SYNTHETIC SUBSTITUTION OF TRADITIONAL KNOWLEDGE ENHANCED GENETIC RESOURCES: REGULATION AND BEST PRACTICES

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ABSTRACT

Many indigenous genetic resources attain notoriety because of the benefits highlighted by traditional knowledge. These genetic resources attract a growing international market, which encourages large-scale cultivation by indigenous peoples and triggers a cycle of socio-economic dependence. The commercial and beneficial attractiveness of these genetic resources accounts for the desire of foreign corporations to synthetically substitute their properties. How is such substitution regulated? No instance of copying identically typifies the synthetic substitution of genetic resources, but akin rights like copyright derivatives are protected under copyright law. The rationales for such protection range from the need to protect the integrity of the original work, deter unfair harvesting from another's hard work, and acknowledge the owner's contribution to knowledge. This article examines the current legal framework of synthetic biological substitution, lessons from the protection of allied derivatives in intellectual property law and the application of access and benefit-sharing regulations to synthetic biological substitution. This work is fashioned to address the circumstances described in the case study below.

Keywords: Synthetic Substitution, Traditional knowledge, Genetic Resources, Misappropriation, Regulation of Synthetic Substitution

CASE STUDY

Market women[i] sat despondently in the marketplace at Hunata.[ii] Their brows were knotted with worry and frustration. They spread out in groups and clusters, exchanging pleasant memories of foreign commercial gains in the past and dreaded fears of what the future holds for them and their children. The little village of Hunata lies very far away from modern civilisation. Isolated by a wide expanse of seas, mountains and wild forests. The geographical, infrastructural and linguistic hurdles one had to scale to interact with the Hunatas were practical deterrents to foreign visits until the healing potentials of Suunarak,[iii] the Hunata's healing vine made international headlines. Suunarak had been Hunata's drink and multiple-use herbal remedy for many years. Fevers, coughs, inflammations and many other common ailments bow to its therapeutic prowess.

To the awe of Hunata's locals, foreigners arrived in unrestricted batches; some foreigners bought the Suunarak fruit, some went after the leaves, some requested the branches, others the root and some went as far as buying portions of the soil on which Suunarak grew. No part of the healing vine, its numerous uses, methods of preparation or healing properties were preserved from uncensored foreign curiosity. To grab a portion of the generous foreign gains associated with the sale of Suunarak, farmers shifted their attention to the cultivation of Suunarak. In many Hunata homes, the dream of a bright future rested on the fruitfulness of their healing vines. The Hunata government nursed the new-found revenue generated by tourism and Suunarak foreign trade. For a few years, Hunata gloried in its foreign relevance and income. During these scanty years, foreigners intensely researched the scientific replication of Suunarak's healing properties.

Without notice, foreign crowds dwindled to trickles and abruptly dried up. Images of Suunarak adorned pharmaceutical and nutraceutical packages in foreign countries. Hunata suddenly understood the dramatic foreign activities that had buzzed about its countryside. Something of great value had been taken from Hunata. Suunarak fruits, leaves and branches still grew on Suunarak vines across the countryside. But the essential property that makes Suunarak a healing vine had been replicated. Additionally, the growing demand for Suunarak and the international market had been taken over by substitutes made by foreigners. Dejected farmers sway like drunken men in their farmlands. Successful and attempted suicides among aggrieved Suunarak farmers regularly made local headlines. The government of Hunata took to the media,

trading promises to investigate the misappropriation with threats to fight back and recover all losses. Hunata had lost its international commercial relevance!

INTRODUCTION

Synthetic substitution, the subject matter of this article, is a branch of synthetic biology,[iv] a multidisciplinary field of biotechnology involving engineering the genetic material[v] of organisms like viruses, bacteria, yeast, plants, or animals to have new characteristics.[vi] Synthetic substitution can be beneficial where a genetic resource is insufficient to meet present needs, but it has notable negative socioeconomic and legal implications.[vii] For instance, developing a synthetic substitute for palm oil could crumble national economies dependent on palm oil.[viii] As illustrated in the case study above, dire consequences may follow synthetic substitution, particularly where the substituted property misappropriates resources upon which indigenous communities depend for sustenance and commerce. Concerns about misappropriation arise when indigenous peoples' traditional knowledge and genetic resources are exploited for patents.[ix] Synthetic substitution may facilitate unauthorised copying and diversion of an international audience, market and profit. The next section attempts to trace the legal framework of legislation that may be tailored toward addressing misappropriation arising from the interaction of synthetic biology with genetic resources and traditional knowledge.

LEGAL FRAMEWORK FOR THE REGULATION OF SYNTHETIC SUBSTITUTION

The 1992 Convention on Biological Diversity (CBD),[x] 2002 Bonn Guidelines[xi] and the 2010 Nagoya Protocol[xii] anticipated that derivatives from traditional knowledge and associated genetic resources would be protected.[xiii] According to Article 2(e) of the Nagoya Protocol, derivatives are naturally occurring biochemical compounds resulting from the genetic expression or metabolism of biological or genetic resources, even if they do not contain functional units of heredity. In the CBD and Nagoya Protocol, the use of derivatives finds expression in Article 2(d) of the Nagoya Protocol and Article 2 of the CBD's definition of

biotechnology as any technological application that uses biological systems, living organisms, or derivatives thereof to make or modify products or processes for specific use.

Article 19(2) of the CBD requires that access to genetic resources for biotechnological purposes, including synthetic substitution, be subject to access and benefit-sharing requirements documented in mutually agreed terms. Considering that the application for access precedes the grant of access, the attendant mutually agreed terms and benefit-sharing, paragraph 36(l) of the Bonn Guideline gives the impression that the onus to disclose the purpose for which derivatives are accessed and anticipated products from the commercial and other utilization of accessed genetic resources lies on the potential user. Thus, the provider state is not saddled with the responsibility of investigating the nature and precise location of resources accessed and utilised. In addition to the CBD, Nagoya Protocol and Bonn Guidelines, the 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement)[xiv] plays a very significant role in the promotion of technological innovations such as synthetic substitution.

Article 27(1) of the TRIPs Agreement, makes patent protection available to all fields of new, inventive and industrially applicable technology but offers no specific checks against the misappropriation of traditional knowledge and genetic resources. The scope of the CBD and TRIPs Agreement crisscrosses in their relationship with new technologies. While the TRIPs Agreement protects innovative technology generally, Article 2 of the CBD defines technology to include biotechnology, to which access and benefit-sharing principles apply if genetic resources are utilised. States have adopted several strategies, including the exclusion of traditional knowledge from patenting and mandatory disclosure of utilised genetic resources, to circumvent the general application of patents on technologies, which may lead to the misappropriation of traditional knowledge or associated genetic resources. For instance, Section 3(p) of the 1970 Indian Patent Act prohibits patenting an invention that, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of the traditionally known component(s).[xv]

Another example is Article 15, Sections 1 and 6, of the Belgian Patent Law, which mandates the disclosure of the geographicalorigin of genetic resources as a condition precedent to a patent grant.[xvi]

The current World Intellectual Property Organization Intergovernmental Committee (WIPOIGC) Draft Consolidated Document Relating to Intellectual Property and Genetic Resources contains provisions that would address the misappropriation of traditional knowledge and genetic resources.[xvii] Like the Nagoya Protocol, the draft document maintains a significantly similar definition of biotechnology and its derivatives.[xviii]Focused on addressing issues surrounding the misappropriation of traditional knowledge and genetic resources, it proposes definitions of misappropriation and traditional knowledge associated with genetic resources. The draft legislation highlights the relationship between traditional knowledge associated with genetic resources and erroneous intellectual property rights,[xix] recognises research on the biochemical composition of genetic resources as utilization[xx] and identifies instances and exceptions of misappropriation.

There are still two proposed definitions of misappropriation (the precise definitions are set out in the footnote with undecided texts in brackets).[xxi] The first seems flexible enough to accommodate the diversity of misappropriation scenarios and their exceptions. The second option may breed loopholes, thereby leaving some acts of misappropriation unaddressed. For instance, option two regards the purchase of genetic resources, derivatives and associated traditional knowledge as lawful access. Respectfully, an unqualified "purchase" should not be considered a legitimate acquisition unless access and benefit-sharing requirements have been complied with. A contrary opinion would legitimise cases like In Re Pod-Ners, where the revocation of a US patent obtained for non-distinctive yellow beans purchased from Mexico was upheld by US courts.[xxii] Unauthorised purchases are not legitimate access and would likely be contested by indigenous peoples. Secondly, option two considers reading a publication to be lawful access. Considering the current ease and speed at which publications can be made, it seems that publications made maliciously to thrust traditional knowledge and genetic resources into the public domain should not be lawful access.

Article 55(a) of the European Patent Convention (EPC)[xxiii] provides an example of such an exemption. The provision disregards disclosures that are evidently abusive in relation to the applicant or his legal predecessor. Interpreting this provision, the European Board of Appeal in *T 173/83 (OJ 1987, 465)*[xxiv] considered clear and unquestionable proof that a third party made an unauthorised communication of information received as an evident abuse. Additionally, the Board in *T436/92*[xxv] found that deliberate intention to harm the other

party and probable knowledge of likely harm from a preconceived breach of confidentiality is evidence of abuse. Applied to the current discussion, reading publications should not be lawful access where the reader masterminded, consented to or conspired to maliciously publish traditional knowledge and/or genetic resources. Overall, the first definition of misappropriation seems to be better because it would leave ample room for the court to assess the facts of each case and determine whether or not there has been misappropriation. The primary loophole with option two is that the diversity of facts that amount to the misappropriation of traditional knowledge and/or genetic resources may lead to the exemption of misappropriation in the guise of lawful exceptions, as in the cases of purchase and read publication analysed above.

Indigenous peoples should avoid creating loopholes via publications, sales, inadvertent disclosure and unprotected genetic resources, their derivatives and traditional knowledge associated with genetic resources.[xxvi] Ultimately, the draft instrument aims to contribute to the protection of genetic resources and traditional knowledge associated with genetic resources within the intellectual property/patent system. This would be achieved through enhanced transparency in patent systems and ensuring patent offices' access to appropriate information on genetic resources and associated traditional knowledge to prevent the erroneous granting of intellectual property/patent rights.[xxvii] It recognises the rights of indigenous communities, the principles of free and prior informed consent and mutually agreed terms in relation to access and utilization of genetic resources and the associated traditional knowledge.[xxviii]

The Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) is another source of guidance on the regulation of synthetic substitution. The recommendations of the multidisciplinary SBSTTA highlighted concerns about synthetic biology as worthy of current attention. The SBSTTA was birthed by Article 25(1) of the CBD, which authorised the creation of a subsidiary body to provide scientific, technical and technological advice to the Conference of Parties (The meeting of the Parties to the Nagoya Protocol) and, as appropriate, its other subsidiary bodies in relation to the implementation of the CBD. Synthetic biology was featured as a distinct subject in SBSTTA recommendations at the 18th SBSTTA meeting held in Montreal, Canada, in June 2014.[xxix] States were requested to adopt a precautionary approach in risk assessment, and scientific testing for commercialisation while the committee worked towards a tentative definition of synthetic biology.[xxx] International organisations like the United Nations Permanent Forum on Indigenous Issues were required to consider the possible implications of synthetic biology on their mandates.[xxxi]

The 2016 SBSTTA Recommendation XX/8, referred to the deliberations of the Ad Hoc Technical Expert Group on Socio-economic Considerations **(**AHTEG) on synthetic biology, which concluded that organisms, components and products of synthetic biology fall within the scope of the CBD and that its three objectives may be affected, both positively and negatively, by living organisms resulting from synthetic biology and non-living components and products of synthetic biology.[xxxii] Additionally, the Conference of the Parties was tasked to clarify the relationship between the use of digital sequence information on genetic resources, access and benefit-sharing.[xxxiii] Regarding, access and benefit sharing, the 2018 SBSTTA Recommendation 22/3 recognised synthetic biology as a rapidly developing and cross-cutting issue, with potential benefits and potential adverse effects vis-à-vis the three objectives of the Convention on Biological Diversity.[xxxiv] There has been significant engagement by stakeholders from the scientific community and governments, but it seems that CBD's core objectives are not likely to be deliberated on and met without reasonable participation by indigenous stakeholders.[xxxv] The end of innovations in synthetic biology and their interaction with traditional knowledge and genetic resources is yet to be seen. Regulation should not be lagging.[xxxvi]

REGULATION OF SYNTHETIC SUBSTITUTION: LESSONS FROM EXISTING LEGISLATIONS

The regulation of derivative works is not new to law.[xxxvii] Copyright and unfair competition, which have regulated allied derivative rights, offer insights into the rationales for the regulation of synthetic substitution. There are principles associated with subsisting intellectual property rights that are neither eroded by the sophistication of innovation nor the passage of time. The substitution of desirable attributes of genetic resources is often fueled by the incentive of obtaining monopolised intellectual property rights like patents. In this section, inspiration will be drawn from intellectual property law towards the regulation of lapses arising from the misappropriation and exploitation of genetic resources and associated traditional knowledge via IP rights. While no IP right or its infringement identically matches Hunata's experience or loss, applicable lessons from IP protection and rationales for the regulation of synthetic substitution would be discussed below:

Lessons from Unfair Competition Law:

Unfair competition frowns at competitive acts designed to reap the rewards of another's hard work. This is a viable rationale on which the regulation of synthetic substitutions may rest. Unfair competition encompasses all unfair measures employed in competition, as detailed in Article 10^{bis} of the Paris Convention.[xxxviii] Article 10^{bis}(2) of the Paris Convention compels Member States to redress unfair acts of competition contrary to honest practices in industrial or commercial matters. Unfair competition covers a wide range of competitive acts, including false claims of a competitor's genetic resources and associated traditional knowledge ownership. The cardinal focus of unfair competition regulation is the protection of the weaker and/or honest party against unfair practices. It caters to the innovative range of unfair competitive acts, currently unregulated by IP law. An instance of the use of unfair competition to address commercial unfairness is *International News Service v. The Associated Press*[xxxix], where a court condemned the defendant's attempt to reap the proceeds of another news agency's information-gathering and the associated expenditure of labour, skill and investment.[xl]

The primary elements of unfair competition required by Article 10bis(2) of the Paris Convention include unfair acts of competition like those highlighted in the last sentence. Secondly, those acts should be contrary to honest practices, as the outlined acts above, apparently are. Finally, such acts should have been carried out in industrial or commercial matters; the commercial relevance of the Hunata's healing vine and the corresponding substitution and marketing decisions of the foreigners bear credence to the commercial setting in which the unfair acts have taken place. Did the foreigners compete fairly with the Hunatas? The similarity in the dominant attributes and use of Hunata's healing vine—Suunarak and the substitute and the use of Suunarak images on pharmaceutical and nutraceutical packages to attract the same international audience and market erodes the foreigners' ignorance of commercial unfairness.[xli] The foreigners have reaped the benefits of centuries of Hunata's hard work.

Lessons from the Protection of Copyright Derivatives:

As a general rule, derivative works derive their claim of ownership from the original work. This rule applies to the protection of traditional cultural expressions. For example, Article 4 of Mauritius' 2014 Copyright Act[xlii] provides that "The protection of any derivative work shall be

without prejudice to any protection of a preexisting work or traditional cultural expression or expression of folklore incorporated in or utilised for the making of such a work." Unfortunately, patent rights, commonly used to exploit TKaGR, do not bear a corresponding obligation to make detailed disclosures underlying their inventions. Neither the triune patent requirements in Article 27(1) of the TRIPs Agreement nor Article 29(1) of the TRIPs Agreement, which deals with disclosure, mandate the disclosure of the genetic origin of the resources that inspired patent innovations. Nonetheless, failure to disclose indigenous communities that have birthed or at least significantly contributed to one's "innovation" belies the patent applicant's claim of invention. Acknowledgment and disclosure are only practical where parties comply with access and benefit-sharing requirements mandated by the CBD and Nagoya Protocol.

The protection of derivative works by copyright is illustrated in translation. Translation is the interpretation of a written work from one language to another. Section 14(a)(v) of the 1957 Indian Copyright Act, for instance, reserves the right to translate a work to the owner of the copyrighted work; hence, a translated work is subject to copyright protection. In *ZAO Askeri-ACCA v. International Accounting Standards Committee Foundations*[xliii],by a standard form license agreement, the defendant foundation (Y), the copyright owner of the International Accounting Standards (IAS), had permitted X to translate a version of the IAS into Russian and publish the translation. The court held that the Russian translation was not Y's publication but was a translation by X with Y's permission. X was the copyright owner of its translation of the IAS.[xliv]The obvious lesson from this case is that the consent of the author is required to create a translation from an original copyright-protected work.

Translation significantly mirrors the challenges of indigenous communities like Hunata. The Spanish recipient of the Spanish version of an English text may never need any reference to the original English text. Likewise, consumers of a substituted genetic resource may not have any need for the natural resource, especially if its use has not been acknowledged. For communities like Hunata, it seems the most painful experience indigenous communities are confronted with is the loss of international market share and relevance. Unlike the example of the Spanish text above, where the translator may find customers among Spanish speakers, leaving the original author to trade with English readers, this is not the case with substituted genetic resources. More often than not, manufacturers of the substituted product target the same international market and audience established by the popularity of indigenous resources like

Suunarak. Synthetic substitution disconnects attention from the origin and owners of the genetic resource and shifts the market from the competitive indigenous resource to the substituted product. It substantially copies genetic resources groomed by indigenous communities and enhanced by traditional knowledge, making natural resources like Suunarak commercially irrelevant. Like copyright derivatives, ownership of genetic resources and associated traditional knowledge should be vested in indigenous communities from which such resources and knowledge of their utility originated.

ETHICAL CONCERNS AND BEST PRACTICES

The SBSTTA, CBD, Bonn Guidelines and Nagoya Protocol have pointed towards the application of access and benefit-sharing principles to inventions and products derived from indigenous genetic resources. Compliance with the CBD and the Nagoya protocol's access and benefit-sharing requirements would have given the Hunatas in the introductory illustration ample opportunity to interact meaningfully with the foreigners and document their respective interests and anticipated benefits as mutually agreed terms. Compliance with prior informed consent, mutually agreed terms and benefit-sharing would be discussed below.

Prior Informed Consent

Access to genetic resources is subject to the prior informed consent of the providing contracting party unless otherwise determined by that Party.[xlv] In other words, where a providing party waives such consent for whatever reason, the other party can have legitimate access without the requirement of prior informed consent.[xlvi] Prior informed consent is not only required to access genetic resources, it is also required to access traditional knowledge.[xlvii] As a result of the dependence of indigenous communities on traditional knowledge, the involvement of indigenous and local communities is necessary when access is sought for traditional knowledge. Article 19(2) of the CBD specifically makes prior informed consent mandatory when genetic resources sought to be accessed would be utilised for biotechnological purposes like synthetic substitution. The providing state bears the responsibility of providing legislative, administrative or policy access application procedures that are transparent, fair and reasonable.[xlviii]

The Bonn Guideline provides a non-exhaustive list of information the user state would provide to facilitate the grant of access to genetic resources.[xlix] To determine whether access would be granted or not, the user state should disclose, among other things, the type of benefits that could arise from the commercial exploitation and other utilization of genetic resources and their derivatives.[l] It seems the same disclosure can be required to determine the grant of access to traditional knowledge. The grant of access should be accompanied by the establishment of clear rules and procedures for requesting and establishing mutually agreed terms.[li] Providing states are required to maintain a dedicated national focal point to address issues arising from applications for prior informed consent, mutually agreed terms and benefit-sharing.[lii] While having a physical office is a standard requirement, setting up a website and maintaining a virtual office is even more practical for international access and inquiries. Hindrances to requests for prior informed consent include the inability to obtain authentic contact details of the providing state, unreasonable and expensive prior informed consent and access procedures. Providing states should be careful to remove unnecessary hurdles to the application for and issuance of prior informed consent.

Mutually Agreed Terms

Article 15(4) of the CBD provides that where access is granted, such grant shall be based on mutually agreed terms and subject to the provisions of Article 15 of the CBD. The requirement of establishing a mutually agreed term is a prerequisite to the grant[liii] of access to genetic resources, traditional knowledge[liv] and their biotechnological derivatives.[lv] Essential terms to be determined and documented in the mutually agreed terms include terms of benefit-sharing and related intellectual properties, rights, a dispute settlement clause, terms on subsequent third-party use and terms on changes of intent, like converting a genetic resource accessed for research purposes to commercial use.[lvi]

Users and providers of genetic resources should be mindful to include provisions on implementation and reporting requirements in the mutually agreed terms.[lvii] This will enhance accountability and fulfillment of the mutually agreed terms. The decision to grant access and the establishment of mutually agreed terms culminate in the issuance of a permit or an equivalent certification.[lviii] The procedure for obtaining mutually agreed terms and the cost implications should be reasonable for users of genetic resources and traditional knowledge. Unconscionable bargains are a common challenge to the establishment of mutually agreed terms. It is important to promote equity and fairness in the negotiation of mutually agreed

terms between providers and users of genetic resources.[lix]Fairness and equity are the cardinal pillars that would support the relationship between the providing and user states while they work towards the realisation of the mutually agreed terms.

Compliance with the Benefit Sharing Requirement:

The core objective of the CBD and the Nagoya Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources,[lx] including those utilised for biotechnological purposes.[lxi] According to Recitals 12 and 17 of the CBD, benefit-sharing arises from the recognition of the close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on biological resources, an acknowledgment of substantial investments made towards the conservation of biological diversity and the broad range of environmental, economic and social benefits accruing from those investments. The Nagoya Protocol, in its Annex, provides guidelines for monetary and non-monetary benefits that may accrue from the exploitation of genetic resources and traditional knowledge.

Parties may develop and implement other relevant international agreements, such as access and benefit-sharing agreements, provided such agreements do not contradict the objectives of the CBD and Nagoya Protocol.[lxii] In other words, a contradictory implementation of benefit-sharing would not amount to compliance with the CBD and Nagoya Protocol. A common issue that may arise from benefit-sharing is concern about profit-splitting where an invention involves the admixture of more than one access and benefit-sharing-mandated component. Where multiple access and benefit-sharing requirements would have to be fulfilled to commercialise an invention, the user of such genetic resources and associated traditional knowledge should consider proportional benefit-sharing among the relevant provider states or communities. It is wiser to fulfill access and benefit-sharing obligations than to amass "profit" which can be ruined by adverse claims.

CLOSING

A different outcome is possible. Government officials, traditional chiefs from Hunata and a foreign delegation meet at the designated Hunata government office as scheduled. Both parties exchange their intentions and interests. The Hunatas: the acknowledgment of traditional origin,

developmental needs and a fair share of benefits arising from Suunarak and associated traditional knowledge exploitation. The foreigners have sole permission to exploit Suunarak and associated traditional knowledge in compliance with the mutually agreed terms. Several months later, parties meet again at the same venue at the Hunatas' request. The foreigners had made progress in research and development. Barely one month after its launch, the new healing supplement based on mimicked Suunarak-properties had gained wide acceptance in international markets. The Hunatas cannot conceal their gratitude; they have received the first installment of their financial benefit as agreed in the mutually agreed terms and the construction of the modern tertiary institution is underway as promised by the foreigners. The foreign delegation would soon discover that the Hunatas are not only bio-rich, but they are also very generous. The Hunatas announced their intention to grant the foreign delegation access to their secret, natural healing archive on similar terms as the Suunarak. The archive contains over three hundred plant and animal resources and tested traditional knowledge on their usage. Herbal healers are also assigned to aid the foreigners in their research and development. The foreign delegation had gotten much more than they bargained for. The Hunatas' traditional knowledge and biopackage would keep them ahead of their competitors for decades. Centuries of costly hard work, laboratory tests and field research would be averted on a platter of trust.

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[ii] Fictitious place.
[iii] Fictitious plant.
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[xiii] Considerations on the safe use, handling and transfer of living-modified organisms fall within the scope of the 2000 Cartegena Protocol; however, risk assessment and the safety of engineered genetic resources are not the focus of this article. See Cartagena Protocol on Biosafety to the Convention on Biological Diversity 2000 Convention on Biological Diversity 1760 UNTS 79; 31 ILM 818 of 5 June 1992

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[xix] ibid

[xx] ibid

[xxi] ibid Article 1 - Option 1 "Misappropriation" is the [acquisition] [utilization] of genetic resources [and] [or] [traditional knowledge associated with genetic resources] without the [free] [prior informed] consent of [those who are authorized to give [such] consent] [competent authority] to such [acquisition] [utilization], [in accordance with national legislation] [of the country of origin or providing country].]
Option 2 ["Misappropriation" is the use of genetic resources and/or [traditional knowledge associated with genetic resources] of another where the genetic resources or traditional knowledge has been acquired by the user from the holder through improper means or a breach of confidence which results in a violation of national law in a provider country. Use of genetic resources and [traditional knowledge associated with genetic resources] that has been acquired by lawful means, such as reading publications, purchase, independent discovery, reverse engineering and inadvertent disclosure resulting from the holders of genetic resources and [traditional knowledge associated with genetic resources] failure to take reasonable protective measures, is not misappropriation.]

[xxii] United States Patent and Trademark O"ce, Board of Patent Appeals and Interferences 29 April 2008, Appeal 2007-3938 Ex Parte POD-NERS LLC 30-31; United States Court of Appeals, Federal Circuit 10 July 2009, 2008 1492, In Re Pod-Ners LLC

[xxiii] Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000

[xxiv] T 0173/83 (Antioxydant) 01-07-1985 [6]

[xxv] T 0436/92 (Cutting Tools/ACMC) 20-03-1995 [5.2]

[xxvi] Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore "Consolidated Document Relating to Intellectual Property and Genetic Resources" Forty-Seventh Session Geneva, 1 May 2023, Article 1
https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_47/wipo_grtkf_ic_47_6.pdf

[xxvii] Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore "Consolidated Document Relating to Intellectual Property and Genetic Resources" Forty-Seventh Session Geneva, 1 May 2023, Article 2
https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_47/wipo_grtkf_ic_47_6.pdf

[xxviii] ibid Recital 15 and 4 respectfully.

[xxix] SBSTTA Recommendation XVIII/7, "New and Emerging Issues: Synthetic Biology" 23 - 28 June 2014 https://www.cbd.int/recommendation/sbstta/?id=13332

[xxx] ibid

[xxxi] ibid

[xxxii] SBSTTA Recommendation - XX/8, "Recommendation Adopted by the Subsidiary Body on Scientific, Technical and Technological Advice - Synthetic Biology" 25-30 April 2016 https://www.cbd.int/doc/recommendations/sbstta-20/sbstta-20-rec-08-en.pdf

[xxxiii] ibid

[xxxiv] SBSTTA Recommendation - 22/3, "Recommendation Adopted by the Subsidiary Body on Scientific, Technical and Technological Advice - Synthetic Biology" 2-7 July 2018 https://www.cbd.int/doc/recommendations/sbstta-22/sbstta-22-rec-03-en.pdf; The 2022 SBSTTA Recommendation - 24/4 was a compilation of earlier recommendations - SBSTTA Recommendation - 24/4, "Recommendation Adopted by the Subsidiary Body on Scientific, Technical and Technological Advice - Synthetic Biology" 14-29 March 2022 https://www.cbd.int/doc/recommendations/sbstta-24/sbstta-24-rec-04-en.pdf

[xxxv] Felicity Keiper and Ana Atanassova, "Regulation of Synthetic Biology: Developments Under the Convention on Biological Diversity and Its Protocols" 18 https://www.frontiersin.org/articles/10.3389/fbioe.2020.00310/full

[xxxvi] The possibility of using and exchanging DNA sequence information without accessing the source physical resource may result in the misappropriation of genetic resources, which was not anticipated by CBD and Nagoya Protocol ABS requirements. In light of such inventions, should genetic resources be limited to physical resources? A redefinition of the scope of genetic resources is due. Felicity Keiper and Ana Atanassova,

"Regulation of Synthetic Biology: Developments Under the Convention on Biological Diversity and Its Protocols" 17 https://www.frontiersin.org/articles/10.3389/fbioe.2020.00310/full

[xxxvii] The regulation of synthetic biology, specifically the use of Deoxyribonucleic acid (DNA) is also not new to law. For instance, the American Bar Association in 2007 approved a set of criminal justice standards on the collection, preservation and use of DNA evidence. See - American Bar Association, ABA Standards for Criminal Justice: DNA Evidence, 3d ed. 2007 https://www.americanbar.org/groups/criminal_justice/publications/criminal_justice_section_archive/crimjust_standards_dnaevidence/]

[xxxviii] Paris Convention for the Protection of Industrial Property of 20 March 1883, 828 UNTS 305, amended on 28 September 1979

[xxxix] 248 US 215 [1918]

[xl] ibid 239-240

[xli] Inspired by the decision of the Indian Supreme Court in Cadila Health Care Ltd v Cadila Pharmaceuticals Ltd. AIR 2001 SC 1952 [1964]

[xlii] Mauritius Copyright Act 2014 (Act No 2 of 2014)

[xliii] [2004] EWHC 2939

[xliv] ibid [49]

[xlv] Article 15(5) CBD

[xlvi] Article 7 of the Nagoya Protocol

[xlvii] ibid

[xlviii] Article 15(7) of the CBD; Article 6(2-3) of the Nagoya Protocol

[xlix] Bonn Guideline Paragraph 36

[l] Bonn Guideline Paragraph 36(L)

[li] Article 6(3)(g) of the Nagoya Protocol

[lii] Article 13(1)(a) of the Nagoya Protocol

[liii] Article 15(4) of the CBD and Article 5(1) of the Nagoya Protocol have similar provisions.

[liv] Article 7 of the Nagoya Protocol

[lv] Article 19(2) of the CBD

[lvi] Article 5(1) of the Nagoya Protocol

[lvii] Article 17(1)(b) of the Nagoya Protocol

[lviii] Article 14(2)(c) of the Nagoya Protocol

[lix] Recital 9 of the Nagoya Protocol

[lx] Article 1 of the Nagoya Protocol; Article 1 of the CBD

[lxi] Article 19(2) of the CBD; Article 5(1) of the Nagoya Protocol

[lxii] Article 4(2-3) of the Nagoya Protocol