

DIGITAL DNA: THE NAGOYA PROTOCOL, INTELLECTUAL PROPERTY TREATIES, AND SYNTHETIC BIOLOGY



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The views expressed are the author's own and do not necessarily represent those of the Wilson Center.

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Executive Summary

This report builds on “The Nagoya Protocol and Synthetic Biology: A Look at the Potential Issues,”¹ a report released by the Synthetic Biology Project in 2013. In particular, it considers current challenges for the intellectual property protection of synthetic biology outputs, implementation issues concerning the Nagoya Protocol on Access and Benefit Sharing (“NP,” “Protocol,” or “Nagoya Protocol”) to the Convention on Biological Diversity (CBD), and possible interactions between the requirements of the Protocol and the World Trade Organization’s (WTO) Agreement on Trade Related Aspects of Intellectual Property (TRIPS). It also explores emerging concerns regarding synthetic biology and “digital biopiracy” in relation to non-commercial research projects. Finally, it presents highlights of negotiations in the World Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge, and Folklore (IGC), which may relate to both the Nagoya Protocol and TRIPS and thus may be relevant for researchers, particularly those working in the area of synthetic biology.

The intellectual property, genetic resource prior informed consent, and access & benefit sharing (PIC/ABS) landscape is in flux, with new laws and agreements

being developed at the national and international level which quite possibly will be interpreted in ways that will have implications for synthetic biology researchers.

Patent protection remains available for most synthetic biology outputs, although eligibility varies by country. Copyright protection, however, currently appears unlikely. While ratification of the Nagoya Protocol proceeded expeditiously, the drafting and enactment of implementing legislation, as well as the creation of the necessary infrastructure for efficient operation of domestic PIC/ABS/MAT (mutually agreed terms) systems remain a challenge for many countries. Efforts at WIPO to develop a binding treaty to, *inter alia*, obligate countries to require patent applicants to disclose the origin of genetic resources used in creating a claimed invention bear watching as negotiations are scheduled to resume in 2016.

In addition, it remains likely that at least some provider countries will assert that intangible genetic information falls within the scope of national CBD/NP implementing legislation. Thus the counsel from our first report, that researchers would be well-advised to inquire into the origin of genetic material that they use and to ensure that such material was taken in compliance with the domestic law of a provider country, remains salient.

Synthetic Biology in Brief

Synthetic biology is based on the idea that any biological system can be viewed as a combination of functional elements or parts that can be organized in new ways to modify living organisms.² Researchers engaged in “fundamental” or “bottom-up” synthetic biology seek to identify and establish design principles for biologic parts and modules in order to build living systems from raw components.³ For example, in 2014, researchers at the startup Synthorx reported their creation of a bacterium with an expanded six-letter genetic alphabet, adding new bases X and Y to the standard G, A, T, and C bases.⁴ It is theorized that the addition of more bases could eventually enable the engineering of bacteria to produce completely new therapeutic proteins containing unnatural amino acids.⁵ Simultaneously, “translational” or “top-down” synthetic biology researchers seek solutions to pharmaceutical, agricultural, environmental, or other challenges by redesigning gene sequences or existing organisms to achieve new or improved functionality. For example, researchers recently designed and produced a synthetic copy of thebaine, the opiate morphine precursor harvested from poppies for millennia, using yeast embedded with genetic sequence information from several plant species, a bacterium, and a rodent.⁶ While public awareness of synthetic biology remains low, developments in the field are advancing rapidly, sometimes amid controversy.⁷

Furthermore, a growing cadre of companies is marketing synthetic biology-based products in areas including biofuels, specialty chemicals, bioremediation, and therapeutics.⁸

A 2013 Synthetic Biology Project report shows synthetic biology research is continuing to expand, taking place in approximately 30 countries and among 565 unique entities in universities, government laboratories, private companies, and community laboratory space.⁹ Although the U.S. dominates, countries such as the United Kingdom, Canada, China, Brazil, Japan, and South Africa all have scientists engaging in synthetic biology research and most are sharing information across borders.¹⁰ Moreover, commercial activity is not limited to small startups. Large, multinational corporations such as Johnson & Johnson, Merck, and Goodyear Tires are increasingly incorporating synthetic biology projects and partnerships into their portfolios. As the cost of DNA synthesis decreases and the ease of making genetic modifications and genetic information digitally available increases, new questions and potential obligations may be arising regarding synthetic biology and the ABS regimes of the CBD and Nagoya Protocol.

The potential benefits and risks of synthetic biology are the subject of considerable disagreement across the globe and discussions and actions are in varying stages of maturity in different fora. Surprisingly,

“Temporal Scope” refers to the question of what genetic resources are covered by the Nagoya Protocol from a time perspective. Specifically, whether the Protocol applies only to genetic resources physically accessed (i.e. that crossed a border) after the Protocol came into force, or to genetic resources which are utilized after the Protocol came into force, but were/are physically accessed at any time after the CBD came into force, or to genetic resources physically accessed at any time and utilized after the Protocol came into force. **“Breadth of Coverage”** refers to the issue of whether the definitions of genetic resources and genetic material, should or will be interpreted broadly enough to include digital genetic information such as is used in synthetic biology research.¹¹

discussions in the CBD and Nagoya Protocol are not currently focused on the temporal scope and coverage issues concerning synthetic biology and genetic resources discussed in our first report, which were left unresolved at the end of negotiations on the Protocol itself in 2010 (see box).¹¹ Rather, parties are grappling with the more fundamental issues of the nature of synthetic biology research and the risks associated with the release of synthetic biology products. For example, in October 2014 at the Twelfth meeting of the Conference of the Parties (COP) to the Convention on Biological Diversity, which was also the First Meeting of the Parties to the Nagoya Protocol (COP/MOP),¹² some member states defined synthetic biology as a simple extension of genetic engineering, while others characterized work in the field as sufficiently new and different to justify application of the precautionary approach.¹³ Ultimately, the COP concluded that there currently was insufficient information available to classify synthetic biology as a new and emerging biodiversity issue, but it did agree, *inter alia*, to urge Parties to employ the precautionary approach and to approve organisms resulting from synthetic biology techniques for field trials only after appropriate risk assessments have been carried out.¹⁴ Regrettably, it may be some time before the COP/MOP, which meets every two years, returns to serious

consideration of the Protocol’s scope issues. Indeed, it may ultimately choose to leave the decisions for member states to continue to address at the national level. This would entrench the lack of harmonization and legal uncertainty for researchers regarding which genetic materials are subject to Nagoya Protocol obligations.

Intellectual property protection is often sought for the fruits of innovative activity, including synthetic biology products. Patents in particular offer an exclusivity that provides a connection to the access and benefit sharing concerns that animate the Nagoya Protocol. However, as discussed in the following section, recent developments have both cast doubt on the patent eligibility of some synthetic biology outputs and opened the door (very slightly) to the potential availability of another form of intellectual property protection.

Synthetic Biology and Intellectual Property Protection

Researchers are not of one mind when it comes to intellectual property protection for advances in synthetic biology. Two philosophical camps have emerged in the field: an open-source community focused on disclosure, sharing, and free accessibility

of synthetic biology engineered parts and information¹⁵ and those with a more traditional patent-protection-as-an-incentive-for-disclosure-and-investment philosophy.¹⁶ Proponents of open source believe that the free availability of new knowledge will lead to more rapid discoveries that will benefit humanity. Those in favor of patenting synthetic biology products counter that research requires a financial investment and patents allow for the recoupment of returns on that investment. These two approaches, while clearly in tension, are playing out in tandem in the rapidly evolving synthetic biology space.

Synthetic biology products and related materials are likely to see protection under all four of the most common forms of intellectual property: patents, trademarks, trade secrets, and copyrights. For example, product names and packaging can be protected by trademark and trade dress, and software and marketing materials related to production and commercialization can be protected by copyright. Trade secret protection is likely to be used by manufacturers for protecting various aspects of commercial manufacturing processes involving synthetic biology. However, patents and copyrights raise the most interesting intellectual property protection issues, as the full eligibility of synthetic biology subject matter for coverage under either regime is not free from doubt at the time of this writing.

Patents have been, and likely will continue to be, the primary form of IP protection for synthetic biology. Numerous patents have issued on synthetic biology products and processes ranging from methods of artemisinin production for treating

malaria¹⁷ to fuels made using a modified microorganism.¹⁸ However, recent judicial decisions on gene patent subject matter eligibility in the United States and Australia have eliminated patent protection for some synthetic biology inventions. In particular, the United States Supreme Court's decision in *Association of Molecular Pathologists v. Myriad Genetics, Inc.* eliminated patent protection for isolated genomic DNA (gDNA) and other products of nature that do not qualify as machines, compositions of matter, articles of manufacture, or processes made by man.¹⁹ The Supreme Court did distinguish between gDNA and synthesized complementary DNA (cDNA), such as would be involved in synthetic biology research, holding that most cDNA claims would pass the patent eligibility hurdle. However, the court cautioned that short cDNA sequences might not be patentable if indistinguishable from "natural" DNA.²⁰ Moreover, even longer synthetic sequences would not be patentable if they are not "markedly different" to what exists in nature.²¹ Claims already have been rejected for cDNA sequences on that basis in at least one synthetic biology based patent application.²² Several district court and appellate decisions implementing the *Myriad* holding also have invalidated patent claims deemed not markedly different to what exists in nature, such as the cloned animal claims in the *In re Roslin Institute* patent.²³ In addition, the United States Patent and Trademark Office's initial interpretation of *Myriad* and other Supreme Court patent eligibility decisions drew severe criticism and consternation from the biotech industry and patent attorneys, as the office's guidelines for examination appeared to go significantly farther in restricting patentability than the

court decisions. However, more recent guidance from the office indicates a less stringent approach to inventions based on products of nature.²⁴

Patent law is territorial in nature and patents only have effects within the national/regional borders of the offices that grant them. Thus the *Myriad* decision only has effect in the United States; researchers still may be able to obtain patent protection in other countries, such as EU member states, as the European Union Biotechnology Directive explicitly allows for patents on some gene sequences that would fail U.S. patent eligibility requirements.²⁵

On Oct. 7, 2015, Australia's highest court deemed invalid several of *Myriad*'s patent claims covering BRCA1, gDNA and cDNA sequences.²⁶ The country's High Court ruled that such claims cover information which is "discerned" not made, and thus do not come within the statutory requirement of a man-made "manner of manufacture."²⁷ As the decision is so new, it is unclear what its implications will be for the patenting of synthetic DNA sequences or how different from naturally occurring sequences they will need to be in order to be considered made by man and thus patent eligible.

Some scholars and researchers see copyright protection as a preferable alternative to patents as it may produce a more "socially desirable balance" of permitted versus restricted uses of DNA sequences.²⁸ Copyright protection lasts longer than patents – life of the author plus 70 years versus 20 years from filing – but the protection is not as strong. Unlike for patents, independent creation is a defense

to copyright infringement, there are limits on damages for innocent infringement, and the copyright fair use defense might reasonably allow many uses of protected sequences, such as for experimentation and instruction, not allowed by the strict liability patent law system.²⁹ Moreover, copyright protection is seen by some as better able than patents to foster an open source biology regime.³⁰

However, the possibility of copyright protection for synthetic biology is far less certain than that for patents. Copyright protects original works of authorship fixed in tangible mediums of expression such as literary works, musical works, architectural designs, and even computer programs.³¹ Several commentators, making an analogy to computer software, have suggested that copyright may be appropriate for synthetic biology, noting that synthetic DNA sequences meet the originality and fixation requirements and may require expressive choices.³² Moreover, for open source proponents, the exclusivity provided by copyright law possibly could be used to impose sharing requirements on users, an approach that some in the free/open software movement have used effectively with "copyleft" licenses.³³ Detractors, however, argue that copyright is a poor fit for synthetic biology, as sequences are generally dictated by the desired function they are to perform, leaving little room for an author's expressive choices.³⁴ In view of the challenges posed by patent and copyright law, some commentators have suggested that a sui generis IP regime for synthetic biology might be most appropriate.³⁵ In the United States, where the lion's share of synthetic biology

research is performed, the copyright office has indicated that DNA sequences are not copyright-eligible subject matter. However, that decision is currently the subject of a planned appeal.³⁶

Synthetic Biology and the Nagoya Protocol

The COP is the governing body of the CBD and makes decisions at periodic meetings to advance implementation of the Convention. One such decision was the adoption of the Nagoya Protocol on Access and Benefit Sharing to the Convention on Biological Diversity at its Tenth meeting in 2010 in Nagoya, Japan.³⁷ The Protocol was necessary because, while the CBD obligated Parties to facilitate access to their genetic resources on mutually agreed terms (MAT), including users fairly and equitably sharing benefits arising from the utilization of such resources with provider countries, it gave almost no detail on how ABS should be accomplished in practice.³⁸ Consequently, provider countries have either not yet implemented ABS provisions or implemented widely varying legislation, resulting in legal uncertainty for users faced with often burdensome rules for PIC/ABS/MAT that vary, sometimes significantly, by country.

The Protocol, which came into effect on October 12, 2014, was designed to reduce uncertainty and provide increased transparency for both users and providers of genetic resources and associated traditional knowledge. It is a binding agreement and is “the instrument for implementation of the

access and benefit sharing provisions of the [CBD].”³⁹ While the CBD and Protocol may be amenable to interpretations that exclude synthetic biology from their purview, it is likely that researchers in this area will be subject to the provisions of these agreements as they are implemented in national legislation in provider and user countries. As such, it is worth considering whether the Protocol contains provisions that act as “ceilings” or “floors” for national legislation. “Ceilings” are upper limits on the kinds of obligations member states can impose on users in relation to ABS/PIC/MAT. Conversely, “floors” are minimum standards that leave countries free to impose more stringent requirements and/or sanctions.

The Nagoya Protocol contains several important “floors,” minimum standards-type provisions aimed at achieving the objective of the fair and equitable sharing of benefits from the utilization of genetic resources and associated traditional knowledge (GRAATK). For example, it requires Parties that choose to impose prior informed consent (PIC) for access to GRAATK to take necessary legislative, administrative, or policy measures to, *inter alia*, provide fair and non-arbitrary genetic resource access rules and information on how to apply for PIC.⁴⁰ Also, it obligates each member to take appropriate steps to “provide that genetic resources utilized within its jurisdiction” have been accessed in accordance with the domestic ABS/PIC/MAT requirements of another Party. Furthermore, members must cooperate, as far as possible and as appropriate, in cases where another Party’s domestic ABS

Denmark's draft legislation provides one approach to complying with this obligation, as it prohibits the utilization of GRs when the use is based on GRs acquired in violation of GR access regulations in the country where the GRs were accessed. Violations are punishable by fines, or up to two years in prison if willful or grossly negligent, and foreign states and persons appear to have standing to bring relevant actions in Danish courts.⁴¹

legislation has been violated (see box).⁴¹ However, the mandatory “shall” language in such Protocol provisions is weakened by the insertion of vague, broad phrases such as “effective and appropriate legislative, administrative or policy measures,” “as far as possible,” and “as appropriate.” In fact, the Protocol has been called “a masterpiece in creative ambiguity” on a variety of topics.⁴²

A close look at all of the Nagoya Protocol provisions shows only floors – minimum obligations – and not ceilings – upper limits on the kinds of ABS laws and penalties a country can impose. In fact, the only explicit limitation appears to be Article 12(4), which obligates countries to avoid restricting customary uses of GRAATK among indigenous groups and local communities.⁴³ Thus, while the Protocol's requirements should improve transparency and increase certainty overall, researchers will still face a panoply of differing, un-harmonized PIC/ABS laws that may vary significantly in scope, obligations, and penalties. Moreover, while the Parties adopted a recommended compliance process at the 2014 COP-MOP in South Korea pursuant to Article 30, the procedure is designed to be “non-adversarial, cooperative, simple, expeditious, advisory, facilitative, flexible and cost-effective in nature.”⁴⁴ It thus will lack the teeth of, for example, the WTO TRIPS dispute settlement mechanism with its trade-based sanctions regime.⁴⁵

Regrettably, the speed with which fifty countries deposited the necessary instruments of ratification for the Nagoya Protocol to come into effect is unlikely to be replicated in the Protocol's national implementation phase. The Protocol is complex, and while many countries had some type of ABS measure prior to the Protocol going into effect, only six countries and the EU had notified Protocol implementing legislation to the CBD prior to the Protocol's Oct. 12, 2014 effective date.⁴⁶ As of this writing, 39 countries have submitted ABS legislative or policy instruments to the new ABS Clearinghouse but most of those documents (other than the EU member states' submissions of the EU implementing directive) are pre-Nagoya Protocol laws.⁴⁷

Moreover, promptness in drafting implementing legislation has been no guarantee of a smooth operationalization process. For example, the EU adopted a Directive to implement certain aspects of the Protocol in April 2014, but the Directive has already been the subject of two legal challenges.⁴⁸ Also, French Polynesia rapidly developed and passed Nagoya Protocol Implementing legislation in 2012, but the legislation currently is not fully in operation. Moreover, after various changes in political leadership at multiple levels, the government is revisiting whether the law as drafted will meet the needs of the many constituents affected by it domestically and abroad. An

intensive analysis began in the second half of 2015, across ministries and in consultation with indigenous communities and local stakeholders, to evaluate what, if any, changes may be needed to operationalize a Protocol-compliant and effective ABS framework in French Polynesia.⁴⁹

It seems likely that many other countries will face a similar raft of challenges in implementing the agreement, such that it could be many years before all member states are in compliance with their Protocol obligations.⁵⁰ Nevertheless, progress is being made; a total of 68 countries have now ratified the Protocol and the first International Certificate of Compliance (ICC), granted to a University of Kent researcher by India on October 1, 2015, has been notified to the CBD ABS Clearinghouse.⁵¹ Under the Protocol, such an ICC is clear evidence that a researcher has complied with the PIC/ABS/MAT requirements of a country.

A recent comprehensive study of ABS laws pre-and post the Protocol reveals a variety of national approaches existing and emerging on this topic.⁵² The PIC/ABS/MAT legislation differs on numerous issues, such as whether research projects by foreigners require domestic scientist involvement to enhance capacity building, the types and number of compliance checkpoints, the nature and extent of indigenous and local community involvement, and whether users must use due diligence to determine if there has been compliance with a provider country's laws.⁵³

Whether these laws will be deemed to apply to synthetic biology researchers may be influenced by the nature of their research. Natural compounds historically have played

an important role in the development of products in a number of industries including cosmetics, pharmaceuticals, and agricultural products. The role may have peaked for pharmaceuticals in the early 1990s, when approximately 80 percent of marketed drugs were natural products or their analogs; however, natural products are still being developed and interest in natural products and ingredients is on the rise. In 2009, more than 100 natural product-based drugs were in clinical studies and 13 drugs derived from natural products received FDA approval between 2005 and 2007.⁵⁴ Natural products and traditional knowledge are particularly important for advances in the cosmetics industry where stories of traditional uses of cosmetic ingredients can enhance the exotic “experience” for consumers using certain products, and there is an increasing consumer demand for environmentally friendly and socially responsible offerings.⁵⁵ In agriculture, the identification of bacteria that facilitate plant growth, pest resistance, and drought tolerance, and the recognition that there are potentially multiplied thousands of other such bacteria are also fueling natural products research.⁵⁶ Natural compounds are a significant potential source of new ingredients: Less than 15 percent of higher plant species are believed to have been examined for bioactivity, and less than 1 percent of microorganisms are easily cultured.⁵⁷ Much remains to be learned from animal genetic information as well. For example, researchers recently identified the production of multiple copies of p53, a gene known to inhibit cancer growth, in African elephants. This finding helps explain why, despite their size, life span, and significantly higher number of total cells, that elephants

are much less likely to develop cancer than humans.⁵⁸ In turn this finding could lead to better cancer treatments for humans. Interestingly, developments in synthetic biology may increase the importance and viability of natural compounds in all of these areas. The ability to synthesize near copies of natural compounds or genes with designer modifications could both significantly advance knowledge and prove extremely profitable in eliminating some of the regulatory and transactional barriers to new product development.⁵⁹

Because many synthetic biology projects focus on mimicking natural products and processes and then making changes to them, significant amounts of both tangible genetic resources and genetic resource information have been – and are being – used in synthetic biology research. This has raised questions about whether synthetic biology products and developers are subject to the Nagoya Protocol. Also, the increasing amount of DNA sequence information being made freely available in online databases combined with the dramatic reduction in cost and difficulty of DNA sequencing from commercial labs is raising digital misappropriation concerns among NGOs and developing country officials. However, the ability to use intangible genomic information virtually undetected makes assuring compliance by such researchers far from simple.

Use and Misuse of Digital Genetic Information

One of the driving forces behind both the CBD and the Nagoya Protocol has been a desire to prevent the misappropriation and/or misuse of GRAATK, often broadly characterized as

“biopiracy.” “Biopiracy” is a rather pejorative, multi-dimensional term that is often used as a shorthand label for some form of egregious misappropriation. By one definition, it is “the patenting of plants, genes, and other biological products that are indigenous to a foreign country,”⁶⁰ without compensating the conservators of those resources and the holders of knowledge appropriated during ethnobiological research processes. This creates a clear connection to the word “piracy,” which is defined as “the unauthorized use of another’s production, invention, or conception especially in infringement of a copyright.”⁶¹ As explained by one commentator: “What developing tropical nations are saying is that if the West cries foul over piracy of intellectual property, [such as] computer software, then biopiracy in Western labs of jungle extracts should also be considered a high economic crime.”⁶² Pressure to address biopiracy has led to the use of the term by governmental entities and corporate titans alike: Peru has a National Anti-Biopiracy Commission that tracks global efforts to patent a variety of native Peruvian species, and the Sanofi Group recently published a factsheet on biodiversity and biopiracy.⁶³

The biopiracy label is controversial, and is itself subject to criticism, as it has been applied to a wide range of activity and used in vague, imprecise, and politicized ways.⁶⁴ Unauthorized uses of tangible genetic material and intangible genetic information can involve quite different levels of culpability in terms of knowledge and intent. For example, finding and using a DNA sequence of interest in a public database through “digital bioprospecting” seems far removed from intentionally removing genetic material from an *in situ* location without permission. Would both

be deemed biopiracy? It probably depends on whom you ask, with certain NGO and developing country personnel perhaps more likely to use the term than developed country researchers and representatives. Would both be deemed violations of national law? Perhaps yes, if the sequence from the public database was from an improperly acquired sample and if national legislation covers intangible genetic information; but whether in fact that would be the case will vary from country to country and will only be known as Protocol-implementing legislation is developed, operationalized, and enforced (as discussed below). Nevertheless, the broad range of activities to which governments, NGOs and other commentators sometimes apply the handy “biopiracy” label seems impossible to control.

Both the CBD and Nagoya Protocol were drafted primarily with tangible genetic resources in mind⁶⁵ and do not facially address the rather different set of “virtual” concerns implicated by recent developments in the field of synthetic biology. As the NGOs ETC Group and Friends of the Earth note:

While “traditional” biopiracy involves the physical removal of material from a community to private hands, synthetic biology enables “digital biopiracy” where the DNA of an organism is sequenced in situ, uploaded to the internet as information, and then transferred digitally to a DNA synthesizer to be copied and re-built elsewhere. This digital transfer of DNA sequences does not even require a Material Transfer Agreement since no physical material is transferred. Yet, the technology allows corporations, governments and individuals to freely take genetic material for private use in new

synthetic organisms, which can then be patented as inventions.⁶⁶

As discussed above, the term “biopiracy” is controversial in this context, but it is a catchphrase that instantly conveys the nature of the activities and fears at issue. Such fears seem justifiable in light of the wide availability of genome information and tools that can be used to construct modified or fully novel gene sequences that can be emailed or uploaded to commercial enterprises and synthesized to specification.⁶⁷ Indeed, in a report advocating a “broad and dynamic” interpretation of the Protocol definition of genetic resources to include digital information, the Fridtjof Nansen Institute noted that, “new knowledge and technologies [such as synthetic biology] may create new and inventive uses of genetic resources with a future potential for ABS.”⁶⁸

Concerns regarding the potential for “digital biopiracy” may create reluctance on the part of some provider countries to enter into non-commercial research agreements. This is perhaps due to fear that DNA sequence information obtained from analyzing genetic material under a PIC/ABS agreement may be uploaded to publicly accessible databases and then used by synthetic biology researchers to develop lucrative, ABS-free modified organisms and products for commercial applications.⁶⁹ This is particularly ironic and problematic as Article 8 of the Protocol explicitly encourages countries to ease access requirements for non-commercial research projects, such as the Moorea Biocode project in the South Pacific and the Smithsonian-based DNA Barcoding project, both of which are likely to generate voluminous amounts of digital sequence information.⁷⁰

These developments have the potential to influence how the Nagoya Protocol and other treaties may be modified and interpreted in the future. Moreover, the increasing likelihood of such problems led the International Civil Working Group on Synthetic Biology to make the following recommendation regarding the Protocol:

The Conference of the Parties should further invite the parties to the Nagoya Protocol on Access and Benefit Sharing to consider extending agreements on access and benefit sharing to cover digital genetic sequences and products derived from natural sequences using synthetic biology tools such as directed evolution techniques.⁷¹

Even if the Protocol is not construed to cover digital information and products derived therefrom, countries may still incorporate such coverage into their national legislation explicitly or by interpretation.⁷² However, ensuring compliance for such digital information is likely to be significantly more challenging than for tangible genetic material. It is possible to watermark a DNA sequence without interfering with gene coding by inserting the watermark in a non-coding region of the DNA.⁷³ J. Craig Venter used such a technique when developing “Synthia,” the first cell controlled by a synthetic genome.⁷⁴ However, such a process may not be economically feasible or efficient for large quantities of DNA sequences. Moreover, watermarks may be susceptible to degradation through, for example, mutation. Finally, it may be possible for third parties to identify the watermark (e.g., if it contains a start signal) and remove it from the DNA sequence. Thus, until a robust, secure,

watermarking system is available to identify the source of genetic information used in creating an invention, downstream user compliance with PIC/ABS conditions may be impossible to enforce.

Moreover, researchers may not even realize that the use of such digital information is objectionable. A provider country may consider obtaining sequence data on a genetic resource from an internet database to be the functional equivalent of receiving a physical sample from the researcher who uploaded it (in which case compliance with Protocol-implementing legislation would be required). Yet, a researcher may view obtaining sequence data on the internet as no different to obtaining information/data from a publicly available scientific publication.

This difference in views regarding the free availability and/or use of digital sequence information has the potential to create additional controversies between users and providers of genetic resources. In addition, imposing too many barriers to accessing digital data, or generating uncertainty regarding the legality of using digital data, could negatively impact the development of new products and information.

This difference in views is also reminiscent of controversies in other areas where advances in digital copying and an increase in easily accessible digital information have created “piracy” concerns, for example music and movie file-sharing and 3-D printing. Considering that all three phenomena are the result of the increasing digitization of information,⁷⁵ this is not surprising. For more than a decade, the Recording Industry Association of America and the Motion Picture

Association of America have been fighting the facilitators and perpetrators of unauthorized downloads of copyrighted works from the internet, labeling such actions as “theft” and obtaining monetary and, in some cases, criminal penalties against the perpetrators-individuals and organizations alike.⁷⁶ Likewise, 3-D printing is set to allow individuals and companies to cheaply copy patent and copyright protected articles from internet-accessible digital files.⁷⁷

If the 3-D printing controversy is in its infancy, the digital misappropriation controversy is, at best, embryonic; not many people are even aware of the issue. However, there is an important difference between music and movie file-sharing and 3-D printing on the one hand and genomic DNA sequence information on the other. In particular, the former content is protected by traditional intellectual property rights (copyrights and patents) and is seen as creative; the latter, generally speaking, is not.⁷⁸ Moreover, the IP-holding music and movie stakeholders are well-organized and have deep pockets to pay for lobbying, lawsuits, and the media and educational outreach efforts of their sustained campaigns. The indigenous people groups, local communities, and governments in developing countries most likely to be negatively impacted by digital misappropriation are neither well-organized

nor well-funded on this issue, and the origins of the sequence information may be very difficult to ascertain.⁷⁹

If government representatives come to believe that results gleaned in non-commercial research projects are being converted to commercial purposes with no concomitant sharing of benefits, they may eliminate simplified access procedures for such research, put stringent limits on the public sharing of such research results, or even stop such research projects altogether, as contemplated by the Indonesian government in 2014.⁸⁰ On the other hand, if synthetic biology researchers believe that they may be labeled as “biopirates,” subject to various sanctions, or have to engage in high transaction cost negotiations as a consequence of using sequences from publicly accessible databases, they may be inhibited from using such data, which could limit the beneficial discoveries they would otherwise make.

To avoid such a scenario, the CBD/NP COP should accelerate exploration of ways to ameliorate the digital misappropriation concern. One possibility could be employing some form of low transaction costs licensing scheme like, for example, Syngenta’s “E-Licensing” program for plant breeders (see box)⁸¹ or a multilateral benefit sharing fund

As explained on the Syngenta website, “[c]urrently, obtaining licenses for proprietary traits and technologies can be lengthy and costly, especially for small companies. . . . Under our new e-licensing system, the financial terms are clear, no negotiation is necessary and we ensure a fair sharing of benefits (i.e. added value) between patent owner, grower and licensee.” Features of the eLicense system include: internet access to the licenses; transparent FRAND licensing conditions, access to a portfolio of patented enabling technologies; free research licenses for academics/non-profits and standard license agreements for other entities, with terms adapted for small, medium and large entities; and no royalties being due unless newly-developed and commercialized varieties contain patented native traits. The key difference with Syngenta’s system is that the subject matter to be licensed is identified and patented, and access is truly controlled. Nevertheless, it might be possible to develop a system based on aspects of this model for interested provider countries.⁸¹

scheme, such as is present in the U.N. Food and Agriculture Organization's International Treaty on Plant Genetic Resources for Food and Agriculture.⁸² Parties that commercialize products from material accessed through the Treaty's multilateral system agree to pay a fixed percentage of sales into a benefit-sharing fund that provides grants to crop diversity enhancing projects across the globe.⁸³ To date, virtually all contributions to the fund have been made by countries, not commercial enterprises, which is seen as a weakness of the system, and plans were recently announced to adopt a subscription model to ensure consistent income for farmers and conservation efforts.⁸⁴ Nevertheless, such a system, in its current or revamped form, could provide a model to evaluate for addressing user and provider concerns regarding intangible genetic information.

Interestingly, Article 10 of the Protocol explicitly mentions the potential need for such a multilateral benefit sharing fund in the context of transboundary genetic resources and associated traditional knowledge (GRAATK), or for situations in which it is not possible to obtain prior informed consent, and the modalities of such a fund are currently under development.⁸⁵ Some third party commercial uses of genetic resource information from publicly accessible databases can be analogized to a transboundary situation or a situation where it is not feasible to get consent. This is because synthetic biology researchers may be using fragments of DNA sequences from many different species in designing new biosynthesis pathways to generate new, or enhanced compounds. In the absence of a

foolproof watermarking technique, providing for PIC/ABS obligations to be met for such uses through payments into a multilateral benefit sharing fund may be a viable way to avoid the twin specters of provider countries limiting access for non-commercial endeavors and the deterrence of researchers from using digital genetic resource information for fear of liability and/or untenable transaction costs.

Synthetic Biology, the Nagoya Protocol, and Intellectual Property Treaties

In 1984, negotiations began on the Uruguay Round of the General Agreement on Tariffs and Trade.⁸⁶ When those negotiations concluded in 1994, a new organization, the World Trade Organization (WTO) had been formed, and a new semi-global intellectual property regime had been created via the Agreement on Trade Related Aspects of Intellectual Property (TRIPS).⁸⁷ TRIPS was the first significant multilateral agreement requiring member countries to provide certain minimum levels of intellectual property protections to rights-holders.⁸⁸ TRIPS succeeded where prior efforts had failed by tying requirements for substantive protections (such as a minimum patent term) with trade.⁸⁹ This important connection meant that a member state's failure to comply with TRIPS requirements could result in trade sanctions by other members following a binding dispute resolution proceeding.⁹⁰

The Nagoya Protocol does not itself contain any mandatory provisions that are inconsistent with TRIPS. Rather, it allows members to enact legislation that may be inconsistent with their TRIPS obligations.⁹¹ For example, domestic ABS legislation

mandating the sharing of benefits derived from patents could be viewed as an unjustifiable interference with a patent owner's TRIPS-specified exclusive rights.⁹² Also, domestic legislation requiring applicants to disclose the origin of genetic resources and associated traditional knowledge used in developing an invention in order to obtain a patent could be viewed as a violation of TRIPS Article 27, which requires patents to be granted on inventions in all fields of technology as long as the invention is new, industrially applicable and involves an inventive step.⁹³ However, as long as a patent's issuance is not tied to compliance with such a disclosure requirement, there would not be a violation of TRIPS. This is the approach taken by several countries, including Switzerland and Norway, which require disclosure, but punish non-compliance outside of the patent system under laws concerning making false statements to government officials.⁹⁴

While complying with one's international obligations is desirable, it is important to

note that even if implementing the Nagoya Protocol were to put a country out of compliance with TRIPS, there may be no practical consequences to the country from such action. This is because sanctions are only likely to be imposed against a country for TRIPS non-compliance if a WTO Dispute Settlement Body (DSB) action is brought against the country and the panel rules against it.⁹⁵ A number of WTO countries have had laws mandating genetic resource disclosure of origin (DOO) in patent applications upon penalty of patent denial or revocation for several years, yet no WTO actions have been brought against any of them on this basis. There may be a variety of political reasons why no country might deem it worthwhile to bring a DSB action against another country over a disclosure of origin requirement, particularly if industry IP owners are not yet experiencing problems with the requirements. Moreover, even if an action is brought and a country loses, compliance sometimes can still be avoided through negotiation and/or monetary payments.⁹⁶



The Nagoya Protocol is not an IP treaty *per se*; nevertheless, there are strong links between the goals of the Protocol and the patent system in particular. For example, the misappropriation concerns that influenced the creation of the CBD, and ultimately the Protocol, were in large part driven by the fact that patents were being granted on inventions derived from GRAATK obtained without PIC/ABS/MAT while the lucrative proceeds from those patents were not being shared with the sovereign owners, providers, and developers of the GRAATK.⁹⁷

A requirement that patent applicants disclose the origin of genetic resources used in developing their inventions could facilitate compliance with PIC/ABS/MAT laws. Such a requirement is present in some patent laws and biodiversity laws already and even in some ABS contracts. Interestingly, the J. Craig Venter Institute incorporated a “soft” requirement to facilitate such disclosure for genetic sequence information gathered during its Global Ocean Sampling Expedition and submitted to the online CAMERA (Community Cyberinfrastructure for Advanced Microbial Ecology Research and Analysis) database (see box).⁹⁸

As discussed in our first report, the United States does not have a genetic resource disclosure of origin requirement and is not a party to the CBD nor the Nagoya Protocol. Nevertheless, a DOO requirement is already

a fact of life for researchers seeking patent protection in many countries outside of the United States, including China and several European countries such as Norway, Denmark, Italy, Switzerland, and Sweden.⁹⁹ It is also a requirement in Brazil, several other Latin American countries, and several African countries. In fact, more than 20 countries already have such a legal requirement, and that number can be expected to increase due to the Nagoya Protocol coming into effect.¹⁰⁰ Article 17 of the Protocol requires members to designate checkpoints where user compliance with PIC/ABS/MAT in relation to genetic resource utilization can be assessed. It is not a coincidence that a country’s patent or intellectual property office is a logical Nagoya Protocol checkpoint, and a genetic resource DOO requirement is a logical transparency tool to aid in effectuating the goals of the Protocol. The March 2010 draft of the Protocol explicitly identified intellectual property offices as mandatory checkpoints, although such a direct requirement was eliminated from the final document.¹⁰¹ Thus far, two of the four countries notifying checkpoints to the CBD ABS Clearinghouse have specified intellectual property offices.¹⁰² Thus, while designating an intellectual property or plant variety protection office as a checkpoint is not a Protocol requirement, defining the contours of a patent application genetic resource DOO requirement in an international treaty could actually enhance

One example of the JCVI language states:

*This genetic information downloaded from camera.calit2.net may be considered to be part of the genetic patrimony of Madagascar, the country from which the sample was obtained. Users of this information agree to: (1) acknowledge Madagascar as the country of origin in any publications where the genetic information is presented and (2) contact the CBD focal point identified on the CBD website (www.biodiv.org/docinfo-centre.shtml) if they intend to use the genetic information for commercial purposes.*⁹⁸

certainty for all researchers working with genetic material.¹⁰³

Possible Future Treaty based ABS/DOO Obligations

Currently, no multilateral intellectual property treaty mandates that countries impose a genetic resource disclosure of origin requirement in patent applications; it is solely a matter of national and/or regional law. However, that may change sooner rather than later, depending on the ultimate success of negotiations taking place in the World Intellectual Property Organization's (WIPO) Intergovernmental Committee (IGC) on Intellectual Property and Genetic Resources (GR), Traditional Knowledge (TK) and Folklore.

At WIPO, DOO concerns were first raised in the Standing Committee on Patents, but were later moved to the then-newly-created IGC for deliberation in 2000.¹⁰⁴ The IGC's first meeting was in 2001, and, while there has been much talk in successive meetings, real progress arguably did not begin until the start of text-based negotiations in 2009.¹⁰⁵ Recent negotiations have yielded three draft texts: a genetic resource text that would include provisions such as a requirement that inventors seeking patent protection disclose the origin of genetic resources and associated TK used in developing a claimed invention, a TK text that would include access and benefit sharing/compensation requirements and other possible constraints, and a traditional cultural expressions (TCE) text containing, among other things, a suite of moral rights for specified TCEs.¹⁰⁶

The WIPO members seeking a legally binding GR agreement – called *demandeurs* – are

mostly indigenous people groups and developing countries rich in GRAATK.¹⁰⁷ They believe a genetic resource DOO requirement will reduce the grant of erroneous patents (e.g., patents that should not have been granted because the subject matter lacks novelty or is obvious), and facilitate access and benefit sharing agreements in relation to GRAATK. Non-*demandeurs*, on the other hand, are developed countries that, in many cases, have been resisting a binding agreement, and/or want any agreement on genetic resources to employ only defensive measures, such as traditional knowledge databases, to avoid the grant of erroneous patents and *not* to facilitate ABS. Many of these non-*demandeurs* claim that a mandatory genetic resource disclosure of origin requirement would be unworkable, as it would unacceptably reduce legal certainty and place too much of a burden on patent applicants, resulting in diminished innovation.¹⁰⁸ However, DOO requirements can be designed to be reasonable and, as discussed above, the reality is that DOO patent requirements are already a fact of life in many countries and supplying such information will thus, over time, become business as usual.

China, the country that currently receives more patent applications every year than any other country, provides a pertinent example. Article 26 of the Chinese Patent Act (3rd Revision) requires patent applicants to disclose the origin of genetic resources used in creating an invention. According to a recent analysis of China's genetic resource DOO requirement, between Oct. 1, 2009 and June 30, 2013, genetic resource source forms were filed in 7,149 patent applications,

most after the examiner requested submission of the form.¹⁰⁹ While the vast majority of applications were filed by Chinese domestic applicants, thirty-eight were from abroad and filed by applicants from South Korea, Japan, France, Germany, Finland, India, Canada, Switzerland, Indonesia, and the United States.¹¹⁰ Thus, researchers and multinationals, including from the United States, already may have to deal with such a requirement if they are seeking patent protection in DOO countries such as China.¹¹¹

Importantly, the authors of the study conclude that the new genetic resource disclosure requirements are not placing an “undue burden” on patent applicants.¹¹² And DOO requirements should not be an onerous burden on applicants and should not require them to provide information that they do not know. While countries may impose a due diligence requirement on applicants to make efforts to ascertain origin or source, others, including China, will accept as true an applicant’s assertion that the source and/or origin of the genetic material is unknown. Even the United States, which is opposed to a mandatory genetic resource DOO requirement, has a requirement in 37 C.F.R. 1.105 that allows an examiner to request any information from an applicant that might aid in examining the application (including disclosure of origin) and to accept as a complete answer that the applicant does not know the requested information.¹¹³

Nevertheless, even a DOO requirement is not a panacea for ABS ills. Genetic resource DOO requirements can be problematic for a variety of reasons, including the fact that many organisms share common genetic components or can be found in more than

one geographic location. For example, the rosmarinic acid-containing plants used by Pacific islanders to treat cases of ciguatoxin poisoning are found in New Caledonia, French Polynesia, Vanuatu, Tonga, Micronesia, and even Japan.¹¹⁴ Moreover, patent disclosure requirements are not harmonized, resulting in often vague and fairly non-specific DOO descriptions (if any) in relevant patent applications.¹¹⁵ And even if an applicant complies with a disclosure requirement, governments or other groups must still develop and deploy sufficient resources to effectively monitor and investigate and, if appropriate, negotiate and enforce agreements concerning the GRAATK.

Parties took a hiatus from formal IGC discussions in 2015; however, during the WIPO General Assemblies Oct. 5-14, 2015, agreement was reached to resume IGC negotiations in the 2016-2017 biennium toward development of one or more international legal GR, TK, TCE texts. It seems likely that consensus will continue to grow, in particular around the draft GR text and its DOO provision.¹¹⁶ Several IGC delegations appear to be somewhat open to a minimum standard or “floor” in the agreements which, for the GR text, could involve a mandatory DOO requirement as a transparency mechanism that leaves several of the details of scope and specific penalties (e.g., whether violation of the DOO affects patent validity or is only addressed outside of the patent system) to be addressed under national law. Consequently, instead of opposing a DOO requirement in the IGC, non-demandeurs might be better off agreeing to a floor and seeking a *ceiling* on the scope of DOO protections and penalties in national

laws. This could result in a ratcheting back of some of the most onerous and draconian national provisions and provide a greater level of certainty and lower risk of disproportionately severe penalties to their researchers when using genetic resources. It also could be particularly important for facilitating patent transactions, as the origin of some resources may not be known by all parties that could be charged with DOO violations, such as downstream owners in a patent's chain of title.

Synthetic biology issues have not yet meaningfully penetrated the WIPO IGC GR discussions, but as the parties move toward a clearly defined text it seems likely that the scope of “genetic resources” under the instrument, and whether the term includes intangible genetic information, will eventually arise. While much remains to be determined as to the ultimate form, content, nature, and membership of any genetic resource agreement, it seems quite likely that it will incorporate some sort of DOO requirement. Whether, and to what extent, synthetic biology inventions will be considered subject to a DOO requirement remains unknown. It is possible that, as under the Nagoya Protocol, the express issue of the status of intangible genetic information will be left to the vagaries of national implementing legislation.

The traditional knowledge and traditional cultural expressions draft texts appear to be further from consensus than the genetic resource text. While TCEs are unlikely to be at issue in synthetic biology research, TK may be implicated in some situations. For example, TK could include information obtained from members of an indigenous group or local community about uses of a

particular genetic resource which in turn could lead to the extraction and use of pharmacologically active compounds and the synthetic modification of DNA sequence information from such compounds to develop new products. The current draft of the IGC traditional knowledge text includes positive protections such as the right to exclude, economic benefits, and/or moral rights such as the right of attribution, depending on whether the TK can be categorized as, for example, secret, sacred, or closely held.¹¹⁷

The idea of IP-like protection for TK could be anathema to some academic researchers, who may see an analogy to the information they freely share through presentations and in scientific journal publications. Such information may be later used and built upon by third parties who create new, lucrative inventions without any compensation going back to the presenter/author. However, a distinction can certainly be made between groups who seek to share knowledge. For example, knowledge shared by researchers in a government-funded institution of higher education (with a mandate, in many cases, to discover and disseminate knowledge) and knowledge shared by a local community or indigenous people group in a developing country without such a knowledge-sharing obligation and with limited economic resources and opportunities are categorically different. Compensation for knowledge shared by the latter group seems appropriate, is required under the Nagoya Protocol (as benefit sharing), and need not be financial in nature, as the Protocol emphasizes the importance of both non-monetary and monetary benefits.¹¹⁸

Conclusion

Patent protection remains available for most synthetic biology outputs, although eligibility varies by country and copyright protection currently appears unlikely. Also, the relatively amorphous nature of the Nagoya Protocol, which sets minimum obligations but does not constrain maximalist national ABS/PIC/DOO measures, poses no direct conflict to the WTO TRIPS Agreement. In addition, while ratification of the Protocol proceeded expeditiously, the drafting and enactment of implementing legislation, as well as the creation of the necessary infrastructure for

efficient operation of domestic PIC/ABS/MAT systems remain challenges for many countries. Moreover, efforts at WIPO to develop a binding treaty to, *inter alia*, obligate countries to require patent applicants to disclose the origin of genetic resources used in creating a claimed invention bear watching as negotiations resume in 2016. Researchers would be well advised to inquire into the origin of tangible genetic material and, where possible, intangible genetic information that they use and, where applicable, to ensure that such material was taken in compliance with the domestic law of a provider country.



Endnotes

- 1 Margo A. Bagley and Arti K. Rai, *The Nagoya Protocol and Synthetic Biology: A Look at the Potential Issues*, Wilson Center: Synthetic Biology Project (November 2013), <http://www.wilsoncenter.org/publication/the-nagoya-protocol-and-synthetic-biology-research-look-the-potential-impacts>. I am deeply grateful to Arti Rai for her insightful comments and suggestions on this report that, unfortunately, she was unable to join me in writing. Special thanks to Heremoana Maamaatuaiahutapu (Minister), Tea Frogier (Minister), Sylviane Fauvet, and Eliane Garganta in the Ministries of the Environment and Research for French Polynesia, as well as to Komal Jain, Bob Friedman, Keith Kozminski, Xavier Moppert, Neil Davies, and Matthew Markus for helpful comments and insights. Thanks also to Joseph Babitz and the University of Virginia Law librarians for excellent and timely research assistance.
- 2 Antoine Danchin & Victor de Lorenzo, *Synthetic Biology: Discovering New Worlds and New Words: The New and Not So New Aspects of This Emerging Research Field*, 9 EMBO Reports 822 (2008). A strand of synthetic biology research has also focused on de novo organism research. However, in an effort to create a controlled terminology, a 2014 European Commission Scientific Committee report adopted a definition of synthetic biology that begins with a living organism, relegating pre-life de novo research to the field of chemistry. See European Commission Health and Food Safety Scientific Committees, "Final Opinion on Synthetic Biology," available at http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scenihrc_consultation_21_en.htm. Whether this new terminology will be universally adopted remains to be seen.
- 3 See Martin Fussenegger & Weber, Wilfried, *The Impact of Synthetic Biology on Drug Discovery* 14 Drug Discovery Today 956 (2009), and Presidential Comm'n for the Study of Bioethical Issues, *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*, pp. 43-46 (Dec. 2010), <http://bioethics.gov/sites/default/files/PCSBI-Synthetic-Biology-Report-12.16.10.pdf>
- 4 Brian Alexander, *Synthetic Life Seeks Work*, MIT Technology Review (Aug. 19, 2015).
- 5 Id.
- 6 Robert F. Service, *Modified Yeast Produce Opiates from Sugar*, 349 Science 677 (Aug. 14, 2015).
- 7 See Press Release, Woodrow Wilson Center, *Synthetic Biology Still in Uncharted Waters of Public Opinion*, (May 14, 2014) available at <http://www.synbioproject.org/news/project/6683/>; Hart Research Associates, *Perceptions of Synthetic Biology and Neural Engineering* (2014) available at http://www.synbioproject.org/site/assets/files/1073/focusgroup_2014.pdf. See also Presidential Comm'n for the Study of Bioethical Issues, *New Directions: The Ethics of Synthetic Biology and Emerging Technologies* (Dec. 2010), <http://bioethics.gov/sites/default/files/PCSBI-Synthetic-Biology-Report-12.16.10.pdf>; ETC Group, *Synthetic Biology*, <http://www.etcgroup.org/issues/synthetic-biology> (last visited June 8, 2015).
- 8 Synthetic Biology Project, *Synthetic Biology Products and Applications Inventory 2014*. Available at: <http://www.synbioproject.org/cpi/>.
- 9 Synthetic Biology Project. *Tracking the Growth of Synthetic Biology: Findings for 2013*. Available at: <http://www.synbioproject.org/inventories/maps-inventory/>.
- 10 Research by Oldham et. al., indicates that the influence of synthetic biology research has extended to 78 countries, approximately 3,000 organizations, and an estimated 19,751 researchers. Paul Oldham, Stephen Hall & Geoff Burton, *Synthetic Biology: Map-*

- ping the Scientific Landscape, 7(4) PLoS ONE e34368, available at <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0034368>.
- 11 “Temporal Scope” refers to the question of what genetic resources are covered by the Nagoya Protocol from a time perspective. Specifically, whether the Protocol applies only to genetic resources physically accessed (i.e. that crossed a border) after the Protocol came into force, or to genetic resources which are utilized after the Protocol came into force, but were/are physically accessed at any time after the CBD came into force, or to genetic resources physically accessed at any time and utilized after the Protocol came into force. “Breadth of Coverage” refers to the issue of whether the definitions of genetic resources and genetic material, should or will be interpreted broadly enough to include digital genetic information such as is used in synthetic biology research. Both of these issues are discussed in more detail in Margo A. Bagley and Arti K. Rai, *The Nagoya Protocol and Synthetic Biology: A Look at the Potential Issues*, Wilson Center: Synthetic Biology Project (November 2013), <http://www.wilsoncenter.org/publication/the-nagoya-protocol-and-synthetic-biology-research-look-the-potential-impacts>.
 - 12 Hereinafter COP12/MOP1.
 - 13 Conference of the Parties, Report of the Twelfth Meeting of the Conference of the Parties to the Convention on Biological Diversity (2014), available at <https://www.cbd.int/doc/meetings/cop/cop-12/official/cop-12-29-en.pdf>. (hereinafter “COP12/MOP1”) In the environmental context, the precautionary principle reflects the idea that even if there is not conclusive scientific proof of the risk associated with a product or activity, precautions should be taken to protect against the risk or else the product should not be used or the activity should not be undertaken. See Protecting Health and the Environment: Implementing the Precautionary Principle 353–54 (Carolyn Raffensperger & Joel Tickner eds., 1999).
 - 14 Id. ¶ XII/24(3)(C) at 178.
 - 15 See, e.g., www.biobricks.org/about-foundation; www.igem.org/Main_Page. See also Heidi Ledford, *Bioengineers Look Beyond Patents* 499 Nature, July 3, 2013, available at <http://www.nature.com/news/bioengineers-look-beyond-patents-1.13320>. It should be noted that some open source advocates still seek patents on specific outputs on a strategic basis. *Id.*
 - 16 See also William D. Nordhaus, *Invention, Growth, and Welfare: A Theoretical Treatment of Technological Change* (Cambridge: M.I.T. Press, 1969); As the Supreme Court put it in *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150–51 (1989) (internal quotations and citations omitted): “The applicant . . . who is willing to reveal to the public the substance of his discovery and the best mode . . . of carrying out his invention is granted the right to exclude others from making, using, or selling the invention throughout the United States for a period of [20] years. The federal patent system thus embodies a carefully crafted bargain [The inventor] may keep his invention secret and reap its fruits indefinitely. In consideration of its disclosure and the consequent benefit to the community, the patent is granted.”; William Fisher, *Theories of Intellectual Property*, in *New Essays in the Legal and Political Theory of Property* (Stephen Munzer, ed Cambridge University Press, 2001) (describing the Incentive Theory); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1597–99 (2003); F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 Minn. L. Rev. 697, 697 (2001).

- 17 See, e.g., U.S. Patent No. 7,192,751 (published March 20, 2007); U.S. Patent No. 7,541,172 (published June 2, 2009).
- 18 See, e.g., U.S. Patent No. 7,854,774 (published Dec. 21, 2010).
- 19 133 S. Ct. 2107 (2013), interpreting 35 U.S.C. §101. In addition, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012) (“Mayo”) in conjunction with *CLS Bank v. Alice*, 134 S. Ct. 2347 (2014) imposed an “inventive concept” requirement for claimed inventions involving a law of nature or abstract idea; thus both cases are particularly relevant to biotech diagnostic or therapeutic method claims.
- 20 See Matthew B. McFarlane, Tara Guffrey Sharp & John T. Aquino, *Stopped at the Threshold: The Practical Impact of the Supreme Court’s Mayo and Myriad Decisions on Biotechnology Patent Practices*, (Bloomberg BNA Life Sciences Law and Industry Report, 2014), available at <http://www.bna.com/uploadedFiles/Content/Images/StoppedAtTheThresholdMayoMyriadFinal-Report.pdf>.
- 21 *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).
- 22 See the Official Action in US Patent Application Pub. No.: 2012/0231445 A1, “Oligonucleotides and Process for Detection of Swine Flu Virus.”
- 23 750 F.3d 1333 (Fed. Cir. 2015). A related patent claimed the cloning methods used to produce Dolly the sheep. Those method claims are not subject to challenge under the *Myriad* reasoning.
- 24 See United States Patent & Trademark Office, 2014 Interim Guidance on Patent Subject Matter Eligibility (and July 2015 Update), available at <http://www.uspto.gov/patent/laws-and-regulations/examination-policy/2014-interim-guidance-subject-matter-eligibility-0>.
- 25 See Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, Article 5(2), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML> (“An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element”).
- Official Journal L 213, 30/07/1998 P. 0013 - 0021. But see Margo A. Bagley, *Patent Barbarians at the Gate: The Who, What, When, Where, Why & How of U.S. Patent Subject Matter Eligibility Challenges*, in *Patent Law in Global Perspective*, 165 (Ruth L. Okediji & Margo A. Bagley eds., 2014).
- 26 *D’Arcy v Myriad Genetics Inc.*, [2015] HCA 35 (7 October 2015). The Court noted that the isolated nucleic acid claims “[embrace] a nucleic acid sequence or protein removed from its naturally occurring environment and includes recombinant or cloned DNA isolates and chemically synthesised analogs or analogs biologically synthesised by heterologous systems.” *Id.* at para. 3.
- 27 *Id.* at para. 6.
- 28 Andrew Torrance, *DNA Copyright*, 46 Val. U. L. Rev. 27 (2011).
- 29 *Id.* at 37-39.
- 30 *Id.* at 39-40.
- 31 See, e.g., 17 U.S.C. § 102 (1990).
- 32 See, e.g., Andrew W. Torrance & Linda J. Kahl, *Bringing Standards to Life: Synthetic Biology Standards and Intellectual Property*,

- 30 Santa Clara High Tech. L.J. 199, 226-27 (2014); Michael D. Murray, *Post-Myriad Genetics Copyright of Synthetic Biology and Living Media*, 10 Okla. J. L. & Tech. 71, 106-11 (2014); Christopher M. Holman, *Copyright for Engineered DNA: An Idea Whose Time Has Come?*, 113 W. Va. L. Rev. 699 (2011); Andrew Torrance, *DNA Copyright*, 46 Val. U. L. Rev. 1, 26-40 (2011); Dennis S. Karjala, *Protecting Innovation in Computer Software, Biotechnology, and Nanotechnology*, 16 Va. J.L. & Tech. 42, 55-61 (2011); Andrew W. Torrance, *Synthesizing Law for Synthetic Biology*, 11 Minn. J.L. Sci. & Tech. 629, 642-648 (2010).
- 33 The latin phrase “sui generis” means “of its own kind,” and refers, in this context, to a legal regime created specifically for this subject matter, as opposed to trying to fit the subject matter into an existing IP regime like copyright. See Arti Rai A & James Boyle (2007) *Synthetic Biology: Caught between Property Rights, the Public Domain, and the Commons*. 5(3) PLoS Biol 5(3): e58 . doi:10.1371/journal.pbio.0050058 available at <http://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.0050058> (summarizing sui generis approaches).
- 34 *Id.* See also Pamela Samuelson, *Are Gardens, Synthetic DNA, Yoga Sequences, and Fashions Copyrightable?* (unpublished draft on file with author). See also Rai et. al. *supra* note 32.
- 35 *Id.*
- 36 See Heidi Ledford, *Bioengineers Look Beyond Patents* 499 Nature, July 3, 2013, available at <http://www.nature.com/news/bioengineers-look-beyond-patents-1.13320>. See also Christopher M. Holman, *supra* note 32, at pp. 704-705.
- 37 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity, Oct. 29, 2010, C.N.782.2010.TREATIES-1 (Depositary Notification) [hereinafter Nagoya Protocol].
- 38 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, (2012), available at <http://www.cbd.int/doc/measures/abs/post-protocol/msr-abs-eu-en.pdf>.
- 39 Nagoya Protocol, *supra* note 37 at Art. 4(4). See also Thomas Geiber, Sonia Peña Moreno, Mattias Åhrén, Jimena Nieto Carrasco, Evanson Chege Kamau, Jorge Cabrera Medaglia, María Julia Oliva & Frederic Perron-Welch in cooperation with Natasha Ali and China Williams, *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing*, (IUCN Environmental Policy and Law Paper No. 83, 2012).
- 40 See Nagoya Protocol, *supra* note 37 at Art. 6(b)-(c).
- 41 See Nagoya Protocol, *supra* note 37 at Art. 15. Denmark’s draft legislation provides one approach to complying with this obligation, as it prohibits the utilization of GRs when the use is based on GRs acquired in violation of GR access regulations in the country where the GRs were accessed. Violations are punishable by fines, or up to two years in prison if willful or grossly negligent, and foreign states and persons appear to have standing to bring relevant actions in Danish courts. See “Implementing the Nagoya Protocol in Denmark,” Denmark Ministry of the Environment, available at www.cbd.int/abs/side-events/cop-11/denmark-en.pdf.
- 42 Maria Julia Oliva, *Sharing the Benefits of Biodiversity: A New International Protocol and Its Implications for Research and Development*, 77 Planta Med. 1221, 1223 (2011).

- 43 See Nagoya Protocol, *supra* note 37 at Article 12(4).
- 44 See COP12/MOP1 *supra* note 13 at Annex. Article 27 of the CBD does contain a dispute settlement procedure; however, it has never been used. Article 30 of the NP requires Members at the first meeting of the parties, to develop and approve cooperative mechanisms to promote compliance and to address cases of non-compliance.
- 45 Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154 (The Agreement on Trade-Related Aspects of Intellectual Property Rights, January 1, 1995, Annex 1C, Art. 28.) (hereinafter "TRIPS").
- 46 See Jorge Cabrera Medaglia, Frederic Perron-Welch & Freedom-Kai Phillips, Overview of National and Regional Measures on Access and Benefit Sharing: Challenges and Opportunities in Implementing the Nagoya Protocol, 13 (3rd ed., 2014) *available at* http://cisdl.org/biodiversity-biosafety/public/CISDL_Overview_of_ABS_Measures_2nd_Ed.pdf (noting that as of April 25, 2014, the ABS Measures Database had listed fifty-seven countries and seven regions as having some form of ABS measure).
- 47 See CBD, *Measures on Access and Benefit-Sharing for Implementing the Nagoya Protocol*, <https://www.cbd.int/abs/progress/default.shtml> (last visited June 16, 2015).
- 48 Timothy Maler, *Interview: EU Must Deliver Legal Certainty for Seed and Plant Sectors*, Agra Europe, <https://www.agra-net.net/agra/agra-europe/analysis/interview-eu-must-deliver-legal-certainty-for-seed-and-plant-sectors-458540.htm> (last visited June 22, 2015) (discussing the German and Dutch seed companies who have separately formed groups in two separate instances to challenge the Nagoya Protocol in the EU's Court of Justice)
- 49 Communication with personnel in the French Polynesia Ministry for the Environment.
- 50 Interviews with French Polynesia Ministry of Environment and Ministry of Research personnel.
- 51 See Vishwa Mohan, "India allows UK researcher to study medicinal knowledge of ethnic group in Gujarat," *The Times of India*, October 22, 2015, available at <http://timesofindia.indiatimes.com/india/India-allows-UK-researcher-to-study-medicinal-knowledge-of-ethnic-group-in-Gujarat/articleshow/49489130.cms>.
- 52 Jorge Cabrera Medaglia, Frederic Perron-Welch & Freedom-Kai Phillips, Overview of National and Regional Measures on Access and Benefit Sharing: Challenges and Opportunities in Implementing the Nagoya Protocol (3d ed., 2014) *available at* http://www.wageningenur.nl/upload_mm/3/5/4/185268d6-44a9-45eb-a0e5-171739c8ef06_CISDL_Overview_of_ABS_Measures_3rd_Ed.pdf
- 53 *Id.* at 112-117.
- 54 Jesse W. H. Li & John C. Vederas, *Drug Discovery and Natural Products: End of an Era or an Endless Frontier?*, 325 *Science* 161 (Jul. 10, 2009).
- 55 Rachel Wynberg & Sarah Laird, Bioscience at a Crossroads: Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change: The Cosmetics Sector, 15 (2013), available at <https://www.cbd.int/abs/policy-brief/default.shtml/> [hereinafter "Wynberg & Laird, Bioscience at a Crossroads"].
- 56 Jop de Vrieze *The Littlest Farmhands*, 349 *Science* 680 (Aug. 14, 2015).
- 57 Jesse W. H. Li & John C. Vederas, *Drug Discovery and Natural Products: End of an Era or an Endless Frontier?*, 325 *Science* 163 (Jul. 10, 2009).

- 58 "Secret to why elephants rarely get cancer is in their genes," ABC Science News, October 7, 2015, available at <http://www.abc.net.au/news/2015-10-09/genes-explain-why-elephants-rarely-get-cancer/6841096>.
- 59 Martin Fussenegger & Weber, Wilfried, *The Impact of Synthetic Biology on Drug Discovery* 14 Drug Discovery Today 956 (2009). See also Philipp Zerbe, Angela Chiang, Harpreet Dullat, Mark O'Neil-Johnson, Courtney Starks, Bjorn Hamberger & Jorg Bohlmann, *Diterpene Synthases of the Biosynthetic System of Medicinally Active Diterpenoids in Marrubium Vulgare*, 79 The Plant Journal 914, 914-927 (2014). See also Wynberg & Laird, *Bioscience at a Crossroads*.
- 60 The Word Spy, at <http://www.wordspy.com/words/biopiracy.asp> (last visited Aug. 17, 2015).
- 61 Merriam Webster Dictionary, available at <http://www.merriam-webster.com/dictionary/piracy> (last visited Aug. 17, 2015).
- 62 Anthony Faiola, "Amazon Cash Crop," The Washington Post, July 9, 1999.
- 63 See "Peru Accuses Chinese Companies of Biopiracy Involving Maca Root," available at <http://www.moellerip.com/peru-accuses-chinese-companiesof-biopiracy-involving-maca-root/>. See also "Sanofi Position on Biodiversity and Biopiracy," available at http://en.sanofi.com/csr/download_center/download_center.aspx.
- 64 Daniel F. Robinson, *Confronting Biopiracy: Challenges, Cases and International Debates*, p. 15 (Earthscan 2010). See also James M. Chen, *There's No such Thing as Biopiracy . . . And It's a Good Thing Too*, 37 McGeorge L. Rev. 1 (2006); and Paul J. Heald, *The Rhetoric of Biopiracy*, 11 Cardozo J. Int'l & Comp. L. 519 (2003).
- 65 Although there were some discussions of synthetic biology issues in the Nagoya Protocol negotiations, they did not gain sufficient traction to warrant an explicit reference in the final agreement.
- 66 *101 Fact Sheets from Friends of the Earth*, SynBioWatch <http://www.synbiowatch.org/2013/05/synthetic-biology-101-some-technical-details-from-friends-of-the-earth/> (last visited June 15, 2015). See also Friends of the Earth, *About Us*, <http://www.foe.org/about-us/what-we-stand-for>; ETC Group, *About ETC*, <http://www.etcgroup.org/mission>
- 67 One such tool is the free "Gene Designer" software available from www.DNA2.0.com. See Alan Villalobos et al, *Gene Designer: A Synthetic Biology Tool for Constructing Artificial DNA Segments* 7 BMC Bioinformatics 285 (2006) available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1523223/>. As a press release from the J. Craig Venter Institute explains: "Genomic science . . . is enabling researchers to "read" the genetic code of organisms from all branches of life . . . Sequencing genomes has now become routine, giving rise to thousands of genomes in the public databases. In essence, scientists are digitizing biology by converting the A, C, T, and G's of the chemical makeup of DNA into 1's and 0's in a computer." Press Release, J. Craig Venter Institute, First Self-Replicating Synthetic Bacterial Cell (May 20, 2010) available at <http://www.jcvi.org/cms/research/projects/first-self-replicating-synthetic-bacterial-cell/overview/#sthash.2TuEjP2I.dpuf>.
- 68 Fridtjof Nansen Institute, 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), available at <https://www.cbd.int/doc/meetings/abs/abswg-09/information/abswg-09-inf-01-en.pdf>

69 See Alain Pottage, *Too Much Ownership: Bioprospecting in the Age of Synthetic Biology*, 1 *Biosocieties* 137 (2006) (describing J. Craig Venter's Sorcerer II bioprospecting voyages and provider country ownership concerns generated by putting genome data into the public domain.)

70 See www.mooreabiocode.org; www.barcodeoflife.org/content/about/what-dna-barcoding. Nagoya Protocol, *supra* note 37 at Art. 8 states in part:

In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall:

Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research.

71 The International Civil Society Working Group on Synthetic Biology, A Submission to the Convention on Biological Diversity's Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) on the Potential Impacts of Synthetic Biology on the Conservation and Sustainable Use of Biodiversity (Oct. 17, 2011) *available at* <https://www.cbd.int/doc/emerging-issues/Int-Civil-Soc-WG-Synthetic-Biology-2011-013-en.pdf>. The NGOs ETC Group and Friends of the Earth mentioned *supra* note 66, are also members of the Working Group.

72 See, e.g., Brazilian Provisional Act, No. 2,186-16, Title II, Art. 7, ¶ I August 23, 2001, which broadly defines genetic heritage 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, . . ." Lei Provisional No. 2.186-16, de Agosto de 2001, Constituição Federal [C.F.] [Constitution] art. 225 (Braz.) (emphasis added). See also, Article 1 of the Andean Community Decision 391 which defines "access" as "[t]he obtaining and use of genetic resources conserved in situ and ex situ, of their by-products and, if applicable, of their *intangible components*, for purposes of research, biological prospecting, conservation, industrial application and commercial use, among other things." Decision Number 391 Establishing the Common Regime on Access to Genetic Resources, Bol.-Colom.-Ecuador-Peru, July 17, 1996, 213 Cartagena Agreement Official Gazette (emphasis added) *available at* <http://www.wipo.int/wipolex/en/details.jsp?id=9446>.

73 See, e.g., Yamamoto, Naoki, Hiroyuki Kajjura, Shinya Takeno, Nobuaki Suzuki, and Yoshihisa Nakazawa. "A Watermarking System for Labeling Genomic DNA." *Plant Biotechnology. J-STAGE*, 23 Aug. 2014; Authentication of Plant Variety Rights." *Journal of Electronic Science and Technology*. March 2013.

74 Aaron Saenz, "Secret Messages Coded into DNA of Venter Synthetic Bacteria," May 24, 2010, *available at* <http://singularityhub.com/2010/05/24/venters-newest-synthetic-bacteria-has-secret-messages-coded-in-its-dna/>.

75 See Erik Brynjolfsson & Andrew McAfee, *The Second Machine Age: Work, Progress, and Prosperity in a Time of Brilliant Technologies*, (W.W. Norton & Company 2014).

76 See, e.g., *Over 200,000 John Does Sued for File Sharing in the U.S. Since 2010*, *available at* <http://infojustice.org/archives/4724> (last visited Sept. 17, 2015).

77 See, e.g., Timothy R. Holbrook & Lucas S. Osborn, *Digital Patent Infringement in an*

Era of 3d Printing, 48 U.C. Davis L. Rev. 1319 (2015); Lucas S. Osborn, *Regulating Three-Dimensional Printing: The Converging Worlds of Bits and Atoms*, 51 San Diego L. Rev. 553 (2014); Deven R. Desai & Gerard N. Magliocca, *Patents, Meet Napster: 3d Printing and the Digitization of Things*, 102 Geo. L.J. 1691 (2014); and Ben Depoorter, *Intellectual Property Infringements & 3d Printing: Decentralized Piracy*, 65 Hastings L.J. 1483 (2014).

- 78 While isolated genomic DNA sequences may be eligible for patent protection outside of the United States, there appears to be no major effort underway to patent, at considerable cost, the large quantities of DNA sequence information obtained during non-commercial research expeditions.
- 79 Due in part to transboundary issues where species are common to more than one territorial jurisdiction.
- 80 Januar Hakam "Indonesia to Put Moratorium on Foreign Research to Protect its Biodiversity" Ekuatorial (online ed, Jakarta, 21 October 2014) (discussing Indonesian plans for a moratorium on foreign biodiversity research due to biopiracy concerns).
- 81 See Syngenta "E-Licensing" (2012) <<http://www3.syngenta.com/global/e-licensing/en/e-licensing/Pages/home.aspx>>. As explained on the Syngenta website, "[c]urrently, obtaining licenses for proprietary traits and technologies can be lengthy and costly, especially for small companies. . . . Under our new e-licensing system, the financial terms are clear, no negotiation is necessary and we ensure a fair sharing of benefits (i.e. added value) between patent owner, grower and licensee." Features of the eLicense system include: internet access to the licenses; transparent FRAND licensing conditions, access to a portfolio of patented enabling technologies; free research licenses for academics/non-

profits and standard license agreements for other entities, with terms adapted for small, medium and large entities; and no royalties being due unless newly-developed and commercialized varieties contain patented native traits. The key difference with Syngenta's system is that the subject matter to be licensed is identified and patented, and access is truly controlled. Nevertheless, it might be possible to develop a system based on aspects of this model for interested provider countries.

- 82 See The International Treaty on Plant Genetic Resources for Food and Agriculture "Texts of the Treaty: Official Versions" (26 September 2015) available at <<http://www.planttreaty.org/content/texts-treaty-official-versions>>. Interestingly, Article 10 of the Nagoya Protocol provides for the establishment of a benefit-sharing fund for cases of transboundary genetic resources and traditional knowledge.
- 83 See Governing Body of the Treaty "The Standard Material Transfer Agreement for the Multilateral System" (16 June 2006) <http://www.ecpgr.cgiar.org/fileadmin/templates/ecpgr.org/upload/AEGIS/AEGIS_SMTA.pdf>.
- 84 See "Sixth Session of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture," Oct. 2, 2015, available at <http://www.planttreaty.org/news/sixth-session-governing-body-international-treaty-plant-genetic-resources-food-and-agriculture>.
- 85 See CBD, "What has been done on the global multilateral benefit-sharing mechanism?," available at <https://www.cbd.int/abs/benefitsharing-whatdone.shtml>.
- 86 World Trade Organization, *The WTO in Brief: Part 1* http://www.wto.org/english/thewto_e/whatis_e/inbrief_e/inbr01_e.htm (last visited July 7, 2015).
- 87 See TRIPS, *supra* note 45.

- 88 However some regional patent agreements did have substantive requirements. See European Patent Convention, Oct. 5, 1973, 29 I.L.M. 1417.
- 89 See, e.g., Rochelle C. Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPs and Dispute Settlement Together*, 37 Va. J. Int'l L. 275 (1997). In the patent area, these minimum requirements included protection for inventions in all areas of technology, a minimum patent term of 20 years from the patent application filing date, and civil penalties for infringing the patent right during the 20 year term.
- 90 See World Trade Organization, *Dispute Settlement*, http://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm (last visited June 9, 2015). See also Margo A. Bagley, Ruth L. Okediji & Jay A. Erstling, *International Patent Law and Policy*, 154-158 (1st ed., 2013).
- 91 See Ricardo Pavoni, *The Nagoya Protocol and WTO Law*, in *The 2010 Nagoya Protocol on Access and Benefit-sharing in Perspective*, 190 (Elisa Morgera et al. ed., 2013).
- 92 *Id.* at 202-203 (noting that “The Nagoya Protocol [makes] sure that no provision it itself could be interpreted as mandating deviations from the rights purportedly secured by TRIPs”). See also TRIPs, *supra* note 45 at Art. 28.
- 93 See TRIPs, *supra* note 45 at Art. 27. TRIPs Article 28 does contain a sufficiency of disclosure requirement but it does not require disclosure of the origin of genetic resources related to the claimed invention.
- 94 See note 99 *infra*.
- 95 WTO, *Dispute Settlement*, World Trade Organization.Org https://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm (detailing how disputes must be brought before the Dispute Settlement Body by a member country); See also Monika Bütler & Heinz Hauser, *The WTO Dispute Settlement System: a First Assessment From an Economic Perspective*, 16 Oxford J. L. Eco. & Org. 503 (2000) (highlighting the DSB's weak enforcement mechanism during the implementation stage).
- 96 For example, the United States has yet to comply with two TRIPs DSB actions against it, despite the passage of more than 20 years. See Edward Lee, *Measuring TRIPs Compliance and Defiance: The WTO Compliance Scorecard*, 18 J. Intell. Prop. L. 403 (2011). See also DS160 and DS174, available at https://www.wto.org/english/tratop_e/dispu_e/dispu_agreements_index_e.htm?id=A26#.
- 97 See, e.g., Sabrina Safrin, *Chain Reaction: How Property Begets Property*, 82 Notre Dame L. Rev. 1917, (2007). See also Sheila Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States*, 203-04, (2005) (noting that “the extension of patents to the life sciences created new classes of property rights in things that were previously outside the realm of what could be owned, or even thought of as subject to ownership claims”).
- 98 One example of the JCVI language is available at <http://metagenomesonline.org/library-details?prefix=GCU> and states:
- This genetic information downloaded from camera.calit2.net may be considered to be part of the genetic patrimony of Madagascar, the country from which the sample was obtained. Users of this information agree to: (1) acknowledge Madagascar as the country of origin in any publications where the genetic information is presented and (2) contact the CBD focal point identified on the CBD website (www.biodiv.org/docinfo-centre.shtml) if they intend to use the genetic information for commercial purposes.

- 99 Lov om patenter 15 desember 1967 [The Patent Act] (as amended in 2013) (Nor.); Lov. nr. 91 af 28. januar 2009 Bekendtgørelse af patentloven [Consolidated Patent Act] (Den.); Decreto Legislativo 12 dicembre 2002, n.273 [Industrial Property Code] (It.); Lag (1967:838) Patentlag [Patents Act as amended July 1, 2014] (Swed.). Moreover, the EU Biotech Directive nominally includes a DOO, however, there is no penalty for non-compliance.
- 100 Queen Mary Intellectual Property Research Institute, Report on Disclosure of Origin in Patent Applications, (2004); For example, Belgium, Brazil, Chile, China, Egypt and Switzerland all require DOO as a condition of patentability. Loi modifiant la loi du 28 mars 1984 sur les brevets d'invention, en particulier la brevetabilité des inventions biotechnologiques [Law Modifying the Law on Patentability of Biotechnological Inventions] of April 28, 2005, Moniteur Belge [Official Gazette of Belgium], *available at* http://www.wipo.int/wipolex/fr/text.jsp?file_id=180969; Brazil: Brazilian Provisional Act, No. 2,186-16, Title II, Art. 7, ¶ I August 23, 2001, Lei Provisional No. 2.186-16, de Agosto de 2001, Constituição Federal [C.F.] [Constitution] art. 225 (Braz.); Law No. 20569, Febrero 6, 2012, Reperorio de Legislación y Jurisprudencia Chilenas [Rep. Leg. Jurisp.] (Chile); The Decision of the Standing Committee of the National People's Congress on Amending the Patent Law of the People's Republic of China (promulgated by the Standing Comm. Eleventh National People's Cong., December 27, 2008, effective October 1, 2009) (China) [hereinafter "Chinese Patent Law"]; Law No. 82 of 2005 (Law on the Protection of Intellectual Property Rights) *Al-Jarida Al-Rasmiyya*, 3 June 2002 (Egypt); Schweizerisches Zivilgesetzbuch [ZGB], Code Civil [CC], June 25, 1954, SR 232.14 *as amended* Jan. 1, 2012 (Switz.).
- 101 AD Hoc Open-Ended Working Group on Access and Benefit Sharing, Report of the First Part of the Ninth Meeting of the AD Hoc Open-Ended Working Group on Access and Benefit Sharing, (26 April 2010) *available at* <https://www.cbd.int/doc/?meeting=ABSWG-09>.
- 102 See <https://absch.cbd.int/>.
- 103 Joshua D. Sarnoff & Carlos M. Correa, Analysis of Options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications (UNCTAD ed., 2005), *available at* http://digitalcommons.wcl.american.edu/pijip_trad_knowledge/3/.
- 104 Ahmed Abdel Latif, *Genetic Resources, Patents and Benefit Sharing: State of Play and Challenges Facing Multilateral Discussions*, in *Intellectual Property in the Pharmaceutical Industry*, 59-88 (Jacque de Werra ed., 2012).
- 105 International Centre for Trade and Sustainable Development, *WIPO Traditional Knowledge Committee Pushes Toward Text-Based Talks* 13 Bridges (Dec. 16, 2009) *available at* <http://www.ictsd.org/bridges-news/bridges/news/wipo-traditional-knowledge-committee-pushes-toward-text-based-talks>.
- 106 See Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Joint Recommendation on Genetic Resources and Associated Traditional Knowledge, WIPO/GRTKF/IC/28/7 (May 9, 2014); Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, The Protection of Traditional Knowledge: Draft Articles WIPO/GRTKF/IC/28/5 (June 2, 2014); Intergovernmental Committee on Intellectual

Property and Genetic Resources, Traditional Knowledge and Folklore, The Protection of Traditional Culture Expressions: Draft Articles WIPO/GRTKF/IC/28/6 (June 2, 2014).

107 Parties seeking a new agreement are colloquially known as “demandeurs” (a French term meaning “one who asks”) while those opposing or simply not seeking an agreement are called “non-demandeurs.”

108 See, e.g., Council for Trade-Related Aspects of Intellectual Property Rights, Communication from the United States: Views of the United States on the Relationship Between the Convention on Biological Diversity and the TRIPS Agreement, IP/C/W/257 (June 13, 2001); Council for Trade-Related Aspects of Intellectual Property Rights, Communication from the United States: Article 27.3(B), Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore, para. 4, IP/C/W/469 (Mar. 13, 2006) (noting in paragraph 5 “legal uncertainty and other negative consequences”). See also Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, para. 34, IP/C/M/44 (July 19, 2004) (European Communities arguing PIC would be hard to verify); Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, para. 155, IP/C/M/29 (Mar. 6, 2001) (Japan arguing that DOO would violate TRIPS).

109 Qingkui Zhang and Dongcheng Pang, *Chinese Patent Law and Protection for Genetic Resources, IP in the Life Sciences Industries*, 66 Intellectual Asset Management Mag., 113, 116 (May 30, 2014) available at <http://www.iam-media.com/Magazine/Issue/66/Management-report/Chinese-patent-law-and-protection-for-genetic-resources>. For context,

the authors report that 825,000 total patent applications (utility, design, and utility model) were filed in the Chinese patent office in 2013 alone.

110 *Id.*

111 See Chinese Patent Law *supra* note 100 at art. 5 and art. 26.

112 *Id.* at 113.

113 37 C.F.R. 1.105 states in part: (3) Any reply to a requirement for information pursuant to this section that states either that the information required to be submitted is unknown to or is not readily available to the party or parties from which it was requested may be accepted as a complete reply.

114 See International (PCT) Patent Application No. WO 2011012780 A1, “Use of rosmarinic acid and the derivatives thereof to treat ciguatera” (published Aug. 16, 2012).

115 Of course, it is possible to make DOO requirements more useful. As Paul Oldham notes “Enhancing disclosure is important because taxonomic information about existing species and biodiversity is, and will always be, imperfect.” He suggests enhancing disclosure through, among other things, requiring identification of the source country in the application text and whether any indigenous and local communities were involved in the identification and/or invention process. He also advocates introducing an ABS statement into patent applications detailing the ABS country and agreement number. Paul Oldham, Tracking & Monitoring Genetic Resources in the Patent System *available at* http://www.abs-initiative.info/fileadmin/user_upload/Activities/2011/Addis_IP_09-2011/Documents/2_-_Tracking___Monitor-

ing__GRs_in_the_Patent_System__Paul_Oldham__ESRC_Cesagen__UNU_.pdf.

- 116 It should be noted that at least 108 countries, more than two thirds of the WTO's members, expressly endorsed a DOO amendment (not ultimately adopted, however) to the TRIPS Agreement. See WTO, WTO Council for Trade-Related Aspects of Intellectual Property Rights, "*Minutes of Meeting Held in the Centre William Rappard on 26-27 October 2010*," (17 February 2011) IP/C/M/64, paragraph 22, available at https://docs.wto.org/dol2fe/Pages/FE_Browse/FE_B_S005.aspx?MeetingId=83282&Language=1&StartDate=&EndDat

e=&SubjectId=&SearchPage=&&CatIds=85459,100052,96586,100631,104287,105400&languageUIChanged=true#.

- 117 Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, The Protection of Traditional Knowledge: Draft Articles, WIPO/GRTKF/IC/28/5, June 2, 2014, available at http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=276361.
- 118 See Nagoya Protocol, *supra* note 37 at Annex.



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