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The Impact of Co-Existing Access and Benefit-Sharing Obligations ("Hybrid System") on Life Sciences Companies: A View from Private Legal Practice

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About the Authors and the Objective of this Paper

Covington & Burling LLP ("Covington") is a global law firm advising the innovative (bio)pharmaceutical, food and biotechnology companies (website profile). We are the only law firm that is ranked "band 1" for life sciences in the United States, UK, Europe, China and globally.

Within its life sciences industry group, Covington Partner Bart Van Vooren and his team have grown a unique legal practice focusing on Access and Benefit-Sharing ("ABS"). Since 2013, we have advised on a whole range of ABS legal issues including, *e.g.* ABS permit filings in 'provider' countries; 'user' country compliance checks (*e.g.* EU, UK, Switzerland); due diligence programs; M&A transactions; supply, licensing and R&D agreements; patent filings and disclosures; public policy; as well as litigation. By our last count there are more than 100+ ABS regulations globally, and we have a working knowledge of ABS across all seven continents.

Using this background and experience, this paper seeks to provide a legal analysis of interactions between national ABS systems and the Convention on Biological Diversity ("CBD") Conference of the Parties ("COP") 15 multilateral mechanism ("MLM") on ABS from digital sequence information ("DSI"). Specifically, we explain how (1) the MLM might be interact with existing national ABS laws; and (2) how a life sciences company might navigate and be impacted by a landscape of multiple national ABS laws that exist concurrently with the MLM – often referred to as "the hybrid system."

We have drafted this non-paper solely to share our legal opinion as attorneys with significant experience on ABS. The views, analyses and conclusions are entirely those of the two authors.

Paper Summary and Conclusion

In section I, we distinguish between three types of ABS systems: (1) a bilateral, national ABS system; (2) a multilateral, supranational system; and (3) a hybrid of the two. We explain what we mean by each of these categories. In short, for a user of genetic resources, a "hybrid" ABS system means that there are potentially multiple, co-existing legal sources for ABS obligations that could apply to the same (activity on) that genetic resource. Whether one or the other ABS requirements apply will depend on material (*e.g.* physical vs digital), geographic (*e.g.* territorial sea vs high sea), temporal (before or after 12 October 2014), or personal (public or private entity) "triggers" that determine the applicability of one or the other ABS instrument. A user wishing to conduct R&D on genetic resources will have to determine which of the conditions are fulfilled, to determine which ABS regime to comply with.

In order to explain how ABS affects life sciences companies, Section II briefly explains how companies "think" when deciding to develop a product or process from a genetic resource, and how compliance with ABS laws enters this decision-making process.

In sections III, IV and V, we explain as concretely as possible, from the perspective of attorneys advising life sciences companies that will decide to commence R&D on genetic resources and/or DSI, the kinds of legal-factual questions that users must resolve in order to determine whether ABS applies, and what obligations might be. We draw on our past experience with the Nagoya Protocol and implementing ABS laws, and explain what the impact of layering the Multilateral Mechanism on DSI from genetic resources ("MLM-DSI") on top of these laws might be:

- Section III explains general questions such as determining whether an activity is considered "utilization"; whether an ABS law covers genetic resources and DSI; whether it is relevant when a genetic resource was physically acquired or the DSI was sequenced; and the relevance of geographic origin of the genetic resource or the DSI. These are issues that any user, falling under any ABS system, has to contend with.

- Section IV looks at the proliferation of ABS systems relating to specific genetic resources: plant genetic resources, marine genetic resources, and pathogenic genetic resources. Especially since R&D projects may draw on different types of genetic resources, this multitude of ABS regimes, combined with the MLM-DSI, may create extraordinary legal complexity.

- Section V looks at a question that is particularly important to companies and their lawyers. Namely, how is all of this enforced in practice, and what are the sanctions if we get it wrong? Environmental law is often penalized with significant criminal fines and even jail terms. Companies consistently want to comply, but if a legal system is as complex as ABS, the risk of sanctions has a significant deterring effect on R&D on genetic resources and DSI.

Finally we draw a brief conclusion, which we can already state at the outset: On the one hand, users face a landscape of ABS laws in 141 Nagoya Protocol Parties, that have at least 100+ ABS laws, of which 39+ apply to DSI. There are three specialized ABS regimes for plants, marine genetic resources, and pathogens; and the MLM-DSI may be layered on top of these international regimes and their national implementation. On the other hand, users face real enforcement, massive and potentially criminal fines. Therefore, the MLM-DSI presents countries with a real opportunity. We urge them to opt for a watershed moment on

ABS, and negotiate a *truly* multilateral system that will simplify ABS for DSI as well as physical genetic resources. Only such a system will generate *any* resources for biodiversity preservation and restoration. The principles of paragraph 9 of Decision 15/9, on efficiency, feasibility, effectiveness, legal certainty, and generating more benefits than cost, are of paramount importance. Currently, the negotiators are not taking them seriously enough. In our practice, we have had the unfortunate privilege of witnessing first-hand how getting ABS means stifling R&D and halting innovation. This is not merely a problem for companies. Given the staggering rate of species extinction, achieving the Kunming-Montreal Global Biodiversity Framework will require major innovation on a global scale. Thus, the devastating effect on R&D of well-intended but poorly executed ABS laws is a major societal problem. As it stands, these attorneys are deeply concerned that the MLM-DSI is likely to complicate ABS through further fragmentation and proliferation of conflicting and overlapping requirements. If we may implore the negotiators: Do not rush the MLM-DSI, and do not seek "constructive ambiguity" as is so often the case in global legal instruments. Welcome companies in the room as trusted partners. And above all, keep laser-focused a single, comprehensive, user-friendly, global ABS regime, requiring reasonable contributions from the private sector, generating real benefit-sharing to address the biodiversity crisis that threatens life on Earth.

I. <u>What is a "hybrid" system for Benefit-Sharing from DSI on GRs?</u>

A. Distinguishing national, multinational and hybrid ABS systems

For the purpose of this non-paper, we distinguish between three types of ABS systems: (1) a bilateral, national ABS system; (2) a multilateral, supranational system; and (3) a hybrid of the two. We explain what we mean by each of these categories.

1. A Bilateral, National ABS System

The bilateral, national approach to ABS is one that requires a user to seek a permit for access, and agree to terms on benefit-sharing, with the "provider country" of the genetic resources (*e.g.* Afghanistan, Albania … to Zambia or Zimbabwe). The Nagoya Protocol to the CBD adopts this approach. This has led to a proliferation of national ABS measures. Depending on how one counts,[1] there are 100+ ABS laws in the 141 Parties to the Nagoya Protocol. Aside from the Nagoya Protocol, there are also countries that are Party to the CBD and not the Nagoya Protocol, but still have ABS measures (*e.g.* Australia; and until 2021, Brazil). Even the United States, although not a member of CBD or the Nagoya Protocol, has ABS requirements for genetic resources found in its National Parks. Finally, there are also Parties to the Nagoya Protocol that have expressly chosen *not* to adopt ABS laws at all (*e.g.* Austria, Germany and the Netherlands), or only partial ABS laws (*e.g.* Switzerland which requires registration but not benefit-sharing; or Belgium, where one region adopted ABS laws, and another region expressly chose not to adopt ABS laws).

The Nagoya Protocol will celebrate the 10th anniversary of its entry into force on 12 October 2024. This decade of experience with ABS has shown that navigating this patchwork of national ABS laws is challenging for anyone conducting R&D in the life sciences – companies large and small, but also universities, government research institutes, botanical gardens, zoos, philanthropic research organizations, *etc.* Typical questions these entities need to

[1] Two key elements determined our count which dates from January 2023: (1) We have counted only ABS laws at national level, and not counted regional-level ABS laws such as in, *e.g.* in Argentina, Spain, French Overseas Territories. If we had counted those, the figure would be significantly higher than 100. (2) We have counted both hard legal and soft legal ABS regimes.

examine are: where does my genetic resource "originate"? What if my resource is indigenous to multiple countries each with ABS laws? Where do I find these ABS laws? Can I trust the ABS Clearing House to be up-to-date and complete? Is the law available in a language I understand? Is my activity "utilization" that triggers a permit or payment requirement under that ABS law? Will I be (criminally) liable if I misunderstood the ABS law? This is the day-to-day reality of the bilateral, national ABS system.

2. A Multilateral, Supra-national ABS System

The Multilateral approach is one where access and benefit-sharing obligations are imposed on users in a legal instrument that exists at above-country ("supranational") level. In principle, this system imposes "fully harmonized" requirements at international level requiring limited national implementation. At most, national laws may be adopted to give legal binding force to the global system, because international public law is not itself binding on citizens or legal entities. Alternatively, users are incentivized to conclude legally binding ABS contracts with the "provider" of the genetic resources. In ABS, a truly multilateral system is rare- if it even exists at all. The main example is the Pandemic Influenza Preparedness ("PIP" Framework). From a legal perspective, the PIP Framework is based on a non-binding Resolution of the World Health Assembly. Access to influenza samples is presumed to be free from obligations of prior informed consent, and benefit-sharing is arranged through standard contracts between the users of the samples, and the Secretariat of the World Health Organization ("WHO"). Of course, the PIP Framework relies on the Global Influenza Surveillance and Response System ("GISRS"). This is a 70+ year collaboration between the WHO member states, so the PIP Framework does rest on decades of national implementation and investment by public and private stakeholders alike. As regards ABS, the PIP Framework in our view can be considered a "Specialized International Instrument" (SII) under Article 4(4) of the Nagoya Protocol, so that the Nagoya Protocol and its implementing laws in principle should not apply.

3. A "hybrid" ABS system

For a user of genetic resources, a "hybrid" ABS system means that there are potentially multiple, co-existing legal sources for ABS obligations that could apply to the same (activity on that) genetic resource. Whether one or the other ABS requirements apply will depend on material (e.g. physical vs digital), geographic (*e.g.* territorial sea vs high sea), temporal (before or after 12 October 2014), or personal (public or private entity) "triggers" that determine the applicability of one or the other ABS instrument. A user wishing to conduct R&D on genetic resources will have to determine which of the conditions are fulfilled, to determine which ABS regime to comply with.

In our view, the International Plant Treaty on Genetic Resources for Food and Agriculture ("ITPGRFA" or "Plant Treaty") is a "hybrid" ABS system. It has elements of multilateralism and global harmonization, like the standard material transfer agreement and the common fund under the FAO. However, the multilateral system only applies insofar as Plant Treaty State Parties have expressly designated which of their collections of plant genetic resources are in scope of the Plant Treaty. Thus, the applicability of ABS obligations depends on what genebank you acquired the plant genetic resource from. If the national genebank is not in scope of the Plant Treaty, ABS under the Nagoya Protocol may apply. Moreover, the Plant Treaty does not apply to utilization of a plant genetic resource that is used for other purposes than food and agriculture. But again, ABS under the Nagoya Protocol may apply. That is the essence of a hybrid ABS system: depending on the purpose of the utilization, or the entity that provides the plant genetic resource, the applicable ABS requirements will be different. Against that background, the seemingly multilateral PIP Framework also results in a hybrid

system: *seasonal* influenza samples may fall under the Nagoya Protocol implementing ABS laws; whereas *pandemic* influenza falls under the PIP Framework.

A brief example. A single R&D project may use multiple genetic resources in both physical and/or digital form. Take squalene, a natural lipid that is used in cosmetic products to soften the skin. Sharks use squalene to stay buoyant.[2] The most concentrated source of high-purity squalene is found in the livers of sharks that live in deep water. A skin-care product may contain shea butter and shark-based squalene, so that a single product may trigger national ABS laws for the shea butter, as well as squalene from sharks caught in the territorial regime, or the new high seas regime. A similar example. Pharmaceutical companies sometimes use squalene as an adjuvant to strengthen the human immune response. A therapeutic or vaccine would also draw on physical samples or Digital Sequence Information from the pathogenic genetic resource it is developed against – like seasonal or pandemic influenza strains. The result is that for a single pharmaceutical product, national ABS laws may apply (squalene from the territorial sea, and seasonal influenza), the PIP Framework may apply (if the seasonal influenza turns out to be pandemic influenza), the high seas ABS regime may apply (squalene from sharks caught in the high seas but not the territorial sea), and the MLM-DSI may apply (possibly, DSI on squalene or seasonal influenza).

In summary, a hybrid system implies co-existing ABS obligations at national and international level. The result is that the user will need to make complex legal-factual assessments to determine which system applies. As we will illustrate further in this paper, these assessments can be extraordinarily time and resource consuming.

In what follows we first briefly recall the COP15 Decision to establish the multilateral mechanism, and we briefly summarize the stakeholders' views on the hybrid system on benefit-sharing from DSI on genetic resources.

B. COP15 to establish a "multilateral mechanism for the benefit-sharing from the use of DSI on genetic resources"

On 19 December 2022, the State Parties convening in the COP to the CBD adopted Decision 15/9. At paragraph 16 of that Decision, the COP:

> "*Decides to establish, as part of the Kunming-Montreal Global Biodiversity Framework,* ***a multilateral mechanism*** *for benefit-sharing from the use of digital sequence information on genetic resources, including a global fund.*" (our emphasis)

While Decision 15/9 establishes the MLM-DSI, the relationship with national ABS laws was hotly contested at COP15. An earlier version of the COP Decision 15/9 had the following paragraph:[3]

> *"Recognizes that a* ***purely bilateral approach*** *to benefit-sharing from the use of digital sequence information on genetic resources is unlikely to meet the criteria identified in paragraph 1* [paragraph 9 of the final Decision 15/9]*, and that a*

[2] https://cen.acs.org/pharmaceuticals/vaccines/hunt-alternatives-shark-squalene-vaccines/98/i47

[3] The non-paper of 10 December at 1730 Montreal time, on file with the author.

> ***multilateral approach has the most potential to meet these criteria;***" (our emphasis)

The highlighted wording "purely bilateral approach" did not make it in the final COP Decision. It was a recognition that a Nagoya Protocol-style approach to ABS would not provide the efficiency, transparency, and legal certainty to attain benefit-sharing from DSI. Unfortunately, some Parties were reticent to yield some national sovereignty in favor of the multilateral mechanism, resulting in the following paragraph in the final Decision 15/9:

> "*11. Agrees that the approach to fair and equitable benefit-sharing from the use of digital sequence information on genetic resources set out in the present decision* ***does not affect existing rights and obligations under the Convention and the Nagoya Protocol****, including, as applicable, those related to traditional knowledge and the rights of indigenous peoples and local communities,* ***and is without prejudice to national access and benefit-sharing measures****;*" (our emphasis)

This co-existence of the multilateral approach with the national bilateral approach to ABS, is a hybrid ABS system for DSI. In what follows, we explore concretely what that would mean for companies in the life sciences sector. First, we briefly explain how companies make cost-benefit analyses and decisions to conduct R&D. Thereafter, we explain how ABS assessments impact this decision-making process.

II. How do Life Sciences Companies make Decisions to Conduct R&D?

The "life sciences" sector comprises companies that are active in a variety of areas, including: cosmetics; food and feed; human and veterinary medicines; biotechnology; plant breeding; animal breeding; and biocontrol. All life sciences companies constantly need to innovate to stay relevant and to respond to changing needs: climate change requires draught-resistant agricultural crops; anti-microbial resistance requires new antibiotics; consumers want natural instead of synthetic cosmetic ingredients; and so on. These research and development cycles typically range from 5-7 years in cosmetics, to 10 years in food and 15+ years in pharmaceuticals and plant breeding.

Companies will consistently have a tailored project management process to manage these yearslong innovation cycles. This process typically consists of key milestones. These are clearly identifiable moments on the path of an R&D project that represent the completion of a significant activity and subsequently the beginning of a new phase. For example:

- For a food company, phase 1 might be to define consumer trends and needs; phase 2 to explore potential ingredients to address this need; phase 3 to develop the ingredient and product to incorporate it; phase 4 to upscale for industrial production; and phase 5 to commercialize the product.

- A typical pharmaceutical company process would be to begin with the exploratory stage to examine *e.g.* the mechanism of action of multiple compounds; the pre-clinical stage of a selected few compounds; and the clinical development stage of a single active pharmaceutical ingredient. Clinical development will typically comprise phase 1, phase 2 and phase 3 clinical trials; as well as post-commercialization phase 4 clinical trials.

At any of these milestones, a company may determine that an R&D project has failed. For instance because a new nature-based flavor is not well-received by the tasting panel; or

because a pharmaceutical compound turns out no more effective than a placebo. The risk of failure is real and exists in all life sciences sectors. But even for R&D projects with potential success, at each milestone a company decides whether or not to (continue) investing their limited, available financial and human resources into the next stage of the R&D process. This is commonly referred to as the "business case" to continue to the next stage of the R&D process. Companies will look at a variety of financial and non-financial criteria, including at the size of the business opportunity, critical performance criteria of the product, projected sales upon commercialization, positive impact on the environment or public health, and so on. In this cost-benefit analysis, a company will seek to predict costs as early as possible, and as reliably as possible.

The life sciences sectors are highly regulated industries. Compliance with applicable legal requirements is taken very seriously and deeply integrated into the management of innovation cycles. Thus, the legal function of a company is extensively involved in drawing up the cost-benefit analysis at each milestone of an R&D project. They will contribute to cost estimates of complying with applicable legal requirements. For instance, the marketing team has devised a wonderful sales pitch to market a product in the EU based on Rooibos from South Africa. The idea is to use health claims that Rooibos contains anti-oxidants that protect against free radicals. Unfortunately, legal informs marketing that health claims require prior approval in the EU, and that this is a long application process before the European Food Safety Authority (EFSA) that requires significant scientific evidence to be approved. The company may decide to make that investment because it believes in the product and the health claim; or it may decide that the application cost is simply too high. Thus, in life sciences, legal compliance has a real impact on the business case to pursue an R&D project.

When a proposed R&D project will rely on genetic resources, or DSI, or both; compliance with ABS requirements is part of a company's cost-benefit analysis. In doing that analysis, speed, transparency, and certainty are of prime importance. First, a company will want to have a legally sound determination whether and how much monetary or non-monetary benefit-sharing will be required, and how this will be calculated. Second, because committing to begin an R&D innovation cycle can take upwards of 10+ years and typically involves huge investment, companies want to know the benefit-sharing amount early in the life cycle, typically many years before the eventual commercialization of a final product. Third, companies are under pressure to make R&D decisions quickly – often a matter of months, weeks, or days. Waiting a year or (much) longer for clarification on ABS requirements is typically not possible. Overall, when drawing up the business case, companies will never "wait and see" what the benefit-sharing requirement will be until the very end of their innovation cycle.

In the next and final section of this paper, we deep-dive into the types of factual-legal challenges that companies face when they are assessing ABS requirements for a given R&D project. On 14 October 2024, the world will celebrate the 10-year anniversary of the Nagoya Protocol's entry into force. Having advised on ABS since 2013, Covington partner Bart Van Vooren has significant first-hand experience with the challenges that life sciences companies and public entities (*e.g.* universities, national research institutes, philanthropic research organizations) face in complying with ABS laws. In what follows, we explain as concretely as possible, from the perspective of attorneys advising life sciences companies that will decide to commence R&D on genetic resources and/or DSI, the kinds of legal-factual questions that users must resolve in order to determine whether ABS applies, and what obligations might be:

1) First, is my activity considered **utilization** under the relevant ABS law?

2) Second, is that utilization of a **genetic resource, or DSI** in scope of that ABS law?

3) Third, is it relevant **when** that genetic resource or DSI was physically acquired, sequenced, or utilized?

4) Fourth, what is the **geographic origin** of the genetic resource or DSI, and how does that impact what ABS law applies?

5) Fifth, if I am utilizing a **pathogenic genetic resource or DSI** are there specific ABS rules relating to public health?

6) Sixth, if I am using a **plant genetic resource or DSI**, what is the importance of its geographic origin, and the purpose of my utilization?

7) Seventh, if I am using a **marine genetic resource or DSI**, what is the importance of its geographic origin, and when the access or utilization occurs?

8) Eighth and finally, how is all of this **enforced** in practice, and what are the **sanctions** if we get it wrong?

III. Complying with a Hybrid ABS System in Practice

A. Whether the activity "based on" the DSI, constitutes "utilization" under the relevant ABS law or under the MLM-DSI

At paragraph 16, COP Decision 15/9 states that the MLM-DSI will apply to the "use" of genetic resources. In contrast, the Nagoya Protocol applies to the "utilization" of genetic resources. This is an important difference with real relevance for users.

University and company researchers in the life sciences conduct all kinds of "research and development" on genetic resources. For instance, they may test how much annatto to add to color Cheddar cheese;[4] they may examine whether dog food containing essential oils of cloves, rosemary and oregano is good for a pet's health;[5] they may test whether quadrivalent MRNA vaccines protect against certain influenza B strains;[6] they may research the safety of naturally sourced chlorophyl as a green food colorant;[7]; they may test the type or quantity of enzymes necessary for a washing detergents to function;[8] and so on. This means that users must determine whether their "research and development" in the *colloquial* sense will fall under the definitions of "use" or "utilization" in the *legal* sense as defined in the relevant ABS regime. Under the Nagoya Protocol we have already seen significantly diverging interpretations of "utilization", and if the MLM-DSI will apply to "use", it may add another layer of complexity.

Article 2 of the Nagoya Protocol defines utilization as "*[to] conduct research and development on the genetic and/or biochemical composition of genetic resources.*" Just like the term "genetic resource", there are significant differences in the definitions of "utilization"

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[4] https://pubmed.ncbi.nlm.nih.gov/38608957/
[5] https://pubmed.ncbi.nlm.nih.gov/32602378/
[6] https://pubmed.ncbi.nlm.nih.gov/36322769/
[7] https://pubmed.ncbi.nlm.nih.gov/36322769/
[8] https://pubmed.ncbi.nlm.nih.gov/33184763/

in national ABS laws. For example, Switzerland's definition of "utilization" is identical to that of the Nagoya Protocol. In contrast, India's ABS law defines "commercial utilization" so widely that nearly any form of trade in biological resources (which notably includes DSI, see next section B below) is in scope. In our view this likely violates WTO trade law, but that is the topic of another paper altogether. Similarly, France's ABS law defines "utilization of genetic resources" as R&D on the genetic resources, as well as the "valorisation of genetic resources, the applications and commercialization that results from it." Finally, the European Union has published in 2021 a guidance document of 68 (!) pages to explain the meaning of "utilization" under its Regulation 511/2014 that requires users to conduct due diligence to ensure compliance with ABS laws of provider countries.[9]

The Annex of the Synthesis Paper for the AHOEWG-2 contains elements proposed by the Co-Chairs for the operationalization of the MLM. At paragraph 1 of the Annex it refers to "users that generate revenue from the use of DSI." From a legal certainty perspective, it is important to have a definition of "use". Presumably, "use" is broader than "utilization" as defined in the Nagoya Protocol. The Co-Chairs have also proposed two triggers for the MLM-DSI to apply in paragraph 2 of the Annex. They do not refer to "utilization" but to, under option A, "placing products on the market that benefited from DSI", or under option B, "being highly dependent on the use of DSI". Option A creates a wider scope of application, whereas option B creates a narrower scope of application. It will be absolutely essential for the CBD Parties to define the connection between the users' activities and the DSI, and do so in a harmonized way between the Parties to the MLM-DSI, as well as between the MLM-DSI and other ABS regimes and the national implementing laws.

Based on the experience with the Nagoya Protocol, diverging interpretations of the same concepts results in users facing multiple legal triggers for ABS-related obligations: (1) "utilization" of physical GRs in 100+ ABS laws around the world, at least 39 of which also apply to DSI; or (2) "use", or "benefiting from" under the MLM-DSI. It is therefore essential that the MLM-DSI is seized as the opportunity for true harmonization, and that Parties adhere to internationally agreed terms and definitions.

B. The physical or digital nature of the genetic resource that is being utilized

At paragraph 11, COP Decision 15/9 states that the MLM-DSI "*does not affect existing rights and obligations under the Nagoya Protocol and is without prejudice to national ABS measures.*" Thus, each of the CBD Parties will individually decide whether to maintain its national ABS law; and if so, the relationship with the MLM-DSI. Moreover, during the first Ad Hoc Open-ended Working Group (AHOEWG) in Geneva in November 2023, the Secretariat provided a note that stated at paragraph 48 :[10]

> "*In terms of policy options other than the multilateral one established in decision 15/9 some submitters proposed* ***hybrid approaches whereby endemic species, products from the use of DSI from a single country of origin, products from the territories of indigenous peoples and local communities or products associated with traditional knowledge would all fall under a bilateral exception system.*** *However, other submitters expressed concerns about the potential for added* ***administrative complexity,***

[9] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC0112(02)&from=EN
[10] https://www.cbd.int/doc/c/d479/f5f9/30b94a531fd169d758c2ff4e/wgdsi-01-02-en.pdf

> *jurisdiction shopping and the lack of affordable and reliable technology for tracking and tracing DSI*." (our emphasis)

From a user perspective, *any* approach under the MLM-DSI that where even a single national ABS could apply to the same use/utilization, or the same genetic resource or DSI, is certain to require (1) tracking and tracing; (2) and complex legal assessments. Without it, it is not possible to determine which ABS mechanism applies.

In January 2023, we were asked by a client to count and review all ABS laws of the world – to the extent possible. For physical genetic resources, we found that there are at least **100 ABS laws** regimes in Parties to the CBD and the Nagoya Protocol. We also found that there are at least **39 national laws** that also apply to DSI in some way:

- Some ABS laws apply **expressly** to DSI: (i) Brazil through the definition of "genetic heritage" that includes "information", (ii) Uruguay that imposes ABS on "*all genetic resources and derivatives located in the areas under the jurisdiction of the Republic, including the sequences of genetic information generated from them…*"; (iii) Malawi that applies ABS to *"physical biological resources, traditional knowledge associated with genetic resources, genetic information, or any forms of DNA/RNA sequences or sequence data in any format including in microbiological, digital or synthetic or in any other format associated with genetic resources,*" and (iv) Malaysia's ABS rules that apply to "*genetic resources*" and "*information relating to*" genetic resources.

- Other ABS laws apply **indirectly** to DSI. In Costa Rica and Kenya obligations on DSI may be imposed when granting PIC and agreeing MAT when accessing genetic resources; or countries that interpret the term "genetic resources" to include DSI. This is the case in *e.g*. South Africa, Uganda, India, Colombia and Peru.

From a user perspective, it is essential that if the MLM-DSI applies, national ABS laws do not apply. A hybrid MLM-DSI that co-exists with the 100+/39+ existing national ABS laws, will simply further exacerbate an already complex situation.

It may even be worse than that. As we understand it, Co-Chairs' Paper for AHOEWG-2 suggests that there may be national divergences within the implementation of the eventual MLM-DSI itself: "*the implementation of any eventual decision by the Conference of the Parties on DSI would be carried out at the national level,* ***according to national circumstances****, and that it would be up to individual Parties, within the parameters of that specific decision, to* ***determine the precise nature of the obligations that users of DSI would be put under*** *with respect to the global mechanism.*"

If CBD State Parties maintain their national laws as Decision 15/9 permits, or implement according to national circumstances, or some Parties exempt their national ABS laws in case the MLM-DSI applies, but others do not; severe legal challenges are inevitable.

Across life sciences, users typically conduct work on both physical genetic resources and DSI as part of an integrated R&D process. They also have multiple research projects simultaneously. A hybrid MLM-DSI creates a real likelihood of exponentially complicating an already challenging ABS ecosystem. Benefit-sharing with lawyers is guaranteed, benefit-sharing for biodiversity, not so much. What is worse, when companies make the cost-benefit analysis as part of their R&D innovation cycle, and they are presented with an ABS ecosystem that makes it nearly impossible to comply; companies are likely to stop the R&D or avoid using genetic resources or DSI that may trigger multiple, competing ABS systems.

C. The time when the genetic resource was physically acquired or was sequenced

CBD Parties have not yet reached an agreement on what is the official date from which the Multilateral Mechanism will start to apply. Possible answers are: (i) the date of creation of the Mechanism - December 19, 2022; (ii) the date of operationalization of the Mechanism by COP 16 in October 2024; or (iii) the date from which the Mechanism is enforced on national level through a legislative act. However, from the Co-Chairs reflection paper for AHOEWG 2 it appears that the date of "accessing" DSI from public databases is crucial.[11] Notably, it is irrelevant whether the DSI have been sequenced and uploaded to public databases before or after the date of entry into force of the MLM-DSI, but what matters is the date when the DSI was downloaded. Thus, if we assume that the Multilateral Mechanism will apply from December 19, 2022, the access (meaning: download) by one entity in 2021 will be out of scope, while a download in 2023 would trigger the MLM-DSI. But of course, as the Co-Chairs suggested, Parties may implement the Decision in line with their own national circumstances and remains without prejudice to their national ABS laws.

Under the Nagoya Protocol, experience of users already shows the real difficulties presented by the date of application of ABS laws.

Many ABS laws apply from the date of entry into force of the Nagoya Protocol on 12 October 2014, but others apply from the date the law itself entered into force (*e.g.* 6 July 2016 in France). However, under the French ABS law, a genetic resource that was accessed before the law was in force and held in a collection, and that is put to a "new use", will trigger ABS. In Brazil, the first ABS law was adopted in 2001, and then replaced with a new law in 2015. The 2015 law has specific provisions that essentially extend the applicability of the 2001 law.

Some ABS laws also apply retroactively because of how they define the activity that triggers the application of the ABS law. Some ABS laws are triggered when the user gains "access" to the genetic resource meaning the physical acquisition by the user. Other ABS laws state that "utilization" triggers the application, meaning the moment the R&D is carried out, and this regardless of whether the genetic resource was physically acquired before the law was adopted and entered into force. The result is that currently the effective application date of ABS laws under the Nagoya Protocol and the CBD can differ widely. For some laws, 12 October 2014 is a cut-off date, while others apply back to 1992.

D. The "geographic origin" of the genetic resource or the DSI

Article 6 of the Nagoya Protocol re-affirms that countries exercise sovereignty over their natural resources. It is in exercise of this sovereignty that "provider countries" of genetic resources can adopt ABS laws to access or utilize these resources. For users, there are a number of practical problems. First, Article 6 of the Nagoya Protocol recognizes that the country that can impose ABS is either the "*country of origin*" of the genetic resources; or the country "*that has acquired the genetic resources in accordance with the CBD*." Secondly, countries have diverging views on how far their "sovereignty" reaches. Some countries take the view that their sovereignty, and hence their ABS laws, only extend to their territory. Other countries hold the view that sovereignty, and hence their ABS laws, can extend to genetic resources even if these are physically located on the territory of another country. The end result for users: competing ABS claims that may apply to the same genetic resource or the same utilization. We illustrate with a few examples:

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[11] Reflections of the Co-Chairs, paras 80–82.

- Brazil considers that "utilization" of Brazilian Genetic Heritage triggers the ABS law. This is without regard to how or where the physical material (or even the sequence information) was acquired from. The ABS law of Ecuador applies to genetic resources and derivatives of which "*the Ecuadorian state is the country of origin*", whether it exists in the territory of Ecuador under *in situ* conditions, but also if they are held *ex situ* in another country.
- Conversely, the ABS rules of Costa Rica apply to those genetic or biochemical resources that are "found in" or "located" on the national territory (including *ex situ* collections). Along the same lines, European Union Regulation 511/2014 defines "access" as the "acquisition of genetic resources or aTK **in a Party** to the Nagoya Protocol." This means that if a genetic resource was physically and demonstrably acquired from a non-Party, that the EU ABS compliance requirements will not apply.

The geographic "hook" will also raise complexities for the MLM-DSI. The Co-Chairs' reflections paper for AHOEWG-2 l says that "*any DSI accessed or downloaded from public databases would then be subject to the terms of the Multilateral Mechanism. The "boundary" between treatments arises* ***at the point of deposition of DSI in an open database***."[12] But what will be the geographic factor to determine if a database is covered by the mechanism? Will it be the location of the server of the database in a country that has chosen to participate to the exclusion of the national ABS law; or is it the registration of the legal entity managing the database? Or quite differently: will the metadata in the DSI indicate the "origin" of the DSI, so that *any* public database falls under the MLM-DSI? Thus, including databases located in countries that do not participate to the MLM-DSI, or that are not Party to the CBD (like the United States)? Finally, will it be national law that determines whether a database is "private" or "public"? Should there be no payment whatsoever, or would a payment to cover the running cost of the database be acceptable? Is it the public or private ownership that matters? The public or private funding for the database; and what if funding is mixed? Or does "public" database rather refer to the terms for accessing the DSI? "Open access" generally means that anyone can download without registering; whereas "controlled access" means that prior registration and identification is required. Does "public" database refer to "open access", and conversely, "private" database to "controlled access"?

In short, a hybrid MLM-DSI, and the ABS system more generally, must be carefully designed in order to avoid competing (sovereignty) claims by countries.

IV. The Proliferation of ABS Regimes for specific genetic resources

Aside from the Nagoya Protocol, its many implementing ABS laws, and the MLM-DSI, there are three additional ABS regimes for specific genetic resources: the Plant Treaty that is already in force; the new regime for marine genetic resources from the high seas that is being ratified by Parties and will soon enter into force; and the new regime for pathogens that is being negotiated at the World Health Organization. For users of these genetic resources, if the relationship between these regimes and the MLM-DSI is not clarified, that will add another layer of complexity.

[12] Reflections of the Co-Chairs, paras 80–82.

A. Whether a plant genetic resource will be used for food or agriculture, or for another purpose

Just like for micro-organisms; users of plant genetic resources already face specific challenges relating to ABS due to the co-existence of the Nagoya Protocol as well as the International Treaty on Plant Genetic Resources for Food and Agriculture ("Plant Treaty").

Determining whether a plant is covered by the Plant Treaty requires a number of steps. The starting point is to check Annex I of the Plant Treaty. It lists crops such as barley, potato, lentil, apple, rice, banana, beans, wheat, maize. A country will have notified the FAO Secretariat which institutions hold plant genetic resources in scope of the treaty.[13] Genetic resources under Annex I but acquired from an entity not included in that notification, are in principle not subject to the Plant Treaty. In addition, there are also plant materials that are not listed in Annex I but still covered by the Plant Treaty (*e.g.* coffee and cocoa). Finally, the Plant Treaty only applies if these genetic resources have been used for food or agricultural purposes. If they are used for *e.g.* cosmetic or medicinal purposes, then national ABS laws under the Nagoya Protocol or CBD may apply.

Distinguishing between physical plant genetic resources and DSI on these resources, may result in DSI for food and agriculture falling under ABS of the Plant Treaty; while DSI from the same genetic resource for non-agricultural or non-food use, would fall under the CBD MLM-DSI, or national ABS laws under the Nagoya Protocol.

Discussions on the inclusion of DSI under the Plant Treaty are ongoing, with a decision possibly at the next Governing Body in November 2025. The Parties are currently considering whether DSI should be dealt with by the CBD, or be included in the scope of the Plant Treaty. The payment model – including the subscription system to genetic resources under the multilateral system are also under review. In short, depending on how the relationship between the MLM-DSI and the Plant Treaty is resolved, there may be multiple regimes and payment models for DSI and/or genetic resources.

B. The pathogenic or non-pathogenic, or pandemic vs non-pandemic nature of the genetic resource:

For users in the pharmaceutical sector, genetic resources that are pathogens pose distinct challenges that the MLM may render more complicated.

First, if a genetic resource is a *seasonal* influenza sample, then national ABS laws under the Nagoya Protocol or CBD will apply. If that influenza sample is determined to have *pandemic potential*, then the PIP Framework will apply. The PIP Framework contains a reference to "genetic sequence data" but currently does not appear to apply to Digital Sequence Information. Therefore, DSI on influenza with pandemic potential could fall under national ABS laws, or under the MLM for DSI.

Second, for other pathogenic micro-organisms that are not influenza, it is likely that the WHO Pandemic Accord will contain a "Pathogen Access and Benefit-Sharing" (PABS) System. It will apply to both physical "*biological material from a pathogen with pandemic potential*" as well as to "*sequencing information relevant to the development of pandemic-related health products*." Thus, if a pathogen sample does not have "pandemic potential" national ABS laws may apply to the physical as well as DSI, or the MLM may apply to the

[13] https://www.fao.org/fileadmin/user_upload/faoweb/plant-treaty/notifications/BU012e.pdf

DSI though not the physical material. When it is (Scientifically? Politically?) determined that a sample has pandemic potential, then the PABS would apply. Presumably, PABS would apply to the exclusion of ABS laws under Nagoya as well as the MLM.

In public health, where a rapid response to disease outbreaks is absolutely essential, legal complexities resulting from ABS compliance can be particularly problematic. In January 2023 Covington published a separate study that is available here.

C. Marine Genetic Resources and DSI from territorial seas or from high seas

The BBNJ Agreement was adopted on 19 June 2023 by the UN Intergovernmental Conference on Marine Biodiversity of Areas Beyond National Jurisdiction,[14] and created the first ever ABS regime for use of "marine genetic resources" (MGRs are, *e.g.*, "*any material of marine plant, animal, microbial or other origin containing functional units of heredity of actual or potential value*")[15] of areas beyond national jurisdiction and associated DSI.[16]

The territorial seas of a country extend 8 Nautical Miles (NM) from the coastline, the Exclusive Economic Zone (EEZ) 200NM from the coastline, and beyond it, the areas beyond national jurisdiction begin (*i.e.*, the High Seas) If a marine genetic resource was physically accessed from the territorial sea, then presumably national ABS under the Nagoya Protocol would apply; or the Multilateral Mechanism on DSI if the resource has been sequenced. If the same resource was accessed from the High Seas, the BBNJ would apply and the MLM presumably not. Thus, any user would need to retain GPS coordinates of where the MGR was accessed would need to be retained for both the GR and the DSI. Migratory species will result in competing jurisdictional claims.

The BBNJ Agreement foresees retroactive application of the ABS obligations to DSI collected or generated before the entry into force of the BBNJ Agreement. A State Party can make an exception in writing when signing up to the BBNJ, but that could add an additional layer of complexity.

V. What are the risks if a user gets ABS wrong?

When companies make cost/benefit analyses that involve compliance with ABS laws, they must also understand the "risk of non-compliance." Concretely, what types of legal, financial, business, reputational, or other risks is the user exposed to, if it gets ABS compliance wrong? In the previous sections, we've already described the extraordinary complexity of complying with ABS. It requires significant legal, financial and human resources to navigate the ABS landscape. Even with that investment, it remains very difficult to pin down a user's obligations to a high degree of certainty. In the cost/benefit analysis, this complexity then needs to be offset against the risk that the user is exposed to when getting it wrong. If the risk of sanctions is low or manageable, then a user will be more likely to continue utilization of the chosen genetic resource(s) and DSI, even if the ABS rules are complex. The user will accept that there is "learning by doing" and that this may involve some risk of getting it wrong the first time. If, however, the risk of sanctions is high, a user is much more likely to seek other materials to conduct R&D, or quite simply "kill" an R&D

[14] Agreement under the United Nations Convention on the Law of the Sea on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction, 19 June 2023 (link).
[15] Article 1(8), BBNJ Agreement.
[16] Articles 9(a), 10(1) and 14, BBNJ Agreement.

project because the risk of sanctions is disproportionate to the potential benefits from the R&D project.

We briefly explain the legal risks that a company is exposed to in the European Union, the regime where we've seen the most active enforcement by authorities.

First, companies that conduct R&D in any of the 27 countries of the European Union are subject to EU Regulation 511/2014 on compliance measures for users from the Nagoya Protocol.[17] This Regulation requires tracking and tracing of utilization on all genetic resources in scope of Nagoya Protocol ABS laws, and users must ensure that genetic resources which they utilize have been "*accessed in accordance with applicable ABS laws*." If "*information in their possession is insufficient or uncertainties about the legality of access and utilization persists*"[18], users are expected to "discontinue utilization". In light of the incredible complexity described in section III and IV of this non-paper, it should be clear that this sets an incredibly high legal standard of compliance. In the present ABS landscape, uncertainty about the legality *is* a certainty. What is more, the enforcement of this Regulation in the EU is implemented at country-level, meaning there are 27 different sanction regimes. The sanctions can be severe. For instance, in France, failure to comply is subject to one year imprisonment or a criminal fine of up to 150,000 EUR. Conducting "commercial" R&D without the required documentation is subject to a fine of up to 1,000,000 EUR (possibly times five for legal entities).

Second, on 5 July 2024, the EU published the Directive on Corporate Sustainability Due Diligence ("CSD3") in its Official Journal. Over the next two years, the CS3D will be implemented in the 27 laws of the EU Member States. The CS3D will apply to large companies with significant turnover in the EU, even if they are established in another country anywhere in the world (e.g. the Americas or Asia). The CS3D contains due diligence obligations for companies to manage *e.g.* environmental law compliance in their own operations, as well as those of their subsidiaries, direct and indirect business partners. The CS3D expressly applies to compliance with the Nagoya Protocol, **and** the Convention on Biological Diversity. This means that companies' legal obligations under CS3D will extend to ABS laws under the Nagoya Protocol, as well as the MLM-DSI that is currently being negotiated. Under Article 27(4), the CS3D states that "when pecuniary penalties are imposed, they shall be based on the company's net worldwide turnover. The maximum limit of pecuniary penalties shall be not less than 5 % of the net worldwide turnover of the company in the financial year preceding that of the decision to impose the fine." Additionally, Article 29 of CS3D contains a new civil liability regime, and the right to full compensation for e.g. "negligently failing" to prevent adverse impacts as regards the Nagoya Protocol and the CBD.

Aside from legal risk in the European Union as a "user" jurisdiction, provider countries themselves are also proactive in enforcing their ABS laws. For instance, a 2022 paper by Jungman and Avila on the Brazilian ABS law notes that "*the failure of users to comply with their obligations incurred different types of penalties, including fines, confiscation of samples and products, suspension of product sales, closure of establishments, suspension or cancellation of registrations, patents, licenses or authorizations, prohibition of contracting*

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[17] https://eur-lex.europa.eu/eli/reg/2014/511/oj

[18] Article 4(6) of EU Regulation 511/2014

with the public administration and restriction of tax incentives."[19] They also found that "*for each R$ 1.00 obtained through monetary Benefit-Sharing, R$ 25.34 (nominal value) or R$ 32.64 (adjusted to inflation until August 2022) were issued in fines.*"

No doubt there are stakeholders in the ABS debate that welcome this strict, global enforcement environment. It is certainly legitimate for governments to enforce the laws they adopt, and this paper does not question that. But the impact of harsh enforcement for users is undeniable, even if it is difficult to prove and quantify on a global scale. Based on our years of first-hand experience, there is no doubt that when users face the almost insurmountable legal complexity of ABS, coupled with strict sanctions; that they will adapt by focusing R&D efforts on areas that do not pose these legal challenges. What this paper therefore questions is whether there is a correct balance between, on the one hand, the proliferation of ABS regimes seeking fair and equitable benefit-sharing; and on the other hand, the enforcement of non-compliance with these ABS regimes. In these authors' personal view, the *current* global ABS system is failing to achieve non-monetary and monetary benefits to preserve biodiversity, while detrimentally impacting research and development by public and private users. That is not just a business problem, but a major societal challenge that must be urgently resolved.

VI. Conclusion

The Nagoya Protocol sets out a relatively simple framework for ABS: receive a permit and agree to benefit-sharing in a provider country, and prove that you have a permit and share benefits in a user country. In practice, across 141 jurisdictions and legal systems, countries have widely divergent ways of regulating ABS. The determination of applicable ABS obligations, the cost/benefit analysis of conducting R&D, and the appreciation of risk in case of non-compliance, have already been made extraordinarily complicated by the existing ABS landscape. Although I cannot quantify it, from my experience over the past decade, it is also very likely that ABS has so far failed its objective of fair and equitable benefit-sharing for biodiversity.

The MLM-DSI presents countries with a real opportunity. I urge them to opt for a watershed moment on ABS and to negotiate a *truly* multilateral system that will simplify ABS – for DSI, but also for physical genetic resources. The principles of paragraph 9 of Decision 15/9, on efficiency, feasibility, effectiveness, legal certainty, and generating more benefits than cost, are of paramount importance. The impact of getting it wrong means stifling R&D. This is not merely a problem for companies. In light of the staggering rate of species extinction, achieving the Kunming-Montreal Global Biodiversity Framework will require major innovation on a global scale. The devastating effect on R&D of well-intended but poorly executed ABS laws is a major societal problem. As it stands, these attorneys are deeply concerned that the MLM-DSI is likely to complicate ABS through further fragmentation and proliferation of conflicting and overlapping ABS requirements.

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[19] Diana Jungman and Jorge de Paula Costa Avila2, Data-Driven Assessment on the Brazilian Regulatory Framework for Biodiversity Access and Benefit Sharing (ABS)m December 2022, https://doi.org/10.20944/preprints202212.0106.v1