Morgera, Matthias Buck & Elsa Tsioumani, eds. (Martinus Nijhoff Pub. 2012). While such provisions do not govern private sector and non-U.S.-government public sector research, certain entities, such as the Biotechnology Industry Organization (BIO), have published best practice guidelines for members to follow to comply with the CBD. See BIO, *Guidelines for BIO Members Engaging in Bioprospecting*, http://www.bio.org/sites/default/files/Guidelines%20for%20BIO%20Members%20Engaging%20in%20Bioprospecting_0.pdf.

Implementation Issues

In this section, we address specific CBD/NP implementation issues relevant for synthetic biology researchers. These issues, which are somewhat interrelated, include the impact of legislation predating the NP, the temporal scope of CBD/NP obligations, and the scope of materials and information covered.

By way of preface, we note that the NP does not explicitly address synthetic biology at any point, nor does it appear that the topic received much discussion during negotiations on the NP. A 2008 CBD ad hoc expert group report did note that the term "derivative," while not the subject of any common understanding, denotes "a continuum of very general to very specific concepts." This broad language is not, however, found in the NP itself. The NP's definition of a derivative is discussed further below.

(c) Gene segments produced or isolated by human manipulation of genetic material.

(d) Synthetic gene segments produced by human manipulation (one segment being a derivative of all the various genetic materials used in its construction).

(e) Information or knowledge derived from genetic materials in general or a specific gene sequence in particular.

(f) Synthetic analogue chemicals or gene segments inspired by a particular naturally occurring metabolite or gene segment. . . .

(j) Something derived from biological and genetic resources such as varieties, strains or breeds, blood, proteins, oils, resins, gums, genes, seeds, spores, pollen, urine, bark, wood, leaf matter and the like as well as the products derived from, patterned on, or incorporating manipulated compounds and/or genes[.][22]

In Decision XI/11, adopted during the Eleventh COP meeting 9-18 October 2012 in Hyderabad, India, the CBD COP requested input from parties and other stakeholders on new and emerging issues relating to the components, organisms and products resulting from synthetic biology techniques that may have impacts on the conservation and sustainable use of biological diversity and associated social, economic and cultural considerations.[23] This request is further evidence of the lack of any meaningful discussion of, or consensus regarding, the NP's applicability to synthetic biology inputs and products during negotiation of the agreement. Draft documents submitted to the COP in response to the request identify a wide range of issues and uncertainties regarding the NP and synthetic biology that will need to be resolved over time if there is to be a harmonized approach to this topic.[24] In the meantime, individual countries seem free to interpret their existing domestic biodiversity legislation, or insert provisions in their draft NP implementing legislation, to cover synthetic biology inputs and products. To date, we have been unable to identify any country's legislation, draft or existing, that explicitly addresses synthetic biology as such.[25] That said, as discussed below, language in certain legislation may be deemed to encompass activities conducted by synthetic biologists.

Legislation Predating the NP

At least fifty-seven countries and seven regions have some type of patchwork biodiversity and/or ABS/PIC legislation for implementing the CBD that predates the NP.[26] Such legislation, often contained in biodiversity and/or patent laws, takes a wide variety of forms.

China: For example, China has over fifty biodiversity-related laws, at least some of which regulate access and benefit sharing in relation to genetic resources.[27] The country also incorporated genetic resource provisions in the most recent (third) amendment to the Chinese Patent Act which went into effect in 2009.[28] Article 5 of the Third Amendment denies patentability to any invention created using genetic resources obtained in violation of Chinese law.[29] The new Article 5 states:

> *"Patents shall not be granted for inventions or creations that violate the law, run counter to social ethics or jeopardize the public interest. If genetic resources are obtained or used in violation of laws or administrative regulations and an invention or creation is completed on the basis of such genetic resources, the patent shall not be granted therefor."*

However, once a patent has been granted, the fact that it is later determined that the inventor violated a Chinese genetic resource law would not be a basis for invalidating that patent.

The implementing guidelines for the revised Chinese Patent Act define genetic resources to include genetic material extracted from the human body, animals, plants, or micro-organisms which contain functional units of heredity.[30] In addition to Article 5, the revised Act contains another provision related to genetic resource acquisition, Article 26, which requires applicants to disclose the country of origin of relevant genetic resources in addition to the direct supplier.[31] Article 26, states in part:

> *"For an invention or creation completed based on genetic resources, the applicant shall give an account in the patent application documents of the direct origin and ultimate origin of the genetic resources. If the applicant is unable to give an account of the ultimate origin, it/he/she shall give the reason therefor."*

Failure to supply the required information is a basis for rejecting claims in an application, but apparently not for invalidating an already issued patent.[32]

Brazil: The laws of some other countries go further. For example, a Brazilian law regulating access to components of Brazilian genetic heritage contains a variety of penalties for violation of genetic resource laws in creating patentable inventions. Such penalties include: payment to the Federal Government of at least twenty percent of the gross income or royalties from commercializing or licensing the resulting product (benefit sharing); suspension or cancellation of the resulting patent, and much more. Additionally, the origin of genetic material used in creating an invention must be disclosed in the patent application.[33]

India: India's Biodiversity Act has even stiffer penalties for applying for patent protection on an invention created with genetic resources obtained without complying with the ABS/PIC provisions of the Act: fines and imprisonment, although the law does allow violators to obtain the necessary permissions after the fact. However, whether provider countries actually enforce these laws consistently or even arbitrarily, is unknown. (See Box, India's Biodiversity Act)[34]

Section 2 of the Act defines "biological resources" as including plants, animals and micro-organisms or parts thereof, their genetic material and by-products. Unlike the Chinese regime, India's legislation does not encompass human genetic material; likewise, the NP, incorporating CBD Decision X/1, does not currently include human genetic resources although that may be further considered by the COP in the future.[35] This wide diversity of approaches to ABS/PIC was part of the impetus for negotiation and adoption of the NP, especially as pre-NP provider country legislation tends to focus on illegal access and use of genetic resources obtained from that country as opposed to the NP's more global focus on ensuring that genetic resources and associated traditional knowledge are acquired under the relevant ABS/PIC legislation of any country from which they are originally obtained. However, as discussed below, the NP, while bringing uniformity to some aspects of ABS/PIC, leaves several areas for continued member country divergence.

Others: As of this writing, only six countries and the EU have submitted, to the CBD COP, implementing legislation for the NP and, in most cases, that legislation is still in draft form (and in a non-English language, namely French, Danish, or Spanish). For example, draft implementing legislation in Denmark provides for fines and up to two years imprisonment for utilizing genetic resources acquired in violation of a given country's access regulations, so long as the activity in question was willful or grossly negligent.[36] Thus, entities that use genetic resources obtained from a provider country in a manner that violates the PIC/ABS legislation of the provider will risk the imposition of penalties (civil and/or criminal) against them not only in the provider country but perhaps also in other countries that penalize extraterritorial genetic resource access violations. In addition, it is important to remember that many provider countries already have PIC/ABS legislation in effect that complies with many of the requirements of the NP despite predating it, and may thus require only minimal adjustments (particularly to harmonize with the NP's access requirements) to be fully compliant.

Temporal Scope (Retroactivity)

As noted, the NP will come into effect ninety days after fifty countries ratify the agreement. But that fact does not resolve the question of whether the agreement will apply to genetic material acquired prior to the NP's effective date under conditions that would not satisfy its requirements. Indeed, an important question not clearly addressed by the NP and currently the subject of intense debate is whether user obligations are triggered only at

the time of initial resource access/removal or extend to the time of utilization. This issue is also referred to as temporal scope, with two primary temporal triggers: CBD ratification (1993) and NP ratification (TBD).[37] Significant genetic resources will have been accessed in provider countries prior to the entry into force of the NP (and others even before the CBD). But new utilization of many of those resources, currently held in gene or seed banks, botanical gardens, or private collections outside the provider country, will take place only after the effective date of the NP. Legislation implementing the NP clearly will make users of genetic material physically accessed for the first time after the NP takes effect subject to its obligations. However, it is unclear if governments will impose NP obligations on entities making new uses of genetic resources obtained from provider countries prior to the entry into force of the NP.

Article 28 of the Vienna Convention on the Law of Treaties, an agreement on treaty interpretation, provides that a treaty does not have retroactive effect unless the parties agree otherwise.[38] Because the parties to the NP were unable to agree on temporal scope during the multiyear negotiations, the Agreement is silent on the topic. This silence does not, however, settle the question, as the parties may also disagree on what represents retroactivity. Provider countries may view a utilization trigger as not prohibiting retroactivity but, rather, giving effect to the terms and spirit of the NP.[39] This is particularly likely to be the case because more than twenty such countries have, since 1993, enacted PIC/ABS legislation with obligations tied to access and/or utilization, to effectuate the CBD. These countries include the Andean Community (Bolivia, Columbia, Ecuador, and Peru), Denmark, Ethiopia, India, Brazil, Kenya, Norway, Panama, the Philippines, South Africa, and Vietnam.[40]

Definitions of what constitutes true access are also contested. As two observers of the NP negotiations explain:

> *One fairly common opinion among user countries was that a genetic resource is accessed at the point in time when the biological sample is crossing a border; by contrast, provider countries often opined that access occurs when biological material is used for the purpose of taking advantage of its genetic material, independent of when and under which conditions the biological material actually crosses a border. . . . To establish a functional system for implementing the NP, countries will need to agree on when "access" happens.*[41]

Because the NP is silent on "when access happens," user countries may choose to implement the agreement in a manner that imposes obligations only on genetic resources that cross a border after the NP comes into force. That is the apparent approach of the draft implementing legislation for the EU, which states

Article 2: Scope

> *This Regulation applies to genetic resources over which states exercise sovereign rights and to traditional knowledge associated with genetic resources that are accessed after the entry into force of the Nagoya Protocol for the Union. It also applies to the benefits arising from the use of such genetic resources and to traditional knowledge associated with genetic resources. . . .*[42]

The EU draft legislation is expected to comprehensively implement only the user-compliance obligations of the NP by means of a regulation, which will ensure the highest level of harmonization because it will apply in all member countries without implementing legislation. However, the legislation leaves member countries free to craft their own NP implementing legislation to address ABS and PIC if they so desire. Consequently, there is expected to be no direct conflict between EU and member state NP implementing legislation.[43]

Similarly, implementing legislation proposed by Switzerland states that NP obligations apply only to "access to genetic resources or associated traditional knowledge that has occurred after the said provisions came into force."[44] Japan has also indicated that its implementing legislation will not have what it considers retroactive effect.[45]

The EU/Swiss approach has been criticized by NGOs and a special European Commission rapporteur, all of which argue that to achieve the goals of the NP and provide legal certainty for users and providers, new uses of genetic resources accessed prior to the NP must be subject to its requirements.[46] Under such a construction, genetic resources acquired decades ago from a member country without complying with ABS/PIC, and maintained in repositories in another country during the intervening time period, would be subject to the NP's ABS/PIC requirements at any future time they were used in research and/or to create new products.

Similarly, the *ABS Management Tool: Best Practice Standard and Handbook for Implementing Genetic Resource Access and Benefit Sharing Activities* recommends that users of genetic resources comply with the domestic legislation in the providing country, which would include legislation that makes utilization the trigger for NP compliance.[47] Parties pushing for a utilization trigger for Protocol obligations point to several concerns, as explained in comments on the EU draft legislation:

> *First, a significant share of GRs and associated TK used in the EU will not be covered by the Regulations, thereby undermining the spirit of the Nagoya Protocol. Second, individual users of GRs and TK will not be able to receive what they always wanted: legal certainty. In many cases, the utilization of GR and TK will be legal under EU law, but illegal under the law of the provider country. Although the user has received an approval from European authorities, he or she could be pros-*

ecuted in a provider country upon setting foot in that country. Nobody is interested in such scenario.[48]

Consequently, the issue of the temporal scope of the Nagoya Protocol obligations remains very uncertain and is likely to stay that way for the foreseeable future.

The Breadth of CBD/NP Coverage

In addition to temporal scope, issues regarding the scope of materials covered by the CBD/NP remain unresolved. As noted in Part II, an initial open question revolves around what is meant by the term "functional unit of heredity." In the time period (1989-1992) when the CBD was negotiated, the scientific focus was on full gene sequences that coded for proteins. Thus, at the time, the term may have referred primarily to full sequences that coded for proteins.[49] By contrast, the DNA "parts" that synthetic biology researchers develop may represent only parts of coding regions or may emerge from non-coding regions that regulate gene expression. It is unclear whether a partial coding sequence or a DNA sequence that regulates gene expression constitutes a functional unit of heredity. In general, as biological science, including synthetic biology, moves away from a focus on individual full gene sequences towards a focus on parts of genes as well as the full genome and proteome, it is unclear how the notion of a "functional unit of heredity" will map onto the new science. Provider countries are likely to argue that the term encompasses all DNA sequences, while user countries may argue for a narrower interpretation.

Provider countries may also point to a 2008 Report by a Working Group of Legal and Technical Experts that specifically discusses the utilization of genetic resources as encompassing "[g]enetic modification of a micro-organism for a specific purpose" as well as "use of genetic material as a 'factory' to produce organic compounds." As currently practiced, synthetic biology does indeed use genetically engineered micro-organisms (e.g., yeast) to produce chemical compounds such as artemisinin, isoprene, and vanillin.[50]

With improvement in DNA synthesis technology, synthetic biology increasingly relies on transfers of digital information rather than transfer of physical material. The use of the term "genetic material" in the CBD/NP suggests that intangibles do not fall within the scope of the CBD/NP. On the other hand, some have argued for a "broad and dynamic" understanding of the concept of genetic resources that would encompass digital information.[51] In this regard, it is notable that the Andean Community Commission's Common Regime on Access to Genetic Resources, adopted in 1996, includes a reference to genetic information. It defines genetic resources as "all biological material that contains genetic information of value or of real or potential use."[52] In addition, the Brazilian Provisional Act of 2001 defines genetic heritage broadly as "information of genetic origin, contained in samples of all or part of a plant, fungal, microbial or animal species . . ." [53]

Note that although sequence information could conceivably be a genetic resource, it is unlikely to have been derived from the provider community and thus seems unlikely to constitute traditional knowledge.

If the CBD/NP is deemed to cover sequence information, and access is deemed to occur when that information "crosses a border," (see discussion in Section IV.B), the issue of what constitutes a border becomes an interesting one. User countries, which have pushed for a "crossing the border" definition of access, might try to argue that the movement of digital information out of the country should not be considered the equivalent of crossing a physical border.

Further questions arise in the context of so-called derivatives. As noted, synthetic biology currently uses genetically modified organisms to produce chemicals, such as artemisinin, isoprene, and vanillin, which have natural analogs.[54] Article 2 of the NP defines a derivative as "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." Thus various products of synthetic biology would appear to fall within Article 2. However, derivatives are not explicitly included in the scope of Article 3, and thus commentators differ on whether the NP's obligations should be deemed to extend to them or should be confined to genetic resources.[55]

Like the controversy over temporal scope, the controversy over the NP's breadth, particularly with respect to derivative products, is likely to pit provider countries against user countries. Provider countries are likely to view any use of genetic resources, even uses much farther down the supply chain in which the original genetic resource has been very substantially modified, or comprises only a very small part of the whole, as triggering ABS obligations. Conversely, countries that limit obligations to the time of accessing the genetic resource may, to some degree, effectively limit the NP's applicability to derivative products, as later uses of the resources simply will not be known at the time the genetic resource is accessed and the ABS agreement is drawn up. Making the NP applicable to derivative products could have the negative effect of dis-incentivizing the use of genetic resources in research and commercialization endeavors. By the same token, denying the applicability of the NP to derivative products could result in provider countries making access requirements more onerous which could dis-incentivize research into previously un-accessed genetic resources.

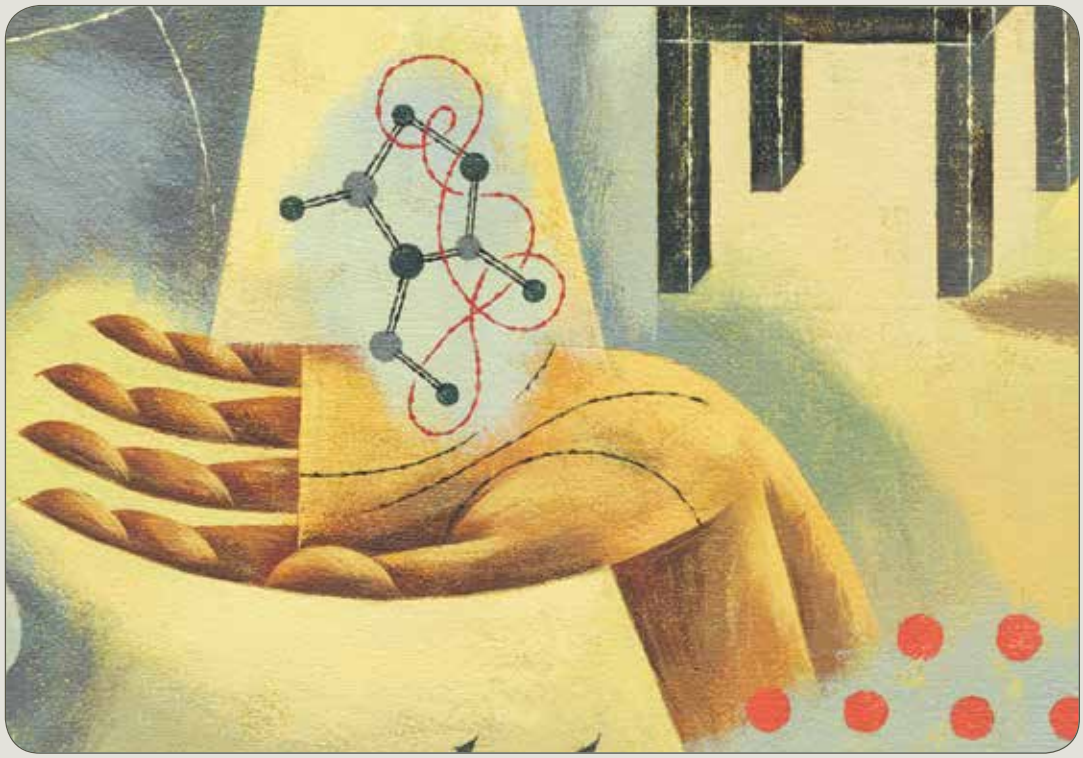
One NP bright spot for researchers is the Article 8 provision requiring Parties to create "simplified measures on access for non-commercial research purposes." This provision was included in recognition of the need for streamlined access to genetic resources for initiatives such as the International Barcode of Life (iBOL) project on DNA barcoding species identification efforts.[56] Article 8 does suggest, however, that a change in the nature of such research from non-commercial to commercial would need to be addressed.

Relevance for Researchers

Article 15 of the NP requires each party to take appropriate measures to ensure that genetic resources utilized within its jurisdiction have been accessed in compliance with the PIC/ABS domestic legislation of the providing country and that mutually agreed terms

(MATs) have been established. Because the United States is not a party to the NP, it is not likely to impose any such requirement for the use of genetic resources. Nevertheless, U.S. researchers entering provider countries, seeking to obtain new genetic resources from such countries, or even seeking to obtain intellectual property rights in any country (including a user country) that has PIC/ABS legislation over inventions developed with genetic resources accessed and/or used in violation of a provider country's domestic legislation, may be subject to the range of legal action specified in such legislation, including, in some cases, imprisonment. Consequently, researchers in the United States would be well-advised to:

- Inquire as to the origin of genetic resources used in research and seek to comply with the domestic legislation of the identified provider country regarding PIC/ABS/ MAT (the ABS Handbook provides a "best practices" approach).
- Continue to monitor the development of both NP implementing legislation in member countries and the COP exploration of emerging issues under COP Decisions VIII/10 and XI/11, including synthetic biology and its relation to the NP. Both in the submissions to the COP and in the choice of agenda items for future DOP meetings.[57]
- Provide input and advice to legislators in user and provider countries who are drafting NP implementing legislation to ensure concerns regarding synthetic biology coverage, and temporal scope are considered and addressed.



BOX 2

India's Biodiversity Act

The Biodiversity Act provides in part:

"6. (1) No person shall apply for any intellectual property right by whatever name called in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application:

Provided that if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the sealing of the patent by the patent authority concerned.

(2) The National Biodiversity Authority may, while granting the approval under this section, impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilisation of such rights.

. . . .

Penalties.

55. (1) Whoever contravenes or attempts to contravene or abets the contravention of the provisions of section 3, section 4, or section 6 shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to ten lakh rupees and where the damage caused exceeds ten lakhs such fine may be commensurate with the damage caused, or with both . . .

57. (1) Where an offence or contravention under this Act has been committed by a company, every person who at the time the offence or contravention was committed was in charge of, and was responsible to the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the offence or contravention and shall be liable to be proceeded against and punished accordingly:

. . . .

Provided that nothing contained in this sub-section shall render any such person liable to any punishment provided in this Act, if he proves that the offence or contravention was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such offence or contravention."

Conclusion

Significant genetic resources will have been accessed in provider countries prior to the entry into force of the NP (and others even before the CBD). But new utilization of many of those resources, currently held in gene or seed banks, botanical gardens, or private collections outside the provider country, will take place only after the effective date of the NP. Consequently, until countries agree on the temporal scope of NP obligations (i.e., whether they apply only to materials accessed in a member country after ratification of the NP or also to genetic materials accessed before, but utilized after, ratification of the NP), there will continue to be a lack of uniformity and legal uncertainty for researchers using genetic resources in their work. Moreover, failure to comply with the ABS/PIC provisions of any country may affect the ability of researchers to obtain IP rights, certain kinds of funding, or other benefits in jurisdictions such as the EU.

Synthetic biology researchers, who often work on DNA sequences that do not code for a full protein, or with genetic information only, face additional uncertainty. Neither the CBD nor the NP defines "functional units of heredity." Thus it is unclear whether all categories of DNA sequences are covered. In addition, important questions regarding the reach of the CBD/NP into intangible genetic information or so-called derivative products remain unanswered.

Implementation of the Nagoya Protocol by member countries is in its infancy, thus many questions regarding how the agreement will be implemented cannot currently be answered. This can be seen as an opportunity however, for researchers and other interested parties to actively engage the political process in particular countries to provide input into how the NP should be implemented.

Appendix

Bonn Guidelines

A major achievement of COP VI was the adoption of the Bonn guidelines on access to genetic resources and the fair and equitable sharing of the benefits arising from their utilization (see Decision VI/24).

The Guidelines were recognized as a useful first step of an evolutionary process in the implementation of relevant provisions of the Convention related to access to genetic resources and benefit-sharing. They will be kept under review by the COP and the need for their further refinement will be considered on the basis of relevant developments under the Convention, including those on issues such as traditional knowledge and technology transfer.

The guidelines should assist Parties, Governments and other stakeholders in developing an overall access and benefit-sharing strategy, and in identifying the steps involved in the process of obtaining access to genetic resources and benefit-sharing. More specifically, these voluntary guidelines are meant to assist Parties, Governments and other stakeholders when establishing legislative, administrative or policy measures on access and benefit-sharing and/or when negotiating contractual arrangements for access and benefit-sharing.

Parties and relevant organizations have been invited to provide financial and technical assistance to support developing countries, in particular least developed countries, small island developing states, as well as countries with economies in transition, in implementing the Bonn Guidelines.

The second meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, held in Montreal from 1 to 5 December 2003, considered experience gained from the use of the Bonn Guidelines, based on information shared by Parties and stakeholders.

The Conference of the Parties at its seventh meeting, in Decision VII/19 addressed the Bonn Guidelines under section A. The COP recognized “that the Guidelines are making a useful contribution to the development of national regimes and contractual arrangements for access and benefit-sharing and to the implementation of the objectives of the Convention”. It also recognized that some developing countries had encountered constraints due to inadequate capacity to fully utilize the guidelines in the formulation of their national access and benefit-sharing legislation. Parties, Governments, indigenous and local communities and all relevant stakeholders were invited to continue to promote the wide implementation of the voluntary Bonn Guidelines. They were also encouraged to submit further information on relevant experience and lessons learned, including successes and constraints, in the implementation of the Guidelines. The Executive Secretary is to make this information available through appropriate means, including the Clearing House Mechanism of the Convention. Other issues of relevance to the Bonn Guidelines were also addressed by the Conference of the Parties in Decision VII/19, such as the use of terms, and other approaches, complementary to the Bonn Guidelines to assist with the implementation of the ABS provisions of the Convention.

Appendix (continued)

At its eighth meeting, in decision VIII/4 B, the Conference of the Parties noted the progress already accomplished and urged Parties to continue implementing the Bonn Guidelines and to share experiences and lessons learned in their implementation as well as in the development and implementation of national and sub-national measures. Information provided to the Secretariat related to the implementation of the Bonn Guidelines has been compiled in information documents.[58]



Endnotes

1 Drew Endy, Foundations for Engineering Biology, 483 Nature 449 (2005).

2 Roberta Kwok, Five Hard Truths for Synthetic Biology, 463 Nature 288 (2010).

3 Brent Erickson, Rina Singh, and Paul Winters, Synthetic Biology: Regulating Industry Uses of New Biotechnologies, 333 *Science* 1254 (2011).

4 *See, e.g.,* BioFab, www.biofab.org

5 For an overview of recent trends in the cost of DNA synthesis and sequencing, see Rob Carlson, Cost Per Base of DNA Sequencing and Synthesis, October 2012, available at htt://www.synthesis.cc

6 For clarity and ease of use, a glossary of terms is provided at the front of this Report, with definitions gleaned from the CBD and Nagoya Protocol.

7 Morten Walloe Tvedt and Tomme Young, Beyond Access: Exploring Implementation of the Fair and Equitable Commitment in the CBD 54 (noting this point).

8 Convention on Biological Diversity, art. 1, June 5, 1992, 1760 U.N.T.S. 143, 144.

9 Convention on Biological Diversity, art. 15, June 5, 1992, 1760 U.N.T.S. 143, 152; *see also* Cynthia M. Ho, *Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies*, 39 U. Mich. J. L. Reform, 433, 473 (2006).

10 The Word Spy, http://www.wordspy.com/words/biopiracy.asp. For examples and discussions of perceived instances of biopiracy, see Lorna Dwyer, Biopiracy, Trade, and Sustainable Development, 19 COLO. J. INT'L ENVTL. L. & POL'Y 219, 227 (2008); Kaitlin Mara, Indigenous Groups Express Concerns On IP Protection Of Their Knowledge, INTEL. PROP. WATCH, Mar. 3, 2008, http://www.ip-watch.org/weblog/2008/03/03/indigenous-groups-express-concerns-on-ip-protection-of-their-knowledge/.

11 The Convention on Biological Diversity (June 5, 1992), Articles 8, 15, 1760 U.N.T.S. 143, 152.

12 David J. Bederman, International Law Frameworks, 151-152 (Foundation Press 2001).

As explained by David Bederman:

"There has long been a debate about the incorporation of international law into domestic law. The two sides in this polemic have been given the unfortunate names of monist and dualists. [M]onism is the idea that international law and domestic law are parts of the same legal system, but that international law is higher in prescriptive value than national law. Dualism is the position that international law and municipal law are separate and distinct legal systems which operate on different levels and that international law can only be enforced in national law if it is incorporated or transformed."

13 See Frederick M. Abbott, Thomas Cottier, and Francis Gurry, InternationAl Intellectual Property in an Integrated World Economy, 101 (2d Ed., Wolters Kluwer 2011).

14 For more on the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, which governs the movements of living modified organisms (LMOs), produced by biotechnology, across national boundaries, see http://bch.cbd.int/protocol/background/. For information on the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety which deals with compensation for damage caused by the trans-boundary movement of LMOs, see http://bch.cbd.int/protocol/supplementary/.

15 For more on the Bonn Guidelines, which were considered an important first step in implementing the ABS provisions of the CBD, see http://www.cbd.int/abs/bonn/default.shtml.

16 *See* European Commission, Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization in the Union, 2 (2012), available at http://www.cbd.int/doc/measures/abs/post-protocol/msr-abs-eu-en.pdf.

17 Thomas Geiber, Sonia Peña Moreno, Mattias Åhrén, Jimena Nieto Carrasco, Evanson Chege Kamau, Jorge Cabrera Medaglia, Maria Julia Oliva and Frederic Perron-Welch in cooperation with Natasha Ali and China Williams., *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing*, 18 (IUCN Environmental Policy and Law Paper No. 83, 2012) [hereinafter "Greiber, Explanatory Guide"].

18 *See* CBD Art. 32.

19 *See* European Commission, Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization in the Union, 3 (2012), available at http://www.cbd.int/doc/measures/abs/post-protocol/msr-abs-eu-en.pdf

20 Such a certificate is basically a permit containing the issuing authority, date of issuance, identification of the provider, PIC grantee, genetic resource covered, intended use (commercial or non-commercial), some unique identifier, and MAT/PIC confirmation. Art. 17(4).

21 *See* Greiber, Explanatory Guide, at 80.

22 Report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches, UNEP/CBD/WG-ABS/7/2, 12 December 2008, available at http://www.cbd.int/doc/?meeting=ABSGTLE-01.

23 *See* REPORT OF THE ELEVENTH MEETING OF THE CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY (Dec. 5, 2012), available at http://www.cbd.int/doc/meetings/cop/cop-11/official/cop-11-35-en.pdf. In particular, the Decision noted "the need to consider the potential positive and negative impacts of components, organisms and products resulting from synthetic biology techniques on the conservation and sustainable use of biodiversity." Id. at 141.

24 *See* draft reports available under "New and Emerging Issues, available at http://www.cbd.int/emerging/.

25 As discussed in Section IV.C, however, some broad language in the Andean Community Commission's Common Regime on Access to Genetic Resources seems more amenable to possible stretching to include the types of informational inputs used in synthetic biology. Also, the Brazilian Provisional Act of 2001 does define genetic heritage broadly as "information of genetic origin, contained in samples of all or part of a plant, fungal, microbial or animal species, in the form or molecules or substances originating in the metabolism of these living beings, and in extracts obtained from in situ conditions, . . ." Brazilian Provisional Act, No. 2,186-16, Title II, Art. 7, August 23, 2001.

26 See "List of Countries and Regions with Measures," available at http://www.cbd.int/abs/measures/groups.shtml. However, a report from an officer in the Chinese State Environmental Protection Administration asserts that by 2007, 147 countries had completed their CBD-mandated National Biodiversity Strategy and Action Plans. *See* Cai Lee, China Biodiversity Strategy and Action Plan, available at http://www.7c.gov.cn/color/DisplayPages/download/pdf/06en.pdf.

27 *See, e.g.*, Measures for the Examination and Approval of Entry and Exit and the Foreign Cooperative Research on the Application of Genetic Resources of Livestock and Poultry, Art. 7 (2008) (requiring an application and benefit sharing plan be submitted in order to export livestock and poultry genetic resources), available at http://www.cbd.int/doc/measures/abs/msr-abs-cn-en.pdf. See also Minister of Environmental Protection, *China's Fourth National Report on Implementation of the Convention on biological Diversity* (2008), available at http://www.cbd.int/doc/world/cn/cn-nr-04-en.pdf (listing the various biodiversity-related laws); and Biodiversity Legislation (China), in THE BERKSHIRE ENCYCLOPEDIA OF SUSTAINABILITY: CHINA, INDIA, AND EAST AND SOUTHEAST ASIA: ASSESSING SUSTAINABILITY (2012), available at http://www.clapv.org/UploadFile/2013-01/E35_20130104102820963.pdf.

28 Yan Wenfeng, NPC Oks New Patent Law, China Rep.: Intell. Prop. (Dec. 31, 2008) http://www.sipo.gov.cn/sipo_English/news/ChinaIPNews/2008/200904/P020090408579902833623.pdf.

29 Third Revision of China's Patent Law, Legal Text and Documents on the Drafting Process 2006-2008, p. 11 available at http://www.ipr2.org/images/eu_patent_law-090805-7-final.pdf

30 Implementing Regulations of the Patent Law of the People's Republic of China (2010), available at http://www.ccpitpatent.com.cn/references/Implementing_Regulations_Patent_Law_China.htm#ChapterI

31 Third Revision of China's Patent Law, Legal Text and Documents on the Drafting Process 2006-2008, p. 15 available at http://www.ipr2.org/images/eu_patent_law-090805-7-final.pdf. Comments by the Chinese State Intellectual Property Office (SIPO) on the 2006 draft revised patent law provide some insight into the motivations for

Articles 5 and 26. After discussing CBD principles, the comments state:

> Measures taken to protect China's genetic resource[s] at least include the following two aspects: . . . establish a management mechanism for genetic resource through special legislation to prevent any person from obtaining China's genetic resource without the approval of the relevant department and impose an administrative fine or even criminal punishment to the violator; and the other is to add relevant provisions to the Patent Law so as to stop the act of illegal obtaining or use of the genetic resource based on which the creations are completed.

Third Revision of China's Patent Law, Legal Text and Documents on the Drafting Process 2006-2008, p. 55 available at http://www.ipr2.org/images/eu_patent_law-090805-7-final.pdf.

32 Implementing Regulations of the Patent Law of the People's Republic of China (2010), available at http://www.ccpitpatent.com.cn/references/Implementing_Regulations_Patent_Law_China.htm#ChapterI

33 Brazilian Provisional Act, No. 2,186-16, Title VII, Art. 26, Title VIII, Art. 30, Title IX, Art. 31, August 23, 2001.

34 India Biodiversity Act (2002), available at http://www.grain.org/brl/?docid=322&lawid=1378. *See* also Andean Community Common Regime on Access to Genetic Resources, Decision 391 of 1996, Complementary Provisions, available at http://www.sice.oas.org/trade/JUNAC/decisiones/DEC391e.asp ("The Member Countries shall not acknowledge rights, including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components, that were obtained or developed through an access activity that does not comply with the provisions of this Decision.").

35 *See* CBD COP Decision X/1, paragraph 5, October 18-29, 2010..

36 Danish Ministry of the Environment, Implementing the Nagoya Protocol, available at http://www.cbd.int/abs/side-events/cop-11/denmark-en.pdf.

37 *See* Evanson Chege Kamau, Bevis Fedder and Gerd Winter, The *Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is New and What are the Implications for Provider and User Countries and the Scientific Community?*, 6/3 Law, Environment and Development Journal, 246, 254-255 (2010), available at http://www.lead-journal.org/content/10246.pdf.

38 Article 28 states:

> Unless a different intention appears from the treaty or is otherwise established, its provisions do not bind a party in relation to any act or fact which took place or any situation which ceased to exist before the date of the entry into force of the treaty with respect to that party.

Vienna Convention on the law of Treaties, United Nations, Treaty Series, vol. 1155, p. 331 (1969), available at http://untreaty.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf.

39 See Greiber, *Explanatory Guide,* supra at 72-73.

40 Denmark and Norway are not considered predominantly provider countries; however, their legislation makes access or use actionable.

41 Tvedt, W..Morten and Ole K. Fauchald. *Implementing the Nagoya Protocol on ABS; A Hypothetical Case Study on Enforcing Benefit Sharing in Norway,* J. World Intell. Prop., Vol. 14, no. 5, 2011: 385.

42 European Commission, Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization in the Union (2012), available at http://www.cbd.int/doc/measures/abs/post-protocol/msr-abs-eu-en.pdf.

43 *Id.* at 7.

44 Federal Act on the Protection of Nature and Cultural Heritage (NCHA), Section 3(c), Art. 25(d), draft of 16 May 2012, available at http://www.cbd.int/doc/measures/abs/post-protocol/msr-abs-swt-en.pdf.

45 *See* Hiroji Isozaki, Summary of the Views from the Consultative Committee on Major Issues Relevant to the Domestic Measures to be Taken in Japan, slide 5, available at http://www.cbd.int/abs/side-events/cop-11/japan-en.pdf.

46 Natural Justice and the Berne Declaration, *Access or Utilisation-What Triggers User Obligations? A comment on the Draft Proposal of the European Commission on the Implementation of the Nagoya Protocol on Access and Benefit Sharing,* (2013), available at http://naturaljustice.org/wp-content/uploads/pdf/Submission-EU-ABS-Regulation.pdf.

47 Geoff Burton and Jorge Cabrera, *ABS Management Tool: Best Practice Standard and Handbook for Implementing Genetic Resource Access and Benefit Sharing Activities*, 59-61 (2012) available at http://www.sib.admin.ch/uploads/media/Updated_ABS_Management_Tool_May_2012_01.pdf. The ABS Management Tool was prepared by Stratos Inc. with the support of the Swiss State Secretariat for Economic Affairs.

48 Natural Justice and the Berne Declaration, *Access or Utilisation-What Triggers User Obligations? A Comment on the Draft Proposal of the European Commission on the Implementation of the Nagoya Protocol on Access and Benefit Sharing,* (2013), available at http://naturaljustice.org/wp-content/uploads/pdf/Submission-EU-ABS-Regulation.pdf .

49 Peter Johan Schei and Morten W. Tvedt, *The Concept of "Genetic Resources" in the Convention on Biological Diversity and How It Relates to A Functional International Regime on Access and Benefit Sharing"* (2010).

50 See Report of the Group of Technical and Legal Experts on Concepts, Terms, Working Definitions and Sectoral Approaches, UNEP/CBD/WG-ABS/7/2, 12 December 2008. Although the Working Group Report is instructive on how terms in the Protocol could be interpreted, it is not a binding document as is the NP itself.

51 *See id.*

52 Andean Community Commission, Decision 391: Common Regime on Access to Genetic Resources, available at htt://www.sice.oas.org/trade/JUNAC/decisiones/DEC391e.asp.

53 Brazilian Provisional Act, No. 2, 186-16, Title II, Art. 7, August 23, 2001

54 *See* ICSWGSB Submission, p. 31 for a list of such chemicals.

55 See Greiber, Explanatory Guide, supra at 70.

56 See "iBOL, CBD Pledge to Work Together Towards Common Goals," available at http://ibol.org/ibol-cbd-pledge-to-work-together-towards-common-goals/.

57 *See* http://www.cbd.int/emerging/ for progress and submissions relating to new and emerging issues.

58 *See:* http://www.cbd.int/doc/meetings/abs/abswg-05/information/abswg-05-inf-02-en.pdf and http://www.cbd.int/doc/meetings/abs/abswg-05/information/abswg-05-inf-02-add1-en.pdf

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