

WIPO Negotiations for an International Legal Instrument on Intellectual Property and Genetic Resources

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Abstract

Over the past few years, Member States of the World Intellectual Property Organization (WIPO) have engaged in negotiations for concluding an international legal instrument on intellectual property and genetic resources. While developing countries have a major interest in securing through this instrument a mandatory requirement for applicants of IP rights over innovations that utilize genetic resources or associated traditional knowledge to disclose their source or origin, certain developed countries that are major markets for such products are absolutely opposed to recognizing the disclosure requirement as an objective of the legal instrument under negotiation. Other developed countries are agreeable to a disclosure requirement with a narrow scope, broad exceptions, and weakened remedies against non-compliance. This Policy Brief analyses the current state of play in the negotiations considering the different positions as reflected in the draft negotiating text, as well as a proposal by the Chair of the WIPO intergovernmental committee where the negotiations are taking place, to bridge the difference and take the negotiations forward. This brief concludes that any meaningful international legal instrument on IP and GRs in WIPO must recognize the fundamental issue of misappropriation of GRs through the IP system that should be resolved through a mandatory disclosure requirement as the principal mechanism. It would also be critical to ensure that the WIPO instrument is coherent with other related international legal instruments such the Convention on Biological Diversity, the Nagoya Protocol on access and benefit-sharing; specialized instruments like the FAO Plant Treaty as well as related mechanisms or fora like the WHO (on use of pathogens as a genetic resource) and the United Nations Convention for the Law of the Sea (UNCLOS) negotiations on marine genetic resources beyond areas of national jurisdiction.

En los últimos años, los Estados Miembros de la Organización Mundial de la Propiedad Intelectual (OMPI) han entablado negociaciones para concertar un instrumento jurídico internacional sobre la propiedad intelectual y los recursos genéticos. Si bien los países en desarrollo tienen un gran interés en asegurar mediante este instrumento un requisito obligatorio para los solicitantes de derechos de propiedad intelectual sobre las innovaciones que utilizan recursos genéticos o conocimientos tradicionales asociados para revelar su fuente u origen, algunos países desarrollados que son importantes mercados para esos productos se oponen absolutamente a que se reconozca el requisito de divulgación como un objetivo del instrumento jurídico que se está negociando. Otros países desarrollados están de acuerdo con un requisito de divulgación de alcance reducido, con amplias excepciones y con remedios debilitados contra el incumplimiento. En el presente informe de política se analiza la situación actual de las negociaciones teniendo en cuenta las diferentes posiciones reflejadas en el proyecto de texto de negociación, así como una propuesta del Presidente del comité intergubernamental de la OMPI en el que se están llevando a cabo las negociaciones, para salvar la diferencia y hacer avanzar las negociaciones. En este informe se concluye que cualquier instrumento jurídico internacional significativo sobre la propiedad intelectual y los recursos genéticos en la OMPI debe reconocer la cuestión fundamental de la apropiación indebida de los recursos genéticos a través del sistema de propiedad intelectual, que debe resolverse mediante un requisito de divulgación obligatoria como mecanismo principal. También sería fundamental garantizar que el instrumento de la OMPI sea coherente con otros instrumentos jurídicos internacionales conexos, como el Convenio sobre la Diversidad Biológica, el Protocolo de Nagoya sobre el acceso y la distribución de beneficios; instrumentos especializados como el Tratado sobre las Plantas de la FAO, así como otros foros conexos como la OMS (sobre la utilización de patógenos como recurso genético) y las negociaciones sobre los recursos genéticos marinos fuera de las zonas de jurisdicción nacional en el marco de la Convención de las Naciones Unidas sobre el Derecho del Mar (" UNCLOS ").

Depuis quelques années, les États membres de l'Organisation mondiale de la propriété intellectuelle (OMPI) ont engagé des négociations en vue de la conclusion d'un instrument juridique international sur la propriété intellectuelle et les ressources génétiques. Tandis que les pays en développement ont un intérêt majeur à obtenir par cet instrument une exigence obligatoire pour les demandeurs de droits de propriété intellectuelle sur les innovations qui utilisent des ressources génétiques ou des connaissances traditionnelles associées de divulguer leur source ou leur origine, certains pays développés qui sont des marchés importants pour ces produits sont absolument opposés à la reconnaissance de l'exigence de divulgation comme un objectif de l'instrument juridique en cours de négociation. D'autres pays développés acceptent une obligation de divulgation avec un champ d'application étroit, de larges exceptions et des recours affaiblis en cas de non-respect. Cette note d'orientation analyse l'état actuel des négociations en tenant compte des différentes positions telles qu'elles sont reflétées dans le projet de texte de négociation, ainsi que d'une proposition du président du comité intergouvernemental de l'OMPI où se déroulent les négociations, visant à combler les différences et à faire avancer les négociations. Ce document conclut que tout instrument juridique international significatif sur la PI et les ressources génétiques au sein de l'OMPI doit reconnaître la question fondamentale de l'appropriation illicite des ressources génétiques par le biais du système de la PI, qui devrait être résolue par une obligation de divulgation en tant que mécanisme principal. Il serait également essentiel de veiller à ce que l'instrument de l'OMPI soit cohérent avec d'autres instruments juridiques internationaux connexes tels que la Convention sur la diversité biologique, le protocole de Nagoya sur l'accès et le partage des avantages, les instruments spécialisés comme le traité de la FAO sur les plantes ainsi que les mécanismes ou forums connexes comme l'OMS (sur l'utilisation des agents pathogènes comme ressource génétique) et les négociations de la Convention des Nations unies sur le droit de la mer (UNCLOS) sur les ressources génétiques marines dans les zones situées au-delà des juridictions nationales.

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Countries that are rich in genetic resources (GRs) – and these are mostly developing countries – have a major interest in ensuring that intellectual property (IP) rights are not acquired wrongfully over the GRs that originate or are sourced from their territories and associated traditional knowledge about their use. To this end, while a number of countries have introduced a requirement for applicants seeking IP rights to mandatorily disclose the country of origin or source of a genetic resource used in the making of the claimed product, some developed countries that are the major markets for such products do not have such a requirement, risking the possibility of wrongful grant of IP rights over claims based on GRs or associated traditional knowledge. Therefore, an international legal instrument requiring all countries to introduce such a mandatory disclosure requirement has been a long-standing demand of developing countries at the multilateral level.

In the World Intellectual Property Organization (WIPO), developing countries are currently engaged in negotiations for a draft text of an international legal instrument on intellectual property and genetic resources (GRs). These negotiations are ongoing in the WIPO Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (IGC) since 2010, with no outcome so far. The mandate of the IGC has been renewed for the 2020-2021 biennium by the WIPO General Assembly.¹

The IGC negotiations in WIPO have been fraught with tensions. The biggest obstacle to advancing the work in IGC is the lack of genuine interest among some developed countries in reforming their national IP laws. They deny any need for reforming the IP system to address issues related to access and benefit-sharing of GRs and associated traditional knowledge. While some developing countries have advanced proposals on a disclosure requirement informed by their experience in implementing such a requirement in their national laws, there are many other developing countries who lack experience with related national legislation, and thus play a passive role in the negotiations.² This means that the fundamental proposals in the IGC negotiations reflect the following: a) a contention between countries that seek a disclosure requirement and those that are absolutely opposed to the idea, and b) a difference of views between countries that agree to a disclosure requirement but differ on the scope and extent of the disclosure requirement. While progress has been made towards reaching agreement among the countries that are in principle supportive of the disclosure requirement, consensus has been blocked by countries like the United States and Japan that fundamentally view that a disclosure requirement

would weaken the patent system and are thus strongly opposed to it. As of the last session of the IGC in 2018 that discussed the GRs text, this fundamental opposition has blocked consensus on a text which enjoyed broad support from most countries.³

For developing countries, the key objectives to pursue through an international legal instrument on IP and GRs are: 1) establishing an obligation for all countries to adopt a mandatory disclosure requirement regarding the origin or source of GRs utilized in an IP application, and 2) ensuring mutual supportiveness of IP laws with obligations under ABS laws (the international legal obligation of access and benefit-sharing and prior informed consent (PIC) for accessing and using GRs).⁴

According to a WIPO study, about 35 countries have introduced some form of disclosure requirement in relation to GRs in their patent laws.⁵ In this context, harmonization of minimum standards of the disclosure requirement through a WIPO instrument is desirable.

Ensuring Consistency of a WIPO Instrument with the CBD and the Nagoya Protocol

An effective international legal instrument that introduces a mandatory disclosure requirement for IP applications to state the country of origin or source of a GR or associated traditional knowledge utilised in an IP application can be supportive of the obligations that most of the member States of WIPO have agreed to in relation to access to GRs and the sharing of benefits arising from their utilisation under the Convention on Biological Diversity, and more specifically, the Nagoya Protocol.⁶ At the same time, developing countries should ensure that the instrument does not derogate from the obligations under the CBD and the Nagoya Protocol. In particular, it will be important to ensure that the definition of GRs to which the disclosure requirement would apply is consistent with the scope of GRs under the CBD and the Nagoya Protocol. In this sense, the disclosure requirement under the WIPO instrument must also apply to derivatives or biochemical compositions of GRs and not be limited to the use of the genetic material of biological organisms that contain functional units of heredity, as the derivatives of GRs are included within the scope of the Nagoya Protocol.⁷ Similarly, any provision creating exceptions to the mandatory disclosure obligation under the WIPO instrument should also not derogate from the CBD and the Nagoya Protocol.

Current Draft Negotiating Text

The current draft consolidated text on GRs is comprised of 13 articles. These include articles on general definitions of terms (article 1); articles on mandatory disclosure requirement – objective (article 2), subject matter (article 3), disclosure requirement (article 4),

exceptions and limitations (article 5), sanctions and remedies (article 6); articles on defensive or complementary measures – due diligence (article 7), prevention of erroneous grant of patents and voluntary codes of conduct (article 8); and final provisions – preventive measures for protection (article 9), relationship with international agreements (article 10), international cooperation (article 11), transboundary cooperation (article 12), and technical assistance, cooperation and capacity building (article 13). The provisions on mandatory disclosure requirement in particular have been highly contested, with polarized alternative provisions advanced by some developed countries that reject or limit the scope of a mandatory disclosure requirement.

Definition of Genetic Resources

A fundamental aspect of the WIPO instrument is the understanding of the term genetic resources in the instrument. The current draft consolidated text advances alternative definitions of the term. One approach, advanced by developed countries, is that genetic resources should be understood as genetic material of actual or potential value, wherein genetic material is defined as plant, animal, microbial or other origin containing functional units of heredity. As explained above, this approach excludes biochemical components or derivatives of GRs, and thus derogates from the Nagoya Protocol. Developing countries have proposed an alternative formulation that includes derivatives and genetic information of genetic material within the definition of GRs. This approach is consistent with the Nagoya Protocol and is also evolutionary in accommodating sequence information of genetic material within the scope of GRs.

Objective

In the current version of the consolidated draft text on GRs⁸ the objective of the proposed instrument is:

1. to contribute to the protection of GRs and associated traditional knowledge within the IP system by ensuring mutual supportiveness between international instruments relating to GRs, such as the Convention on Biological Diversity (CBD) and 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 (Nagoya Protocol), and instruments relating to IP;
2. enhance transparency in the IP system in relation to GRs; and,
3. ensure access to appropriate information relating to GRs to IP offices in order to prevent erroneous grant of IP rights.⁹

This provision also enjoyed broad support from most countries at the conclusion of the latest round of negotiations on the GRs text in 2018.

However, the United States has rejected any reference to the protection of GRs and associated traditional knowledge as an objective of the instrument and has rather proposed an alternative text that the objective of the instrument should be restricted to prevention of grant of patent rights for inventions that do not meet the criteria of patentability.¹⁰

Subject Matter

There is a divergence of views on whether GRs in the context of all IP rights should be within the scope of this instrument or whether the scope should be limited to protection of GRs in the context of patent rights. Developing countries favor a broad application of the instrument to all kinds of IP protection,¹¹ while developed countries favor a very restrictive scope of this instrument and limit it to patent applications for inventions directly based on GRs.¹² Thus, the disclosure requirement about the source and origin of GRs used in IP applications is at the heart of the proposed instrument.

Developing countries have proposed that where a subject matter of an IP application includes utilization of GRs and associated traditional knowledge, the applicant shall be required by each country to disclose the country of origin and/or source of the GR and associated traditional knowledge. Developed countries which prefer a softer disclosure requirement have sought to limit the scope of the disclosure requirement to only claimed inventions in patent applications that are directly based on GRs and associated traditional knowledge.

Disclosure Requirement

The GRs text is based on two pillars – establishing a mandatory disclosure requirement about the origin and source of the GRs; and adopting complementary measures for defensive protection of GRs from misappropriation. These two pillars reflect two mechanisms that are proposed in the GRs text for preventing misappropriation of GRs and associated TK – disclosure requirements and databases. These mechanisms also reflect the respective preferences of the countries that generally are providers of GRs (developing countries) and the countries that primarily utilize the GRs to develop inventions based on them (developed countries). While the disclosure requirement is essential to the former, databases that provide information to avoid erroneous grant or registration of IP rights are the preferable option for the latter.¹³

There is a fundamental divergence of views between the proponents of a disclosure requirement and the United States in particular. While there are differences

about the framing of the disclosure requirement among some countries, the United States completely rejects any disclosure requirement on GRs, other than the standard disclosures to be made in patent applications. The alternative proposal from the United States affirms that the disclosure of the source location of the GR may be required of the patent applicant only where such disclosure is relevant to the determination of novelty, inventive step or industrial applicability of the application. This mirrors a similar approach pursued by the United States under bilateral FTAs with developing countries.

Developing country proponents of the disclosure requirement have also sought to enable States that would be parties to the instrument to require applicants to provide relevant information regarding compliance with ABS requirements, including prior informed consent, in particular from indigenous peoples and local communities, where appropriate. However, developed countries that support the disclosure requirement prefer to keep compliance with ABS requirements outside the scope of the instrument.

In keeping with its position rejecting any mandatory disclosure requirement, the United States has suggested an alternative provision stating that patent applicants could be required to disclose the source of a GR only where the knowledge of the location is necessary for a person skilled in the art to carry out the claimed invention.¹⁴ The United States also suggests making the disclosure requirement subject to the terms of an agreement between the patent applicant and the provider of the GR. This is in line with the US approach of addressing the terms of acquisition and use of GRs through contractual agreements between the bioprospector and the country or community who have legal rights over the GR.¹⁵

Exceptions and Limitations

Draft art. 4 of the consolidated text is focused on exceptions and limitations to the disclosure requirement. It presents two alternative options. One option is to introduce a general enabling provision allowing State parties to adopt justifiable exceptions and limitations necessary to protect public interest provided that these exceptions and limitations do not unduly prejudice the implementation of the instrument on GRs, or mutual supportiveness with other instruments. The alternative option proposes to introduce specific exceptions for human genetic resources including human pathogens, derivatives of GRs, use of GRs as commodities, GRs beyond national jurisdictions and economic zones (an expression which applies to marine genetic resources in the high seas and in the international seabed), GRs acquired

before the entry into force of the CBD and the Nagoya Protocol, and GRs necessary to protect human, animal or plant life or health.

It will be important to ensure while carving out exceptions from the obligations under the WIPO instrument that it does not derogate from the CBD and the Nagoya Protocol. Notably, the Nagoya Protocol allows its parties to develop and implement other relevant international agreements, such as the WIPO instrument, provided that they are supportive of and do not run counter to the objectives of the CBD and the Nagoya Protocol. The Nagoya Protocol does not create specific exceptions such as use of derivatives of GRs, use of GRs as commodities or for human genetic resources, unlike one of the approaches proposed in the draft WIPO instrument. Article 8 of the Nagoya Protocol allows parties to create limited exceptions such as create conditions for simplified access to GRs for non-commercial research, or pay due regard to expeditious access to GRs such as pathogens in cases of present or imminent emergencies that threaten or damage human, animal or plant health. The specific exceptions proposed in the draft text of the WIPO instrument would therefore mark a substantial derogation from the Nagoya Protocol. Moreover, a specific exception for marine genetic resources in areas beyond national jurisdictions would undermine the ongoing negotiations under the United Nations Convention on the Law of the Sea for an agreement on the use of marine genetic resources in areas beyond national jurisdiction in the seas, wherein a provision on IP is also included, and addressing IP issues relating to such GRs through a WIPO instrument has been one of the approaches proposed.¹⁶

Sanctions and Remedies

A major issue of contention with regard to the disclosure requirement is the question of sanctions and remedies to ensure compliance with the disclosure requirement. The draft text presents three alternate approaches in this regard. One approach is that of setting general principles or standards of remedy that must be satisfied while leaving States free to determine the specific means of ensuring compliance in accordance with those standards. Another approach presents specific remedies and sanctions that are set as desirable measures that national laws should adopt. The third alternative approach is to have a very weak enforcement provision which safeguards IP rights obtained without complying with the disclosure requirement.¹⁷

Defensive/Complementary Measures

The draft consolidated text also contains two provisions (articles 7 and 8) titled within square brackets as “defensive/complementary measures.” The language of the heading of this section of the consolidated text reflects the difference in perspectives between developed and developing countries. The word “defensive”

reflects the preference of developed countries to use mechanisms such as databases of GRs and associated traditional knowledge as an alternative to a disclosure requirement, while the word “complementary” reflects the position of developing countries that while such mechanisms may be useful, they cannot be an alternative to the disclosure requirement, and hence could, at best, be considered as complementary measures to a disclosure requirement. While a database could be useful in enabling patent offices examining a patent claim that utilizes a GR to determine the patentability of such an application in the light of the GR and associated traditional knowledge already disclosed in the database, such databases may not be exhaustive or comprehensive of all GRs and associated traditional knowledge of country, especially if such knowledge is undocumented.¹⁸

Proposed Text of the Chair

In view of the divergent objectives pursued by different parties in the IGC negotiations on the GRs text, the Chair of the IGC, Prof. Ian Goss from Australia, has advanced a proposal on the way forward with a view to bridging the differences and balancing the rights and interests of users vis-a-vis that of the providers and holders of GRs and associated traditional knowledge.¹⁹ While the proposed Chair’s text includes disclosure as a core element, it can be significantly strengthened through possible modifications to the proposed provisions on the objectives of the instrument, definitions of terms that would trigger the disclosure requirement, limiting the scope of exceptions to the disclosure requirement, and by requiring parties to the instrument to ensure the availability of adequate and effective sanctions and remedies, including the possibility of providing for revocation as a possible sanction.

Objectives: No Reference to Misappropriation

The Chair’s draft text advances two objectives of the instrument: 1) to enhance the efficacy, transparency and quality of the patent system; and 2) to prevent the erroneous grant of patents that are not novel or inventive with regard to GRs and associated traditional knowledge. The text lacks a clear acknowledgement of the problem of misappropriation which is the core issue that developing countries are seeking to address through a disclosure requirement in IP or, more specifically, patent applications. Instead, the Chair’s text on the draft articles proposes objectives such as enhancing transparency and quality of the patent system and compliance with patentability requirements with regard to GRs. Thus, countries such as the United States that wish to avoid an obligation to introduce a mandatory disclosure requirement could still be accommodated under such an

objective insofar as those countries adopt other, even though less satisfactory means, that could, in a limited way, be said to be in compliance with such broad objectives.

The explanatory note to this draft provision in the Chair’s proposal states that the provision does not make any reference to misappropriation or ABS as these issues are dealt with under international instruments such as CBD, the Nagoya Protocol, the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, and the WHO Pandemic Influenza Preparedness Framework. However, the fact that misappropriation has been addressed in other international instruments does not mean that the issue of misappropriation is not relevant for the WIPO instrument. In fact, an instrument that seeks to address IP related issues concerning misappropriation should clearly mention prevention of such misappropriation as an objective.

Unless this core issue concerning GRs and associated traditional knowledge is not specified in the objectives provision of the instrument, this will create uncertainty about the problem that the instrument seeks to resolve through the promotion of transparency and prevention of erroneous grant of patents. In the event of ambiguity in interpretation of the text, the preamble can be referred to for guidance. However, it should be noted that even the preamble in the Chair’s text does not mention any recognition of the problem of misappropriation of GRs and associated traditional knowledge. Article 31 of the Vienna Convention on the Law of Treaties states that the provision of a treaty shall be interpreted in the light of its objects and purposes. Thus, it is critical that the preamble and the provision on the objectives of the WIPO instrument recognize the problem of misappropriation and state the intent to resolve the IP related aspects of this problem as the main objective of the instrument.

Definitions

The Chair’s text defines genetic resources as genetic material of actual or potential value, and it also defines genetic material as any material or plant, animal, microbial or other origin that contains functional units of heredity. This definition excludes any scope of including derivatives within the meaning of genetic resources, in a significant derogation from the Nagoya Protocol.

Definitions that are unique in this instrument are the expressions “materially/directly based on”, “source of GRs” and “source of TK associated with GRs”. Of these the most critical is the expression “materially/directly based on.” The European Union (EU) in particular has been seeking to limit the scope of disclosure requirement in patent applications to inventions that are “directly” based on GRs. The Chair has proposed to use

the expression “materially based on” as an alternative to the expression “directly based on”, because the latter signifies the need to establish physical access to GRs in order to trigger the disclosure requirement. However, the expression “materially” literally means the extent to which something is present or involved in the development of something. Therefore, this expression means that the disclosure requirement can only be triggered if the GRs in question are materially or substantially present in a claimed invention. This would give significant discretion to patent offices to determine whether any GR is substantially present in a claimed invention. Thus, countries that seek to limit the disclosure requirement could adopt very high thresholds for determining whether the invention is materially based on GRs, thus limiting the instances where the disclosure requirement could be triggered. This would frustrate the very purpose of a disclosure requirement. Therefore, it would be pertinent to have any use of a GR in a patent application as a trigger for the disclosure requirement rather than setting a fictional threshold of the extent to which an invention is materially based on GRs.

Perhaps, disclosure can be made a requirement based on any use of a GR in an invention, but countries could still retain the policy space to determine the extent to which such use is material to the patentability of the invention. This would ensure that disclosure is made in all countries if a GR is used in an invention, but all countries may not rely on that disclosure in deciding on the application unless they regard the use of the GR to be materially significant.

With regard to the definitions of source of GRs and associated traditional knowledge, the Chair’s proposal refers to any source from which the applicant has obtained the GR or associated traditional knowledge, but then gives examples of the kind of sources referred to with the expression “such as.” In accordance with the principle of *ejusdem generis* that is applied in interpretation of legal texts, the nature of specific examples given in a text can determine the kind of source which is included within the definition. When applied in respect of the definition of source of associated traditional knowledge, this suggests that only published material on the associated traditional knowledge will be within the scope of the definition of sources. Therefore, instead of referring to specific examples, the definition should make the examples inclusive and read “Source of associated traditional knowledge means any source from which the applicant has obtained the associated traditional knowledge including both written and oral sources.”

My main comment is that the need for consistency with CBD, etc. could have been included in a separate section or in the section on “Exceptions” and not

in the conclusions with a bit more elaboration (e.g. the exception of “derivatives” is clearly in conflict with the Nagoya Protocol, ABS for viruses is contemplated under the PIP Framework, etc.).

Exceptions

The draft provision on exceptions in the Chair’s proposal is also very broad, even though it requires such exceptions to be mutually supportive with other instruments, such as the Nagoya Protocol and the CBD, and they do not unduly prejudice the implementation of the WIPO instrument. It provides considerable flexibility to any country to significantly limit the scope of the disclosure requirement, particularly when read in conjunction with the provision on objectives which does not specifically mention disclosure as an objective of the instrument, as well as the narrow definition of GRs that excludes derivatives from the scope of the instrument.

Remedies

The provision on remedies states that each Contracting Party shall put in place appropriate, effective and proportionate legal, administrative, and/or policy measures to address an applicant’s failure to provide the information in terms of the disclosure requirement. It would be better to use the expression “adequate” instead of “appropriate” as a standard of the legal, administrative or policy measures to remedy failure to comply with the disclosure requirement. The provision also excludes revocation as a possible remedy for non-compliance with disclosure requirement, except in circumstances where non-disclosure or wrongful disclosure with fraudulent intent can be established. In the minimum, the option of revocation as a sanction should be available for countries that wish to make revocation a possible remedy for non-disclosure.

Conclusions

Though a WIPO agreement on IP and GRs with an effective disclosure requirement will be ideal, the fundamental problem is that a small group of countries, that also constitute territories where IP applications based on use of GRs is most frequent, are opposed to any form of mandatory disclosure requirement. In effect, this has rendered the outcome of the negotiations uncertain. In the current situation, if there is any agreement at all, it is likely to be one with a very weak and ineffective disclosure requirement.

Even so, developing countries should seek to ensure that in the minimum an international legal instrument negotiated in WIPO IGC acknowledges and recognizes the problem of misappropriation of GRs and associated traditional knowledge through the IP system. Even if it is not possible to have consensus on including all types IP protection within the scope of a disclosure requirement, to be effective the instrument must include

patents and plant variety protection within its scope. The instrument should also be consistent with the Nagoya Protocol to allow countries to include any subject matter that is derived from the utilization of GRs within the scope of a disclosure requirement in an IP application. Thus, the instrument should define genetic resources as inclusive of derivatives as defined in the Nagoya Protocol.

Moreover, the source or origin of the GRs disclosed should not be limited to published sources and should include even unpublished or undocumented sources that the applicant is aware of or should be reasonably aware of. The instrument should also require parties to provide for adequate remedies where the disclosure requirement is not complied with. Even if revocation of a granted IP right cannot be agreed to as a specific obligation, the instrument should not limit interested parties from adopting remedies including revocation, monetary fines, or making an IP right non-enforceable.

Any use of a GR for the registration of an IP right covered under the instrument should be a trigger for the disclosure requirement rather than setting a fictional threshold of the extent to which an invention is directly or materially based on GRs that has been proposed by developed countries in the WIPO negotiations. Disclosure should be a mandatory requirement for applications submitted to IP offices in all countries that are party to the instrument, even if the instrument allows national IP offices the discretion to decide on the material relevance of the disclosed information in the process of examination of the application. The disclosed information could be shared with other national IP offices through an information sharing mechanism, similar to information sharing mechanisms relating to search and examination reports between patent offices.

Developing countries should also ensure coherence with CBD, the Nagoya Protocol, and specialized ABS instruments like the FAO Plant Treaty, or related mechanisms or fora like WHO and the UNCLOS negotiations on marine genetic resources in areas beyond national jurisdiction, in the normative discussions in WIPO and WTO. Specific exceptions and limitations have been proposed which can limit the application of a disclosure requirement under an international instrument on IP and GRs in WIPO, in respect of marine genetic resources, pathogens, use of GRs as derivatives and commodities. It should be noted that an instrument on IP and GRs will essentially create exceptions and limitations to the scope and modalities of grant of IP rights over products derived from GRs. Hence, exceptions and limitations to such an instrument should be extremely restricted as overly broad exceptions could be creatively applied to defeat the very objective of prevention of

misappropriation of GRs and associated traditional knowledge through IP protection.

Endnotes:

¹ World Intellectual Property Organization, Assemblies of the Member States of WIPO, List of Decisions – 2019, pp. 11-13. Available from https://www.wipo.int/export/sites/www/about-wipo/en/assemblies/pdf/2019_decisions.pdf.

² Viviana M. Tellez, "The WIPO Negotiations on IP, Genetic Resources and Traditional Knowledge: Can it Deliver?", Policy Brief No. 22 (South Centre, September 2015). Available from https://www.southcentre.int/wp-content/uploads/2015/10/PB22_The-WIPO-Negotiations-on-IP-Genetic-Resources-and-Traditional-Knowledge-Can-It-Deliver_EN_rev.pdf.

³ Catherine Saez, "WIPO IP and Genetic Resources Committee Makes Progress Despite Block at End", *Intellectual Property Watch*, 2 July 2018. Available from <https://www.ip-watch.org/2018/07/02/wipo-ip-genetic-resources-committee-makes-progress-despite-block-end/>.

⁴ See, e.g., World Intellectual Property Organization, Like-Minded Countries Contribution to the Objectives and Principles on the Protection of Genetic Resources and Preliminary Draft Articles on the Protection of Genetic Resources, WIPO/GRTKF/IC/19/11, 18 July 2011. Available from https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_19/wipo_grtkf_ic_19_11.pdf.

⁵ See World Intellectual Property Organization, "Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge", 2nd edition (WIPO, 2017). Available from https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1047_19.pdf.

⁶ See Oluwatobiloba O. Moody, "WIPO and the Reinforcement of the Nagoya Protocol: Towards Effective Implementation of an Access and Benefit Sharing Regime for the Protection of Traditional Knowledge Associated with Genetic Resources", PhD Thesis, Queen's University, 2016. Available from https://qspace.library.queensu.ca/bitstream/handle/1974/15302/Oluwatobiloba_O_201612_PhD.pdf?sequence=2.

⁷ Article 2(f) of the Nagoya Protocol defines a derivative as a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity. See Gurdial S. Nijar, *The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries*, Research Paper 36 (Geneva, South Centre, 2011). Available from https://www.southcentre.int/wp-content/uploads/2013/08/Ev_130201_GNjar1.pdf.

⁸ World Intellectual Property organization, Consolidated Document Relating to Intellectual Property and Genetic Resources, IGC/GRTKF/IC/41/4, 18 December 2019. Available from https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_41/wipo_grtkf_ic_41_4.pdf.

⁹ *Ibid.*, article 2.

¹⁰ *Ibid.*, alt article 2.

¹¹ *Ibid.*, article 3.

¹² *Ibid.*, alt. article 3.

¹³ David Vivas-Eugui, *Bridging the Gap on Intellectual Property and Genetic Resources in WIPO's Intergovernmental Committee (IGC)*; Issue Paper No. 34 (Geneva, International Centre for Trade and Sustainable Development, January 2012). Available from <https://www.ictsd.org/sites/default/files/downloads/2012/02/bridging-the-gap-on-intellectual-property-and-genetic-resources-in-wipos-intergovernmental-committee-igc.pdf>.

¹⁴ World Intellectual Property Organization, *supra* note 6, alt. article 4.

¹⁵ *Ibid.*

¹⁶ See Siva Thambisetty, “Biodiversity Beyond National Jurisdiction: (Intellectual) Property Heuristics”, working draft paper presented at the 43rd Centre for Oceans Law and Policy Annual Conference, World Maritime University, Malmo, Sweden, 14-17 May 2019. Available from <https://dx.doi.org/10.2139/ssrn.3483670>.

¹⁷ World Intellectual Property Organization, *supra* note 6, alt., article 6.

¹⁸ See Biswajit Dhar, “Relevance of Databases for Protecting Traditional Knowledge: Evidence from India”, Presentation made in the “Seminar on Intellectual Property and Genetic Resources”, organized by the World Intellectual Property Organization, Geneva, 26-27 May 2016. Available from https://www.wipo.int/edocs/mdocs/tk/en/wipo_ip tk_ge_16/wipo_ip tk_ge_16_presentation_13dhar.pdf.

¹⁹ See World Intellectual Property Organization, IGC Chair’s Draft: International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources, 30 April 2019. Available from https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_40/wipo_grtkf_ic_40_chair_text.pdf.



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