



## American Intellectual Property Law Association

March 18, 2025

Michael Buckler, Patent Attorney,  
Mail Stop OPIA, U.S. Patent and Trademark Office,  
P.O. Box 1450,  
Alexandria, VA 22313-1450.

*Via Federal Rulemaking Portal at <https://www.regulations.gov>*

**RE: Comments on the World Intellectual Property Organization Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge (90 Fed. Reg. 11, Docket No.: PTO-C-2024-0048, January 17, 2025; FR Doc 2025-01090)**

Dear Mr. Buckler:

The American Intellectual Property Law Association (“AIPLA”) appreciates the opportunity to reply to the notice of January 17, 2025, from the United States Patent and Trademark Office’s (“USPTO” or “Office”) requesting comments on the World Intellectual Property Organization Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge.

AIPLA is a national bar association of approximately 7,000 members that include patent attorneys, patent agents, and other IP 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 (“IP”). 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.

AIPLA has a number of comments which will be summarized and addressed in detail below in response to the questions included in the Federal Register Notice.

***1. In your view, should the United States sign and become a party to the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge? In your response, please identify and explain your reasoning in detail, including legal and policy considerations.***

The United States (U.S.) should not sign and become a party to the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge (hereinafter “WIPO GRTK Treaty”). There are various important reasons to not sign and become a party, including that the requirements are unclear, it would be impossible to comply in some instances, there are apparent conflicts of law and procedure, the burden on the patent system and patent applicants

is immeasurable and undue, and history shows that such requirements are impractical and cannot be met.

As a threshold matter, the vague, absent, or conflicting references to genetic resources (GRs) and associated traditional knowledge (ATK), the lack of metes and bounds of what this might or might not encompass, make it impossible to ascertain whether there is a need for additional disclosure in the U.S. As such, AIPLA underscores that any such new patent disclosure requirement must be understandable,<sup>1</sup> qualified, appropriately limited in scope, not retroactive nor incurable.

A practical reality, which has not been addressed, are instances where it is impossible for applicants to determine the original source of GRs or ATK.<sup>2</sup> Without unambiguous limits of any new disclosure requirement, it is unclear to applicants if patent validity is detrimentally affected. Corrective action should always be available, in every country that signs and becomes a party to the WIPO GRTK Treaty, when and if a disclosure is later found to have been omitted or in need of revision.

For these reasons alone, which are further detailed in the below Comments and in Comments submitted on the 22<sup>nd</sup> of January 2024,<sup>3</sup> the U.S. should not sign or become a party to this treaty as currently written.

***2. In your view, please explain whether the Treaty is consistent with existing U.S. patent law. In your response, please explain your legal reasoning and identify the provision(s) of the Treaty that you view as consistent or inconsistent with U.S. patent law.***

No, the WIPO GRTK Treaty is not consistent with U.S. patent law and would create a disclosure obligation when there is none, and where such disclosure would not benefit the United States nor facilitate the USPTO's review of patentability.

The WIPO GRTK Treaty's proposed mandatory disclosure requirements (Article 3) would be unnecessarily burdensome to a patent applicant and run counter to the basic tenets of U.S. patent law.

The U.S. patent system has stringent and robust disclosure requirements which address all technologies. The patent applicant must describe and enable how to make and use an invention

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<sup>1</sup> The scope of what is a GR or ATK is further muddled by Article 8 of the WIPO GRTK Treaty, which commits parties to a review of the scope and content of the treaty after four years of its entry into force, including the possible extension of the disclosure requirement of Article 3 to "derivatives", which are not defined in the treaty.

<sup>2</sup> Furthermore, digital sequence information (DSI) is not specifically mentioned in the WIPO GRTK Treaty, nor is it explicitly excluded. AIPLA believes requiring the disclosure of the source or origin of DSI, would create further ambiguity and confusion, and thus it should be excluded from the treaty.

<sup>3</sup> Available at: <https://www.aipla.org/detail/news/2024/01/31/aipla-comments-on-wipo-igc-negotiations-on-genetic-resources-and-associated-traditional-knowledge?SSO=Y>.

and applicants are required to provide known prior art material to novelty and obviousness of each asserted patent claim. Therefore, a GR and/or ATK is already addressed, and if knowledge of it is deemed material to the question of patentability of any claimed invention, the applicant is already obligated to disclose the details of this information to the patent office, for example, as prior art, prior acts, or otherwise.

If the GR and/or ATK is not material to the question of patentability, under the U.S. patent system, the patent applicant is not obligated to disclose it. Any added requirement to disclose something that may not be material to the question of patentability would force patent applicants to decide subjectively when and to what extent an additional disclosure, beyond that required by existing U.S. patent law, would be required to comply with the WIPO GRTK Treaty and would introduce ambiguity into patenting an invention.

***3. If, in your view, the Treaty is inconsistent with existing U.S. patent law, please identify and explain the change(s) to U.S. patent law necessary for compliance with the Treaty. In doing so, please describe any impact(s) of adopting such changes.***

Should the WIPO GRTK Treaty be ratified by the U.S., establishing new legal obligations for a U.S. patent applicant, U.S. patent law would need to be modified. Currently, there is no duty to disclose the country of origin or source of GRs and ATK *unless* related to patentability. See, e.g., 37 CFR § 1.56 – Duty to disclose information material to patentability.

Additionally, U.S. patent law would need to be modified to establish that the new disclosure requirement is a formality, not a requirement for patentability and to safeguard patent applicants from potential negative consequences for failure to disclose the country of origin or source of GRs and ATK when they do not relate to patentability of the invention or where, in good faith, such disclosure was incomplete. And the issue of exposure to sanctions for a good faith violation of such requirement would need clarification, since a potential loss of a patent, transfer of rights, or unenforceability in these instances, would be destructive and untenable.

***4. In your view, please explain whether the Treaty is consistent with existing U.S. international obligations, including treaties, free trade agreements, and other binding international agreement(s). In your response, please explain your legal reasoning and identify any provision(s) of the Treaty that you view as consistent or inconsistent with specific U.S. international obligations.***

AIPLA views the WIPO GRTK Treaty as inconsistent with at least certain provisions of the Trade-Related Aspects of Intellectual Property Rights agreement (“TRIPS”). For example, Article 31 of TRIPS<sup>4</sup> provides that other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by

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<sup>4</sup> Available at: [https://www.wto.org/english/docs\\_e/legal\\_e/27-trips\\_04c\\_e.htm](https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm).

the government, is only permitted under limited circumstances. For example, Article 31 specifies that “such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.”

The WIPO GRTK Treaty provisions of Article 5 may contravene Article 31 of TRIPS because Article 5.1 states that “Each Contracting Party shall put in place appropriate, effective and proportionate legal, administrative, and/or policy measures to address a failure to provide the information required in Article 3 of this Treaty.” Any “appropriate, effective and proportionate” measures cannot include unauthorized use of the subject matter of a patent under Article 31 of TRIPS under any circumstance.

Article 3 of the WIPO GRTK Treaty contains a mandatory disclosure requirement against patent applicants if the claimed invention is “based on” genetic resources or traditional knowledge. This is inconsistent with TRIPS Article 39 which states that “Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to government or governmental agencies in accordance with paragraph 3.” Paragraphs 2 and 3 are reproduced below:

“2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information:

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) has commercial value because it is secret; and

(c) has been subjected to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”

Article 39 paragraph 2 requires member states to provide protections for trade secrets; paragraph 3 reinforces this requirement for pharmaceuticals and agricultural chemicals specifically, given the importance of trade secret protection in these industries. This provision is especially relevant to genetically based technology, which finds particular use in the pharmaceutical and agricultural industries. Under TRIPS member states have an obligation to protect trade secrets pertaining to pharmaceuticals and agricultural chemicals. Any mandatory

disclosure requirement may contravene such rights, especially because Article 3 of the WIPO GRTK Treaty uses language that is not clear, such as “based on” rather than “recited in the claims.”

The current requirement under 35 U.S.C. § 112(a) to fully disclose the invention in such a way as “to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use” the invention, as claimed, is sufficient. 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.” This level of disclosure makes the invention available to the public, conditioned on the possibility of patents rights during the term of any patent that might issue. Insofar as Article 3 of the WIPO GRTK Treaty compels disclosure beyond what the public needs to carry out the invention, this provision conflicts with PCT Article 5, and imposes a needless duty on the applicant.

***5. If the United States does not become a party to the Treaty, please identify any Treaty provision(s) you believe should be incorporated into U.S. patent law. In your response, please explain the reason(s) for and any impact(s) of incorporating the identified provision(s) into U.S. patent law.***

If the U.S. does not become a party to the WIPO GRTK Treaty, AIPLA does not believe that any treaty provisions should be incorporated into U.S. patent law. As discussed above, the current requirements to fully disclose the invention in such a way as to enable the skilled artisan to practice the invention under 35 U.S.C. § 112 is sufficient. The longstanding requirements under U.S. law for a complete written description and an enabling disclosure are the heart of the “transaction” between the inventor and society, wherein society grants limited exclusivity only for the invention as disclosed by the inventor. Amending the Patent Act to include novel disclosure requirements, such as that under WIPO GRTK Treaty Article 3, would necessarily disturb the balance of benefits between the inventor and the public. Adding any WIPO GRTK Treaty provisions, such as a mandatory disclosure requirement as in Article 3 of the treaty, would unnecessarily burden, confuse, and stifle innovation, and detrimentally impact the U.S. patent system.

AIPLA is concerned that incorporation of any WIPO GRTK Treaty provisions into U.S. patent law will add uncertainty and risk, such as increased numbers of unfounded bio-piracy claims, will jeopardize trade secret protections, and will not promote the validity of patents, etc.

A further disadvantage of burdening the Patent Act with additional compulsory disclosure requirements is the possibility that such a disclosure could be used to unfairly invalidate a patent. Patent applicants have a high duty of candor to the United States to disclose information that is relevant to the requirements of the Patent Act, and alleged deficiencies in the performance of this duty are a ubiquitous defense by patent infringers. It is very important that patent

applicants understand the metes and bounds of their duty of candor. Affirmative duties to disclose can pose particular compliance difficulties, because the applicant may be uncertain as to what scope of disclosure is expected or adequate. In such cases patent applicants often over-disclose rather than run a risk of being accused of having withheld something relevant. The USPTO has tried to cope with these affirmative disclosure requirements by enacting regulations to clearly circumscribe what is required of the applicant in particular situations.<sup>5</sup>

***6. In your view please identify and explain the impact(s) of implementing the Treaty in the United States on domestic and global innovation, including science and innovation leadership.***

Early innovation requires funding, research, and development of the innovation to a stage wherein it is more mature and can be translated into a benefit to society. Meeting this endpoint with life science innovations, such as methods, treatments, and products, for example generally requires meaningful patent protection.

The current patent systems, both globally and domestically, already face serious challenges to them, causing a narrowing of available innovative benefits to society. The challenges are real – for example, research costs are high, a large percentage of innovative projects fail, others do not survive regulatory approval, and some do not qualify for patent protection. The overall result is that many promising early innovations die early not because of inherent technical problems but also outside forces leaving them unprotected as an investment.

The WIPO GRTK Treaty proposals for mandatory disclosure of GRs and ATK origin/source go far beyond the stringent requirements of the PCT system and U.S. patent laws. This will increase costs, and potentially risk bringing innovation to society inspired by medical and agricultural advances.

Innovators will be loath to use materials and methods that would trigger these requirements, funders would prefer not supporting projects that pose barriers due to use of “genetic resources” if similar projects are available that could avoid such risks. That would tend to steer away from materials and methods that may indeed be in the hands of Indigenous People or countries with potentially beneficial plants, minerals, and methods. In particular research in countries with potentially beneficial materials and methods might be curtailed at the start whereas focus to achieve sharing of resources would best be started at the research level.

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<sup>5</sup> For example, when a patent application that is entitled to “small entity” status is filed, there is the possibility that small entity status will be lost, increasing fees. Although the applicant has a duty to confirm small entity status, the duty only applies when the application filing fees are paid, when the issue fee is paid, and when maintenance fees are paid. The applicant is not required to investigate small entity status prior to paying every patent fee during prosecution. 37 CFR § 1.27(g)(1).

Even if the WIPO GRTK Treaty were enacted globally, there would be disparity of protection of innovation depending on both the interpretation by individual patent offices of the terms in the treaty, and the tolerance level of the individual patent offices. PCT applications could help smooth the level of protection, but those applications must be ratified in individual countries. This also will put burdens on patent offices in smaller, less wealthy countries. Forum shopping will still be encouraged.

It seems that smaller countries will be less likely to have the ability to manage the new burdens when many of them may be having difficulties even conducting patent processing under current laws.

The scope and content of the disclosure requirement is unclear and in instances, internally inconsistent. This, in itself, renders an evaluation of the effect of the treaty on innovation unpredictable. Consistency and predictability of IP protection are necessary to attract investments in pharmaceutical and biotechnology industries where cost of product developments can run into billions of dollars. Ratification of the treaty has the potential to introduce inconsistent applications between various district courts and patent offices, which could lead to lengthy litigation to resolve issues.

***7. In your view, please identify and explain any impact(s) of implementing the Treaty in the United States on businesses, consumers, investors, and the economy.***

Implementing the Treaty in the U.S. would cause confusion and more cost, which would negatively impact businesses, consumers, investors, and the economy. Additional disclosure requirements generate direct and indirect costs that are significant. In many instances, additional significant resources and hours will be needed to conduct due diligence investigations, resulting in delays, significantly increased costs and will ultimately lead to confusion and, likely, litigation. Although it is unclear what might be required to be disclosed, at a minimum, due to the nature of the analysis, international investigations, international travel, translations, extensive coordination and work with authorities, etc., would likely be required.

The disclosure requirement, such as proposed, has already been shown in some countries to be burdensome and ineffective. For example, Indian Patent Law requires disclosure in the patent specification of the origin or source of genetic resources. Even though the Indian Patent Office insists on this requirement during examination, some believe the provision has been ineffective, as this mode of disclosure does not facilitate tracking or monitoring. Also, 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).<sup>6</sup>

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<sup>6</sup> Available at:  
[https://www.wipo.int/edocs/mdocs/tk/en/wipo\\_ip tk\\_ge\\_15/wipo\\_ip tk\\_ge\\_15\\_presentation\\_manisha\\_desai.pdf](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](https://www.wipo.int/edocs/mdocs/tk/en/wipo_ip tk_ge_16/wipo_ip tk_ge_16_presentation_7desai.pdf).

Similarly, the current patent law in China requires a patent applicant to disclose the direct source and original source of genetic resources for any invention. Under China's patent law, the term "based on genetic resources" is construed broadly and includes "any material taken from human, animal, plant or microorganism which contains functional units of heredity and is of actual or potential value, and genetic information generated from the use of such material." China's patent law further permits a rejection of any patent right where the required information for the genetic resources is not disclosed. Accordingly, the Chinese law introduces special considerations, time, and costs that only bring additional uncertainty into patent application preparation.

In Indonesia, the Patents Act of 2016 requires the disclosure of the "origin" of relevant GR and/or ATK in the description of a patent application. Penalties for noncompliance include the rejection of the patent application. A granted patent can be invalidated by the Indonesian Commercial Court if noncompliance with a GR or ATK is established during a lawsuit.<sup>7</sup> Likewise, in Brazil, failure to disclose the required "access registration" disclosing, where known, the source and geographical origin of "genetic heritage" material may result in rejection of the patent application or invalidation of an issued patent.<sup>8</sup>

In Colombia, similar to the situation in Brazil, failure to disclose the origin of the GR or the acknowledgment of the use of ATK can result in abandonment of the patent application. Furthermore, according to provisions of the Andean community,<sup>9</sup> there is not only an obligation to disclose the origin of the GR or the acknowledgment of the use of ATK, but also it is mandatory to have either government authorization for its exploitation or a license granted by the specific community.

The South Korean delegation at an IGC meeting in 2013 recounted the following concerning experience:

"In 2012, the Korea Intellectual Property Office (KIPO) had spent six months figuring out what kinds of GRs were used in Korean patent applications<sup>10</sup>. More than 100,000

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<sup>7</sup> Undang-Undang Republik Indonesia Nomor 13 Tahun 2016 Tentang Paten [The Law of the Republic of Indonesia No. 13 of 2016 on Patents], art. 132b, as translated by GloboMark, available at [https://www.globomark.com/uploads/2/3/2/6/2326743/0\\_law\\_on\\_paten\\_no\\_13\\_2016\\_official\\_eng.pdf](https://www.globomark.com/uploads/2/3/2/6/2326743/0_law_on_paten_no_13_2016_official_eng.pdf) [Indonesian Patents Act]; Dede Mia Yusanti (Indonesia's Director of Patent, Integrated Circuit Layout Design and Trade Secrets), "Information Systems and Due Diligence Mechanisms Relating to GR and Associated TK," presentation delivered at the WIPO Roundtable Seminar on IP and Genetic Resources (January 21, 2021), available at

[https://www.wipo.int/edocs/mdocs/tk/en/wipo\\_iptk\\_ge\\_21/wipo\\_iptk\\_ge\\_21\\_presentation\\_8\\_yusanti.pdf](https://www.wipo.int/edocs/mdocs/tk/en/wipo_iptk_ge_21/wipo_iptk_ge_21_presentation_8_yusanti.pdf).

<sup>8</sup> Regulations Implementing Brazilian Law No. 13.123, art. 8o, as translated in WIPO, Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge, pp. 62-65 (2nd ed. 2020), available at [https://www.wipo.int/edocs/pubdocs/en/wipo\\_pub\\_1047\\_19.pdf](https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1047_19.pdf) [Regulations Implementing Brazilian Law No. 13.123].

<sup>9</sup> Andean decision 486.

<sup>10</sup> WIPO/GRTKF/IC/23/8 PROV. 2 page 26, available at:

[https://www.wipo.int/edocs/mdocs/tk/en/wipo\\_grtkf\\_ic\\_25/wipo\\_grtkf\\_ic\\_25\\_ref\\_grtkf\\_23\\_8\\_prov\\_2.pdf](https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_25/wipo_grtkf_ic_25_ref_grtkf_23_8_prov_2.pdf).



patent applications were filed at the KIPO yearly. The scope of the study was restricted to biotechnology according to the IPC. Even with that restriction, there had been still an overflowing number of applications. Therefore, the study was further restricted to the past two years. The results of the study showed that the patents regarding GRs needed a systematical database. Most of the GRs in patent applications were disclosed in several ways, including academic terms in Latin, typical names and even terms used by local communities. Thus, patent examiners needed to search more than 5,000 GRs one by one to clarify which specific GR was used. The origins of the used GRs were usually unclear with some coming from traditional markets, mountains or regular companies. Even with the restrictions, the study required lots of resources from the KIPO to finger out the type of the used GRs. Therefore, the study could not be extended to include other IPCs over a longer period of time because of the overwhelming amount of resources that was needed. Thus, the Delegation was very concerned about disclosure requirements in a practical sense. If mandatory disclosure requirements were adopted, it would be a great burden on the IP offices of Member States.”

AIPLA submits that the current disclosure requirements of the USPTO are sufficient to ensure transparency and legal certainty. Disclosure requirements, such as written description and enablement, are already required in the U.S. Each requirement has an indirect and a direct cost. Adding yet another disclosure requirement for PCT applicants will unnecessarily burden, confuse, and stifle innovation, and ultimately detrimentally impact patent systems.

Some sectors may be at greater risk than others. The agricultural sector is estimated to experience significant impact from the WIPO GRTK Treaty. For example, plant materials (including plants, seeds, genes, and products) and methods relating to plants (e.g., methods of breeding and improving) have several routes of intellectual property protection available in the U.S. and other countries, but the impact on these varied rights stemming from the various intellectual property laws relevant to them in view of the WIPO GRTK Treaty has not been considered.

For example, in the U.S. multiple protective laws are created to balance one another in areas of technology and innovation deemed critical economic sectors, including the agricultural sector. Such plant protection intellectual property laws and rights are varied, and include utility patents, plant patents (U.S. only), plant variety certificates, and breeders’ certificates. The WIPO GRTK Treaty provides new mandatory disclosure of GR and TK in PCT applications but there are already restrictions on protection of many aspects of “plant IP” in the PCT process, in particular on living materials (e.g., seeds) but also other forms of genetic material.<sup>11</sup> The WIPO GRTK

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<sup>11</sup> Although PCT applications may include claims to actual seeds, trees, plants, genes, and the like, the opinions on patentability very frequently do not, and are unlikely, to address such claims and will so state. Claims for which utility patents are available in some countries (notably the U.S.) may be covered in the PCT opinion. If

Treaty's new disclosure requirement will cause additional complexity and variation among protection in individual countries (such as in the U.S. and the varying laws that protect plant rights) as well as in different countries, and increase burden at the member states patent offices.

There are other routes for protecting rights in plants other than a PCT application. Most countries will only consider certain components, such as "live" material, such as through The Union for the Protection of New Varieties of Plants (UPOV). How will the WIPO GRTK Treaty extend to, conform with or conflict with UPOV applications? There are also questions about specimen deposit – there are various countries in which live materials may be protected through deposit, via the Budapest Treaty. But it is unclear if under the WIPO GRTK Treaty such deposits will now require additional disclosure as to sources and/or origins? Various disclosures are already frequently required (e.g., location of growth, location where the specimen was found, means of obtainment, etc.).

In the U.S., the patent system and patent disclosure requirements are neither designed nor intended to regulate access and/or benefit sharing of any resource, including genetic resources or specific sectors. Under the U.S. 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 to inventors of exclusivity in and to discoveries. As a result, the U.S. patent system provides a mechanism to *protect* investment in innovation and creativity in order to advance science across various types of innovation. The U.S. Patent Act, however, does *not* regulate access to genetic materials or track the sharing of benefits for any resource or related technological advancement. Expanding mandates under the Patent Act to serve other purposes arguably goes beyond the grant of Congressional power to grant patents and copyrights in Article I, Section 8, Clause 8 of the U.S. Constitution.

AIPLA believes that benefit sharing should never obfuscate disclosure requirements in patenting.

***8. Based on your experiences with other countries that require patent applicants to disclose the source or origin of GRs or ATK, please identify and explain any possible impact(s) of Treaty implementation in the United States.***

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such claims are not considered why would patent applicants include them in PCT applications, when applicants know they will not be addressed? Those claims are included because in some PCT countries, such claims may be allowable in some, perhaps alternative, form(s). By entering the PCT application the priority dates of the "inventions" is clear and of record. The living materials for which protection will be sought in the countries allowing such coverage generally require live materials to be deposited, i.e., in accordance with the Budapest Treaty, prior to filing in member countries through the PCT. The PCT application does not lead directly to patents, the PCT application must be verified in member countries to obtain patents in those countries. For plant technologies, at what stage would the mandatory disclosure of GR and TK be required? If not at the PCT stage, would member countries need to impose the requirement at the national stages?

Patent practitioners who have applications in life sciences may try to avoid filing in countries with mandatory disclosure of “source/origin” of GRs or TK. If necessary, however, the patent practitioner will try to determine if the claims to be patented fit under the definition of the terms in that country. Next the practitioner will try to determine what type of evidence is required for compliance in that country and try to determine if such information is available or could be obtained. In some cases, only very recent data is available from the inventors, e.g., “we purchased some fruit in country X in a market and the fruit extract had antiviral properties”. No information may be found on the source of the fruit used. Some countries will accept that, but the degree of evidence required is likely to vary among countries. If such disclosure is mandatory under the Treaty, without further definition of the extent of proof needed, and the limit of “source” or “origin”, each country will choose to follow its own levels of compliance required causing great difficulties in coordinated global patenting.

AIPLA members surveyed report that jurisdictions with the patent disclosure requirement should be avoided. 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.<sup>12</sup> If the treaty is enacted in the U.S., patentees may avoid patenting in the U.S. to avoid having to disclose the source of a GR and/or ATK.

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. Forum shopping will still occur if the WIPO GRTK Treaty is enacted in all countries. Risks of invalidity of patents issued in countries with different levels of enforcement will lead to costly litigation, therefore filing in those countries will be avoided. Countries who are not signatories to the Treaty could benefit if they have no disclosure requirements such as those in the Treaty, but those countries may not be desirable for other reasons, e.g., market value.

The decision for practitioners will increasingly be to use trade secrets or other methods of protection or to draft less valuable claims to avoid any disclosure problems.

## ***9. General Concluding Comments***

In summary, the WIPO GRTK Treaty creates novel requirements for patenting that are unclear, diminish the value of patents, reduce incentives to innovate, and do not share the goals of the patent system. A patent is a critical bargain between an inventor and society: society pays the

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<sup>12</sup> Statistics for 2017-2023 are available at: <https://www.ige.ch/en/services/publications/statistics/patent>.

inventor in exclusivity, and the inventor repays society by adequately disclosing the invention. Because disclosure (or more precisely the loss of nondisclosure) is the cost to the inventor for the patent, the quantity and nature of the disclosure dictate the magnitude of the cost. The net value of the patent to the inventor is the value of the exclusivity less the value of nondisclosure. By increasing the burden of disclosure, the net value of the patent is reduced. As the function of a patent is to incentivize innovation and the disclosure of innovation, it is foreseeable that implementation of the WIPO GRTK Treaty will reduce incentives to innovate and disclose.

It is also clear that the goal of the WIPO GRTK Treaty is something other than providing incentives to innovate. This presents a problem under U.S. law. The Patent Act falls under Congress's power "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." Tacking a provision onto the Patent Act that has no clear relationship with promoting the progress of science and technology arguably falls outside of Congress's "patent power." Such a law would need to be drafted so as to invoke another congressional power.

AIPLA believes the WIPO GRTK Treaty would not benefit the U.S. and is incompatible with the values of our intellectual property system. AIPLA counsels against becoming a party.

AIPLA appreciates the opportunity to comment on these important matters and stands ready to respond to any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Salvatore Anastasi". The signature is fluid and cursive, written in a professional style.

Salvatore Anastasi  
President-Elect  
American Intellectual Property Law Association