



American Intellectual Property Law Association

January 22, 2024

The Honorable Kathi Vidal
Under Secretary of Commerce for Intellectual Property and
Director of U.S. Patent and Trademark Office
U.S. Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314
Via Online Submission: Regulations.gov

Re: Comments of AIPLA on WIPO IGC Negotiations on Genetic Resources and Associated Traditional Knowledge, 88 Fed. Reg. 204 (October 24, 2023), Docket No. PTO-C-2023-0019

Dear Director Vidal:

The American Intellectual Property Law Association (“AIPLA”) appreciates the opportunity to offer the following comments in response to the October 24, 2023 Notice on WIPO IGC Negotiations on Genetic Resources and Associated Traditional Knowledge.

Founded in 1897, the American Intellectual Property Law Association is a national bar association of approximately 7,000 members including professionals engaged in private or corporate practice, in government service, and in the academic community. AIPLA members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, trade secret, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property. Our mission includes helping establish and maintain fair and effective laws and policies that stimulate and reward invention while balancing the public’s interest in healthy competition, reasonable costs, and basic fairness.

The World Intellectual Property Organization (WIPO) Intergovernmental Committee (IGC) on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore was established in 2000 and its first session was held in 2001. In 2022 the WIPO members voted to convene a diplomatic conference in 2024. The USPTO published a Request for Comments in view of the upcoming diplomatic conference which will take place in May 2024 at WIPO headquarters in Geneva, Switzerland.

AIPLA supports strong, efficient, transparent, and quality patent systems as they function to incentivize innovation. The diplomatic conference seeks to create a mandatory disclosure requirement¹ in PCT applications for the origin or source of genetic “resources” (GRs) and

¹ Many countries already have such requirements when you file patent applications directly in them (e.g., Switzerland, Brazil, and China), but there is currently not a PCT requirement. AIPLA has sent representatives to several WIPO IGC meetings in Geneva, Switzerland. Some have read statements on behalf of AIPLA, emphasizing that AIPLA is opposed to a mandatory disclosure requirement for the source of a genetic resource (GR) in PCT applications.

“traditional knowledge” (TK) “associated with” GRs.² However, the benefits of the proposed disclosure requirements are unclear, substantial, and likely outweighed by the burdens they would add. While the stated objective is to “enhance the efficacy, transparency and quality of the patent system” the underlying issue is to facilitate access and benefit sharing (ABS) of genetic resources. There is a need therefore, to proceed with caution, and to more deliberately and thoroughly consider the potential detrimental impact of the text under consideration.

Assuming, *arguendo*, the proposed patent disclosure requirement (PPDR) is adopted, *which it should not be*, the PPDR must be qualified (i.e., formal, appropriately limited in scope, not retroactive, not incurable, etc., as discussed in detail as follows). For example, the limits of such a PPDR must be explicitly delineated (e.g., the requirement is *solely* a formal one, patent validity is in no way affected, benefit sharing is not concerned, correction is available, etc.). The current disclosures of the USPTO and PCT (i.e., enablement, written description) are sufficient to ensure transparency and legal certainty.

Section I – Observations and Experiences

1. Have you or any of your members, partners, co-workers, legal representatives or clients filed for patent protection in a jurisdiction that requires disclosure of the source of genetic resources and associated traditional knowledge in a patent application seeking protection for inventions based on genetic resources (hereafter “patent disclosure requirement”)? A list of disclosure requirements can be found here: https://www.wipo.int/export/sites/www/tk/en/docs/genetic_resources_disclosure.pdf. If yes, to the extent possible, please identify the jurisdiction(s) that required disclosure and describe the circumstances and your experiences associated with satisfying the patent disclosure requirement in that jurisdiction.

Applicants file, and must continue to be able to confidently pursue, patent applications to protect investment in new innovations in various jurisdictions of relevance to them.³ As to countries already having disclosure requirements (DRs) as to the *source* of a genetic resource in a patent application, AIPLA is unaware of any comprehensive, published reports of their usefulness or value. The WIPO Summary Table, which includes three dozen countries already having such laws, is “non-exhaustive” and therefore, under-representative of the numbers of nations where extensive, stringent DRs are already in force. For example, the United States (US) is not included in the WIPO Table. The US has applicable stringent and robust disclosure requirements in the form of written description and enablement, materiality requirements, and other laws in addition to patent laws and procedures. In addition, patent systems require that prior art not be patented, including genetic resources or traditional knowledge.

Jurisdictions in which patent protection is sought throughout the world require disclosure of the invention, and this includes inventions related to genetic resources or traditional knowledge. For example, genetic innovations are frequently described in extraordinarily detailed form by

² The definition of GRs in the Chair’s Text is vague, and there is no definition for TK associated with GRs. The Chair’s Text includes nebulous concepts that will only introduce confusion, more work, and more costs to applicants.

³ Including jurisdictions corresponding to those listed in WIPO’s Disclosure Requirements Table Available at https://www.wipo.int/export/sites/www/tk/en/docs/genetic_resources_disclosure.pdf.

their sequences, in written form within the patent application’s description, within illustrations and/or figures, etc., and when appropriate, include attribution of materials, samples, specimens, starting materials, etc. of potential use with patentable innovations.

Some AIPLA members report⁴ having sought patent protection “rarely” in jurisdictions that require disclosure of the source of genetic resources and/or associated traditional knowledge (GRTK). Such aversion already disincentivizes innovation and the positive outcomes of obtaining a patent to protect new innovations, as further detailed in response to question 6.

2. How would you characterize the level of difficulty in complying with the aforementioned patent disclosure requirement? Please describe any anticipated or unanticipated problems that resulted or may result from the disclosure itself or the associated requirement for the disclosure.

Direct and indirect costs of the PPDR are significant. The confusion and ensuing costs would be considerable and would suppress innovation. There would also be confusion because the scope and content of the PPDR is unclear and in instances, internally inconsistent. Important terms are undefined and unclear. Further, the Chair’s Text⁵ does not reflect its intention as expressed in the notes. It is unclear how the proposed patent disclosure requirement would be implemented, and it is unclear how the PPDR would function with existing law and procedure.

In limited numbers of countries, solely formal, ministerial DRs add to direct and indirect costs. But these added DRs are somewhat less burdensome with which to comply (e.g., Brazil, China, and Ecuador) compared to the PPDRs, for instance, when the DRs are explicitly limited in scope (e.g., Brazil requires the disclosure of associated GRTK from Brazil, if it is unequivocally known). How the PPDR would be implemented by nations already having such preexisting formal requirements has not been addressed, but must be.

Indeed, the PPDR under consideration by the IGC would require significantly more burdensome compliance. The vague or absent definition of genetic resources and traditional knowledge in the Chair’s Text make it impossible to ascertain whether there is relevant GRTK to disclose in a given case, and if so, the metes and bounds of such GRTK.

A mandatory PPDR⁶ of a genetic resource in a PCT application, for example, would be unduly burdensome to patent applicants. For example, in some instances it could require a significant

⁴ AIPLA’s Genetic Resources and Traditional Knowledge Task Force sent out a survey to its members and to the Biotechnology, Chemical Practice, and Food & Drug Committees. Many of the answers to Section I are based on responses to the survey questions.

⁵ Document WIPO/GRTKF/IC/43/5 available at: https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_43/wipo_grtkf_ic_43_5.pdf. Substantive Articles 1-9 of the Chair’s Text as revised in the Special Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, held in Geneva on September 4–8, 2023 are available as an Annexe to Document WIPO/GRTKF/IC/SS/GE/23/4 available at https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=620066. Revisions made in Articles 1-9 were minor and included replacing “GR” with “genetic resources” and “Associated TK” with “traditional knowledge associated with genetic resources.”

⁶ The Chair’s Text definition in Article 2 for “source of genetic resources” states: “refers to any source from which the applicant has obtained the GRs, such as a research centre, gene bank, the Multilateral System of the

number of legal hours to conduct diligence, resulting in delays, significantly increased costs, and ultimately leading to more confusion. Depending on what might be required in the PPDR, which is unclear, it may be difficult or impossible for an applicant to determine the *original* source of any genetic resource. This means all industries that would possibly use genetic resources would have significant difficulty understanding what is required by the PPDR.

3. *Please describe how your experiences with the patent disclosure requirement in the aforementioned jurisdiction or other jurisdictions across the globe affect your business. Where possible, please identify the jurisdiction as well as any relevant details of the patent disclosure requirement.*

AIPLA members that were surveyed report current national GRTK disclosure requirements complicate their practices. This is due, for example, to the difficulty in defining what is and is not being required, in some instances requiring a significant number of legal hours to conduct diligence. It was noted that some national GRTK disclosure requirements, such as the one in Switzerland,⁷ can be avoided altogether by filing patent applications with regional offices that lack the requirement. Another option is to maintain the technology as a trade secret, which would deny the public the benefit of public knowledge sharing.

4. *Please identify any type of patent disclosure requirement, in the context of Genetic Resources and Traditional Knowledge, you believe is necessary and any benefits or detriments stemming from a patent disclosure requirement.*

The current requirements to fully disclose the invention in such a way to enable the reader to practice the invention are sufficient.⁸ Assuming *arguendo* the PPDR is added, *which it should not be*, the PPDR must be understandable, limited in scope, clear, necessary, practical, etc.

For example, the limits of such a PPDR must be explicitly delineated (e.g., the requirement is *solely* a formal one, patent validity is in no way affected, benefit sharing is not concerned, correction is available, etc.).

AIPLA is opposed to any PPDR that would be retroactive or could result in or implicate revocation or unenforceability of a patent. Without this assurance, investments already made and incentives to continue to innovate would be dramatically impacted. Applicants should be given fair opportunity and time to supplement or correct disclosures relating to the source of such genetic material.

Most jurisdictions require patent applicants to submit specimens of material that are required to practice the invention in a publicly available depository, for example, under the Budapest

International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), or any other ex situ collection or depository of GRs.” Stating where an item was purchased or from where it was obtained should satisfy the disclosure requirement for the source of a genetic resource, without a need to investigate its original source. If a source is not known, an applicant should be able to simply state that it is not known.

⁷ An applicant may file a patent application in the EPO and upon grant validate in Switzerland, thus avoiding a patent disclosure requirement that would have to be met if filing directly in Switzerland.

⁸ Article 5 of the Patent Cooperation Treaty (PCT) requirement states that “[t]he description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.”

Treaty.⁹ This practice is in many cases necessary to enable others to use the invention. How this practice is impacted by the PPDRs is guesswork.

It is not disputed that new PPDRs would impose administrative and financial costs on both patent applicants and patent offices, but the lack of clarity and potential confusion caused by such PPDR is alarming. Many nations have laws that would address attribution of sources of materials, and patent systems that provide for transparency through a *quid pro quo* – where disclosure of an invention rewards the applicant with a patent and rewards the public with disclosure of the invention and how to practice the invention.¹⁰ This contribution of knowledge by innovators is forever, whereas the lawful monopoly the patent system provides is extraordinarily limited.

AIPLA is concerned that the PPDR will add risk, such as increased numbers of unfounded bio-piracy claims, will jeopardize trade secret protections, and will add little or nothing with respect to promoting the validity of patents, etc.

5. *Please identify any instances where you are aware of patent rights—yours, someone you represent or another party's—being impacted by the existence of a patent disclosure requirement, including but not limited to, any loss of rights, additional costs or other negative impacts.*

Disclosure requirements such as written description and enablement are already required by the patent system. Each requirement comes at indirect and direct cost. Adding the PPDRs for PCT applications would unnecessarily add burden, create confusion, stifle innovation, and detrimentally impact patent systems.

6. *Please share whether or not the existence of a patent disclosure requirement was (or is) a consideration in pursuing patent protection on an invention in a given jurisdiction. Please provide details in relation to relevant technologies where this may be a consideration as well as alternative actions you took or would take in lieu of pursuing patent protection in the jurisdiction.*

AIPLA members surveyed report that jurisdictions with the PPDR should be avoided. It is unnecessary. Members report favoring jurisdictions and offices that do not have additional, poorly understood patent disclosure requirements. This is at least one reason that very few patent applications are filed in Switzerland directly, instead of going through the European Patent Office and validating in Switzerland.¹¹ If a GRTK requirement cannot be understood, and therefore cannot be met, it is possible the patent system would be avoided altogether, perhaps in favor of trade secret protection. It is also possible that applicants would avoid the PCT in favor of the Paris Convention to avoid a mandatory disclosure requirement in PCT applications.

⁹ See <https://www.uspto.gov/ip-policy/patent-policy/budapest-treaty#:~:text=The%20Budapest%20Treaty%20eliminates%20the,treaty%20members'%20national%20patent%20laws>.

¹⁰ Article 5 of the Patent Cooperation Treaty (PCT) requirement states that “[t]he description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.”

¹¹ Statistics for 2017-2022 are available at: <https://www.ige.ch/en/services/publications/statistics/patent>.

Some have expressed concern that GRTK patent disclosure requirements will include excessive, rigid, and/or redundant regulations. Also, that there is no clear pathway for engaging in benefit sharing in jurisdictions that require it (e.g., Eli Lilly slides presented by Manisha Desai at WIPO IGC).¹²

It should be emphasized that Article 1 of the Chair’s Text does not mention access and benefit-sharing (ABS) as an objective of the instrument. The Notes on Article 1 state that those issues are already dealt with in the Convention on Biological Diversity (CBD) and the Nagoya Protocol. This is not enough – assuming *arguendo* the PPDR is adopted, it should be explicitly stated within the agreement that ABS is excluded.

The goal of the patent system is a critical one – to incentivize disclosure of inventions to the public forever in return for a lawful monopoly for a very limited time. The alternative is concealing the invention as a trade secret, which is generally considered not preferred or possible. Efforts such as the PPDR that will likely increase the difficulty of obtaining a patent should be avoided, particularly when current disclosures of the USPTO and PCT (i.e., enablement and written description) are sufficient to ensure transparency and legal certainty.

Section II – Need and Effectiveness of a Patent Disclosure Requirement for Genetic Resources and Traditional Knowledge

7. Do you believe the patent system- through the use of a patent disclosure requirement in jurisdictions where such requirement exists- has been an effective regulator of access and benefit sharing for genetic resource? Please explain.

To determine whether the patent system has been an effective regulator of access and benefit sharing for genetic resources, AIPLA believes that additional studies and more data must be generated to determine whether patent disclosure requirements – as they relate to genetic resources and associate traditional knowledge – can be an effective regulator of access and benefit sharing. Studies showing the efficacy of such regulations, or lack thereof, would help to determine the balance between access and benefit sharing and the cost of implementation and maintenance of such regulations. The few reports that have been published are equivocal, at best, and in some instances have been contradicted by others.

In the US, the patent system and patent disclosure requirements are not designed nor intended to regulate access and/or benefit sharing of any resource, including genetic resources. Under the US Constitution, the purpose of a patent system is to promote the progress of science and useful arts by securing for a limited time a governmental grant of exclusivity in and to discoveries that have utility and are novel and unobvious. As a result, the US patent system provides a mechanism to limitedly protect new innovations and investment in innovation and creativity to advance science. The US Patent Act, however, does *not* regulate access to genetic

¹² Available at:

https://www.wipo.int/edocs/mdocs/tk/en/wipo_ip tk_ge_15/wipo_ip tk_ge_15_presentation_manisha_desai.pdf
and
https://www.wipo.int/edocs/mdocs/tk/en/wipo_ip tk_ge_16/wipo_ip tk_ge_16_presentation_7desai.pdf.

materials or track the sharing of benefits for any resource or related technological advancement. Without investigations into systems already established (such as that in Switzerland), or soon to be put into place, it is unknown whether a mandatory disclosure requirement administered as part of the patent system can be an effective regulator of access and benefit sharing.

8. *Do you believe that a patent disclosure requirement would enable interested groups to locate information on the use of a country's genetic resources?*

No, particularly not beyond what is already required to be disclosed. It is theoretically possible that a mandatory requirement for the disclosure of genetic resources and associated technology could help to locate information on the use of a country's genetic resources. This is unproven and speculative at best. In fact, the very opposite could be true.

However, AIPLA believes that the most effective mechanism to locate information on future uses of a country's genetic resources is to utilize, or alternatively implement, national laws and regulations that govern the disclosure and use of genetic resources and associated traditional knowledge. Such laws should be clear, and any disclosure requirement should be unambiguous.

9. *Where a claimed invention is based on genetic resources, please identify the appropriate range of subject matter of genetic resources that should be within the scope of a disclosure requirement.*

Unfortunately, it is not possible to meaningfully respond to this question, as there is lack of clarity (e.g., what is meant by "based on" a genetic resource, what is a "resource," etc.). As noted in the Chair's comments to Article 2 of the Chair's Text, there is currently divergence in what activates an obligation to disclose (a "trigger") at national and regional levels.¹³ For example, the Chair acknowledges various examples of such divergence where the claimed invention is: "directly based on, based on, based on or derived from, is the basis of, ..." a genetic resource. This is impossible to understand.

Under the US Patent Act, disclosure of the basis of an invention is not required unless such basis is relevant and material to the patent claim. If not, the patent applicant is not obligated to teach how he/she arrived at the invention. The patent applicant must describe and enable how to make and use the invention and provide known prior art that affects novelty and obviousness of the patent claim.

Therefore, if a genetic resource and/or associated traditional knowledge is relevant and knowledge of it is material to the patentability of a claimed invention, this information is already obligated to be disclosed to the patent office, for example, as prior art, prior acts, or otherwise. Beyond this, prior to burdening the US Patent and Trademark Office with unclear proposed regulations related to the disclosure of genetic resources and traditional knowledge, other mechanisms should be considered.

¹³ Even the Federal Register notes that there has yet to be agreement on a definition of the "trigger."

10. Please comment on the effectiveness of the following options relating to disclosure of genetic resources and/or traditional knowledge associated with genetic resources in a patent application:

a. Disclosure when genetic resource information is material to patentability.

All necessary information, including genetic resource-type information, *relevant* and *material* to patentability is effective in assisting the patent examiner in their determination of a proposed patent claim.

b. Voluntary disclosure of genetic resource information.

Any disclosure of the source of genetic material should be limited, clear, practical, and voluntary, etc. when the resource is not material to patentability.

c. Disclosure requirement if the genetic resource information is known

Patent disclosure requirements are one of the many possible legal mechanisms for disclosing and understanding the utilization of genetic resources and traditional knowledge. Other options should also continue to be used for the benefit of all. Therefore, at best, a patent disclosure requirement may potentially help to address, at least theoretically and partially, an understanding of uses of genetic resources and associated traditional knowledge. This is not best accomplished by adding on additional, unnecessary requirements to patent systems. Rather, this should be legislated, in accordance with importance, relevance, and local practice, at a national or regional level. It should not be done as an all-encompassing, pervasive, and sweeping international instrument. It must be done with legal clarity, to avoid disrupting collaboration and the patenting of inventions.

d. Mandatory disclosure requirement in all instances when an invention is based on genetic resources

An unclear, unprecedented, and unnecessary legally binding obligation placed on all countries in a multilateral system, to adopt and harmonize patent disclosure requirements, would be ineffective at best, and potentially stifle the benefits of innovation. Existing patent disclosure laws already aid in maintaining global justice, fairness, and equity with regards to genetic resources and associated traditional knowledge.

The means to assist in fairness and equity is to govern access of genetic resources and associated traditional knowledge on a *national* level. National laws are flexible and based on the concerns of the population, their leadership, and legislative bodies.

e. Disclosure of access and benefit sharing compliance

Article 1 of the Chair's Text does not mention access and benefit-sharing (ABS) as an objective of the instrument. The proposed PPDR should not include ABS. Any such instrument should explicitly state this is out of scope.

f. Compliance/non-compliance with a disclosure requirement

Article 1 of the Chair's Text does not mention invalidity as an objective of the instrument. The proposed PPDR should not include invalidity. Any such instrument should explicitly state this is out of scope.

11. Please describe your views on what trigger mechanism should be used, if any for a patent disclosure requirement pursuant to the Chair's text or the consolidated text.

The Chair's Text is uncertain. It apparently refers to a PPDR to be adopted and regulated on a national level without identifying its necessity, scope, administration, operation, guidance, guardrails, etc.

Without clarification the PPDR is not necessary and is unworkable.

12. Please describe your views on what a patent applicant should be compelled to disclose in a patent application in the context of a patent disclosure requirement

Unless the source of the genetic material has absolute and unequivocal materiality, a mandatory disclosure requirement will increase risks to all applicants who use genetic materials.

Disclosure of the source of a genetic resource (for example, where it was purchased) should be sufficient. An applicant should not have the burden of investigating the origin of a genetic resource.

13. Please describe your views on whether a patent disclosure requirement should include provisions that impact the grant or the validity and enforceability of a patent in cases of non-compliance with a disclosure requirement.

AIPLA opposes any impact on the grant or validity/enforceability of a US patent based solely on non-compliance of a mandatory disclosure requirement of the source of a genetic resource or associated traditional knowledge.

14. Please describe your views on the working text from an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources, which has been approved for consideration by the Diplomatic Conference. Please describe recommendations, if any, for additions, deletions or changes that you would recommend to Articles 1 through 9 ("substantive articles") from the Chair's text and Articles 10 through 23 ("administrative provisions and final clauses") drafted by the WIPO Secretariat, including whether any language from the "consolidated text," a previous working text in these discussions, should be incorporated into or replace the current working text. These texts can be found at the links below:

a. Current Working Text Substantive Articles ... (Articles 1 through 9 from the WIPO IGC "Chair's text"), as revised in the Special Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, held in Geneva on September 4–8, 2023, is included as the Annex to document

WIPO/GRTKF/IC/SS/GE/23/4 on the Decisions adopted by the committee on genetic resources and associated traditional knowledge, which can be found on the WIPO website, https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=620066.

The Chair admittedly notes that currently there is a divergence in mandate for disclosure (a trigger) at the national and regional levels. This is problematic for several reasons. First, the Chair maintains that the divergence creates legal uncertainty in compliance of the mandatory disclosure requirement. Second, variations in the trigger by jurisdiction will raise the cost of compliance. Third, risk of non-compliance will be greater if the trigger is not uniformly implemented. Fourth, leaving the definition of what is traditional knowledge to individual nations creates a mandate for disclosure that in and of itself is ambiguous. While it is true that divergence in triggers at the national level will create limitless variations in implementation, there is no way around adoption and/or enforcement of such a mandate but on a national level. The trigger should be unequivocal and certain. Anything less than “absolute and unequivocal materiality to patentability” or absolute and unequivocal “materially based on” should *not* be a trigger.

As to the Chair’s Text, the objectives in Article 1 of the PPDR are stated as being to enhance transparency and quality of the patent system and prevent patents from granting erroneously. This is not what would be accomplished.

b. Current Working text “administrative provisions and final clauses” are contained in GRATK/PM/2, which can be found on the WIPO website, https://www.wipo.int/edocs/mdocs/diplconf/en/gratk_pm/gratk_pm_2.pdf, with a minor revision to delete “to advise it on the matters referred to in Articles [7] and [9], and on any other matter” in Article 11.2(e), as reflected in Summary Report of the Preparatory Committee, which can be found on the WIPO website, https://www.wipo.int/edocs/mdocs/diplconf/en/gratk_pm/gratk_pm_5.pdf.

Regarding Article 18 of document GRATK/PM/2, the instrument should not enter into force unless all eligible parties have ratified the instrument.

15. Please describe whether you believe any additional requirements, in particular a mandatory disclosure requirement relating to genetic resources and associated traditional knowledge, would negatively impact your patent filing strategy in overseas markets, your ability to protect innovation or your business and investment strategy.

There is no doubt the PPDR would negatively impact costs, filing strategies, protection of innovation, consideration of opportunities to protect innovation, and business and investment strategies. AIPLA is of the view that the ambiguous and unascertainable risks of infraction, and uncertainty regarding obligations imposed on patent applicants will lead to questioning, reconsideration, abandonment of potential projects, etc.

Innovation is costly. Collaboration(s) involving the limitless scope of materials covered by the PPDR will be impacted.

Section III – Need and Effectiveness of Sui Generis Exclusive Rights, Intellectual Property Rights, or Other Methods for Protecting Traditional Knowledge and Traditional Cultural Expressions

16. Please describe your views and experiences regarding the use of sui generis exclusive rights to protect traditional knowledge and traditional cultural expressions.

AIPLA views many of the *sui generis* proposals¹⁴ as contrary to the policy goals of existing intellectual property systems around the world. AIPLA is concerned that the proposals could have negative societal effects.

Existing intellectual property systems reward the creator of an innovative idea, while some of the *sui generis* proposals reward non-creators based on something else. Thus, there is a risk of reduced incentive to create in such *sui generis* proposals. Rather, they risk creating an incentive to claim broadly that certain ideas and expressions originated from a particular place, or from a particular group of people, geographic region, or culture. Such incentives seem to have a basis in factors others than the exchange of knowledge that could otherwise foster individual innovation, broaden individual perspectives, and spark individual creativity.

Existing intellectual property systems (not just Western systems, but systems found globally) balance temporary exclusivity with perpetual revelation. This provides a benefit to society as a whole and to the individual holder of the intellectual property. The *sui generis* proposals mentioned above would create perpetual exclusivity, and no requirement to divulge or disseminate knowledge. The unintended consequence will be to stymie the dissemination of such knowledge for the greater good of society, which will hinder the expansion of its collective intelligence.

Some of the proposals would restrict or prohibit the dissemination of knowledge that is currently publicly available. AIPLA is concerned that such prohibitions could be difficult if not impossible to enforce and will have a chilling effect on freedom of expression.

The proposals would allow certain individuals in indigenous groups the exclusive right to use traditional knowledge and cultural expression, but some indigenous groups have no official membership, and there is uncertainty as to whether a given individual is a member. In addition, certain indigenous groups decide for themselves who and what qualifies for inclusion within their group, and who and what does not qualify, without any consistency amongst the various groups nor formal codification for qualification. This could create uncertainty as to who has the right to use the given traditional knowledge and cultural expression. These decisional outcomes might vary inconsistently from one group to another.

Many forms of cultural expression and knowledge that are presently worldwide were previously associated with people indigenous to certain regions of the world (e.g., maize and tobacco cultivation from North America). Granting exclusivity over these forms of cultural expression would be profoundly disruptive to global culture that has already assimilated these expressions,

¹⁴ See for example <https://www.intepat.com/blog/a-sui-generis-system-of-ip-protection-for-traditional-knowledge/>.

transformed them, and/or made derivative works based upon them under the existing intellectual property paradigms including the concept of a public domain.

Cultural exchange is the primary mechanism by which disparate groups come to understand and appreciate one another. Many of the proposals could limit or curtail certain culture exchange between certain groups, maintaining or increasing divisions between them.

17. Please describe your views and experiences regarding the use of intellectual property rights to protect traditional knowledge and traditional cultural expressions.

Existing trademark law can be used to protect traditional knowledge and traditional cultural expressions (TKTCE). Indigenous groups can create and register trademarks and certification marks that indicate the origin of products of TKTCE as coming from their groups. As an example, currently the Navajo Nation owns trademark registrations for NAVAJO related to several classes of goods that are described as “manufactured by the Navajo Nation or its individual members.”

Indigenous groups can “defensively publish” TKTCE to prevent others from wrongfully obtaining intellectual property rights over the TKTCE.

Copyright has also been used to protect specific works that could be considered to embody TKTCE. However, copyright cannot be used to protect ancient TKTCE, nor can it be obtained by someone other than the creator of the TKTCE.

Geographical Indications can be used to differentiate competing goods embodying TKTCE, defined in TRIPS, Article 22.1 as “indications which identify a good as originating in the territory of a member [of the World Trade Organization], or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin.”

For certain jurisdictions, database rights may be used to assist in the identification, preservation, and mechanism for obtaining protection for TKTCE.

18. Please describe your views and experiences regarding the use of means or methods other than sui generis exclusive rights or intellectual property rights to protect traditional knowledge and traditional cultural expressions. Among other means and methods, this could include soft law, such as declarations, recommendations, best practices, toolkits, and voluntary codes of conduct.

Systems in some jurisdictions of “geographic indications” protect subject matter that in some cases could be viewed as a form of TKTCE. This is true where a product made in a certain geographical area is made by indigenous people in that area using traditional knowledge. In some countries, these merely inform the consumer of a genuine product of the region, in others it is a crime to label a product that is not from the region in a way that could indicate it is from the region. These sometimes effectively protect TKTCE, although that is not their intended purpose.

Unfair and deceptive trade practice laws also can provide protection to TKTCE by preventing unscrupulous trading off and misrepresentations of authenticity.

19. Please provide your recommendations regarding how best to address unauthorized uses of traditional knowledge or traditional cultural expressions.

AIPLA recommends use of local law, in accordance with the local interests, preferences, concerns, culture, etc. For example, certifications of indigenous origin could be asserted and allowed to be challenged by others. Such system could require official deposition, identification, detailed cataloguing, and approval of a material for certification. For example, such a system could be administered by indigenous groups, by national governments, or by an international body in accordance with law protecting their lands and ecosystems. The system could optionally be legally enforceable by the indigenous group or by the government. Coupling such certifications with strong unfair and deceptive trade practice laws would enable protection of TKTCE while also protecting consumers.

Thank you for the opportunity to provide our comments and thank you in advance for consideration of these comments. Please do not hesitate to contact us at any time.

Sincerely,

A handwritten signature in cursive script that reads "Ann M. Mueting". The signature is written in dark ink and is positioned above the typed name.

Ann M. Mueting
President
American Intellectual Property Law Association