



January 22, 2024

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

*Submitted via: [https:// www.regulations.gov](https://www.regulations.gov)*

**Re: WIPO IGC Negotiations on Genetic Resources and Associated Traditional Knowledge; Docket No.: PTO-C-2023-0019**

Dear Director Vidal:

Intellectual Property Owners Association (IPO) appreciates the opportunity to provide comments in response to the Notice and Request for Comments related to WIPO IGC Negotiations on Genetic Resources and Associated Traditional Knowledge (Docket No.: PTO-C-2023-0019), published in the Federal Register on October 24, 2023 (“Notice”).

### **Background**

IPO is an international trade association representing a “big tent” of diverse companies, law firms, service providers and individuals in all industries and fields of technology that own, or are interested in, intellectual property rights. IPO membership includes over 125 companies and spans over 30 countries. IPO advocates for effective and affordable IP ownership rights and offers a wide array of services, including supporting member interests relating to legislative and international issues; analyzing current IP issues; providing information and educational services; supporting and advocating for diversity, equity, and inclusion in IP and innovation; and disseminating information to the public on the importance of IP rights.

IPO’s vision is the global acceleration of innovation, creativity, and investment necessary to improve lives. The Board of Directors has adopted a strategic objective to foster diverse engagement in the innovation ecosystem and to integrate diversity, equity, and inclusion in all its work to complement IPO’s mission of promoting high quality and enforceable IP rights and predictable legal systems for all industries and technologies.

Below, IPO first provides overviews of its position on the proposed instrument and the key points relating to issues raised by the Notice, followed by specific comments on issues raised in the Notice.

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***The Proposed Instrument Would Not Accomplish the Intended Goal and Would Harm the IPO Ecosystem***

IPO supports the Objectives of the Draft International Legal Instrument and recognizes the challenges associated with trying to find practical ways to accomplish these goals that will not undermine the innovation ecosystem. IPO, however, believes that the proposed instrument, adopting a mandatory disclosure rule for the country of origin or source of genetic resources or associated traditional knowledge in patent applications, would not protect community rights in genetic resources or associated traditional knowledge.

Adoption of a mandatory disclosure requirement for patent applications will harm the international IP system, thereby discouraging innovation, creativity and human progress. More specifically, patent laws that impose patent disclosure requirements regarding the source and origin of genetic resources introduce uncertainties into the patent system that inhibit innovation in relevant technologies (*See, e.g.*, response to question 5 below.) In some cases, compliance with such requirements is impossible, particularly where the existence or origin of any genetic resources incorporated into a product may be unknown or untraceable or, in the case of origin, in dispute among nations. (*See, e.g.*, response to question 2 below.)

Mandatory patent disclosure requirements related to genetic resources (GR) and/or associated traditional knowledge (ATK) introduce uncertainty for innovators and undermine the sustainable use of technology related to biological resources. IPO therefore does not support the current text of the proposed legal instrument.

***Overview of Other Key Points Relating to Issues Raised by the Notice***

IPO strongly opposes implementation of a mandatory international disclosure requirement of the country of origin or source of genetic resources or associated traditional knowledge in patent applications.

If any mandatory disclosure requirement is established, however, IPO encourages member states to ensure that the requirements are limited in scope, and explicitly exclude from the definition of “genetic material” any materials from human sources. IPO also suggests that the instrument clarify that failure to disclose is not a ground for invalidity and would not impact the patent owner’s ability to assert its patent rights.

However, if the failure to disclose could be a ground for patent invalidity, IPO also strongly recommends that the provisions include that there shall be no effect on validity for errors made without deceptive intent. IPO further believes that the provisions should provide the right to rectification in pre- and post-grant proceedings. In addition, while any instrument should be non-retroactive per the Vienna Convention on the Law of Treaties, if the non-retroactivity is not extended to the Date of Collection, the instrument could create a trap that could itself be disruptive to the innovation ecosystem. These provisions are necessary to ensure patent law predictability. Moreover, IPO urges that any traditional knowledge subject to the proposed treaty should explicitly exclude all knowledge that is publicly or readily available to one of ordinary skill in the art.

To further explain regarding the definition of genetic material and genetic resources, IPO discourages the use of any definition of “genetic resources” that includes digital sequence information or human information used during the innovative process. Unrestricted access to public collections of genetic DSI is essential to encourage innovation and promote scientific progress. In addition, inclusion of human materials in the definition of “genetic materials” under the treaty would create great burdens for the protection of innovations.

As noted above, IPO supports the goals of ensuring an effective, transparent patent system and preventing the grant of erroneous patents and respect for genetic resources and traditional knowledge. IPO encourages member states to find practical ways to accomplish these goals that will not undermine the innovation ecosystem. However, IPO believes that adoption of a mandatory disclosure requirement, particularly impacting patent validity, will pose a great risk of disrupting the IP ecosystem by introducing uncertainty for innovators and undermining the sustainable use of technology related to genetic resources.

### *Specific Comments on Issues Raised in Notice*

- 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”)? 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.**

IPO understands that many IPO members have filed and prosecuted patent applications in jurisdictions that require disclosure of the source of genetic resources and associated traditional knowledge in the application. Jurisdictions that have robust disclosure requirements include Andean Community countries, Brazil, China, and India. Examples are found below.

Andean Decision 486 requires that patent applications include requirements relating to the acquisition or use of genetic resources if the relevant inventions “were obtained or developed from” genetic resources originating in one of the Andean Community countries (Bolivia, Peru, Ecuador or Colombia). It similarly applies to inventions derived from traditional knowledge originating in the Andean Community.

IPO also understands Brazil imposes the following requirements: a declaration containing the priority identifying data (priority number, country, filing date, and applicant’s name); an assignment of priority rights if the Brazilian filing applicant is different from the priority applicant; an assignment of PCT rights if the Brazilian filing applicant is different from the PCT applicant; and a declaration of access to a sample.

In China, Article 26 of the Patent Law requires patent applicants to indicate the “direct source” and the “original source” of genetic resources if the completion of the claimed invention relies on access to genetic resources. These provisions are intended to implement provisions of the Convention on Biological Diversity (CBD) relating to access to genetic resources and equitable sharing of benefits from utilization of these resources. These special disclosure requirements are ambiguous and, as a result, impose unreasonable burdens on patent applicants, subjecting valuable patent rights to great uncertainty.

China’s human genetic resource (HGR) regulations, which came into effect on July 1, 2019, prohibit human sample collection by foreign parties and restrict the use, analysis and transfer of such samples and related data except in the context of an approved collaboration with Chinese parties, such as medical institutions or enterprises with no foreign investment. The regulations also contain provisions regarding mandatory IP sharing that are inconsistent with Chapter 2 of the Trade Agreement, which provides that any transfer of technology as part of securing marketing approval for innovative medicines occurs on voluntary, market-based terms.

India’s Patents Act requires applicants to disclose the source and geographical origin of biological materials used to make an invention that is the subject of a patent application. Failure to correctly identify the geographical source of a biological material is a ground for pre-grant and post-grant oppositions, as well as revocation proceedings. Further, even when the origin of the source of biological material is not India, the Applicants are required to identify the specific location / city of origin, which is onerous and unwarranted. These special disclosure requirements and the scope of what constitutes a genetic resource are at best ambiguous, subjecting the validity of valuable patent rights to damaging uncertainty.

**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.**

The requirements imposed at the national level can be difficult and burdensome for patent applicants to comply with. In some cases, compliance with such requirements is impossible, particularly where the existence or origin of any genetic resources incorporated into a product may be unknown or untraceable. IPO believes patent disclosure requirements implemented in various countries introduce uncertainty for innovators and undermine the sustainable use of technology related to biological resources.

IPO members anticipate additional problems resulting from the imposition of an international disclosure requirement. For example, under the proposed legal instrument, the country of origin of genetic resources is defined as the “country which possesses those genetic resources in *in situ* conditions.” “In situ conditions” is in turn defined as “conditions where genetic resources exist within ecosystems and natural habitats and in the case of domestic adulterated species in this case where they have developed their

distinctive properties.” It is very likely that, for certain genetic resources, more than one country may fit the country of origin definition. Applicants may be subject to facing an objection or rejection from a patent office that has a different conclusion on the country of origin.

Issues with the country of origin of genetic resources have previously been the subject of disputes. For example, in 2014 Australia and New Zealand were involved in a trademark dispute regarding whether Manuka Honey is a New Zealand or Australian based material.

These issues of unclear origin are not new. For example, much research was conducted in the 1950s on material from vinca alkaloid plants. Plants used in the commercialized products were obtained from commercial suppliers in the United States. Evidence also clearly demonstrated that vinca plants could also be found in Italy, South Africa, Australia, and the United Kingdom. Nevertheless, there are continued baseless references to the commercialized products having been derived from plants originating in Madagascar.

**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.**

IPO does not believe that there are benefits to a specific disclosure requirement for genetic resources and associated traditional knowledge as part of the patent application process. IPO believes that the requirement to disclose generic resources and associate traditional knowledge in a patent filing will negatively impact the innovation ecosystem, while providing no improvement in the recognition or respect for genetic resources and associated traditional knowledge. Therefore, IPO opposes a mandatory disclosure requirement.

The patent application process is governed by various international treaties, including the Paris Convention, the Patent Cooperation Treaty, and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). These provisions together define the requirements for a substantive patent application, including sufficient disclosure to support the patent claims. In order to help better facilitate examination of applications, IPO does support the development of databases to establish an accurate and accessible record of genetic resources and traditional knowledge. Patent Offices and Examiners can use the databases to assess novelty and inventive step of inventions related to the genetic resources. IPO does note, however, that the geographic origin of the genetic resources is rarely related to these issues.

**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.**

Access to genetic resources is regulated in the Andean Community (Bolivia, Colombia, Ecuador and Peru) by Decision 391, which, among others, defines what is considered such access. Under current practice, if the resource is considered indigenous or native to any of these countries, and it has been accessed or is going to be accessed, it is expected

that a contract will be requested before the corresponding Agency in each country (regardless of the status of the research and possible patent applications). Decision 486 establishes that a copy of the contract should be provided upon filing, but it could be later requested either in formal or substantive examination.

Each patent office in the Andean Region handles this issue differently, and in the Andean Patent Manual (APM), a chapter was included explaining the general procedure and providing examples of cases in Colombia and Peru where a contract was required during prosecution and the rationale for that requirement. IPO understands that applications have been declared abandoned for not being able to formally comply with the requirements. As a result, innovation can be inhibited, and innovators will be reluctant to invest in related research.

As noted above, India's Patents Act requires applicants to disclose the source and geographical origin of biological materials used to make an invention that is the subject of a patent application. Failure to correctly identify the geographical source of a biological material is a ground for pre-grant and post-grant oppositions, as well as revocation proceedings. Further, even when the origin of the source of biological material is not India, the Applicants are required to identify the specific location / city of origin, which is onerous and unwarranted.

There are many examples of patent applications rejected in the Indian Patent Office, due to objections by the Indian National Biodiversity Authority (NBA) concerning the use or reference to genetic materials that are potentially of Indian origin. In one reported case, the High Court of Delhi upheld the decision of the Indian Patent Office to reject an application covering a vaccine, where the application referenced a human rotavirus strain that had been originally isolated in India. The Court ruled that in order to obtain patent rights, the applicant needed to first obtain approval of the Indian NBA, and to satisfy the access and benefit sharing requirements of Indian law.<sup>1</sup>

**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.**

As noted above, in some cases, compliance with such requirements is impossible, particularly where the existence or origin of any genetic resources incorporated into a product may be unknown or untraceable or, in the case of origin, in dispute among nations. IPO believes that burdensome disclosure requirements can discourage an applicant from filing for patent protection in those jurisdictions that impose them. In lieu of pursuing patent protections, innovators could choose to protect their inventions as trade secrets, but that would deny the public the benefit of knowledge of the invention.

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<sup>1</sup> Inventprise, Inc. v. Controller of Patents, W.P. ©-ICP 26/2023 (High Court of Delhi, Dec. 20. 2023)

## **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 resources? Please explain.**

IPO does not believe that the patent disclosure requirement has been an effective regulator of access and benefit sharing for genetic resources in those jurisdictions where it exists. In contrast, voluntary agreements between parties have demonstrated significant monetary and non-monetary 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? Please explain.**

IPO does not believe that a patent disclosure requirement would be effective in enabling interested groups to locate information on the use of a country's genetic resources. As noted herein, IPO believes the development and use of databases of GR/ATK can serve both objectives of the draft instrument, as it would allow for increased efficacy and transparency, as well as aiding in the prevention of erroneously-granted patent applications. Well maintained databases can be used by patent offices and examiners worldwide to find prior art genetic resources and non-secret traditional knowledge associated with genetic resources. IPO does note, however, that the geographic origin of the genetic resources is rarely related to issues concerning the patentability of an invention.

### **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.**

IPO is concerned with the definition of genetic resources used in any international instrument. IPO urges that any definition of genetic resources exclude human genetic resources. IPO's position is consistent with other legal instruments addressing genetic resources and associated traditional knowledge. With the recognition that Member States should not claim sovereignty over human genetic resources, any text should maintain explicitly that human genetic resources are outside the scope of any disclosure requirement. IPO notes that the September 4-8, 2023 Conclusions exclude human genetic resources from the definition of "genetic resources," in the Article 2 definitions, footnote 1.

IPO also urges that any definition of "genetic resources" exclude digital sequence information (DSI). Genetic resources can be utilized in archived electronic DSI form and accessed from publicly available databases. Unrestricted access to public collections of genetic DSI is essential to encourage innovation and promote scientific progress. Accordingly, IPO is opposed to any restrictions on access to public collections of DSI and to any mandatory benefit sharing mechanisms for the use of such DSI.

Furthermore, for the purpose of clarity, IPO urges that any instrument be limited to only those patents that explicitly recite a specific property of the genetic resources and/or traditional knowledge associated with genetic resources as a claim limitation.

**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.**

IPO believes that the disclosure requirements related to GR/ATK would go beyond the requirements for supporting a patent application pursuant to international treaties such as TRIPS. Under TRIPS and the Patent Cooperation Treaty, patents are not granted for subject matter that is known or that lacks an inventive step.

In the event that a disclosure requirement is enacted, however, IPO suggests a narrower trigger requirement for disclosure. A narrower trigger requirement will ease the burden on patent applicants. More importantly, a narrower trigger requirement will ensure that the requirement only arises when the genetic resources are relevant to any evaluation of patentability. The current proposed language below, from the Decisions adopted on September 4-8, 2023, provides a narrower definition:

“[Materially/Directly] based on” means that the genetic resources and/or traditional knowledge associated with genetic resources must have been necessary or material to the development of the claimed invention, and that the claimed invention must depend on the specific properties of the genetic resources and/or traditional knowledge associated with genetic resources.

**b) Voluntary disclosure of genetic resource information.**

IPO does not oppose voluntary disclosure of genetic resource information.

**c) Disclosure requirement if the genetic resource information is known.**

IPO opposes a disclosure requirement for genetic resource information which is “known.” IPO is concerned about how an applicant can prove that the “origin” of genetic resources is unknown and questions whether the applicant will bear the burden of proof on this issue.

IPO maintains that it will be difficult in practice for patent applicants to comply with any requirement to identify the country of origin, given the realities of scientific research. Often, the existence or origin of any genetic resources incorporated into a product may be unknown or untraceable. Patent applicants may have records of the acquisition of the generic resources, for example whether it was obtained from a gene bank. However, innovators may not always have a record of the acquisitions. In addition, as explained above, more than one member state may lay claim to be the “country of origin” for a particular resource. In such instances, even genuine efforts to comply with a disclosure requirement may be deemed insufficient.



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

IPO opposes a disclosure requirement for genetic resource information when an invention is “based on genetic resources.”

The term “based on” is ambiguous and could be so broadly interpreted as to be meaningless. Inventions are “based on” known materials or substances, in that they build on prior knowledge and learnings. The invention itself may meet all the requirements for patentability, including novelty and inventive step. IPO believes that this disclosure requirement could be interpreted or applied to go beyond the requirements for supporting a patent application pursuant to international treaties such as TRIPS.

Adoption of a broad trigger requirement such as “based on genetic resources” will impose a significant burden on patent applicants. The broader trigger requirement will also result in the compilation of genetic resources information that is irrelevant to any evaluation of patentability, and thus of limited value.

**e) Disclosure of access and benefit sharing compliance.**

IPO opposes a disclosure requirement for access and benefit sharing. Access and benefit sharing requirements are present in certain jurisdictions and are unique to each jurisdiction. For example, Brazil has an access and benefits sharing system for use of the genetic resources of Brazil. IPO does not believe that compliance with access and benefits sharing under the Brazilian rules for Brazilian genetic resources would seem to be relevant to another jurisdiction but, in contrast, requiring such a disclosure of access and benefit sharing compliance would create an additional unnecessary burden for patent applicants.

Furthermore, access and benefit sharing rules have been enacted in the Nagoya Protocol. More than 100 countries are members to the Nagoya Protocol. Hence, there is no need to enact access and benefit sharing rules as part of a new international instrument. IPO strongly opposes the use of the patent system as a means to enforce unrelated legal requirements.

**f) Compliance/non-compliance with a disclosure requirement.**

IPO opposes a disclosure requirement. If a disclosure requirement were to be included, however, such provisions should also include the right to rectification in pre- and post-grant proceedings.

IPO also suggests that the instrument clarify that failure to disclose is not a ground for invalidity and would not impact the patent owner’s ability to assert its patent rights. However, if the failure to disclose could be a ground for patent invalidity, IPO also strongly recommends that the provisions include that there shall be no effect on validity for errors made without deceptive intent, to preserve patent law predictability.

In addition, while any disclosure requirement should be non-retroactive, if the non-retroactivity is not extended to the Date of Collection, the instrument could create a trap

that could itself be disruptive to the innovation ecosystem. This is because many genetic resources may have been collected long before filing of the patent application, and before applicants were aware that such information would be necessary for patentability.

These provisions are necessary to ensure patent law predictability.

**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.**

As noted above, IPO does not support a mandatory disclosure requirement. IPO believes that a mandatory disclosure requirement will not achieve the stated goals or protect the genetic resources and associated traditional knowledge. In the event that a disclosure requirement is established, IPO supports a narrow trigger requirement.

IPO particularly objects to a broad trigger requirement, such as “based on” or “materially based on.” These broad triggers raise questions, such as: What is the meaning of “based on” or “directly based on” or “materially based on?” How is an applicant to determine what is “necessary or material to the development” of the claimed invention? Is it a “but-for” analysis, or something more? What guidance will be provided to applicants, patent offices, or examiners?

In the event that a disclosure requirement is enacted, IPO encourages a narrower trigger requirement for disclosure. A narrower trigger requirement will ease the burden on patent applicants. More importantly, a narrower trigger requirement will ensure that the requirement only arises when the genetic resources are relevant to any evaluation of patentability. The current proposed language below, from the Decisions adopted on September 4-8, 2023, provides a narrower definition:

“[Materially/Directly] based on” means that the genetic resources and/or traditional knowledge associated with genetic resources must have been necessary or material to the development of the claimed invention, and that the claimed invention must depend on the specific properties of the genetic resources and/or traditional knowledge associated with genetic resources.

**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.**

IPO opposes a disclosure requirement related to GR/ATK. Such a requirement would go beyond the requirements for supporting a patent application pursuant to international treaties such as TRIPS. Under TRIPS and the Patent Cooperation Treaty, patents are not granted for subject matter that is known or that lacks an inventive step.

In addition, while any new disclosure requirement related to GR/ATK should be non-retroactive, if the non-retroactivity is not extended to the Date of Collection, the instrument could create a trap that could itself be disruptive to the innovation ecosystem. This is because many genetic resources may have been collected long before filing of the

patent application, and before applicants were aware that such information would be necessary.

With the recognition that Member States should not claim sovereignty over human genetic resources, any text should maintain explicitly that human genetic resources are outside the scope of any disclosure requirement. IPO notes that the September 4-8, 2023 Conclusions exclude human genetic resources from the definition of “genetic resources,” in the Article 2 definitions, footnote 1.

It is particularly important that any new disclosure requirement related to GR/ATK does not apply to digital sequence information. Genetic resources can be utilized in archived electronic digital sequence information (DSI) form and accessed from publicly available databases. Unrestricted access to public collections of genetic DSI is essential to encourage innovation and promote scientific progress. Accordingly, IPO is opposed to any restrictions on access to public collections of DSI and to any mandatory benefit sharing mechanisms for the use of such DSI.

Given that other UN forums are still in the process of collecting views on DSI, attempts to include DSI as part of a disclosure requirement would be without proper analysis/discussion in the IGC, and are therefore premature. This is particularly so because, as noted in other forums, identifying source or origin of DSI could prove even more difficult, as public databases from which DSI is obtained have not historically required or included such information in the databases.

**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.**

As noted above, IPO opposes a new disclosure requirement related to GR/ATK. IPO maintains that if a new disclosure requirement were to be included, however, such provisions should also include the right to rectification in pre- and post-grant proceedings. IPO also suggests that the instrument clarify that failure to disclose is not a ground for invalidity and would not impact the patent owner’s ability to assert its patent rights. IPO supports a “shall” statement such as found in brackets in current proposed Articles 8.3 and 8.4:

8.3 Failure to fulfill the disclosure requirement [shall]/[should] not affect the validity or enforceability of granted [IP] [patent] rights.

8.4 [IP] [patent] offices [shall]/[should/may] provide an opportunity, within a reasonable time, for applicants to correct any disclosures that are erroneous or incorrect.

However, if the failure to disclose could be a ground for patent invalidity, IPO also strongly recommends that the provisions include that there shall be no effect on validity for errors made without deceptive intent, to preserve patent law predictability.

**14. Please describe your views on the current working text for 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](https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=620066).**

**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](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](https://www.wipo.int/edocs/mdocs/diplconf/en/gratk_pm/gratk_pm_5.pdf).**

**c) The latest consolidated text, contained in the Annex to document WO/GRTKF/IC/43/4, which can be found on the WIPO**

**website, [https://www.wipo.int/edocs/mdocs/tk/en/wipo\\_grtkf\\_ic\\_43/wipo\\_grtkf\\_ic\\_43\\_4.pdf](https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_43/wipo_grtkf_ic_43_4.pdf).**

IPO has concerns about the various texts. Imprecise definitions of necessary terms leave discretion for signatories to the text to determine the scope and content of the rules. IPO is very concerned about unpredictability being created in the patent system by ambiguous definitions.

IPO has concern about the following items, among others:

In Article 1 (Definitions) of the Consolidated Text, the definition of “materially/directly based on,” is overly broad and ambiguous. IPO raises the following questions: What is the meaning of “based on” or “directly based on” or “materially based on?” How is an applicant to determine what is “necessary or material to the development” of the claimed invention? Is it a “but-for” analysis, or something more? What guidance will be provided to applicants, patent offices, or examiners?

IPO suggests, if there is to be a disclosure requirement, a narrower trigger requirement for disclosure should be used. The current proposed language below, from the Decisions adopted on September 4-8, 2023 (Chair's Text), provides a narrower definition:

“[Materially/Directly] based on” means that the genetic resources and/or traditional knowledge associated with genetic resources must have been necessary or material to the development of the claimed invention, and that the claimed invention must depend on the specific properties of the genetic resources and/or traditional knowledge associated with genetic resources.

IPO has concerns about the definition of “country of origin” of genetic resources, as used in the Chair's text. The definitions in the Chair's Text include “country of origin” as “the country which possesses those genetic resources in *in situ* conditions;” and “*in situ* conditions” as “conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of cultivated species, in the surroundings where they have developed their distinctive properties.” These definitions could lead to more than one country having a claim of origin. As noted above, genetic resources may be found *in situ* in more than one jurisdiction. This could lead to patent applicants being unable to satisfy the requirements of one or more jurisdictions. Patent applicants may be forced to choose jurisdictions and potentially surrender patent rights in some jurisdictions.

This is further complicated by the fact that, in some cases, compliance with patent disclosure requirements regarding the source or origin of genetic resources would be impossible, particularly where the existence or origin of any genetic resources incorporated into a product may be unknown or untraceable.

One proposed definition of “genetic resources” in the Consolidated Text covers “any material of plant animal or microbial origin containing functional units of heredity of actual potential value and includes derivatives and generic genetic information thereof.” IPO is very concerned about the increased uncertainty that would be introduced into the patent system by any attempted inclusion of a disclosure requirement for “derivatives.”

IPO objects to the trigger language in section 3.2 of the Chair's Text requiring disclosure when the claimed invention in a patent application is “materially” or “directly” “based on traditional knowledge associated with genetic resources.” IPO maintains that the definition is too broad and will likely be interpreted to require disclosure of genetic resources for a wide range of patent applications. Inventions are “based on” known materials or substances, in that they build on prior knowledge and learnings. The invention itself may meet all the requirements for patentability, including novelty and inventive step.

IPO acknowledges that Article 6 of the Chair's text states that no contracting party can revoke a patent “solely on the basis of an applicant's failure to disclose the information specified in Article 3 of this instrument.” IPO strongly recommends that the instrument clarify that failure to disclose is not a ground for invalidity and would not impact the patent owner's ability to assert its patent rights.

Article 6 of the Chair's text only addresses non-retroactivity with respect to the filing date of the patent application. This fails to take into account that many genetic resources

may have been collected long before filing of the patent application, and before applicants were aware that such information would be necessary. While any instrument should be non-retroactive, if the non-retroactivity is not extended to the Date of Collection, the instrument could create a trap that could itself be disruptive to the innovation ecosystem.

Article 9 of the Chair's Text suggests that the disclosure requirement may be reviewed and possibly extended. To ensure legal certainty for innovators and the public, IPO urges that any review under Article 9 should not be limited to contracting parties, as the potential outcome is likely to affect innovation ecosystems involving non-contracting parties.

**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.**

A mandatory disclosure requirement would negatively impact patent filing strategies for IPO members. IPO maintains that it will be difficult in practice for patent applicants to comply with any requirement to identify the country of origin, given the realities of scientific research. Often, the existence or origin of any genetic resources incorporated into a product may be unknown or untraceable. In addition, as explained herein, more than one member state may lay claim to be the "country of origin" for a particular resource. Patent applicants may be forced to choose jurisdictions and potentially surrender patent rights in some jurisdictions. Furthermore, burdensome disclosure requirements could also discourage an applicant from filing for patent protection in any of those jurisdictions that impose them.

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

**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.**

IPO believes the development and use of databases for the defensive protection of genetic resources and traditional knowledge associated with genetic resources should be considered. Well maintained databases can be used by patent applicants and examiners worldwide to learn about the prior art effect of genetic resources and non-secret traditional knowledge associated with genetic resources.

IPO takes note of the stated objective included in the preamble to the Consolidated Document Relating to Intellectual Property and Genetic resources, for the purposes:

- 7. Stressing the need for Members to ensure the correct grant of patents for novel and non-obvious inventions related to genetic resources and traditional knowledge associated with genetic resources
- 9. Emphasizing the importance of IP patent offices having access to the appropriate information on genetic resources and traditional knowledge associated with genetic resources to prevent the erroneous granting of IP patent rights

These objectives can best be met by establishing an accurate and accessible record of genetic resources and traditional knowledge, so that Examiners can use the record to assess novelty and inventive step of inventions which are related to the genetic resources. IPO does note, however, that the geographic origin of the genetic resources and traditional knowledge is rarely related to these objectives.

WIPO is also encouraged to further develop its role in advocating for IP use in developing countries and by groups and individuals holding traditional knowledge. These groups and individuals may be able to seek intellectual property protection for the knowledge or its application, or may take advantage of WIPO databases or other publication methods to prevent others from obtaining patent rights.

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

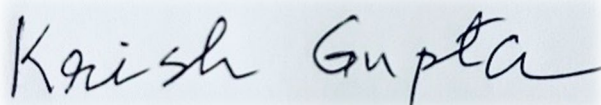
As noted above, IPO encourages the development and use of databases for the defensive protection of genetic resources and traditional knowledge associated with genetic resources. Databases can be used by patent applicants and examiners worldwide to identify prior art. An effective database of genetic resources and associated traditional knowledge will prevent third parties from obtaining rights in known subject matter.

Erroneous granting of patents can be effectively addressed by improving databases for storing genetic resources and non-secret traditional knowledge associated with genetic resources that are used for prior art or reference material searches, as well as through utilizing certain existing institutional systems in coordination more efficiently.

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IPO thanks the USPTO for its attention to IPO's comments submitted herein and welcomes further dialogue and opportunity to provide additional comments.

Sincerely,



Krish Gupta  
President