

**Expert opinion on the applicability of the Convention on  
Biological Diversity and the Nagoya Protocol to digital  
sequence information**

**submitted on behalf of the German  
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from

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## A. Object of investigation

In view of the fact that some Parties to the Convention on Biological Diversity (CBD) or the Nagoya Protocol have implemented very extensive requirements for the handling of digital sequence information (DSI) in their national legal systems, at the end of 2016, the COP Decision XIII/161 also addressed the question of whether and to what extent digital sequence information would fall within the scope of the distribution mechanism implemented by the CBD and the Nagoya Protocol. International legal literature has also taken up the issue.<sup>2</sup>

Against this background, the present expert opinion essentially addresses the question of whether digital sequence information falls within the scope of the Convention or the Nagoya Protocol. In addition, the consequences of such a subsumption in terms of normative, practical and administrative aspects are examined.

## B. Normative background

The normative framework of the question under study is largely defined by the Convention on Biological Diversity (CBD) on the one hand, and by the complementary Nagoya Protocol on the other. In order to prevent friction losses

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<sup>1</sup> [https://www.cbd.int/doc/decisions/cop-13 / cop- 13-dec-16-en.pdf](https://www.cbd.int/doc/decisions/cop-13/cop-13-dec-16-en.pdf) (01/09/2017).

<sup>2</sup> See, for example, Bagley, *Digital DNA: The Nagoya Protocol, Intellectual Property Treaties, And Synthetic Biology*, 2015; Bagley, *Towering Wave or Tempest in a Teapot? Synthetic Biology, Access & Benefit Sharing, and Economic Development*, in: Frankel/Gervais (Eds.), *Intellectual Property and Regulation of the Internet: The Nexus with Human and Economic Development* (working paper), [https://www.researchgate.net/publication/305709215\\_Towering\\_Wave\\_or\\_Tempest\\_in\\_a\\_Teapot\\_Synthetic\\_Biology\\_Access\\_Benefit\\_Sharing\\_and\\_Economic\\_Development\\_in\\_Susy\\_Frankel\\_and\\_Daniel\\_Gervais\\_ed\\_Intellectual\\_Property\\_and\\_Regulation\\_of\\_the\\_Internet\\_The\\_N](https://www.researchgate.net/publication/305709215_Towering_Wave_or_Tempest_in_a_Teapot_Synthetic_Biology_Access_Benefit_Sharing_and_Economic_Development_in_Susy_Frankel_and_Daniel_Gervais_ed_Intellectual_Property_and_Regulation_of_the_Internet_The_N) (01/09/2017); Lawson/Rourke, *Open Access DNA, RNA and Amino Acid Sequences: The Consequences and Solutions for the International Regulation of Access and Benefit Sharing*, 2016 (Griffith University Law School Research Paper No. 16-12, [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2848136](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2848136) (01/09/2017)); Hammond, *Digital genebankers plan to ignore UN request on the impact of genomics and synthetic biology on access and benefit sharing*, Third World Network, A preliminary report, 04/04/2016, [http://www.twn.my/announcement/digital\\_genebanks\\_final\\_uslet.pdf](http://www.twn.my/announcement/digital_genebanks_final_uslet.pdf) (01/09/2017); Dedeurwaerdere / Melindi-Ghidi / Broggiato, *Global scientific research commons under the Nagoya Protocol: towards a collaborative economy model for the sharing of basic research assets*, in: *Environmental Science & Policy* 2016, 1 ff. ; Manheim, *Regulation of synthetic biology under the Nagoya Protocol*, in: *Nature Biotechnology* 2016, 1104 f.

from occurring in the context of the standard interpretation to be applied, the authentic<sup>3</sup> English or French version of the documents<sup>4</sup> is taken as a basis.

## **I. The interpretation of international treaties**

The legal positioning of the questions to be clarified depends to a significant extent on the international legal framework, which is defined by the corresponding international legal documents to be detailed below. In view of the fact that international law is essentially characterised by a certain "openness of formulations", which in turn can be understood as an expression of complex political compromises<sup>5</sup>, international law notably proves to be a matter of interpretation, but also of need. The interpretation follows basic rules of interpretation, which, however, have some specific facets.

### **1. General: Interpretation according to VCLT**

In this respect, the Vienna Convention on the Law of Treaties (Vienna Convention on the Law of Treaties, VCLT) proves to be the authoritative source of law.<sup>6</sup> Art. 31 VCLT establishes the following definitions as a general rule of interpretation:

"(1) A treaty shall be interpreted in good faith in accordance with the ordinary meaning and purpose of its terms in its context and in the light of its object and purpose.

(2) For the interpretation of a treaty, beyond the terms of the treaty, including the preamble and annexes, the treaty means

a) any agreement relating to the treaty made between all Contracting Parties on the occasion of the conclusion of the treaty;

<sup>3</sup> See also the specification of Art. 33 VCLT, which is dealt with in more detail below.

<sup>4</sup> In addition, pursuant to Art. 42, the authentic versions include CBD Arabic, Chinese, Russian and Spanish.

<sup>5</sup> Also often hidden behind these compromises is an "agreement to disagree"; cf. Krajewski, *Völkerrecht*, 2017, Art. 4 Marg. 74.

<sup>6</sup> Of 23 May 1969, German Civil Code (BGB) I 1985 II p. 926.

b) any document drawn up by one or more Contracting Parties on the occasion of the conclusion of the treaty and accepted by the other Contracting Parties as a document relating to the treaty.

(3) External to the context, to be considered in the same way is

a) any subsequent agreement between the parties concerning the interpretation of the treaty or the application of its provisions;

b) any subsequent practice in the application of the treaty from which arises agreement between the parties on its interpretation;

c) any relevant international law applicable to relations between the parties.

(4) A particular meaning shall be attached to an expression if it is established that the Contracting Parties intended to do so. "

Supplementary means of interpretation are of particular relevance, as per Art. 32 VCLT, if the primary interpretation requires support or supplementation:

"Supplementary means of interpretation, in particular the preparatory work and the circumstances of the treaty, may be used to confirm the meaning resulting from the application of Article 31 or to determine its meaning if the interpretation as per Article 31

a) leaves the meaning ambiguous or obscure, or

b) leads to an obviously absurd or unreasonable result. "

Finally, Art. 33 VCLT positions itself on the international law issue of priority for treaties with two or more authentic languages.

## 2. In particular: the wording

The wording of Article 31 (1) of the VCLT is therefore of primary importance for the interpretation of an international treaty. As a glance at the English and French versions of the VCLT shows, this is less concerned with the wording of the comprehensive "provisions" than with the wording of the expressions or terms used.<sup>7</sup> In this respect, a regular reminder is provided of the usual wording in the context of the entire treaty in its context<sup>8</sup>; in this regard, the "ordinary meaning rule" applies.<sup>9</sup>

In the supreme court case law, these framework conditions are generally recognised:

"A (...) convention as an international treaty shall be interpreted, in principle, in good faith in accordance with the ordinary meaning of its terms in its context and in the light of its object and purpose (...). For this interpretation rule, which is transcribed in Art. 31 VCLT, is a provision of international customary law (...). The treaty under international law, unlike EU law, the interpretation of which is based on the objectives and activities of the European Union (ECJ Judgement of 9/2/1982 - C-270/80 - ECR 1982, 329 Marg. 16 <Polydor/Harlequin>) is therefore to be initially interpreted in and of itself, and primarily on the basis of the wording to which the "ordinary" meaning of the words used (so-called "ordinary meaning-rule") is attached."<sup>10</sup>

If the German version of the VCLT requires an interpretation in the light of the "object and purpose" of the treaty, a look at the formulation of the authentic language of the Convention is again required. The English version speaks of "object and purpose" and the French text reads "objet et ... but", which expresses

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<sup>7</sup> Lehner, in: Vogel/Lehner (eds.), DBA, 6th edition, 2015, Grundlagen des Abkommensrechts, Marg. 106.

<sup>8</sup> Lehner, in: Vogel/Lehner (eds.), DBA, 6th edition, 2015, Grundlagen des Abkommensrechts, Marg. 106.

<sup>9</sup> von Arnould, Völkerrecht, 2nd edition, 2014, Marg. 225.

<sup>10</sup> Decisions of the German Federal Social Court (BSGE) 118, 110 ff., Marg. 23 at Juris. Cf., for example, German Federal Court (BGH), NSTZ 1998, 149 ff., Marg. 60 at Juris.

that the subjective will has no overriding importance.<sup>11</sup> By dedicating itself to "object and purpose", it is thus stated that what is meant is not a subjective notion of the Contracting Parties but of the purpose of the treaty objectified in the whole of the treaty.<sup>12</sup> According to the prevailing opinion, the term "object and purpose" is understood as a uniform concept and also refers to the wording in whose light they are to be evaluated.<sup>13</sup> Of particular importance for the concretisation of "object and purpose" are the considerations of the preamble, which by no means merely represent legally non-binding general political considerations.<sup>14</sup> Overall, this shows that the VCLT combines subjective and objective elements of contractual interpretation, but clearly prioritises objective criteria.<sup>15</sup>

Lastly, the rule in Article 31 (4) of the VCLT emphasizes the prominent role of word-centred interpretation in that definitions of terms made in the treaty itself, in particular, must be understood in a general objective understanding of the word.<sup>16</sup>

### **3. In particular: system**

According to Art. 31 (2) and (3) VCLT, the regulatory context extends beyond the respective treaty document to include the other international legal acts cited there. The term "context" thus means the "internal context" and the "external context".<sup>17</sup> In the interests of the unity of the international legal order, this procedure counteracts the risk of fragmentation.<sup>18</sup>

In this respect, however, it is of central importance that the corresponding conventions, practices, legal acts and documents always aim at the acceptance of

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<sup>11</sup> Lehner, in: Vogel/Lehner (eds.), DBA, 6th edition, 2015, Grundlagen des Abkommensrechts, Marg. 106a.

<sup>12</sup> von Arnould, Völkerrecht, 2nd edition, 2014, Marg. 224; Lehner, in: Vogel/Lehner (eds.), DBA, 6th edition, 2015, Grundlagen des Abkommensrechts, Marg. 106a with citations; Krajewski, Völkerrecht, 2017, Art. 4 Marg. 76 ff.

<sup>13</sup> Lehner, in: Vogel/Lehner (eds.), DBA, 6th edition, 2015, Grundlagen des Abkommensrechts, Marg. 106a.

<sup>14</sup> Krajewski, Völkerrecht, 2017, Art 4 Marg. 83.

<sup>15</sup> Herdegen, Interpretation in International Law, in: Wolfrum (ed.), Max Planck Encyclopaedia of Public International Law, 03/2013, Marg. 7.

<sup>16</sup> Cf. also Krajewski, Völkerrecht, 2017, Art. 4 Marg. 77.

<sup>17</sup> Krajewski, Völkerrecht, 2017, Art. 4 Marg. 79.

<sup>18</sup> von Arnould, Völkerrecht, 2nd edition, 2014, Marg. 226.

"the Contracting Parties". This refers to all Contracting Parties. Obligations under other treaties and other documents which bind only a portion of the parties to the treaty to be issued are thus irrelevant to the treaty interpretation.<sup>19</sup> The same applies in principle to individual reservations or one-sided explanations of interpretation.<sup>20</sup> Sometimes, however, differentiation is made in this respect: Thus, it should not be necessary for the following practice to be shared by all Contracting Parties; on the contrary, it is sufficient for all Contracting Parties to accept the new practice in view of the understanding of the treaty in question.<sup>21</sup>

This would not require a comprehensive consensus; rather, toleration from differing parties would suffice in this case. However, even such toleration presupposes a conscious decision and thus knowledge of the dissent and the consequences resulting from toleration. Openly manifesting dissent means that each of the above approaches negates "acceptance by the Contracting Parties".

#### **4. In particular: teleology**

The teleological interpretation is also of crucial importance in the interpretation of international treaties.<sup>22</sup> In this context, the particular complexity of the treaty amendment procedures means that international law emphasises the need for dynamic interpretation.<sup>23</sup> Particularly prominent in this regard is the case law of the ECHR, according to which the "Convention is a living instrument that must be interpreted in the light of present-daily conditions and the notions currently prevailing in democratic States."<sup>24</sup>

A more detailed analysis shows, however, that under the concept of dynamic interpretation a total of three different interpretive approaches come into

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<sup>19</sup> von Arnould, *Völkerrecht*, 2nd edition, 2014, Marg. 226; Krajewski, *Völkerrecht*, 2017, Art. 4 Marg. 80.

<sup>20</sup> On this: Schweitzer/Dederer, *Staatsrecht III*, 11th edition, 2016, Marg. 417.

<sup>21</sup> Herdegen, *Interpretation in International Law*, in: Wolfrum (ed.), *Max Planck Encyclopaedia of Public International Law*, 03/2013, Marg. 18.

<sup>22</sup> von Arnould, *Völkerrecht*, 2nd edition, 2014, Marg. 227.

<sup>23</sup> Dupuy, *Evolutionary Interpretation of Treaties: Between Memory and Prophecy*, in: Cannizzaro, *The Law of Treaties Beyond the Vienna Convention*, 2011; Böth, *Evolutionäre Auslegung völkerrechtlicher Verträge*, 2013; Greschek, *Die evolutionäre Auslegung völkerrechtlicher Verträge am Beispiel des GATT*, 2013; von Arnould, *Völkerrecht*, 2nd edition, 2014, Marg. 227; Krajewski, *Völkerrecht*, 2017, Art. 4 Marg. 87.

<sup>24</sup> ECHR, *EuGRZ* 2007, 671 ff., Marg. 105 at Juris.

operation.<sup>25</sup> It is therefore more of an evolutionary interpretation in the sense that "changes made after the conclusion of the treaty to the circumstances and valuations in the determination of the understanding of each norm to be interpreted, are/must be considered. The application of evolutionary interpretation is based on the question of to what extent international norms and the legal concepts contained in them are to be interpreted in the light of actual circumstances; that is, to what extent are international treaties in their content connected with the political, technical and social circumstances of the actual life order. An evolutionary interpretation concerns an understanding of the norm that does not want to discount the actual and legal changes."<sup>26</sup>

However, it is not true that the dynamic or evolutionary interpretation may give the treaty to be interpreted a completely new meaning. Rather, the interpretation "is associated (...) with an original intention of the contracting states to be taken from the treaty, which is aimed at the inclusion of subsequent developments. The evolutionary interpretation thus concerns the question of whether the contracting states, as "masters of the treaties", have relinquished the right to include developments and to update norms in that sense, following the conclusion of the treaty, to the legal practitioners."<sup>27</sup>

Against this background, the meaning of the principle of effectiveness, known as "effet utile", and of the principle of "necessary implication", which aims for the implicit guarantee of the rights required to achieve the regulatory objective, but also of implied powers, can be explained.<sup>28</sup>

## **5. In particular: history**

The historical interpretation plays only a subordinate role in the context of international law. Art. 32 VCLT locates "the preparatory work and the circumstances of the treaty" under the term "supplementary interpretative means".

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<sup>25</sup> Böth, *Evolutive Auslegung völkerrechtlicher Verträge*, 2013, p. 17

<sup>26</sup> Böth, *Evolutive Auslegung völkerrechtlicher Verträge*, 2013, p. 17 f.

<sup>27</sup> Böth, *Evolutive Auslegung völkerrechtlicher Verträge*, 2013, p. 18.

<sup>28</sup> See also: von Arnald, *Völkerrecht*, 2nd edition, 2014, Marg. 227.

## **II. Convention on Biological Diversity**

The Convention on Biological Diversity, under international law, is the central normative framework for the issue to be clarified here.

### **1. Wording**

Art. 15 CBD proves to be the normative core for questions of access to genetic resources and the corresponding equitable sharing of benefits. The regulation is:

"Article 15 - Access to Genetic Resources

1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.
2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.
3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.
4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.
5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.

6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.

7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.“

While the term "genetic resources" could be applied to physical genetic samples as well as to mediated resources in the form of virtual or digital samples by a superficial reading of Art. 15 CBD, an in-depth consideration of Art. 15 CBD nonetheless points in another direction.

#### **a. Principle of territoriality and principle of operation**

Article 15 (1) CBD emphasises the sovereign rights of states with regard to their natural resources and derives therefrom the power of the governments of the respective member states to determine access to genetic resources by means of national legislation. Firstly, Article 15 (1) of the CBD is an immediate expression of the principle of territoriality under international law, which itself follows from the principle of territorial sovereignty and, *inter alia*, establishes the validity of state law for foreign nationals.<sup>29</sup>

However, in the present form, Article 15 (1) of the CBD only makes sense if "genetic resources" is understood to mean only physical resources. This is because the sequencing, storage, use, processing and transfer of genetic data carried out abroad is, from the outset, not a suitable object of national legislation.

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<sup>29</sup> von Arnould, *Völkerrecht*, 2nd edition, 2014, Marg. 345.

Although the so-called principle of operation in foreign offences ("shot across the border") allows an extension of national legislation from foreign acts.<sup>30</sup>

The more "indirect and less tangible the effects become, the more dubious the right of the state becomes to subject such acts to its punitive power."<sup>31</sup> In that regard, a "direct, foreseeable and substantial effect" is rightly required "to avoid an unnecessary jurisdiction conflict in an interdependent world."<sup>32</sup>

However, the prerequisites for such an increased domestic connection are not clearly given here. For example, it is questionable whether individual genetic datasets can even reconstruct an association with specific countries of origin. In many cases, especially with marine microbes, there is already the possibility that an identical gene sequence exists in a wide variety of organisms that are found in various parts of the world<sup>33</sup>, so that a single state can hardly demonstrate the required specific domestic reference. Also, in the absence of uniform standards for documentation, cooperation and access agreements or registers, the open access culture of modern international research leads to the absence of a system of traceability, such as exists in certain areas of food law.

Genetic information can thus not be assigned to a single genetic sample in many, if not most cases. In this case, however, the domestic reference required to activate the principle of operation also fails. The fact that individual states have nonetheless issued appropriate provisions in the recent past does not contradict this finding. On the contrary, this is likely to concern political manoeuvres that have been detached from normative basic requirements.

But even if such a specific assignment of genetic data to genetic resources from a specific country of origin succeeds, there is a lack of an increased domestic reference in the sense of a "direct, foreseeable and substantial effect". For with the conversion of physical samples taken into data sets, which in turn are only

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<sup>30</sup> von Arnould, *Völkerrecht*, 2nd edition, 2014, Marg. 1227.

<sup>31</sup> von Arnould, *Völkerrecht*, 2nd edition, 2014, Marg. 1227.

<sup>32</sup> von Arnould, *Völkerrecht*, 2nd edition, 2014, Marg. 345.

<sup>33</sup> See also Servick, Rise of digital DNA raises biopiracy fears, <http://www.sciencemag.org/news/2016/11/rise-digital-dna-raises-biopiracy-fears> (01/08/2017).

considered to be minuscule components in highly complex structures of research measures that are increasingly shaped by the big data approach, maximum mediatization takes place.

The individual genetic sample is thus not only barely identifiable in a data-driven research project, but as such it does not play any significant role in the overall success of a project. Rather, here it is only the systematic combination of massive data sets using extraordinarily powerful data processing systems that lead to a significant gain in knowledge. The single sample and the corresponding data set thus has a more homeopathic effect. However, such an effect is neither "direct" nor "substantial" enough to justify national sanctions, which may even be punishable under criminal law.

In recognising these fundamental differences between the principle of territoriality on the one hand and the principle of operation on the other hand, member states can only determine access to genetic resources if and when it relates to accessing material subject to the respective national jurisdiction. In the light of the prerequisites of the principle of operation, an extension of Art. 15 (1) CBD to genetic information abroad can not be construed.

The fact that the CBD also explicitly addresses the ex-situ aspect does not contradict this clear finding. This is because Art. 9 CBD makes it sufficiently clear that measures for the ex-situ area are aimed only at maintaining and cultivating the resources thus available, but do not justify a national competence for the cross-border regulation of ex-situ substances. In addition, Art. 3 of the CBD also indicates that the Contracting Parties have obligations (and rights) only in relation to activities "within their jurisdiction or control"; Art. 4 CBD repeats this principle and thus restricts the scope of the Convention. In this way, the CBD confirms the general principle of international law that an increased domestic connection is required in order to justify international government regulations; at the same time, Arts. 3, 4 and 9 of the CBD make it clear that the presence of substances ex situ alone is not sufficient to construct such an increased domestic connection.

Incidentally, these standards, which are generally accepted under international law, also play a central role in the context of conventions under international law, often emphasising the possibility open to the contracting states to implement at national level provisions that go beyond the level of protection guaranteed by the convention in question.

However, the CBD clearly can not be included in the scope of such international documents. As clarified by Article 15 (7) of the CBD, the CBD provides a conclusive framework for cooperation between contracting states on biodiversity issues. Cooperations and conflicts between the contracting states must therefore be governed exclusively by the instruments made available by the CBD. Irrespective of this, the parties must indeed adapt their national law to the requirements of the CBD - but always under the normative umbrella of the CBD. Incidentally, Art. 37 CBD, which explicitly declares reservations to the CBD as inadmissible, also makes it clear that national unilateral actions are not tolerated by the CBD.

Legislative and other measures by individual contracting states, which amount to a sanction not covered by the CBD, are therefore already "contra legem" in the light of the CBD, but they also prove to be a flagrant violation of the principles of the principle of territoriality.

#### **b. Concept of genetic resource according to Art. 2 Subpar. 10**

The direct inclusion of DSI in the scope of the CBD would be made possible, in particular, by an extensive interpretation of the term "genetic resources". Art. 2 Subpar. 10 defines the term as follows: "Genetic resources' means genetic material of actual or potential value." The legal definition of the "genetic resource" thus in turn draws on the concept of "genetic material", which in turn is defined in Art. 2

Subpar. 9 CBD as follows: "Genetic material' means any material of plant, animal, microbial or other origin containing functional units of heredity." In the context of

the word-based analysis, there are thus three relevant points of contact, which are presented and examined separately below.

#### **aa. The term "material"**

The interlocking of the definitions under Art. 2 Subpar. 10 and Art. 2 Subpar. 9 CBD means that genetic resources must always also signify genetic material. If one uses the "ordinary meaning rule"<sup>34</sup> here, since the concept of the material is not further defined but simply assumed, it is clear that the understanding of the term presupposes a physical component.

To fall back on a popular scientific definition, the term "material" is to be understood as follows:

„Material is a broad term for a chemical substance or mixture of substances that constitute a thing.

In the metaphysical sense, materials can be anything something else is consisting of, whether pure or impure, a singular composite or a complex mix, living or non-living matter, whether natural or man-made, either concrete or abstract.

Materials can be classified based on different properties such as physical and chemical properties (see List of materials properties), geological, biological, choreographical, or philosophical properties. In the physical sense, materials are studied in materials science.

In industry, materials are inputs to production or manufacturing processes. They may either be raw material, that is, unprocessed, or processed before being used in more advanced production processes, either by distillation or synthesis (synthetic materials).

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<sup>34</sup> See B I 2.

Types of materials include:

- Biomaterial, of biological origin
- Composite material, composed of multiple materials with differing physical properties
- Textiles, sometimes referred to as "material"
- Genetic material.<sup>35</sup>

Without it being appropriate for subject-specific, i.e. ethical or legal discourses on the terminology of the matter, it can be assumed on the basis of a general understanding of terms, that "material" must have substance or a material characteristic in the colloquial sense. Required therewith is physical existence. Data derived from material, on the other hand, is non-physical in nature and accordingly cannot be qualified as "material".

#### **bb. The term "containing"**

Required for the presence of a genetic resource within the meaning of Art. 2 Subpar. 10 CBD is in accordance with Art. 2 Subpar. 9 CBD that the relevant genetic material "contains" functional hereditary units. The Cambridge Dictionary defines the term "containing" as "to have something inside or include something as a part".<sup>36</sup> Indeed, the exemplifying examples are directed primarily to cases of physical containment; however, the fact that, for example, files may contain information, shows that the concept of "containing" does not, as such, necessarily aim at physical inclusion. The term is therefore open in relation to the question to be clarified.

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<sup>35</sup> <https://en.wikipedia.org/wiki/Material> (02/08/2017).

<sup>36</sup> <http://dictionary.cambridge.org/dictionary/english/contain> (02/08/2017).

**cc. The term "functional units of heredity"**

"Genetic material" as an indispensable prerequisite for "genetic resources" only lies under Art. 2 Subpar. 9 CBD if it contains functional units of heredity. This term is not further defined or limited in the CBD itself and is also the subject of some intense controversy. This is also due to the fact that "functional units of heredity", as far as can be seen, in an undisputed manner, do not constitute a clearly defined scientific category.

From a scientific point of view, it is possible under various conditions to subsume intact living cells as well as complete chromosomes, genes and DNA fragments under this term.<sup>37</sup> From the other side, however, in this context it is pointed out that it is not a scientific-technical, but a political citation that could possibly also be seen as a hint from the "legislator" due to the lack of concrete indications, such as with the term "gene" or "molecule", to allow the greatest possible degree of flexibility.<sup>38</sup>

Of considerable importance in this respect, however, should be the fact that, despite all partially recognisable politically motivated turns, Art. 2 Subpar. 9 CBD now just requires one "functionality" on the one hand, and one "heredity" on the other. However, both terms, even under the widest possible understanding of the term, can be based exclusively on physically existing material. Regardless of the scientific foundations, a hereditary unit is only given if it is of any such material that allows an inheritance to a subsequent organism. Digital sequence information is based on the decryption or transcription of such units, and can help clarify the question of why heredity exists or to which factors it relates. However, digital sequence information itself is never equal to "units of heredity". In other words, digital sequence information cannot be inherited by an organism.

This evaluation is valid even if one understands the unsatisfactory terminology of the "functional unit of heredity" as evidence of the need for a flexible interpretation

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<sup>37</sup> Cf. Kate/Laird, *The Commercial Use of Biodiversity. Access to Genetic Resources and Benefit Sharing*, 1999, p. 18.

<sup>38</sup> Tvedt/Young, *Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD*, 2007, p. 54 f.

from a scientific-technical point of view. For while the term "functional unit of heredity" may be scientifically inaccurate, at the same time it is sufficiently particular or highly specific that any interpretation in this regard must be kept within the limits of the wording.

The considerable discourse about terminology can thus be seen as unmistakable proof that the legislator wanted to provide clear indications as to which material falls under the definition and which does not. Had the creators of the CBD wanted to issue a definitive licence, they would either have renounced an exact definition altogether, or would have developed an extremely broad definition. Instead, an unusual and highly specific definition has been developed that does not capture every mediated reference to the original resource in situ. The "units" concerned must therefore be "functional" and aim for "heredity". Digital sequence information cannot be assigned to these respective generic terms and is therefore not subject to Art. 2 Subpar. 10 and 9 CBD.

### **c. The term "biological resource" as per Article 2 Subpar. 2 CBD**

The results generated above are further supported by analysing the term "biological resource". Art. 2 Subpar. 2 CBD defines the term "biological resource" as follows: "Biological resources' includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity."

#### **aa. No categorical break**

The term thus proves to be a generic term that includes not only genetic resources but also organisms or parts thereof, populations or another biotic component of ecosystems. Although an isolated consideration of Art. 2 Subpar. 2 CBD does not seem, at first glance, to provide a compelling case that genetic resources need to have a physical character, the overall relationship with the CBD provisions already outlined shows that this is precisely the case. In addition, however, the isolated consideration of Art. 2 Subpar. 2 CBD supports this view:

because organisms, and parts of organisms are all physical, so extending the notion of "genetic resource" to digital sequence information would mean a categorical break, for which, however, clues cannot be found in either the regulation itself nor in the overall context of the CBD.

#### **bb. "Biotic component of ecosystems"**

In addition, the fact that the list of the legal definitions in Art. 2 Subpar. 2 CBD is in turn obliged to be bound by a parenthetical term is of paramount importance. Indeed, the addendum of "or any other biotic component of ecosystems" makes it clear that all biological resources must at the same time be biotic components of ecosystems.

According to a popular scientific definition, the term "biotic" is to be understood as follows: „Biotic describes a living or once living component of a community; for example organisms, such as plants and animals.“<sup>39</sup> Biotic components thus always represent biotic material, on its part, is limited as follows:

"Biotic material or biological derived material is any material that originates from living organisms. Most such materials contain carbon and are capable of decay. (...) Examples of biotic materials are wood, straw, humus, manure, bark, crude oil, cotton, spider silk, chitin, fibrin, and bone.

The use of biotic materials, and processed biotic materials (bio-based material) as alternative natural materials, over synthetics is popular with those who are environmentally conscious because such materials are usually biodegradable, renewable, and the processing is commonly understood and has minimal environmental impact.

However, not all biotic materials are used in an environmentally friendly way, such as those that require high levels of processing, are harvested unsustainably, or are used to produce carbon emissions.

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<sup>39</sup> <https://en.wikipedia.org/wiki/Biotic> (04/08/2017). Likewise also <http://www.biology-online.org/dictionary/Biotic> (04.08.2017)

When the source of the recently living material has little importance to the product produced, such as in the production of biofuels, biotic material is simply called biomass. Many fuel sources may have biological sources, and may be divided roughly into fossil fuels, and biofuel.

In soil science, biotic material is often referred to as organic matter."<sup>40</sup>

Digital sequence information can thus, on the basis of a general understanding of words, under no conceivable aspect be qualified as a biotic component of an ecosystem: it is not a (formerly) living component of an ecosystem. Clues for a deviating specific understanding of the word, which would arise according to the rules of international interpretation laid out in the introduction<sup>41</sup>, are not recognisable in this case.

### **cc. Supplementary inclusion of Art. 10 Lit. c) CBD**

The result prepared above is additionally supported by the additional inclusion of Art. 10 Lit. c) CBD, which reads as follows:

"Each Contracting Party shall, as far as possible and as appropriate:

(...)

(c) Protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements (...)."

The provision thus seeks to ensure adequate protection for the traditional use of biological resources in accordance with traditional culture procedures. The provision therefore necessarily assumes that biological resources, and thus under Article 2 Subpar. 2 CBD also, necessarily, genetic resources, have been used

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<sup>40</sup> [https://en.wikipedia.org/wiki/Biotic\\_material](https://en.wikipedia.org/wiki/Biotic_material) (04/08/2017).

<sup>41</sup> See B I.

conventionally, for example in the form of traditional culture procedures. Although such use is conceivable with respect to genetic resources that play a role in the application of selection methods, it is definitely ruled out with regard to digital sequence information. Art. 10 Lit. c) CBD thus also clarifies that the term "biological resource" (and thus also ") genetic resource" requires physicality of the samples in question.

#### **dd. Interim results**

The term "biological resource", which according to Art. 2 Subpar. 2 CBD, includes genetic resources in turn, extends only to the physical components of ecosystems. Digital sequence information clearly does not fall under this term.

#### **d. "Resources provided" as per Art. 15 (3) CBD**

Art. 15 (3) of the CBD restricts the concept of genetic resources on an ad hoc basis: "For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention." The Access and Benefit Sharing Regime of Arts. 15 and 16 CBD and the corresponding specification for biotechnology purposes in Art. 19 CBD therefore only covers such genetic resources that are acquired by Contracting Parties which are the countries of origin of these resources or by the Contracting Parties which have acquired these resources in accordance with this Convention, and that been made available.

Art. 2 Subpar. 5 CBD, in this respect, thus only legally defines the country with genetic resources available in the following way: "Country providing genetic resources" means the country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country." The

question of interest in this case gives rise to two essential clues from this understanding of the term.

**aa. "Collected from"/"taken from"**

The fact that genetic resources have to be collected in situ within the meaning of the Access and Benefit Sharing Mechanism, or have been extracted from corresponding ex-situ collections, illustrates once again the physical and physical approach of the CBD. The source of the in-situ collection is exemplified by "populations of both wild and domesticated species"; This again shows that a physical sampling is meant for populations of certain species.

**bb. "May or may not have originated in that country"**

When extracted from ex-situ sources, it is explicitly irrelevant to the CBD whether or not the genetic resource originated in the country concerned. In such a case, therefore, the country in which the ex-situ source is located, from which the extraction is made, is fabricated as the "genetic resource-providing land". The fact of including genetic resources in ex-situ collections thus, by definition, shifts the rights of disposal to the Party that may have the ex-situ collection. It explicitly does not matter if the ex-situ collection is in the actual country of origin of the resource.

Not only for reasons of protection of the stock and legitimate expectations, but also with regard to the lack of traceability and, at the same time, aspects of practicability, the CBD thus relies on the actual power of disposal over the genetic resources.

However, this idea must be applied to genetic resources of all kinds, regardless of the objections that have been developed, as genetic resources within the meaning of the CBD.

In other words: Article 15 (3) CBD, provided and to the extent that digital sequence information is to be assigned to the term "genetic resources", ensures that in the case of the storage of such information in ex-situ collections, such as databases, the power of disposal does not lie with the country from which the original resource originates, but with the country where the ex-situ collection is located.

#### **e. Genetic resources for biotechnology research**

As the wording analysis of international law, as shown in<sup>42</sup>, goes beyond the wording of the individual norm and includes in particular the wording of the entire Convention, a role is also played in the interpretation of the term "genetic resource" by Art. 19 CBD, which exclusively addresses the challenges of modern biotechnology. Article 19 (1) and (2) CBD state:

"1. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.

2. Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms."

On the one hand, it is about benefit sharing for the benefit of those states that make their genetic resources available for biotechnological research or for access to the results and benefits of biotechnologies based on the genetic resources made available by these Contracting Parties. Genetic resources are thus made

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<sup>42</sup> See B I 2.

available for biotechnological research from the perspective of Art. 19 CBD, or used as a support for such research.

Genetic resources in this sense are therefore always the starting point for biotechnological research, with the term "biotechnology" in turn being used in accordance with Art. 2 Subpar. 3 CBD and to be understood as follows: "Biotechnology' means that it uses biological systems, living organisms, or derivatives thereof to make or modify products or processes for specific use." Art. 2 Subpar. 3 CBD thereby also clarifies what is understood by Article 19 (1) and (2) CBD as "genetic resources" used for biotechnological research.

If biotechnology presupposes that the technological application in question uses biological systems, living organisms or products thereof, and biotechnological research uses such resources as starting materials, the following applies:

Only the physically present samples constitute "biological systems, living organisms, or derivatives thereof" within the meaning of Art. 2 Subpar. 3 CBD and can thus be classified as "genetic resources for such research" within the meaning of Art. 19 (1) and (2) CBD.

#### **f. Interim results**

The comprehensive analysis of the wording of the CBD therefore only allows the conclusion that the "genetic resource" within the meaning of the CBD is exclusively the physically present, embodied biological sample and that, conversely, digital sequence information cannot be qualified as a "genetic resource" in this sense.

## **2. System of the CBD**

Although the findings on the wording of the CBD are already clear, it is nevertheless necessary to apply the additional methods of interpretation in the interests of a comprehensive overall picture. In that regard, the view of the system of the CBD also promotes relevant findings.

### **a. Research and ex-situ conservation**

It is well known that the CBD addresses both in-situ conservation and ex-situ conservation measures, with the former being reserved a certain level of priority. This priority is self-explanatory given the main objectives of the CBD. As already illustrated by the grading of the CBD purposes in Art. 1 CBD, the primary concern is the preservation of biological diversity, then the sustainable use of its components and, finally, a balanced and equitable sharing of benefits.

Preservation of biological diversity, however, necessarily starts where the corresponding diversity is found, i.e. in situ. However, given the high relevance of ex-situ collections, this issue also needed to be addressed in the CBD. Against this background, Art. 9 Lit. b) CBD declares that:

"Each Contracting Party shall, as far as possible and as appropriate, and predominantly for the purpose of complementing in-situ measures:

(...)

(b) Establish and maintain facilities for ex-situ conservation of and research on plants, animals and micro-organisms, preferably in the country of origin of genetic resources".

It explicitly states that each Party, irrespective of its status as the (non-)country of origin of the resource in question, is required to establish and maintain facilities for research on plants, animals and micro-organisms. As the wording clearly shows, the relevant research activities do not have to be aimed at the ex-situ preservation, but may, rather, be devoted to plants, animals and micro-organisms. Furthermore, the wording of that provision leaves no doubt that the relevant facilities should preferably (sic!) be created and maintained in the country of origin of the genetic resources, but at the same time it is also stated that this is a declaration of intent that does not entail the full commitment of the Parties.

Research is thus required and protected regardless of the location of its implementation.

Art. 9 Lit. b) CBD thus includes an explicit mandate for the most comprehensive and purposeful research on plants, animals and microorganisms available ex situ. However, this provision should not be counteracted by the fact that the results of research carried out in compliance with this mandate and which have produced digital sequence information, regardless of existing and generally accepted human rights standards on the rank of freedom of research and scholarship<sup>43</sup>, are forcibly socialised. The relevance of research freedom and the obligation of the Contracting States to maintain the relevant research infrastructure, as clearly emphasised by Art. 9 Lit. b) CBD, are therefore diametrically opposed to the assumption that the term "genetic resource" extends to digital sequence information.

## **b. Technology transfer and intellectual property rights**

For the systematic interpretation of the term "genetic resource", the technology transfer mechanism is of central importance, supplemented by Art. 15 CBD and implemented in Art. 16 CBD.

### **aa. Normative findings and significance**

The provision of Art. 16 CBD reads as follows:

#### Article 16. Access to and transfer of technology

1. Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.

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<sup>43</sup> See also B II 2 b bb bbb.

2. Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights. The application of this paragraph shall be consistent with paragraphs 3, 4 and 5 below.

3. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below.

4. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1, 2 and 3 above.

5. The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives."

Art. 16 CBD reflects the fact that the paramount importance of access to technology has been widely recognised for some time. In 1974, the demand for a "New World Economic Order" in the "Charter of Economic Rights and Duties" had

already culminated in Resolution 3281 of the General Assembly of the United Nations<sup>44</sup>, albeit with a majority abstention or rejection by the main industrialised countries, being adopted.<sup>45</sup> In this context, the apostrophised duty of a comprehensive technology transfer was justified by a supposed "universal heritage of technology".<sup>46</sup> However, in view of the open contradiction to core elements of intellectual property rights, this approach could not prevail in international law. Nonetheless, with regard to the medium- and long-term perspective, Art. 16 CBD responds to the fact that countries of origin must be much more interested in technological development and expansion of the domestic economy than, for example, the one-time payment of a usage fee for extracted resources.<sup>47</sup>

## **bb. Intellectual property rights**

The conflict on the rights of intellectual property, which was more or less open in various places in Article 16, was the subject of intensive academic and legal discourse<sup>48</sup> at a very early stage, which does not have to be discussed in depth here. In fact, legal practice has shown a preference for intellectual property rights, not least because of the various explanations given by the CBD itself.

## **aaa. Priority of intellectual property**

In that particularly Article 16 (2) Clause 2 CBD emphasises that technology covered by patents or other intellectual property rights need only be "opened up"

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<sup>44</sup> <http://www.un-documents.net/a29r3281.htm>

<sup>45</sup> See Herdegen, *Internationales Wirtschaftsrecht*, 10th edition, 2013, Art. 3.

<sup>46</sup> Cf. Blakeney, *Access to Genetic Resources: The View from the South*, in: *Bio-Science Law Review* 1997, 94.

<sup>47</sup> Mugabe/Barber/Henne/Glowka/La Viña, *Managing access to genetic resources*, in: the same, (eds.), *Access to Genetic Resources*, 1997, p. 13; Mayers, *The UN Biodiversity Convention, Biotechnology and Intellectual Property Rights*, in: *Bio-Science Law Review* 1999/2000, 131 (146).

<sup>48</sup> Cf. Spranger, *Der Zugriff auf pflanzliche Genressourcen im internationalen Regelungsgeflecht. Zum Konflikt zwischen Biodiversitätskonvention und Welthandelsrecht*, in: *AVR* 40 (2002), 64 ff.; Slonina, *Gesundheitsschutz contra geistiges Eigentum? - Aktuelle Probleme des TRIPS-Übereinkommens*, 2003; Godt, *Von der Biopiraterie zum Biodiversitätsregime - Die sog Bonner Leitlinien als Zwischenschritt zu einem CBD-Regime über Zugang und Vorteilsausgleich*, in: *TO* 2004, 202 ff.; Müller, *Der gerechte Vorteilsausgleich nach der Biodiversitätskonvention*, in: *FoR* 2008, 45 ff.

and passed on if adequate and effective protection of intellectual property rights is ensured, it is simultaneously emphasised that the CBD is not likely to unilaterally minimize or at all violate intellectual property rights. The Memorandum of Understanding of Article 16 (5) CBD also makes no difference to this finding, according to which the Contracting Parties should work together to ensure that patents and other intellectual property rights support and do not conflict with the objectives of the Convention.

In this context, it should only be pointed out that the interaction described has meanwhile also "arrived" in German patent law and is generally accepted. In response to Recital No. 27 of Directive 98/44/EC, Art. 34 (a) of the Patents Act now determines that:

"(1) Where an invention relates to biological material of plant or animal origin or where such material is used, the declaration shall include information on the geographical origin of that material, where known. The examination of the applications and the validity of the rights based on the granted patents remain unaffected.

(2) If the application contains information on the geographical place of origin pursuant to (1) Clause 1, the Patent Office shall notify the German Federal Office of Nature Conservation as the competent authority within the meaning of Art. 6 (1) of the Act implementing the Nagoya Protocol Regulation (EU) No. 511/2014 of November 2015 (BGBl. I p. 2092) after publication of the notice in accordance with Art. 32 (5)."

However, the norm is explicitly designed in such a way that non-compliance does not result in any negative legal consequences.<sup>49</sup> Unanimity also reigns to the extent that no indirect adverse consequences can be derived from the norm.<sup>50</sup>

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<sup>49</sup> Ruttekolk, Der Schatten des zahnlosen Art. 34 a PatG – Mögliche Konsequenzen des Inkrafttretens des Nagoya-Protokolls für die Praxis, in: Mitt 2015, 434 (435).

<sup>50</sup> See the evidence in Ruttekolk, Der Schatten des zahnlosen Art. 34 a PatG - Mögliche Konsequenzen des Inkrafttretens des Nagoya-Protokolls für die Praxis, in: Mitt 2015, 434 (435).

Thus, if intellectual property rights are a priority, it makes sense to have at least a brief overview of the stock of appropriate protection instruments and then, in a second step, to consider the impact of this finding on the issue under consideration. Art. 16 (2) and (5) CBD cites patents by way of example, but at the same time expressly makes it clear that all intellectual property rights have the same effect and need to be observed. This signifies above all (but not solely) observance of the following protective rights:

- Patents, such as those protected by the World Trade Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)<sup>51</sup> and Directive 98/44/EC<sup>52</sup>;
- Database protection
- Copyright
- Business and trade secrets
- Variety protection
- Secrets such as those covered by "Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of confidential and business information (trade secrets) against their unlawful acquisition, use and disclosure"<sup>53</sup>.

The fact that research activities are not aimed primarily at the acquisition and commercial exploitation of such intellectual property rights must not disguise the fact that university institutions are also increasingly paying attention to a corresponding legal safeguarding of the inventions and findings made or achieved by their researchers. In some jurisdictions, such as the United States, this fact has

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<sup>51</sup> [https://www.wto.org/english/docs\\_e/legal\\_e/27-trips\\_01\\_e.htm](https://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm) (06/09/2017).

<sup>52</sup> OJ L 213/13 of 30/07./1998.

<sup>53</sup> OJ L 157/1 of 15/06/2016.

long since described the state of affairs and is now expected to be standard not only in all industrial nations.

### **bbb. Human rights protection of intellectual property**

The fact that intellectual property not only serves to realise an idea founded on natural law, but rather forms part of a positive legal form and enjoys human rights protection, is now likely to be internationally recognised. For example, the European Court of Human Rights has consistently held that Art. 1 of the first Additional Protocol to the European Convention on Human Rights states that:

"The complaining company criticised the fact that the prohibition on the use of the Internet domains in question or the disposal thereof and the requirement to apply to the Registry for the removal of those domains had violated its property rights. It relied on Article 1 of Protocol No. 1 to the Convention, which reads as follows:

"Every natural or legal person has the right to the respect of their property. No one may be deprived of his property unless the public interest so requires, and only under the conditions provided by law and by the general principles of international law.

Paragraph 1, however, does not prejudice the right of the State to apply the laws which it deems necessary for the regulation of the use of property in the general interest or in order to secure the payment of taxes or other charges or fines. "

In deciding whether the denial of the right of the complaining company to use the domain names registered to it interfered with its right to "property", the Court points out that the term "property" in Article 1 Protocol 1 has an independent meaning which is not limited to the ownership of tangible goods and is not related to the formal classification in national law. Certain other rights which constitute assets may also be considered as "property rights" and thus as "property" within the meaning of that provision (see Cases Gasus Dosier- und Fördertechnik GmbH

./. Netherlands, judgement of 23 February 1995, Series A Volume 306-B, p. 46, Marg. 53; Anheuser-Busch Inc. ./ Portugal [GC], Individual Complaint No. 73049/01, Marg. 63, ECHR 2007 -...). In the case of intangible assets, the Court took into account, in particular, whether the legal status in question gave rise to economic claims and therefore constituted an economic value (cf. Anheuser-Busch Inc. Cases, cited above, Margs. 76 and 78, and Tre Traktörer Aktiebolag ./ Sweden, judgement of 7 July 1989, Series A, Volume 159, p. 21, Marg. 53). Consequently, it evaluated as property, for example, intellectual property such as trademarks and copyrights (see Melnychuk ./ Ukraine (dec.), Individual Complaint No. 28743/03, ECHR 2005-IX; Anheuser-Busch Inc., margs. 72 and 78) or licences for the specific use of the property (such as licences to serve alcoholic beverages or fishing rights, see Tre Traktörer Aktiebolag, cited above, p. 21, Marg. 53, Alatulkkila and Others ./ Finland, Individual Complaint No. 33538/96, Marg. 66, July 28, 2005)"<sup>54</sup>

In addition to the already existing primacy of intellectual property rights, which are protected by copyright, this human rights dimension brings about a further appreciation of research interests: On the one hand, the enshrining of human rights results in special rights of recourse in the case of state restrictions; on the other hand, Art. 16 (3) of the CBD itself clearly states that technology transfer measures must be made exclusively in accordance with international law.

According to Art. 16 (3) CBD, the observance of the requirements set out in Art. 16 (4) and (5) CBD is clearly cumulative in addition to the aforementioned requirement. Art. 16 CBD itself requires observance of international human rights standards.

### **ccc. Consequences**

From a systematic point of view, these normative framework conditions gain significance, because extending the concept of the "genetic resource" to digital

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<sup>54</sup> ECHR, MMR 2008, 29 ff., Marg. 52 ff. at Juris.

sequence information would lead to a scarcely manageable number of collisions with numerous industrial property rights, not only in the industrial but also in the university environment. The fact that university researchers work with digital sequence information must not lead to the erroneous assumption that all such data is free from intellectual property rights.

Rather, corresponding exchange relationships are based on individual or institutional contracts and agreements that correspond to good scientific practice, but are now also regularly fixed by means of appropriate transfer agreements and / or licensing agreements; this applies a fortiori when scientific exchange relationships are enriched by economically active cooperation partners.

### **cc. Interim results**

The usefulness of extending the term "genetic resource" to digital sequence information is also lacking against this systematic background: the extensive and sometimes highly specific intellectual property rights that are used in the exploitation of digital sequence information for the protection of intellectual property rights would, in the case of an extension of the ABS system to data, be in vain. The fact that this is not a consequentialist argument but an aspect of systematic interpretation is illustrated by the primacy of intellectual property rights laid down in the CBD, and perpetuated in the Nagoya Protocol, as well as the otherwise threatened violation of human rights standards, the observance of which, however, is directly called for by Art. 16 (3) CBD.

### **3. Ratio of the CBD**

The clear finding, which results from literal interpretation but also from systematic analysis of the CBD, is further substantiated by teleological considerations.

### **a. General**

As an objective of the CBD, Art. 1 formulates a triad in a fundamental way: "The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding."

Thus, at least some basic statements regarding the perspective of the implemented distribution mechanism can be taken from the general objective of the CBD. The call for the balanced and equitable sharing of benefits arising from the use of genetic resources should, in particular, be based on adequate access to genetic resources, on the one hand, and adequate transfer of relevant technologies on the other, taking into account all rights to those resources and technologies.

The CBD does not pursue the approach of a "normative one-way street". Although Art. 3 CBD, like Article 15 (1), emphasises state sovereignty with regard to the "rights of states with regard to their natural resources", Art. 1 CBD simultaneously imposes the obligation of states, to the extent possible, to open and enable "reasonable access" to other Contracting Parties.

This approach is formulated in a more pronounced way in Art. 15 (2) CBD: "Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention."

This broad perspective is also repeated in view of the rights to be respected in setting up benefit-sharing mechanisms. This not only ensures adequate access and technology transfer, but also takes into account all rights to resources and

technologies. Although this emphasis on comprehensive consideration of all eligible rights and interests should be taken for granted, the discussion of DSI, sometimes with a certain severity, highlights the fact that the principle of comprehensive balance that shapes the CBD is sometimes hidden or at least not comprehensively appreciated.

#### **b. In particular: relevance for dynamic interpretation**

As already mentioned above, the teleological dimension of interpretation under international law has a special relevance for the question of a dynamic understanding of norms. In the meantime, however, it can be stated as briefly as required that there is no consensus among the Contracting States about the possibility or the meaningfulness of including digital sequence information within the scope of the CBD and the Nagoya Protocol.

On the contrary, the Ad Hoc Technical Expert Group on Synthetic Biology (AHTEG), which was set up as part of COP XII, was split on this issue<sup>55</sup>; above all, however, COP Decision XIII / 16, mentioned at the beginning, shows that the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources set up in this way explores a completely open-minded opinion-forming process to establish completely different and contrary positions.

Dynamism is thus exclusively related to the fact that the topic of digital sequence information has been addressed since the end of 2016. On the other hand, a dynamic that has led to a change in the understanding of the CBD and the Nagoya Protocol among the Contracting Parties, and which could therefore modify the understanding of the norm cannot yet be considered to any extent. The fact that the picture is perfectly comparable in the context of, for example, the WHO Pandemic Influenza Preparedness Framework, the UN Law of the Sea Convention, and the International Treaty on Plant Genetic Resources<sup>56</sup>, may here only be mentioned in addition. A dynamic or evolutionary interpretation, which

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<sup>55</sup> UNEP/CBD/SYNBIO/AHTEG/2015/1/3.

<sup>56</sup> Cf. Manheim, Regulation of synthetic biology under the Nagoya Protocol, in: Nature Biotechnology 2016, 1104 (1105).

would allow the inclusion of digital sequence information within the scope of the CBD and the Nagoya Protocol, is therefore already deprived of ground to some extent.

### **III. Nagoya Protocol**

The Nagoya Protocol on Access to Genetic Resources and Equitable Sharing of Benefits Arising from their Utilization, which came into force in 2014, substantiates one of the key objectives of the CBD.

For this purpose, the international legal framework is specified for basic questions of access to genetic resources and fair compensation of the benefits resulting from their use.

#### **1. Wording**

Following the international interpretation standards already described, the analysis of the Nagoya Protocol is based primarily on the wording of the document.

##### **a. General: Recourse to CBD**

To begin with, the finding that the Nagoya Protocol makes full use of the concept of the genetic resource, but explicitly refrains from specifying the definition made in the CBD, is of crucial importance. Instead, Art. 2 Clause 1 of the Protocol essentially refers to the CBD and its inherent understanding of the term. As a result, the explanations for understanding basic terminology of the CBD also characterise the interpretation of the Protocol, so that reference can be made to the corresponding statements in full.

## **b. The application aspect as per Art. 2 Lit. c) of the Protocol**

In addition to the general recourse to all preconceptions and terminology of the CBD, in Art. 2 the Protocol only makes very cautious specifications of selected terminology. Article 2 reads as follows:

"Article 2. Use of Terms

The terms defined in Article 2 of the Convention shall apply to this Protocol. In addition, for the purposes of this Protocol:

(a) "Conference of the Parties" means the Conference of the Parties to the Convention;

(b) "Convention" means the Convention on Biological Diversity;

(c) "Utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention;

(d) "Biotechnology" as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use;

(e) "Derivative" means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity."

In the present case, Art. 2 Lit. c) of the Protocol is of particular interest. The scope for this original definition of the Protocol stems from the fact that Art. 2 Subpar. 15 of the CBD only defines the concept of "sustainable use" and, moreover, that Art. 2 CBD is dedicated to attempting to limit the term "genetic resource", but excludes the specific aspect of the use of the genetic resource thus defined.

By defining in Art. 2 Lit. c) of the Protocol the carrying out of research and development activities on the genetic and/or biochemical composition of genetic resources as "use of genetic resources", it would be possible to give an unbiased view that each form of research on the genetic resource represents a resource use within the meaning of the Protocol. However, this interpretation is based on the order of precedence of the Convention and the Protocol on the one hand, but also the inherent understanding of Art. 2 Lit. c) of the Protocol on the other.

#### **aa. Convention/Protocol ranking**

Recital No. 2 of the Nagoya Protocol clearly states the focus of the Protocol and in what normative framework it intends to and should therefore move:

"Recalling that the fair and equitable sharing of benefits arising from the utilization of genetic resources is one of three core objectives of the Convention, and recognizing that this Protocol pursues the implementation of this objective within the Convention (...)"

This explicitly makes it clear that the Protocol, which in any case has the legal nature of an international protocol, is the realisation of one of the main objectives of the Convention underlying the Protocol. In addition, Recital No. 2 also states that this goal has to be achieved "within the Convention". The specifications and instruments of the Protocol are thus explicitly linked to the framework set by the CBD and should not and may not extend this framework.

In the legally binding part of the Protocol, this groundbreaking decision is expressly confirmed by the provisions of Art. 3, which reads as follows:

"Article 3. Scope

This Protocol shall apply to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilization of such resources. This Protocol shall also apply to traditional knowledge associated with genetic resources

within the scope of the Convention and to the benefits arising from the utilization of such knowledge."

Thus, Art. 3 of the Nagoya Protocol explicitly assumes that the definition of the genetic resource is to be understood exclusively in the sense given by Art. 15 of the CBD. However, as the CBD, as described in detail above, does not subsume digital sequence information under the concept of genetic resources, Art. 3 of the Protocol is diametrically opposed to a corresponding widening understanding of terms.

This finding is further supported by the supplementary analysis of Art. 4 of the Protocol. The provision reads:

"Article 4. Relationship with International Agreements and Instruments

1. The provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity. This paragraph is not intended to create a hierarchy between this Protocol and other international instruments.

2. Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

3. This Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

4. This Protocol is the instrument for the implementation of the access and benefit-sharing provisions of the Convention. Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to

the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument." Thus, Art. 4 (1) Clause 2 of the Protocol first makes clear that the idea of a hierarchical superordination of the Protocol in relation to other international treaties is foreign to the Protocol. Moreover, Art. 4 (4) Clause 1 of the Protocol reiterates the conviction, expressed in Recital No. 2 and Art. 3 of the Protocol, that the Protocol under the Convention is aimed at achieving one of the central objectives of the Convention.

#### **bb. System-inherent limitations of the definition of use**

In addition to these clarifications of the Protocol regarding its scope, however, quite general system-immanent considerations also speak against an extension of the Protocol to digital sequence information. If, in fact, Art. 2 Lit. c) of the Protocol defines the "use of genetic resources", genetic resources are thus directly given and, especially in view of the final and referenced definitions of terms of the CBD, not self-defined again. Rather, Art. 2 Lit. c) of the Protocol solely addresses the aspect of the use of the resources defined by the CBD. However, the use of an existing and otherwise defined resource can not penetrate or even expand the understanding of the resource term.

The further details of the definition of Art. 2 Lit. c) of the Protocol also make this clear: If indeed one use for the purposes of the Protocol assumes that research and development activities are carried out on the genetic and/or biochemical composition of genetic resources, this also presupposes that there a resource within the meaning of the Protocol and the Convention that can be researched does indeed exist. In other words: research in the sense described requires the existence of genetic resources within the meaning of the CBD. If this is the case, any use falls under the scope of Art. 2 Lit. c) of the Protocol. However, the digital sequence information generated by means of such use no longer constitutes genetic resources due to the normative frameworks already outlined, so that further uses of these "utilization results" do not fall within the scope of the Protocol.

## **cc. Derivatives**

Incidentally, Art. 2 Lit. e) of the Nagoya Protocol, which defines the concept of the derivative, also addresses the viewpoint described above. A general understanding of this term, based on the word origin<sup>57</sup>, implies that derived substances can also be understood as derivatives, such as derived products or even related financial instruments. Thus, while the term "derivative" may well have a significant potential for excessive understanding, the Nagoya Protocol explicitly chooses a narrow interpretation of terms. This interpretation of terms is necessarily preferable to the general understanding of the term "derivative", as Art. 31 (4) of the VCLT requires that an expression be given a special meaning when it is established that the Contracting Parties intended it.

According to Art. 2 Lit. e) of the Nagoya Protocol, a "derivative" is exclusively a naturally occurring biochemical compound that results from gene expression or the metabolic process of biological or genetic resources, even if it contains no functional hereditary units. For the question of interest in this case, different consequences result from this definition:

### **aaa. Physical aspect**

On the one hand, Art. 2 Lit. e) of the Protocol only refers to biochemical compounds that occur naturally. This focus means that even the term "derivative" only covers physical, bodily materials in the form of biochemical compounds. In addition, these links must be natural, expressing that artificial derivatives are not the focus of the Protocol. However, genetic sequence information is neither physical nor can it be understood as naturally occurring. For the data as such must be generated for the first time using bioinformatic systems and thus made available to the (specialist) public.

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<sup>57</sup> Latin derivare: derive.

Incidentally, that not even all physical derivatives can be assigned to the derivative term should be common sense. The Dutch focal point therefore points out: "A derivative has been defined as a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity. The definition of utilization of genetic resources is thus wide, but excludes direct use of genetic resources for production purposes. The Nagoya Protocol does not apply to direct use. However, no DNA has to be present in a product for the Nagoya Protocol to apply, as long as such derivative has been obtained by making use of genetic or biological resources."<sup>58</sup>

Moreover, this Protocol-defining difference between naturalness and derived findings also determines the international biopatent law. Without having to discuss the details of the relevant requirements and discussions in the present case, reference may be made by way of example to Arts. 3 and 5 of Directive 98/44/EC:

#### "Article 3

(1) For the purposes of this Directive, inventions that are new, are based on inventive activity, and are industrially applicable, may be patented even if they contain a product made of or containing biological material or a process producing, editing, or using biological material.

(2) Biological material that is isolated or produced from its natural environment by a technical process can also be the object of an invention even if it already existed in nature.

(...)

#### Article 5

(1) The human body at each stage of its formation and development, as well as the mere discovery of one of its constituents, including the sequence or partial sequence

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<sup>58</sup> [http://www.absfocalpoint.nl/upload\\_mm/6/7/7/dd77f840-bc2c-4cea-8b0d-aa227a087dd8\\_An%20explanation%20of%20the%20Nagoya%20Protocol%20by%20article.pdf](http://www.absfocalpoint.nl/upload_mm/6/7/7/dd77f840-bc2c-4cea-8b0d-aa227a087dd8_An%20explanation%20of%20the%20Nagoya%20Protocol%20by%20article.pdf) (30/08/2017).

of a gene, cannot constitute patentable inventions.

(2) An isolated constituent of the human body or a constituent otherwise obtained by a technical process, including the sequence or partial sequence of a gene, may be a patentable invention, even if the construction of this constituent is identical to the construction of a natural constituent. (...)."

### **bbb. Silence on further derivatives**

Art. 2 Lit. e) of the Nagoya Protocol is, moreover, also of considerable importance for the clarification of the issue of interest here from a different point of view. The norm is in fact a direct proof that the international legislator has dealt extensively with the normative position of derived products and findings.

However, if this referral has only led to the creation of Art. 2 Lit. e) of the Protocol and, conversely, any further definition of the derivative as well as explicit designation of digital sequence information was refrained from, this silence of the legislator can only be understood in the sense that digital sequence information should not fall within the scope of the Nagoya Protocol.

### **ccc. Exclusive specification of the biotechnology term**

The lack of relevance of the derivative term also arises, and particularly so, from another circumstance. In fact, the term "derivative" does not appear in the operational part of the Nagoya Protocol, which in turn merely serves to clarify the term "derivative", which appears in the definition of "biotechnology".<sup>59</sup> The term "biotechnology", for its part, as per Art. 2 Lit. d) of the Protocol, which is literally identical to Art. 2 Subpar. 3 of the CBD - is to be understood as follows: "Biotechnology' as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use (...)." As the term "biotechnology" is used in the present context, the term "biotechnology" as used herein only serves to identify a particularly relevant technology, which may come into

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<sup>59</sup> <http://www.sib.admin.ch/de/nagoya-protokoll/das-nagoya-protocol/index.html> (30/08/2017).

play when using genetic resources, this does not affect the term "genetic resource" as such.

### **c. "Traditional knowledge associated with genetic resources"**

Substantial insights into the notion of genetic resources are also provided by the analysis of the provisions relating to the protection of traditional or indigenous knowledge related to genetic resources. Normative references can be found in Recital No. 12 to the Nagoya Protocol, in Art. 7 of the Nagoya Protocol, and in Art. 8 Lit. j) CBD.

Recital No. 12 to the Nagoya Protocol reads as follows:

"Recognizing that an innovative solution is required to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent,"

Art. 7 of the Nagoya Protocol summarises this requirement in a legally binding form as follows:

"Article 7. Access to Traditional Knowledge Associated with Genetic Resources

In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established."

What exactly the CBD or the Nagoya Protocol concretising the CBD means by traditional knowledge in this sense is described under the heading of "in-situ conservation", and clarified in particular by Art. 8 Lit. j) CBD:

"Each Contracting Party shall, as far as possible and as appropriate:

(j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices; (...)."

Overall, these provisions only make sense if genetic resources are understood in a physical sense. Digital sequence information has never been part of traditional knowledge. Although it could be argued at first glance that the requirements for the protection of traditional knowledge are only intended to depict one facet of the know-how associated with genetic resources, such a view is too short-sighted. Although the protection of traditional knowledge enjoys prominence both in the CBD and in the Nagoya Protocol, it is also a further indication of the already extensively comprehensively detailed focus of the CBD and the Nagoya Protocol on physically present genetic resources through a systematic general overview.

#### **d. In particular: the subsequent use and marketing according to Art. 5 (1)**

The results so far are not shaken by the central norm on the system of fair benefit sharing. Art. 5 (1) of the Nagoya Protocol states:

"In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms."

Here, too, closer examination shows that the Nagoya Protocol is based on the presence of physical substances. Specifically, the following can be stated:

## aa. Integration into the definitional framework of the CBD

It has already been stated in detail that the Nagoya Protocol complies fully with the CBD frameworks in terms of protection objectives, benchmarks and relevant definitions.<sup>60</sup> This approach is consistently pursued by Art. 5 (1) of the Protocol by expressly clarifying that the benefit-sharing mechanism relates to the implementation of Art. 15 (3) and (7) CBD, which in turn read as follows:

"3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.

(...)

7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms."

Since Art. 15 (3) CBD does not make an independent definition of the term "genetic resource", but in turn assumes the definition of Art. 2 Subpar. 10 CBD and only emphasises in this context the aspect of "making available" the resources thus defined, the framework of Art. 5 (1) of the Protocol is also hereby set out. In this context, it is thus not possible, in particular, to extensively understand the "future use and marketing" of genetic resources and to extend this to digital sequence information.

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<sup>60</sup> See in particular under 3 a aa and 3 bb aaa.

## **bb. System-inherent restriction on physical substances**

Once again the objection of a systemic restriction is shown: If and in so far as Art. 5 (1) of the Nagoya Protocol governs the handling of benefits resulting from the use of genetic resources, as well as subsequent use and marketing, the fact that digital sequence information may result following use, it cannot be concluded that this digital sequence information in turn once again represents genetic resources. In other words, the term "genetic resources" cannot logically be extended by the variety of possible uses.

## **2. System**

From a systematic point of view, the analysis of the Nagoya Protocol does not reveal anything beyond the systematic analysis of the CBD and the wording of the Protocol: Since the Nagoya Protocol serves the realisation of a central CBD objective and is fully embedded in the normative framework of the CBD in this regard, the systematic findings on the CBD directly affect the Protocol, without the Protocol itself being able to implement derivative structures.

## **3. Ratio**

The fact that the Nagoya Protocol also places a clear focus on physical substances in terms of sense and purpose and, on the other hand, excludes "virtual substances" in the form of digital sequence information, is further illustrated by a look at the so-called Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization.<sup>61</sup>

As is well known, the Bonn Guidelines provide a central intermediate step from the CBD to the Nagoya Protocol, as the COP Decision IX/12<sup>62</sup> and the COP Decision X/1<sup>63</sup> expressly point out. The legally non-binding Bonn Guidelines were thus often used as a blueprint for the Nagoya Protocol. The Bonn Guidelines the following note can be found under No. 16 Lit. b) Point viii):

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<sup>61</sup> <https://www.cbd.int/doc/publications/cbd-bonn-GDLs-en.pdf> (09/06/2017)

<sup>62</sup> <https://www.cbd.int/decision/cop/default.shtml?id=11655> (01/09/2017).

<sup>63</sup> <https://www.cbd.int/decision/cop/default.shtml?id=12267> (01/09/2017).

"In the implementation of mutually agreed terms, users should: When supplying genetic resources to third parties, honour any terms and conditions regarding the acquired material. They should provide this third party with relevant data on their acquisition, including prior informed consent and conditions of use and record and maintain data on their supply to third parties. Special terms and conditions should be established under mutually agreed terms to facilitate taxonomic research for non-commercial purposes (...)."

Since the concept of the material itself is not further defined, a general understanding of the term must therefore be used. Here it turns out that "material" is usually understood as "the matter from which a thing is or can be made"<sup>64</sup>, as a "physical substance that things can be made from"<sup>65</sup>, or as a "broad term for a chemical substance or mixture of substances".<sup>66</sup> The physical component comes to light so clearly here that further analysis is unnecessary.

### **C. Interim results**

As an interim result, it can be stated that neither the CBD nor the Nagoya Protocol understand digital sequence information as genetic resources. In addition to the above-mentioned authoritative wording of the relevant sources of law, this is particularly supported by the systematic analysis, since the regulatory framework of the CBD and the Protocol requires the presence of bodily substances.

### **D. Alternatively: consequences of deviating assessment**

Since the CBD and Nagoya Protocols do not support the requirement for extending the term "genetic resources" to digital sequence information, a deeper analysis of the implications of deviating assessment is neither appropriate nor expedient. Nevertheless, in the interests of a comprehensive treatment of the topic, it is

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<sup>64</sup> <https://en.oxforddictionaries.com/definition/material> (01/09/2017).

<sup>65</sup> <http://dictionary.cambridge.org/dictionary/english/material> (01/09/2017).

<sup>66</sup> <https://en.wikipedia.org/wiki/Material> (01/09/2017).

appropriate to at least go into the consequences of the subsumption of digital sequence information under the term "genetic resources".

## **I. Enforcement problems**

In the case of an extension of the CBD/Protocol to digital sequence information, problems that are difficult to control would already become apparent at the level of enforcement. Digital sequence information is available worldwide in countless (specialist) public databases, registers, collaborative and individual projects.<sup>67</sup> In the case of science-driven data collections, free access to this information and free exchange between institutions are part of an institution's general policy. It is not clear how the traceability of the resulting<sup>68</sup> effects, which serve the generation of knowledge and are thus completely in the interests of the CBD, can be guaranteed. The quality and quantity of the distortions therefore make it simply impossible to administratively extend the extension of the ABS system to digital sequence information.

## **II. Illegal restriction of research**

With the provisions on access to and transfer of technology (Art. 16), information exchange (Art. 17) and technical and scientific cooperation (Art. 18), the CBD highlights the central role that ought to be played by a functioning science in the context of biodiversity protection.

It is true that these provisions are primarily to be seen in the light of comprehensive and non-biased scientific and technological cooperation between so-called developing and industrialised countries. Nevertheless, it cannot be ignored that

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<sup>67</sup> The Joint Position Paper of the Leibniz Association, the Association of Biology, Biosciences and Biomedicine in Germany (VBIO eV) and the consortium of German Natural Science Research Collections (DNFS) on the draft legislation of the Federal Government on the Nagoya Protocol gives a first impression of this dimension and its national implementation, submitted for public consultation in the German Federal Committee on the Environment, Nature Conservation, Building & Nuclear Safety on 30 September 2015.

<sup>68</sup> The International Chamber of Commerce rightly points to this; cf. <https://iccwbo.org/publication/digital-sequence-information/> (04.09.2017).

guidelines for scientific cooperation are meaningful only if (free) scientific work is possible.

This aspect is strengthened by considerations on the human rights dimension of the freedom of science. It would certainly not be appropriate to raise the national perspective of the constitution to a generally binding standard. Nevertheless, it cannot be ignored that the considerations made by the German Federal Constitutional Court in its decision on the freedom of scholarship also shape the international understanding of this human right:

"The freedom contained in Art. 5 (3) German Constitution (GG) protects, as a right of defence, scientific activity against state interference and is open to anyone who is scientifically active or wants to become active in such a way (...). This freedom of the scientist is fundamentally protected as unconditionally as the freedom of artistic activity is guaranteed. It ensures absolute freedom from any interference of public authority. Covered by this space of freedom, are, above all, processes, behaviours, and decisions in the discovery of knowledge, its interpretation and transmission, which are based on scientific autonomy. Everyone who works in science, research and teaching has (...) a right to ward off any governmental influence on the process of obtaining and communicating scientific findings. In order for research and teaching to be able to align themselves unrestrictedly with the search for truth as "something not yet completely found and never completely found" (Wilhelm von Humboldt), science has been declared an area of personal and autonomous responsibility of the individual scientist that is free from state heteronomy. At the same time, it is stated that Art. 5 (3) GG does not want to protect a particular view of science or a particular theory of science. Its guarantee of freedom extends to every scientific activity, that is, to everything that is to be regarded in content and form as a serious, planned attempt to ascertain the truth. This follows directly from the fundamental incompleteness of any scientific knowledge."<sup>69</sup>

However, scientific work with digital sequence information would hardly be possible given the foreseeable implications and effects to be discussed in more detail below.

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<sup>69</sup> Decisions of the German Federal Constitutional Court (BVerfGE) 35, 79 ff., Marg. 92 at Juris.

### **III. Consequence of unpredictable extensions**

If digital sequence information were understood as a mediated expression of genetic resources and assigned to the regulatory system, and, above all, to the distribution mechanism, of the Nagoya Protocol, then there would be no reason not to push this extension even further. Since digital sequence information is, undoubtedly not explicitly mentioned by CBD and Protocol, and a corresponding extension of the term "genetic resource" ultimately based on the consideration that digital sequence information is an "outflow" of genetic resources, could lead, with the same justification, to an extension covering all other "returns" from genetic resources.

#### **1. Problems of benefit sharing**

If digital sequence information were to be understood as genetic resources within the meaning of the CBD or the Nagoya Protocol, and were the advantage-balancing mechanism of Art. 5 of the Protocol to be thus activated, the consequence would be an obligation for the balanced and equitable sharing of "benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization." What exactly is meant by "benefits" in this sense then follows from the Annex to the Nagoya Protocol, which is non-exhaustive in accordance with Art. 5 (4) of the Protocol, which reads as follows:

"Annex. Monetary and Non-monetary Benefits

1. Monetary benefits may include, but not be limited to:

(a) Access fees/fee per sample collected or otherwise acquired;

(b) Up-front payments;

(c) Milestone payments;

(d) Payment of royalties;

(e) Licence fees in case of commercialization;

(f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;

(g) Salaries and preferential terms where mutually agreed;

(h) Research funding;

(i) Joint ventures;

(j) Joint ownership of relevant intellectual property rights.

2. Non-monetary benefits may include, but not be limited to:

(a) Sharing of research and development results;

(b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;

(c) Participation in product development;

(d) Collaboration, cooperation and contribution in education and training;

(e) Admittance to ex-situ facilities of genetic resources and to databases;

(f) Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation

and sustainable utilization of biological diversity;

(g) Strengthening capacities for technology transfer;

(h) Institutional capacity-building;

(i) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;

(j) Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;

(k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;

(l) Contributions to the local economy;

(m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources;

(n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;

(o) Food and livelihood security benefits;

(p) Social recognition;

(q) Joint ownership of relevant intellectual property rights."

A researcher who is called to a higher-ranking position due to his use of biodiversity publications using digital sequence information could therefore, in the light of No. 1 Lit. g) of the Annex, in relation to his salary increase be liable for benefit sharing. Equally, the use of digital sequence information in the context of scientific publications alone could lead to the author of a technical article, as per No. 1 Lit. j) of the Annex, being obliged to divide the copyright to the relevant contribution; in the case of a (customary) assignment of copyrights to the publisher enabling the publication, this obligation would pass to the publisher. Any author's fees and income from publishing could logically also be qualified as benefits subject to division.

Above all, however, an "infection" of digital sequence information would paralyse any further investigative and commercialising use of this data. For as a central consequence of extending the term "genetic resource" to digital sequence information, any use of this data would necessarily be considered as a use of a genetic resource within the meaning of the Nagoya Protocol. In view of the breadth of the definition of Art. 2 Lit. c) of the Protocol, which would appear as a result of a broad understanding of the term "genetic resource", the delineation of "asset-by-security areas" could no longer be ensured: Any academic or industrial research project, any scientific qualification work, and any scientific or journalistic publication would, as a result of a domino effect, constitute a "use of genetic resources."

## **2. Distortions relating to the assignment of digital sequence information**

But even if the possible effects of a broad understanding of terms are ignored and only the consequences for digital sequence information are illuminated, uncontrollable normative distortions would be a serious concern. The reason for this finding is simply the fact that in many, if not most, cases, digital sequence information cannot be assigned to any specific individual organism, so that the traceability required for benefit sharing is in doubt.

In addition, consideration must be given to the fact that the processing of digital sequence information covers a considerable variety of activities and actions. For clarification, the definition provided for in Art. 3 (2) of Regulation (EU) 2016/679 of the

European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data, on the free movement of persons and repealing Directive 95/46/ EC (General Data Protection Regulation) provides, for the term "data processing":

"(The term)'processing' (means) any process performed with or without the aid of automated procedures or any such series of operations relating to personal data such as its collection, recording, organisation, ordering, storage, adaptation or modification; reading out, querying, use, disclosure through transmission, dissemination or any other form of provision, reconciliation or association, restriction, erasure or destruction (...)."

This definition, which is notable even beyond the scope of personal data, makes it clear that even the mere ordering or changing of data can be understood as a new use. An extension of the term "genetic resource" to include digital sequence information would thus lead to the fact that any handling of this data, which would seem so inconspicuous, could represent a new use that would have to be negotiated or permitted accordingly. How scientific research should take place under such conditions remains a mystery.

### **3. Extensions beyond digital sequence information**

The unpredictable consequences of the extension of the "use of genetic resources" to all conceivable forms of indirect "returns" can be shown by the embedding of the genetic resource in the overarching concept of biological diversity. Here, Recital No. 1 to the CBD prominently points to the following circumstance:

"The Contracting Parties,

Conscious of the intrinsic value of biological diversity and of the ecological, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic values of biological diversity and its components (...)."

So whoever wants to extensively understand the term "genetic resources" and to include indirect "returns", might as well argue, through citing the stated fundamental conviction of the Contracting Parties that textbook publishers, publishing, for example, biodiversity-specific information in books on biology or politics, would be obliged to share benefits with the countries of origin of the genetic resources discussed in the relevant works, as publishers have commercialised the "educational value" of genetic resources. Likewise, it could be argued that educational institutions, such as museums, scientific collections, botanical gardens, or zoos, must distribute some of their entrance fees, as they have commercialised the "cultural value" of genetic resources.

### **E. Agenda**

In view of the above considerations, the purely political motivation of the claimed assignment of digital sequence information to the term "genetic resources" is evident. Against this background, and with a view to the distortions described, which are specifically to be feared, especially in the scientific landscape, the question of alternative regulatory mechanisms arises.

However, the ABS system does not provide such mechanisms for the CBD or the Nagoya Protocol. Given that, as outlined above, the CBD and Nagoya Protocol do not directly capture digital sequence information, from the perspective of the international community there was no reason to implement such alternatives under the auspices of the CBD. Should the international community become convinced in a future discourse that an ABS regime should be created for digital sequence information, this could be done either through a comprehensive overhaul of the CBD/Nagoya regime or through the creation of an original tool, which in turn fits organically into the CBD/Nagoya framework. In both cases, the described distortions would also have to be avoided or, at least, largely mitigated and, in particular, sufficient protection of human rights guarantees, in particular with regard to freedom of research and intellectual property rights, ensured.

## **F. Summary of the main results**

The interpretation of the CBD and the Nagoya Protocol is based on the principles of the Vienna Convention on the Law of Treaties (VCLT). Art. 31 VCLT makes a substantial reference to the wording in this respect, but also adds systematic and teleological considerations.

A dynamic or evolutionary interpretation must not lead to a new meaning being attributed to an international treaty that does not accord with the will of the Contracting States.

Art. 15 (1) CBD emphasises the sovereign rights of States with regard to their natural resources and derives therefrom the power of the governments of the respective member states to determine access to genetic resources by means of national legislation.

Art. 15 (1) CBD is, in that regard, an immediate expression of the principle of territoriality under international law, which in turn follows from the principle of territorial sovereignty and, inter alia, establishes the validity of national law for foreign nationals. In this context, full consideration of Art. 15 (1) CBD makes sense only if "genetic resources" are understood to mean only physical/bodily substances.

The principle of operation does not apply insofar as it lacks the required "increased domestic relevance" (direct, foreseeable and substantial effect).

The definition of the "genetic resource" in Art. 2 Subpar. 10 CBD includes, when considered alone, but also in overall view with Art. 2 Subpar. 9 CBD, only physical/bodily substances. This is supported by a comprehensive analysis of the terms "material", "containing", and "functional units of heredity".

This finding is supported by a supplementary analysis of Art. 2 Subpar. 2 CBD and in particular the term "biotic component" as well as the objective of Art. 10 Lit. c) CBD.

Similarly, Art. 15 (3) CBD assumes the presence of physical/bodily substances

("taken from", "collected from"). In addition, the provision establishes a right of disposal for those Contracting Parties who have control over ex-situ collections.

Art. 19 CBD fits into the said framework, as genetic resources are always the starting point for biotechnological research in this sense, with the concept of biotechnology in turn being defined in accordance with Art. 2 Subpar. 3 CBD is to be understood solely as a "technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use." Here, too, a closer examination deals exclusively with physical/bodily substances.

Moreover, in a systematic general overview, Art. 9 Lit. b) and Art. 16 CBD play a supporting role, whereby the primacy of intellectual property rights actually recognised by Art. 16 CBD, along with its human rights dimension, also favours the exclusion of digital sequence information from the scope of the CBD/Protocol.

In addition, the objective of the Convention, as enshrined in Art. 1 CBD, is to refrain from extending the scope of the CBD and the Protocol to digital sequence information.

Although the Nagoya Protocol makes full use of the term "genetic resource", it explicitly refrains from specifying the definitions made in the CBD. Instead, Art. 2 Clause 1 of the Protocol essentially refers to the CBD and its inherent understanding of the term. The term "genetic resource" is thus to be understood as identical to the CBD in the context of the Protocol. The described ratio of the CBD to the Protocol is further supported by Art. 3 and Art. 4 (1) Clause 2 and (4) Clause 1 of the Protocol.

For this reason alone, the use of digital sequence information does not constitute the use of genetic resources within the meaning of Art. 2 Lit. c) of the Nagoya Protocol.

In addition, reference is to be made to Art. 2 Lit. e) of the Nagoya Protocol. According to Art. 31 (4) of the VCLT, the term "derivatives" as used here must be understood in the sense specified there, which again brings a focus to purely physical/bodily substances.

Vice versa, Art. 2 Lit. e) of the Nagoya Protocol provides direct evidence that the international legislator has dealt extensively with the normative position of derived products and findings, but has refrained from an extension to digital sequence information.

The systematic inclusion of Recital No. 12, Art. 7 and Art. 5 (1) of the Nagoya Protocol also supports the finding described above.

An alternative analysis of the hypothetical consequences, which would show up in the case of an extension of the CBD/Nagoya Protocol on digital sequence information, illustrates that in this regard, barely any controllable enforcement problems, an uncontrollable research restriction, as well as incalculable extensions of the problem to many other areas of life would be a serious concern.