P.O. Box 11145
Tempe, AZ 85284
*www.nativeamericanbar.org*
*Instagram: @NationalNativeBar*

**President** Makalika Nāholowaʻa
**Immediate Past President** Phil Brodeen
**President Elect** Matthew Archer-Beck
**Secretary** Sarah Crawford
**Treasurer** Andrea Snowball
**Directors**:
Paulene Abeyta ● Torey Dolan
Sunshine Nicholson ● Eldred Ledansee
Thomas Pack ● Blair Tarman ● Geneva E.B. Thompson

February 23, 2024

Ms. Susan Anthony
Tribal Affairs Liaison
Office of Policy and International Affairs (OPIA)
United States Patent and Trademark Office
Sent via e-mail to Susan.Anthony@uspto.gov and
TribalConsultWIPOIGC2023@uspto.gov

Re: WIPO IGC FORMAL TRIBAL CONSULTATION 2023
[Docket No.: PTO–C–2023–0020]

Aloha e Ms. Anthony,

We extend sincere greetings to you with hope that you are in good health.

These comments are provided on behalf of the National Native American Bar Association ("**NNABA**") in response to the United States Patent and Trademark Office ("**USPTO**") Notice of Tribal Consultation published on October 24, 2023 regarding World Intellectual Property Organization ("**WIPO**") Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ("**IGC**") negotiations. NNABA appreciates the opportunity to consult with the USPTO on the important issues raised in the above mentioned federal register notice.

NNABA was founded in 1973 and serves as the national association for Native American attorneys, judges, law professors and law students, and NNABA promotes and addresses social, cultural, political and legal issues affecting American Indians, Alaska Natives, and Native Hawaiians. The protection and abuses of traditional knowledge, cultural expressions, genetic resources, and other aspects of Native American culture are among the critically important areas affecting Native American communities, and within the scope of NNABA's mission.

## Consultation Background

The USPTO recently announced that for the first time in its history, it is engaging in a formal tribal consultation process and seeking input from Tribal Nations and Native Communities on "how best to protect the genetic resources, traditional knowledge, and

traditional cultural expressions of Indigenous Peoples." The US government participates in efforts at WIPO, a specialized agency of the United Nations, and its positions and engagement at WIPO are lead by the USPTO. The IGC is a part of WIPO.

The IGC is finalizing an international instrument focused on the protection of genetic resources ("**GR**") and associated traditional knowledge ("**TK**"). Relatedly, there is work underway within the IGC on two other potential legal instruments relating to Intellectual Property and Traditional Knowledge and Traditional Cultural Expressions.

These three text based instruments being negotiated include the following:

- An instrument on genetic resources. Text based negotiations are currently centered on "Substantive articles" (Articles 1 through 9) from WIPO/GRTKF/IC/43/5 Chair's Text of a Draft International Legal Instrument relating to Intellectual Property, Genetic Resources and Traditional Knowledge associated with Genetic Resources: Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore: Forty-Third Session (wipo.int), as revised in the Special Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, September 4–8, 2023. The substantive articles are 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, and can be found here: www.wipo.int/meetings/en/doc_details.jsp?doc_id=620066. These substantive articles are hereafter refered to as the "**Draft Genetic Resources Instrument**."

- An instrument on the protection of traditional knoweldge and instrument on the protection of traditional cultural expressions. Documents for the WIPO IGC meeting on June 5–9, 2023, including the latest traditional knowledge and traditional cultural expressions ("TCEs") texts, can be found here: www.wipo.int/ meetings/en/details.jsp?meeting_ id=75419.

Movement is expected this year within the WIPO IGC and General Assembly ("**GA**") that may result in the finalization and adoption of the Draft Genetic Resources Instrument. Negotiations on the other two instruments are expected to move at a slower pace and are not expected to conclude this year.

## Substantive General Comments

NNABA asks the US government to act in international negotiations and the development of national law and policy consistent with and reflective of the comments below.

1. The US government must do more to engage in meaningful tribal consultation regarding the indigenous rights related to this complex area of law and policy involving traditional knowledge, traditional cultural expressions, cultural property, and genetic resources. It is shocking this is the first time the USPTO has ever engaged in formal tribal consultation.

2. This consultation process is insufficient, though a start is certainly overdue and better than no consultation at all. At the outset, this has been an improper call to action that did not allow ample time for the proper tribal stakeholders to get involved. The USPTO has been aware of the need for tribal consultation on these important issues for at least 24 years as it negotiated intellectual property rights issues that impact Indigenous Peoples on a global scale. And yet, despite being aware of this need, the USPTO began the consultation process—that should be inclusive of all Tribal Governments and Native Communities, including but not limited to 574 federally recognized tribal governments, Native Hawaiians, and other Native communities and people numbering millions of Americans—within only the last several months. Additionally, Tribal Governments and Native Communities were only recently made aware that the USPTO is also holding final negotiations on a legal instrument focused on genetic resources and associated traditional knowledge this May. Thus, not only is there too little time to solicit meaningful contribution from many, maybe most, Tribal Governments and Native Communities, but there is also too little time for the USPTO to fully consider and discuss any comments.[1]

---

[1] The current western intellectual property system fails to take into account each tribe's sovereignty over their own resources and cultural heritage. Thus, meaningful consultation would require each of the 574 recognized tribes, state and non-recognized Tribes and Native Hawaiians, their representatives, and inter-Tribal organizations, to have resources available to evaluate and respond to these 18 detailed and complicated questions within a few weeks. This is not feasible.

At a minimum and as discussed further below, a meaningful consultation consists of an open dialogue, meeting stakeholders where they are (both physically and with regard to resources), and an appropriate amount of time for stakeholders to respond. (FN/Cite: Memorandum on Uniform Standards for Tribal Consultation | The White House**)** The United States has stated its support for

3. The US government must do more to protect the human rights of indigenous people, including with respect to indigenous GR, TK, and TCEs, consistent with the federal government's trust responsibility, and the human rights standards set forth in international legal instruments including but not limited to the UN Declaration on the Rights of Indigenous People ("**UNDRIP**").

4. The US government must invest in providing technical support that enables Tribal Governments, Native Communities, and Native American individuals and organizations to understand the issues at stake related to federal and international law the US government develops impacting their GRs, TK, and TCEs. As preparation for this consultation, the USPTO prepared a single webinar, again scantily marketed to Native peoples, which is far from sufficient to prepare Native Americans and Tribal Governments to meaningfully engage in consultation.

5. The US government should publish regular reports that set forth progress and actions taken to fulfill its trust responsibility and implement such international legal instruments regarding GR, TK, and TCEs in national law and policy. NNABA holds deep concerns reflected by many native communities that the United States to date has done little to fulfill its trust responsibility to native peoples regarding their GR, TK, and TCEs, or to implement indigenous human rights obligations regarding GR, TK, and TCEs in US law or the administration of the intellectual property system.

6. The US government should also invest in meaningful consultation and study to better understand the scope and contours of Native Americans' GR, TK, and TCEs, and both qualify and quantify the impact lack of protections has on Native American communities and their human rights.

7. UNDRIP and its principles for indigenous human rights are the standard that nations must adhere to when taking action that impacts indigenous people, and any instruments should be consistent with those principles, including the principle that states taking action impacting indigenous cultures, GR, TK, and TCEs requires free, prior, and informed consent ("**FPIC**").

---

the principles found in the United Nations Declaration on the Rights of Indigenous Peoples. Thus, the USPTO by extension should be striving to implement those principles in their consultation efforts. This recent shortcoming with respect to the consultation process provides an opportunity to improve how the USPTO engages in government-to-government relations with Tribal Nations.

8. The US government should advocate for consistent instruments internationally and take consistent action to fulfill its trust responsibility and the obligations set forth in those human rights instruments domestically.

9. With respect to the above mentioned draft instruments being negotiated within the WIPO IGC currently, numerous components of the instruments are inconsistent with UNDRIP and potentially out of step with existing standards in US law. The US government should advocate that any instruments meet the human rights standards set forth in UNDRIP and are expressly stated as intended to meet those standards. NNABA provides comments on each substantive Article of the Draft Genetic Resources Instrument below.

10. So long as a new instrument conforms to and provides helpful additional clarity for nations regarding their duties under existing indigenous human rights instruments like UNDRIP, new instruments can be incredibly helpful for empowering nations to develop law and policy that protect indigenous human rights in their territories and meet the needs of indigenous communities. Accordingly, the US government should continue to advocate at WIPO for instruments that conform to UNDRIP's principles and standards and aid the international community in advancing the global intellectual property system in ways that better protect indigenous human rights.

11. At the same time, so far as new instruments are inconsistent with indigenous human rights standards, the US government must evaluate whether the instruments are in fact inhibiting the US government's ability to conform to existing indigenous human rights standards and to fufill its federal trust responsibility to Native Americans. If so, the US government should not agree to them.

12. Turning from international instruments to local law, US law does not provide adequate protection for indigenous GR, TK, and TCEs as required by US trust responsibility to Native Americans and international indigenous human rights. Tribal Governments and Native Communities need enforceable legal protections for their GR, TK, and TCEs that enable them to: realize the benefits they are entitled to as beneficiaries of the US government's federal trust responsibility; live without the individual and collective injuries presently and over the course of all future time caused by violations of their human rights involving these tangible and intangible aspects of their cultures; and maintain the integrity of their cultures, traditional and customary practices, and lifeways, which is at serious risk due to the lack of protections and the significant abuses suffered today.

13. Legal changes are needed to ensure that indigenous peoples provide FPIC before intellectual property rights are granted that use or incorporate their GR, TK, and TCEs. Where specific disclosure of the use of GR, TK, and TCEs for registration of relevant works is not required, it should be. Required disclosure of such uses would allow indigenous peoples to monitor for and take action against such uses; something that is currently severely lacking. Notably, although disclosure is necessary to protect indigenous human rights, it is not sufficient on its own and falls far short of FPIC.

14. So far as law relating to public domain and the intellectual property system has the effect of allowing the US government and other entities to use and incorporate GR, TK, and TCEs into intellectual property assets without FPIC from the indigenous communities, to whom that content originated from and belongs pursuant to their reserved rights and inherent sovereignty as indigenous nations, and international human rights standards, then the current law regarding public domain and intellectual property law is obstructing the US government from fulfilling its trust responsibility and human rights obligations and must be remedied.

15. Effective legal reforms and advancements, that are at the same time as minimally disruptive to the status quo as possible, including but not limited to changes to intellectual property law, will require substantial additional investment by the US government to engage in meaningful comprehensive tribal consultation with all willing Tribal Governments, Native Communities, Native people, and Native organizations. This will not be sufficiently determined after a single, and the USPTO's very first, tribal consultation process, comprising merely four lightly marketed webinars and a written public comment period.

16. The US government must also make investments to build the capacity of professionals in Native American communities equipped to counsel Native communities on the legal issues at stake, and help them to engage in meaningful consultation and other advocacy to protect GRs, TK, and TCEs. The existing legal intellectual property system impacting the protection and abuses of GRs, TK, and TCEs is arcane, and complex with centuries old roots. It is not designed to respect indigenous human rights. Indeed, it could be credibly argued that it was designed to enable the uncompensated extraction of these resources, just as so much of other realms of English, and later American, law was similarly designed to enable extraction and exploitation of Native lands and natural resources. At the same time, Native American traditions, customs, and stewardship practices for GRs, TK, and TCEs are also complex, ancient, and arcane, and in many ways hard to reconcile with Western culture, values, and law. Progress will require culturally competent indigenous professionals that are skilled in the diversity of

these systems. Yet, Native Americans are abysmally underrepresented in the intellectual property bar; there may be less than 20 Native American intellectual property and GR, TK, and TCEs scholars and practitioners in the country. This must change, and the US government urgently needs to make investments to help.

## Specific Comments on Draft Genetic Resources Instrument

In accordance with the above principles and grounding concepts, NNABA now offers comments on specific substantive articles of concern in the Draft Genetic Resources Instrument, including Articles 1, 3, 5, 6, and 7 of the 9.

NNABA is focusing comments on this document, because it is NNABA's understanding that the Draft Genetic Resources Instrument is the document most likely to reach an international decision at the WIPO IGC this year.

Because the other instruments are on a longer pathway towards decision making, and most subject to additional modification and change as member states continue to negotiate them, NNABA asks that the USPTO continue to engage in tribal consultation regarding the text of those instruments, and provide Tribal Governments, Native Communities, Native people, and Native organizations future opportunities to comment on those in additional consultation processes.

### Article 1

A glaring omission in the objectives for this text is to advance the protection of indigenous human rights with respect to indigenous culture, GRs, TK, and TCEs. Without acknowledging that purpose, the burdens of the new requirements called for in the instrument cannot be properly weighed against the benefits and existing human rights requirements instigating the IGC's work to produce this document to begin with.

### Article 3

A duty of disclosure already exists in several patent offices worldwide. For example, in the United States, the duty of candor "includes a duty to disclose to the Office all information known to that individual to be material to patentability" (MPEP 2001[2]). Importantly, "[t]he duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned." The MPEP further defines materiality as "*any* information that a

---

[2] The Manual of Patent Examining Procedure is referenced throughout this document as "MPEP."

reasonable examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent" (MPEP 2001.04). Moreover, information includes but is not limited to: "patents, publications, information on enablement, possible prior public uses, sales, offers to sell, derived knowledge, prior invention by another, inventorship conflicts, and litigation statements" (MPEP 2001.04). Failure to disclose material information to the USPTO during prosecution with respect to any claim in an application or patent renders all claims patentable or invalid (MPEP 2016).

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to the Convention on Biological Diversity (the "Nagoya Protocol") goes a step further than mere disclosure. For example, Article 6 of the Nagoya Protocol requires each Party "take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources." Article 7 of the Nagoya Protocol ensures 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."

Article 6 of the Nagoya Protocol also states "each Party requiring prior informed consent shall take the necessary legislative, administrative or policy measures, as appropriate, to…(e) [p]rovide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit-sharing Clearing-House accordingly." This concept is very similar to a foreign filing license, which is already required and managed by the USPTO and several State patent offices. For example, in the United States, 35 U.S.C. § 181 requires "[w]henever publication or disclosure by the publication of an application or by the grant of a patent on an invention in which the Government has a property interest might, in the opinion of the head of the interested Government agency, be detrimental to the national security, the Commissioner of Patents upon being so notified shall order that the invention be kept secret and shall withhold the publication of the application or the grant of a patent therefor under the conditions set forth hereinafter." If not authorized by the head of the interested government agency, "a person shall not file or cause or authorize to be filed in any foreign country … an application for patent" (MPEP 0140). In some circumstances, foreign filing licenses may be granted retroactively (MPEP 0140). Given additional time and resources, a foreign filing license framework could easily be extended to and set up for Tribal Governments with respect to traditional knowledge, genetic resources, and traditional cultural expressions.

In Article 3.1 and 3.2, there appears to be some remaining debate on disclosure based on whether "the claimed invention in a patent application is" ***materially*** or ***directly*** based on genetic resources or traditional knowledge. The term ***directly*** reduces the disclosure requirement far below the duty of candor currently required by US law and is not acceptable. Disclosure should be, at a minimum, required any time the traditional knowledge or genetic resources are ***material to patentability***.

Referring now to Article 3.4, Offices shall provide "as an opportunity for patent applicants to rectify a failure to include the minimum information referred to in paragraphs 3.1 and 3.2 or correct any disclosures that are erroneous or incorrect." This is also inconsistent with US law as there is not currently an opportunity to correct "***any*** disclosures that are erroneous or incorrect," which would allow for abuse. So far as an international instrument will provide for correction, the opportunity to correct should be limited to situations where the applicant has made a good faith effort to disclose correct information and has later discovered additional information such that the initial disclosure needs to be updated or corrected.

Moreover, the disclosure requirements of Articles 3.1 through 3.3 fall short of meeting the FPIC goals of Articles 6 and 7 of the Nagoya Protocol. Article 3 should require applicants to declare that they have obtained FPIC of the Indigenous Peoples or local community whose human rights are attached to the relevant GR, TK, or TCEs. If the Applicant believes, in good faith, the invention is not derived from GR, TK, or TCEs, Article 3 should additionally require applicants to affirmatively make such a representation.

## Article 5

Currently, this article indicates "Contracting Parties shall not impose the obligations of this instrument in relation to patent applications which have been filed prior to that Contracting Party's ratification of or accession to this instrument, subject to national laws that existed prior to such ratification or accession." This is inconsistent with US law, because the duty of candor exists at the time of filing and throughout the pendency of the application, and that should not change.

## Article 6

Article 6 provides "an applicant an opportunity to rectify a failure to include the minimum information detailed in Article 3 before implementing sanctions or directing remedies" and states "no Contracting Party shall revoke or render unenforceable a patent solely on the basis of an applicant's failure to disclose the information specified in Article 3 of this instrument." This is also inconsistent with US law, because a failure to disclose information material to patentability can render a patent invalid and

unenforceable. This should not change. If this instrument were to set a different standard, at the least, Article 6 should not provide an opportunity to rectify in cases of fraud or inequitable conduct. Moreover, if the patent is already granted, then it is too late to rectify the failure as the patent may have been improperly granted. In each of these scenarios, the patent should be revoked or rendered unenforceable. Article 6.4 does not go far enough.

With respect to Article 6.5, "dispute mechanisms that allow all parties concerned to reach timely and mutually satisfactory solutions" should be modified to ensure that effective redress mechanisms are provided to fulfill the human rights standards set forth in UNDRIP. For example, Article 11 (2) of UNDRIP requires "States shall provide redress through effective mechanisms, which may include restitution, developed in conjunction with indigenous peoples, with respect to their cultural, intellectual, religious and spiritual property taken without their free, prior and informed consent or in violation of their laws, traditions and customs." Consistent with UNDRIP standards, Article 6 should not foreclose and ideally would make clear that the mechanisms for dispute should enable effective redress, which could include, for example, civil liability, criminal penalties, and tribal jurisdiction to further protect traditional knowledge that is or has already been accessed without permission.

Finally, there should be a mechanism for the Indigenous Peoples or local communities to verify and challenge the sufficiency of the disclosure under Article 3. This may be accomplished by the database accessible to Indigenous People, according to appropriate rules and protocols, implicated by the disclosure contemplated by the WIPO IGC and referenced in Article 7 of the Draft Genetic Resources Instrument.

## Article 7

Creating a database of information relating to GR, TK, and TCEs, can have benefits but also can raise numerous serious issues regarding risks of abuse, violations of privacy, violation of traditional customs, rules and protocols, and accessibility. Noting these risks:

- Any database created must not do harm to indigenous people's rights, the integrity of their cultures, or their stewardship of their GRs, TK, and TCEs according to their traditions, customs, laws, and protocols.

- If an indigenous government, organization, or person chooses <u>not</u> to submit information into a database or information system described in this article, that decision should not impact their indigenous human rights or the government's trust responsibility to protect the relevant GRs, TK, and TCEs. Other mechanisms must be provided to enable them to receive notice of impacts on

their GRs, TK, and TCEs; engage in communications to consider FPIC when action impacting their human rights is contemplated; and seek redress when their human rights attached to their GR, TK, and TCEs have been violated.

## Conclusion

NNABA respectfully requests that the US government give serious weight to these comments and the comments of all other indigenous governments, organizations, and people who participate in this tribal consultation. Further, NNABA asks that the US government then take action to address the rights, needs, and concerns of indigenous people consistent with the comments provided, as meaningful consultation requires.

Importantly, NNABA also asks that the US government engage in additional tribal consultation to continue advancing international and federal law and policy in ways that allow the federal government to comply with its trust responsibility and responsibilities under existing international legal instruments to respect tribal sovereignty and indigenous human rights with respect to GRs, TK, and TCEs. Additional time, information, and investments are needed for meaningful tribal consultations on these important instruments to ensure adequate measures are in place to protect tribal information.

Thank you again for the opportunity to participate in this consultation.

Me ka ha'aha'a,
Humbly Yours,

Makalika Naholowaa
NNABA President
makalika@nativeamericanbar.org