

Background Note for the International Conference on TRIPS-CBD Linkage: Issues and way forward¹

PATENT DISCLOSURE REQUIREMENTS IN FREE TRADE AGREEMENTS

Over the last decade, the governments all around the world have pursued an increasing number of bilateral and regional free trade agreements (FTAs). This has marked a considerable shift in international trade diplomacy. A central element of the recent set of bilateral FTAs is the establishment of strong rules for the protection of intellectual property (IP) rights. IP is a key offensive market access interest of developed countries. Developing countries generally have more defensive negotiating interests in IP, but are willing to commit to stronger IP rules as a *quid pro quo* for concessions in other areas—most notably, preferential access to developed country markets for agricultural and manufactured goods. Some recent FTAs include specific measures designed to facilitate access and benefit (ABS) sharing under the Convention on Biologic Diversity (CBD) and the Nagoya Protocol.

There is a growing interest in patent disclosure requirements related to genetic resources (GRs) and traditional knowledge (TK). Disclosure requirements may help to prevent the misappropriation of GRs and TK by ensuring that they are used with the prior informed consent of the provider countries on mutually agreed terms. There is also a complementarity and mutual supportiveness between such disclosure requirements relevant to conservation, sustainable use, and benefit sharing of GRs and TK. Yet, some trade agreements offer a language concerning the efforts needed to establish a mutually supportive relationship

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between the Agreement of Trade Related Aspects of Intellectual Property (TRIPS) and the CBD and introduce disclosure requirements for patent applications related to GRs and TK.

The purpose of this study is to provide information on patent disclosure requirements in FTAs. It offers an overview of the FTA measures related to patent disclosure requirements, outlines key implications from addressing the issue in IP Chapter and elsewhere (e.g. side letters) and concludes with a way forward.

Background

Following the Second World War, free trade policies appeared to be the best strategy to rebuild the world economy and create a more coherent institutional framework to remove the barriers to trade. The General Agreement on Tariffs and Trade (GATT) entered into force in 1948 as the overseer of the multilateral trading system. It was designed to boost the economic recovery through tariff concessions among members and established a code of conduct and procedures for the resolution of trade disputes by negotiation.

The GATT initiated the process of trade liberalization, and since then, the international trade order has become more liberalized and globalized through the founding of the World Trade Organization (WTO) in 1995.

Developed countries and the majority of developing countries became a part of a rapidly integrating world market, regulated by global rules administered by economic governance institutions like the WTO, and international financial institutions. However, conflicts between developing and developed countries over trade liberalization and development policies dominated the WTO talks.

Developing countries, which constitute the great majority of the WTO Members, soon realized the WTO system did not necessarily bring economic growth and development as it was promised. The Doha Development Agenda was launched in 2001 in order to improve trading prospects of developing countries, correct some of the inequities in the WTO Agreements, and remove rules constraining the development focused policies, especially on agricultural trade. Despite years of negotiations, the Doha agenda talks are stalled as tension and disagreements between the developed and developing world impeded progress. Developing country proposals have rarely been discussed, while the United States (U.S.) and other developed countries were eager to close the Doha Agenda and move on to a different agenda for new issues.

The Doha Round is still ongoing sixteen years later, with no clear end in sight. The deep divide between developed and developing countries continuously increasing.

While FTAs have been around in their current form since the 1980s, they became a new governance model for international rulemaking in recent years after governments got disillusioned by the slow pace of

trade liberalization talks at the WTO. Countries have continued engaging, simultaneously or solely, in different modes of trade liberalization – bilateral, regional, and plurilateral.

Strong trade and power asymmetries² exist between the developed and developing countries in FTA negotiations. FTAs tend to favor the country with the best economy and the largest market. That puts the developing countries with a limited market power at a disadvantage. Trade policy making embedded in a larger political process is driven largely by the U.S. and European Union (EU)'s (and other developed countries) self-interests and regional issues. The dispute settlement mechanisms of the FTAs, particularly the US and EU FTAs, offer enforcement measures and stronger incentives for Parties to comply with agreed commitments.

Since 1994, the US has signed 20 free trade agreements (FTAs) with both developed and developing countries including Jordan, Morocco, Peru, Chile, Australia, and Singapore. ³The EU concluded 34 trade agreements with 53 countries worldwide and is in the process of negotiating agreements with many more.⁴

Patent Disclosure Requirements

The concerns over unauthorized access to and use of Genetic Resources (GRs) and Traditional Knowledge (TK) and their subsequent misappropriation have led to the introduction of additional measures for protection. In particular, several countries require Intellectual Property (IP)/Plant Variety Protection (PVP) applicants to disclose, among other things:

- the origin and/or source of GRs and/or traditional knowledge;
- evidence of prior informed consent; and
- evidence of having established a contractual arrangement (mutually agreed terms) for the fair and equitable sharing of the benefit derived from such use if so required by the national legislation of the provider country.

These defensive mechanisms for protection of GRs and TK are generally referred as disclosure requirements. They are deemed to be crucial to the effective functioning of any legislative, administrative or pol-

² Michael Trebilcock, Robert Howse, Antonia Eliason, 2013, The Regulation of International Trade: 4th Edition, Routledge, 2013, p. 98

³ Free Trade Agreements, Office of the United States Trade Representative, available at <a href="https://ustr.gov/trade-agreements/free-trade-agreements

⁴ Negotiations and agreements, The European Commission, available at http://ec.europa.eu/trade/policy/countries-and-regions/negotiations-and-agreements/

icy measures on access and benefit sharing (ABS).⁵ They are widely used as a tool to assist in monitoring the utilization of GRs and TK, and thereby promoting – at least in some cases – compliance with ABS obligations.

Besides these, a vast majority of countries have introduced some sort of disclosure requirements related to GRs and/or TK in their patent law or through other measures within their intellectual property system.⁶ These requirements are implemented in diverse ways, reflecting different policy motivations, political trade-offs, local priorities and needs, and legal and institutional systems. However, key motivations include preventing misappropriation, enhancing efficiency, legal certainty and transparency, and complementarity/mutual supportiveness with international agreements.⁷

Many countries rich in biodiversity regard disclosure requirements as a crucial measure to encourage IP applicants to comply with requirements for prior informed consent and mutually agreed terms. In fact, disclosure requirements may prevent the misappropriation of GRs and TK that have been obtained without the authorization (e.g., in the form of prior informed consent) of the country providing such resources and/or the indigenous peoples and local communities holding such knowledge.

The disclosure requirements can be mandatory or voluntary. Mandatory disclosure requirements may support the ABS system and reduce the free-riding incentives. This may promote positive changes in the attitudes and behaviors of inventors, researchers and intellectual property applicants, and eventually reduce misappropriation. Disclosure requirements may be employed as effective transparency measures improving the examination of IP applications and the determinations of novelty and inventorship (or coinventorship). This may potentially increase legal certainty about the status of granted IP rights and build trust between businesses, governments, and indigenous and local communities. Voluntary disclosure requirements, on the other hand, can be introduced in preamble or a formal part of the patent application process with no bearing on the further processing of the patent application or the validity of granted rights. They may serve as an encouragement and motivation for the patent applicants to disclose origin/source.

Disclosure requirements can also be utilized to fulfil the objectives of the CBD and ensure complementarity and mutual supportiveness. They can be functional for establishing coherence between existing and

⁵ See, the relevant provisions of the Bonn Guidelines (I. General Provisions) and the Nagoya Protocol (Article 6)

⁶ See, WIPO Disclosure Requirements Table, available at http://www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic-resources-disclosure.pdf

⁷ Claudio Chiarolla and Burcu Kilic, Developing Patent Disclosure Requirements Related to Genetic Resources and Traditional Knowledge – Key Questions (Geneva: World Intellectual Property Organization, 2017), https://ssrn.com/abstract=2987820. p.44

future national ABS and national intellectual property laws by showing that GRs/TK were obtained and used in compliance with applicable laws in the country of origin or in compliance with the terms of any specific agreement recording prior informed consent; or showing that the act of applying for an intellectual property IP was in itself undertaken in accordance with prior informed consent.

Several countries, including both developed and developing countries, have already adopted some form of disclosure requirements relating to genetic rights and TK in their national intellectual property laws.⁸ Other countries are currently considering introducing or updating their disclosure requirements in order to achieve one or more of these policy objectives.

Disclosure Requirements in FTAs

Current trend of bilateral and multilateral FTAs has been widely criticized for restricting or removing many of the policy flexibilities embodied in TRIPS, which establishes the minimum standards for protection of IP for all WTO members. These provisions are called "TRIPS-plus" as FTAs parties make commitments for IP standards going beyond TRIPS. TRIPS-plus rules are highly controversial with respect to their negative implications on the preservation of biodiversity. The most significant TRIPS-plus provisions include:

- (a) A relaxed criteria for patentability beyond what is required by Article 27(1) of TRIPS⁹
- (b) The potential extension of patentability to plants and animals by providing no reference or partial reference to Article 27 (3)¹⁰
- (c) The potential adjustment of patent protection beyond the 20-year minimum required by TRIPS¹¹
- (d) Limitation on patent opposition¹²

⁸ *Id*.

⁹ Chapter 14:8.2 of the US Bahrain FTA obliges the parties to the Agreement to make patents available for plant inventions. In addition, the Parties confirm that patents shall be available for any new uses or methods of using a known product, including products to be used for particular medical conditions; Article 46.7 of the EU-South Africa FTA provides that the parties shall ensure adequate and effective protection for patents on "biotechnological inventions".

¹⁰ The US-Jordan FTA includes no reference to Article 27(3) exceptions for plants and animals. The US-Oman FTA includes a provision on the possibility of excluding animals from patentability but says nothing about plants.

¹¹ Under the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), patents expire 20 years after the initial filing date. Measures related to patent term extension go beyond what countries are already obliged to follow under TRIPS. However, such measures appear in U.S. law and the laws of some other countries that have free trade agreements with the U.S., for example Chile , Singapore and the Republic of Korea.

¹² Chapter 15:8.4 of the US FTA with Oman requires that:

[&]quot;Each Party shall provide that a patent may be revoked only on grounds that would have justified a refusal to grant the patent ... Where a Party provides proceedings that permit a third party to oppose the grant of a patent, a Party shall not make such proceedings available before the grant of the patent."

- (e) Adoption of the International Convention for the Protection of New Varieties of Plants¹³
- (f) A ceiling to the patent disclosure requirement¹⁴

However, some recent FTAs include provisions linked to IP which can be used to advance ABS and improve the conservation of biodiversity. These agreements generally include mega-diverse countries such as Peru, Colombia, China or CARICOM. Disclosure related provisions addressing ABS are results of specific requests made by those countries during negotiations. On the protection of GRs and TK, the biodiversity-rich countries share the common interest in recognizing the legal rights of holders and developing mutual agreeable mechanism to protect them.

The scope and depth of the provisions on disclosure differ widely. At one extreme are a number of relatively recent FTAs, whose IP chapters address a wide range of issues, including disclosure of origin/source. The provisions on disclosure of origin/source can be regarded as more of aspirational statements designed to reserve the right of the parties to protect GRs and TK, establishing binding norms. At the other extreme are those that do no more than recognizing the importance of biodiversity and Parties policy space and seek cooperation between regulatory authorities.

Requirements for disclosure are usually incorporated in the substantive IPR Chapter. However, the issue might sometimes be addressed elsewhere such as a letter of understanding or side letters. (*See*, US-Peru, US-Colombia, US-Panama and Japan – Peru FTAs)

Select FTAs on Patent Disclosure Requirements

Peru and Colombia FTAs

The incorporation of obligations on GRs and TK largely depends on the participation of Latin American countries. According to a recent research, out of 50 FTAs which include some kind of provision on GRs over half were signed by at least one country located in Central or South America. The Latin American

¹³ Almost all US FTAs require Parties to ratify the latest version of the UPOV Convention, which provides exclusive property rights for a limited period of time on any plant variety that is novel, distinct, homogenous, and stable. It creates a high degree of harmonization among the parties and leaves little room for flexibilities. The UPOV secretariat strongly opposes disclosure requirement on the basis that "that under the UPOV Convention, protection shall be granted where the variety is new, distinct, uniform and stable. Further or different conditions for protection are excluded. Therefore, disclosure of origin of genetic resources should not be regarded as an additional condition of protection.", International Harmonization Is Essential For Effective Plant Variety Protection, Trade And Transfer Of Technology UPOV Position based on an intervention in the Council for TRIPS, on September 19, 2002

¹⁴ "A disclosure of a claimed invention is considered sufficiently clear and complete if it provides information that allows the invention to be made and used by a person skilled in the art, without undue experimentation [...]". Arguably, the US - Central American Free Trade Agreement (CAFTA) provision aims to limit disclosure requirements to information that allows the invention to be made and used

countries were the first ones to propose obligations (prior informed consent or disclosure requirements) related to GRs in the FTAs as early as the 2000s.¹⁵

Peru and Colombia appear to be the main demandeurs for provisions on disclosure requirements included in FTAs.

EFTA-Colombia FTA (2008)/ EFTA- Peru FTA (2011)

The FTA between European Free Trade Association (EFTA)—which consists of Iceland, Liechtenstein, Norway and Switzerland— and Colombia was the first FTA concluded by a developed country that contains an explicit and separate provision disclosure of origin/source.

The EFTA agreement accommodates the position of Peru and Colombia by encouraging provisions in national legislation on disclosure. Switzerland and Norway took the lead on the disclosure issue during the negotiations in terms of reviewing the proposals, providing specific adjustments for an agreeable language. ¹⁶ It should be noted that both Switzerland¹⁷ and Norway¹⁸ provide mandatory patent disclosure requirements in their domestic laws.

The provision generates a synergy between IP system and the CBD by incorporating important elements of the proposals made in the TRIPS Council and the WIPO IGC. It creates a binding obligation on disclosure and introduces administrative, civil, and criminal sanctions for the enforcement of disclosure requirement. It requires patent applications to be accompanied by a declaration of the origin or source of a

¹⁵ Jean-Frédéric Morin & Mathilde Gauquelin, "Trade Agreements as Vectors for the Nagoya Protocol's Implementation", CIGI Papers No.115 — November 2016, available at https://www.chaire-epi.ulaval.ca/sites/chaire-epi.ulaval.ca/sites/chaire-epi.ulaval.ca/files/publications/paper_no.115.pdf.

¹⁶ David Vivas-Eugui, Oliva MJ, "Biodiversity related intellectual property provisions in free trade agreements", Issue paper 4, ICTSD, available at https://www.ictsd.org/sites/default/files/research/2011/12/biodiversity-related-intellectual-property-provisions-in-free-trade-agreements.pdf.

¹⁷ Article 49(a) of the *Federal Act of June 25, 1954 on Patents for Inventions (status as of January 1, 2012)* states: "The patent application must contain information on the source: a) of the genetic resource to which the inventor or the patent applicant had access, provided the invention is directly based on this resource; b) of [TK] of indigenous or local communities to which the inventor or the patent applicant had access, provided the invention is directly based on this resource."

¹⁸ Section 8(b) of the *Patents Act No. 9 of December 15, 1967 (consolidated version of 2016)* provides: "If an invention concerns or uses biological material or [TK], the patent application shall include information on the country from which the inventor collected or received the material or the knowledge (the providing country). If it follows from the national law in the providing country that access to biological material or use of [TK] shall be subject to prior consent, the application shall state whether such consent has been obtained. [...] Breach of the duty to disclose information is subject to penalty in accordance with the General Civil Penal Code § 221. The duty to disclose information is without prejudice to the processing of patent applications or the validity of rights arising from granted patents."

genetic resource, to which the inventor or the patent applicant has had access as well as the fulfillment of prior informed consent according to the national law. The scope of the provision covers TK too.

Peru and Colombia started negotiations with the EFTA jointly, however the Peru FTA concluded later in 2011. The Peru FTA includes the same language on biodiversity and disclosure related obligations.¹⁹

Box 1: EFTA-Colombia FTA (2008) and EFTA- Peru FTA (2011)

ARTICLE 6.5

Measures Related to Biodiversity

- 1. The Parties reaffirm their sovereign rights over their natural resources and recognise their rights and obligations as established by the Convention on Biological Diversity with respect to access to genetic resources, and to the fair and equitable sharing of benefits arising out of the utilisation of these genetic resources.
- 2. The Parties recognise the importance and the value of their biological diversity and of the associated traditional knowledge, innovations and practices of indigenous and local communities. Each Party shall determine the access conditions to its genetic resources in accordance with the principles and provisions contained in applicable national and international law.
- 3. The Parties recognise past, present and future contributions of indigenous and local communities and their knowledge, innovations and practices to the conservation and sustainable use of biological and genetic resources and in general the contribution of the traditional knowledge of their indigenous and local communities to the culture and economic and social development of nations.
- 4. The Parties shall consider collaborating in cases regarding non-compliance with applicable legal provisions on access to genetic resources and traditional knowledge, innovations and practices.
- 5. According to their national law, the Parties shall require that patent applications contain a declaration of the origin or source of a genetic resource, to which the inventor or the patent applicant has had access.
- As far as provided for in their national legislation, the Parties will also require the fulfilment of prior informed consent (PIC) and they will apply the provisions set out in this Article to traditional knowledge as applicable.
- 6. The Parties, in accordance with their national laws, shall provide for administrative, civil or criminal sanctions if the inventor or the patent applicant wilfully make a wrongful or misleading declaration of the origin or source. The judge may order the publication of the ruling. 7. If the law of a Party so provides: (a) access to genetic resources shall be subject to the prior informed consent of the Party that is the Party providing the genetic resources; and (b) access to traditional knowledge of indigenous and local communities associated to these resources shall be subject to the approval and involvement of these communities.
- 8. Each Party shall take policy, legal and administrative measures, with the aim of facilitating the fulfillment of terms and conditions for access established by the Parties for such genetic resources.
- 9. The Parties shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring the fair and equitable sharing of the benefits arising from the use of genetic resources or associated traditional knowledge. Such sharing shall be based on mutually agreed terms.

Peru/Colombia – US FTA (2009)

¹⁹ Article 6.5 Measures Related to Biodiversity, Peru-European Free Trade Association (entered into force 1 July 2011) http://www.sice.oas.org/Trade/PER_EFTA/Text_e.pd.

The Peru-US FTA is the first US FTA with any language regarding biodiversity and traditional knowledge. At the early stages of the FTA negotiations, Peru made proposals to include a biodiversity-related language in IP chapter. Peru's proposal:

- Recognized that IP rights should be granted in respect of CBD and national biodiversity and TK legislation;
- Incorporated disclosure requirements and sought evidence of prior informed consent (PIC) and benefit sharing arrangements;
- Introduced enforcement measures and cooperation arrangements in patent examination and exchange of information.

This proposal was strictly rejected by the US. The US has insisted on addressing the issue within the context of the WIPO, because of the difficulty of defining and regulating these subjects. The Parties, however, include a memorandum of understanding to the agreement, which is carefully worded to avoid creating obligations for the Parties.²⁰ The memorandum encourages the sharing of information regarding GRs and TK and the benefits derived from that information through mutually agreed contracts.

The US generally favors contractual solutions rather than disclosure of source/ or origin. The Peru – US FTA confirms the position US took in international discussions related to disclosure requirements. ²¹ Interestingly, Peru's strong advocacy for disclosure requirements, which is reflected in its FTAs with the EU and EFTA and in other international forums such as WIPO IGC or WTO's TRIPS council, is not reflected in the US FTA. This demonstrates the power play in FTAs and how priorities of countries could change according to their trading partner.

The US- Colombia FTA incorporates the same "understanding regarding biodiversity and traditional knowledge".

²⁰ David Vivas Eugui, Landmark Biodiversity, TK Provisions Accompany EFTA-Colombia FTA, Biores, Volume 3-Number 2, 12 October 2009, https://www.ictsd.org/bridges-news/biores/news/landmark-biodiversity-tk-provisions-accompany-efta-colombia-fta.

²¹ "The Peru Trade Promotion Agreement serves as a good model of how biodiversity protections can exist without encumbering the patent system, in part by recognizing that 'access to genetic resource or traditional knowledge,' and benefit sharing can be adequately addressed through contracts.", USITC, hearing transcript, Mar. 15, 2006, 16–21; and U.S.-Peru Trade Coalition, written submission, available at https://www.usitc.gov/publications/332/pub3855.pdf.

Box 2: US -Peru Understanding Regarding Biodiversity and Traditional Knowledge US-Colombia Understanding Regarding Biodiversity and Traditional Knowledge

The Governments of the United States of America and the Republic of Peru have reached the following understandings concerning biodiversity and traditional knowledge in connection with the United States – Peru Trade Promotion Agreement signed this day:

The Parties recognize the importance of traditional knowledge and biodiversity, as well as the potential contribution of traditional knowledge and biodiversity to cultural, economic, and social development.

The Parties recognize the importance of the following: (1) <u>obtaining informed consent</u> from the appropriate authority prior to accessing genetic resources under the control of such authority; (2) equitably sharing the <u>benefits</u> arising from the use of traditional knowledge and genetic resources; and (3) <u>promoting quality patent</u> examination to ensure the conditions of patentability are satisfied.

The Parties recognize that access to genetic resources or traditional knowledge, as well as the equitable sharing of benefits that may result from use of those resources or that knowledge, can be adequately addressed through contracts that reflect mutually agreed terms between users and providers. Each Party shall endeavor to seek ways to share information that may have a bearing on the patentability of inventions based on traditional knowledge or genetic resources by providing:

- (a) publicly accessible databases that contain relevant information; and
- (b) an opportunity to cite, in writing, to the appropriate examining authority prior art that may have a bearing on patentability.

Similarly, in Peru's FTA with Canada²² the environment chapter includes a specific provision on biological diversity in which the Parties reiterated their commitment to the CBD, subject to their national legislation. The provision does not mention disclosure of the source/origin. The Parties only endeavor to cooperate in order to exchange relevant information regarding the conservation and sustainable use of biodiversity, avoid illegal access to genetic resources, traditional knowledge, innovations and practices; and the equitable sharing of the benefits arising from the utilization of GRs and associated knowledge, innovations and practices.

The EU- Colombia and Peru FTA (2010)

The EU FTAs with Peru and Colombia are more comprehensive and integrative in terms of protection of biodiversity and TK compared to the other EU FTAs. During the negotiations, Peru and Colombia's ambitious proposals on TK and biodiversity were opposed by the EU. The EU's counter proposal was based on the CBD principles. However, they aimed to reduce the scope and content of obligations and avoid compliance measures. ²³

²² Free Trade Agreement between Canada and the Republic of Peru (entered into force 1 August 2009), Agreement on the Environment between Canada and the Republic of Peru, Article 5, https://www.ec.gc.ca/caraib-carib/default-asp?lang=En&n=8F165B2F-1&pedisable=true

²³ Eugui, supra note 17, page viii.

Apart from reaffirming the objectives and main principles of the CBD, the article includes a best-endeavor clause to facilitate the exchange of information about patent applications and granted patents related to GRs and associated TK so that the information can be taken into account during the substantial examination in determination of prior art. The article also requires cooperation for the training of patent examiners and collaboration in the application of domestic frameworks on access to GR and TK in accordance with the applicable international and domestic law.

Box 3: The EU- Colombia and Peru FTA (2010) PROTECTION OF BIODIVERSITY AND TRADITIONAL KNOWLEDGE Article 201

- 1. The Parties recognise the importance and value of biological diversity and its components and of the associated traditional knowledge, innovations and practices of indigenous and local communities. The Parties furthermore reaffirm their sovereign rights over their natural resources and recognise their rights and obligations as established by the CBD with respect to access to genetic resources, and to the fair and equitable sharing of benefits arising out of the utilization of these genetic resources.
- 2. The Parties recognise the past, present and future contribution of indigenous and local communities to the conservation and sustainable use of biological diversity and all of its components and, in general, the contribution of the traditional knowledge of their indigenous and local communities to the culture and to the economic and social development of nations.
- 3. Subject to their domestic legislation, the Parties shall, in accordance with Article 8(j) of the CBD respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity, and promote their wider application conditioned to the prior informed consent of the holders of such knowledge, innovations and practices, and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.
- 4. In accordance with Article 15 paragraph 7 of the CBD, the Parties reaffirm their obligation to take measures with the aim of sharing in a fair and equitable way the benefits arising from the utilization of genetic resources. The Parties also recognise that mutually agreed terms may include benefit-sharing obligations in relation to intellectual property rights arising from the use of genetic resources and associated traditional knowledge.
- 5. Colombia and the EU Party will collaborate in further clarifying the issue and concept of misappropriation of genetic resources and associated traditional knowledge, innovation and practices so as to find, as appropriate and in accordance with the provisions of international and domestic law, measures to address this issue.
- 6. The Parties shall cooperate, subject to domestic legislation and international law, to ensure that intellectual property rights are supportive of, and do not run counter to, their rights and obligations under the CBD, in so far as genetic resources and associated traditional knowledge of the indigenous and local communities located in their respective territories are concerned. The Parties reaffirm their rights and obligations under Article 16 paragraph 3 of the CBD in relation to countries providing genetic resources, to take measures with the aim to provide access to and transfer of technology which makes use of such resources, upon mutually agreed terms. This provision shall apply without prejudice to the rights and obligations under Article 31 of the TRIPS Agreement.
- 7. The Parties acknowledge the usefulness of requiring the disclosure of the origin or source of genetic resources and associated traditional knowledge in patent applications, considering that this contributes to the transparency about the uses of genetic resources and associated traditional knowledge.
- 8. The Parties will provide, in accordance with their domestic law, for applicable effects of any such requirement so as to support compliance with the provisions regulating access to genetic resources and associated traditional knowledge, innovations and practices.
- 9. The Parties will endeavour to facilitate the exchange of information about patent applications and granted patents related to genetic resources and associated traditional knowledge, with the aim that in the substantive examination, particularly in determining prior art, such information can be considered.
- 10. Subject to the provisions of Chapter 6 (Cooperation) of this Title, the Parties will cooperate on mutually agreed terms in the training of patent examiners in reviewing patent applications related to genetic resources and associated traditional knowledge.
- 11. The Parties recognise that data bases or digital libraries which contain relevant information constitute useful tools for patentability examination of inventions related to genetic resources and associated traditional knowledge.
- 12. In accordance with applicable international and domestic law, the Parties agree to collaborate in the application of domestic frameworks on access to genetic resources and associated traditional knowledge, innovations and practices.
- 13. The Parties may, by mutual agreement, review this Chapter subject to the results and conclusions of multilateral discussions.

Peru – China FTA (2010)

Both Peru and China have strong and long-established positions on disclosure requirements and they are demandeurs of disclosure requirements in international forums. However, Peru -China FTA fails to provide strong norm-setting provisions. The wording of the provision does not go beyond being aspirational. It is a missed opportunity because strong language could have had a potential to influence multilateral deliberations.

Box 4: Peru- China FTA

Chapter 11: Intellectual Property Rights

Article 145: Genetic Resources, Traditional Knowledge and Folklore

Genetic Resources, Traditional Knowledge and Folklore

- 1. The Parties recognize the contribution made by the genetic resources, traditional knowledge and folklore to the scientific, cultural and economic development.
- 2. The Parties acknowledge and reaffirm the principles and provisions established in the Convention on Biological Diversity adopted on June 5th, 1992 and encourage the effort to establish a mutually supportive relationship between the TRIPS Agreement and the Convention on Biological Diversity, regarding genetic resources and the protection of traditional knowledge and folklore.
- 3. Subject to each Party's international obligations and national legislation, the Parties may establish appropriate measures to protect genetic resources, traditional knowledge and folklore.
- 4. Subject to future developments of national legislation, the Parties agree to further discuss the disclosure of origin or source of genetic resources and/or prior informed consent obligations in patent applications.

Peru – South Korea FTA (2011)

South Korea is the third Asian country that Peru signed FTA with. South Korea has been a vocal critique of disclosure requirements in the WIPO IGC.²⁴ Given South Korea's strong opposition to the disclosure requirements, Peru –South Korea FTA has been encouraging in terms of acknowledging the paragraph 19 of the Doha Declaration on the relationship between the TRIPS Agreement and the CBD and the protec-

²⁴ The Delegation of South Korea "(...) expressed some concerns that disclosure requirements were presenting an excessive burden and unexpected obstacles to those wishing to utilize the patent system which was approved as the core momentum for innovation. The users and stakeholders of a series of meetings in the Republic of Korea had expressed concerns which could lead to avoiding patent systems, bypassing the IP regime altogether due to the legal uncertainties caused by disclosure requirements. It underlined that IP policy and the patent system could not be separated from users, and the system should be more convenient for users to encourage its active use. It stated that the most effective form of protecting GRs and associated TK in patent system was to prevent erroneously granted patents through the establishment and use of the databases. It preferred in terms of outcomes of the IGC to have a non-legally binding instrument. It stressed that all aspects of the proposals or options, and users' opinions and the potential ripple effect on industry and other related areas, should be considered. It hoped that all Member States would be open-minded but sincere in discussions to create new international norms.", See, WIPO/GRTKF/IC/29/8, p. 10-11, available at http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_29/wipo_grtkf_ic_29_8.pdf.

tion of GRs, TK and folklore. Instead of vaguely calling for greater cooperation, the parties took a step further and agreed to share views and information at the IGC and further discuss relevant issues on genetic resources.

Box 5: Peru- South Korea FTA Chapter 17: Intellectual Property

ARTICLE 17.5: GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE

1. The Parties acknowledge paragraph 19 of the Ministerial Declaration (WT/MIN/(01)DEC/1), adopted on November 14, 2001 by the WTO Ministerial Conference, on the

between the TRIPS Agreement and the CBD and the protection of genetic resources, traditional knowledge, and folklore.

- 2. The Parties recognize the value and importance of biological diversity, traditional knowledge as well as the contribution of knowledge, innovations, and practices of indigenous and local communities to the conservation and sustainable use of biological diversity. Each Party shall have the authority to determine access to genetic resources in accordance with its domestic legislation and endeavor to create conditions to facilitate transparent access to genetic resources for environmentally sound uses.
- 3. Subject to their domestic legislations and the CBD, the Parties respect knowledge, innovations, and practices of indigenous and local communities embodying traditional lifestyles relevant to the conservation and sustainable use of biological diversity and promote their wider application with the involvement and approval of the holders of such knowledge, innovations, and practices.
- 4. Each Party shall endeavor to seek ways to share information on patent applications based on genetic resources or traditional knowledge by providing:
 - (a) publicly accessible database that contains relevant information; and
 - (b) opportunities to file prior art to the appropriate examining authority in writing.
- 5. The Parties agree to share views and information on discussions in the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore, the WTO TRIPS Council, and any other relevant fora in addressing matters related to genetic resources and traditional knowledge.
- 6. Subject to future developments of multilateral agreements or their respective domestic legislations, the Parties agree to further discuss relevant issues on genetic resources.

Peru- Japan Economic Partnership Agreement (2011)

Japan- Peru FTA includes a joint statement on access to GRs and TK, which recognizes the key objectives of the CBD and sovereign rights of States over their natural resources and reaffirms the importance of prior informed consent, MAT and equitable sharing of benefits. The Parties also agreed to share information on the patentability of inventions based on GRs or TK associated with GRs by utilizing accessible databases and providing an "opportunity to submit in writing, to the appropriate examining authority in accordance with its laws and regulations, information on prior art that may have a bearing on patentability".

Japanese law includes no requirement that the source and/or country of origin of GRs and TK must be indicated in patent applications for inventions based on such GRs or TK. Japan has long been an opponent

of disclosure requirements arguing that disclosure of origin of GRs is an unnecessary complication for the patent system, which would create legal uncertainty and be burdensome to the administer.²⁵

Japan argues that CBD and the patent system do not conflict with each other and that they are mutually supportive. Hence, the patent system should not be "changed due to the provisions of the CBD and that it is not expected to have such changes". Japan promotes "one-click database search system", which contains information about GRs and is accessible by examiners in any country as an effective solution in order to avoid the erroneous granting of patents for GRs and associated TK.²⁶

Accordingly, the joint statement of Japan and Peru is basically the confirmation of Japan's position and does not imply any political concessions.

²⁵ TWN Info Service on Biodiversity and Traditional Knowledge (Feb13/01), 26 February 2013, Third World Network, available at http://www.twn.my/title2/biotk/2013/biotk130201.htm.

²⁶ The Patent System and Genetic Resources, Document submitted by Japan, WIPO/GRTKF/IC/35/6.

Box 6: Agreement between Japan and the Republic of Peru for an Economic Partnership Joint Statement on Biodiversity, Access to Genetic Resources and Traditional Knowledge, on the occasion of the Signing of the Agreement between Japan and the Republic of Peru for an Economic Partnership (March 2011)

We, the Governments of Japan and the Republic of Peru, recalling the longstanding friendship between both countries, which has developed into an enduring cooperative relationship:

Today, welcoming the expeditious conclusion of the negotiations;

Signed the Agreement between Japan and the Republic of Peru for an Economic Partnership. Both sides,

Recognizing the importance of the three objectives of the Convention on Biological Diversity (hereinafter referred to as the "CBD"), which are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources;

Recognizing the importance of the value of biodiversity and its components as stated in the preamble of the CBD, as well as their potential contribution to cultural, economic and social development; Recognizing the sovereign rights of States over their natural resources, and that the authority to determine access to genetic resources rests with the national governments and is subject to their national legislation as provided for in paragraph 1 of Article 15 of the CBD; and

Acknowledging what is set forth in paragraph 5 of Article 16 of the CBD;

Have reached the recognition as follows:

Both sides, as Contracting Parties of the CBD, reaffirm the importance of the following:

- (1) endeavoring to create conditions to facilitate access to genetic resources for environmentally sound uses in view of paragraph 2 of Article 15 of the CBD; obtaining informed consent from the appropriate authority prior to accessing genetic resources
- obtaining informed consent from the appropriate authority prior to accessing genetic resources under the control of such authority in view of paragraph 5 of Article 15 of the CBD;
- 1. sharing in a fair and equitable way the benefits, upon mutually agreed terms, arising from the commercial and other utilization of genetic resources with the country providing such resources in view of paragraph 7 of Article 15 of the CBD; and
- 2. subject to their respective national legislation, respecting, preserving and maintaining knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promoting their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encouraging the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices in view of subparagraph (j) of Article 8 of the CBD.

With a view to promoting quality patent examination to ensure the conditions of patentability are satisfied, each side will endeavor to seek ways to share information that may have a bearing on the patentability of inventions based on genetic resources or traditional knowledge associated with genetic resources by:

- (a) providing or utilizing publicly accessible databases that contain relevant information; and
- (b) providing an opportunity to submit in writing, to the appropriate examining authority in accordance with its laws and regulations, information on prior art that may have a bearing on patentability.

Any part of this Joint Statement does not prejudice ongoing negotiations and their outcomes in other fora in which both sides are participating.

The US FTAs

The U.S. has been long been a fierce opponent of the patent disclosure requirements. The US is one of the only three countries²⁷ worldwide not to have ratified the CBD. The US has not signed or ratified the Nagoya Protocol either.

The US concluded FTAs usually include a provision to limit additional patent disclosure requirements related to GRs and TK, which may be imposed on patent applicants. It was first included in Central American Free Trade Agreement (CAFTA) in 2004. Ever since, most of the US FTAs include a provision to prevent developing countries from imposing patent disclosure requirements.

Box 7: Patent Disclosure in the US FTAs

Each Party shall provide that a disclosure of a claimed invention shall be considered to be sufficiently clear and complete if it provides information that allows the invention to be made and used by a person skilled in the art, without undue experimentation, as of the filing date.

Panama- US Trade Promotion Agreement (TPA) (2007)

The text of the Panama- US TPA provides no clear reference to GRs or TKs. However, the IP chapter establishes a clear and concrete criterion for disclosure forbidding Panama from asking more than "information that allows the invention to be made and used".²⁸

There is no reference to the patent disclosure requirements in the side letter. It suggested that the US was able to limit the ability of Panama to require the disclosure of origin/source. ²⁹ Panama is required to promptly consult on whether to apply provisions addressing TK or folklore between them if the U.S. and another government sign an agreement that contains similar provision. However, it is not clear whether this requirement applies to the US if Panama signs a FTA with provisions on TK and GR. ³⁰

²⁷ The others countries are Andorra and South Sudan.

²⁸ Article 15.9.10: "Each Party shall provide that a claimed invention is sufficiently supported by its disclosure if the disclosure reasonably conveys to a person skilled in the art that the applicant was in possession of the claimed invention as of the filing date."

²⁹ Pei-Kan Yang, "Protection of Indigenous Cultural Heritage in Free Trade Agreements: Issues and Challenges from a North-South Perspective" in Chang-fa Lo, Nigel Li & Tsai-yu Lin (Eds.), Legal Thoughts between the East and the West in the Multilevel Legal Order: A Liber Amicorum in Honour of Professor Herbert Han-Pao Ma. Berlin: Springer, p.329-330.

Box 8: U.S.-Panama Trade Promotion Agreement Letter of Understanding The Honorable Alejandro Ferrer Minister of Commerce and Industry Republic of Panama

Dear Minister Ferrer:

I have the honor to confirm the following understandings reached between the delegations of the United States and Panama in the course of negotiations regarding Chapter Fifteen (Intellectual Property Rights) of the United States - Panama Trade Promotion Agreement between our two Governments signed this day (the "Agreement"):

Each Party recognizes the importance of traditional knowledge and folklore to its people.

Accordingly, the Parties will seek to work together in consulting on issues and positions in the World Intellectual Property Organization Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore in addressing matters related to traditional knowledge and folklore.

If the United States and another government sign a free trade agreement that contains provisions addressing traditional knowledge or folklore, the United States and Panama shall promptly consult after that agreement enters into force on whether to apply similar provisions, as appropriate, between the United States and Panama.1

I have the honor to propose that this letter and your letter of confirmation in reply shall constitute an agreement between our two Governments, to enter into force on the date the Agreement enters into force.

The EU FTAs

In the EU FTAs, the demands on disclosure requirements are linked to the negotiations on stronger protections for geographical indications (GIs). ³¹ GIs are particularly critical for the EU. The EU aims to introduce sui generis register-based systems, strong-form protection for all GIs, and administrative enforcement. ³²

In the EU – Peru and Colombia FTAs negotiations on GIs and biodiversity finalized only in the very final round. ³³ Both FTAs include separate sections on GIs introducing a set of comprehensive obligations. It should be noted that the EU has been able to build the critical mass among developing countries in its FTAs and other multilateral forums on GIs by utilizing this linkage.³⁴

³¹ A geographical indication (GI) is a sign used on products that have a specific geographical origin and possess qualities or a reputation that are due to that origin. In order to function as a GI, a sign must identify a product as originating in a given place. For more information, please see http://www.wipo.int/geo_indications/en/

³² Hazel Moir, "Geographical Indications: An Assessment of EU Treaty Demands", 10.22459/AEUNTA.06.2017.07, available at http://press-files.anu.edu.au/downloads/press/n2494/pdf/ch07.pdf

³³ Eugui, supre note 15, p.13.

³⁴ Moir, supra note 40, p. 134

EC- CARIFORUM EPA (2008)

The CARIFORUM countries (Antigua and Barbuda, the Bahamas, Barbados, Belize, Dominica, the Dominican Republic, Grenada, Guyana, Haiti, Jamaica, Saint Lucia, Saint Vincent and the Grenadines, Saint Kitts and Nevis, Suriname, and Trinidad and Tobago) and the European Union signed Economic Partnership Agreement (EPA), which forms a comprehensive and far reaching agreement covering trade in goods and services, investment, trade related issues like innovation and intellectual property as well as links to development cooperation.

Article 150 of the EPA makes a reference to the protection of genetic resources, TK and folklore. It opens the door for the use of a declaration of source requirement for a patent applicant, recognizes the intense activities taking place multilaterally and provides for a review of the provision to make any amendments that the conclusion of these consultations require. The provision could have been a victory for biodiversity-rich countries, if it has been made mandatory. However, its non-binding nature does not mandate Parties to implement disclosure requirements. In the interim, it ensures that the CBD and the patent provisions are implemented in a mutually supportive way.

In fact, the European law provides for voluntary disclosure. The preamble of the EC Directive 98/44 on protection of biotechnological inventions encourages patent applicants to mention the geographical origin of biological material in the patent application. The disclosure requirement is not obligatory in the EU and failure to comply does not affect the granting or enforceability of patents.³⁵

³⁵ Recital 27 EC Directive 98/44, on the legal protection of biotechnological inventions:

[&]quot;Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents."

Box 9: EC- CARIFORUM EPA Article. 150: Genetic resources, traditional knowledge and folklore

- 1. Subject to their domestic legislation the EC Party and the Signatory CARIFORUM States respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the involvement and approval of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices.
- 2. The EC Party and the Signatory CARIFORUM States recognise the importance of taking appropriate measures, subject to national legislation, to preserve traditional knowledge and agree to continue working towards the development of internationally agreed sui generis models for the legal protection of traditional knowledge.
- 3. The EC Party and the Signatory CARIFORUM States agree that the patent provisions of this subsection and the Convention on Biological Diversity shall be implemented in a mutually supportive way.
- 4. The EC Party and the Signatory CARIFORUM States may require as part of the administrative requirements for a patent application concerning an invention which uses biological material as a necessary aspect of the invention, that the applicant identifies the sources of the biological material used by the applicant and described as part of the invention.

EU- South Korea FTA (2009)

The EU-South Korea FTA provision expressly regulates GRs, TK and folklore. The text appears to be similar to the text in the EU- CARIFORUM EPA but it does not make any reference to the patent disclosure requirements. The parties undertake to respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles, however, the obligation is subject to their respective legislation.

The discussions on disclosure are left open without any binding commitment. A safeguard clause has been included to enable parties to review the provisions relating to biodiversity and TK in the light of the results and conclusions of the related multilateral discussions.

The provisions of the EU-Korea FTA on this issue correspond with the EU's endeavors on the multilateral platform within the WTO. The EU FTAs usually include biodiversity and TK-related provisions based on existing obligations under the CBD recognizing the importance of the CBD (lately Nagoya) principles. However, they avoid making any binding commitment on disclosure of origin/source.

Box 10: EU- South Korea FTA ARTICLE 10.40: GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE

- 1. Subject to their legislation, the Parties shall respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the involvement and approval of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices.
- 2. The Parties agree to regularly exchange views and information on relevant multilateral discussions:
- (a) in WIPO, on the issues dealt with in the framework of the Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore;
- (b) in the WTO, on the issues related to the relationship between the TRIPS Agreement and the Convention on Biological Diversity (hereinafter referred to as the "CBD"), and the protection of traditional knowledge and folklore; and
- (c) in the CBD, on the issues related to an international regime on access to genetic resources and benefit sharing.
- 3. Following the conclusion of the relevant multilateral discussions referred to in paragraph 2, the Parties agree, at the request of either Party, to review this Article in the Trade Committee in the light of the results and conclusion of such multilateral discussions. The Trade Committee may adopt any decision necessary to give effect to the results of the review.

China FTAs

China is party to the relatively high number of FTAs that include a text on protection of GRs and TK. China's FTAs usually do not include broad-reaching provisions on disclosure requirements even with countries, which have implemented disclosure requirements (e.g. China- Peru FTA and China- Costa Rica FTA). China- Switzerland FTA is the only exception to this. It goes one step further and incorporates certain obligations on such requirements in FTAs.

China- New Zealand FTA (2008)

China- New Zealand FTA is a clear example of less ambitious provisions in scope compared the other China FTAs negotiated later. Parties recently launched new negotiations for an upgrade of the FTA. However, the scope of negotiations, which was agreed by Ministers in November 2016, does not include any issue related to GRs and TK.³⁶

³⁶FTA upgrade negotiations, https://www.mfat.govt.nz/en/trade/free-trade-agreements/free-trade-agreements/free-trade-agreements/free-trade-agreement/#upgrade.

Box 11: China - New Zealand FTA **Chapter 12 Intellectual Property**

Article 165

Genetic Resources, Traditional Knowledge and Folklore

Subject to each Party's international obligations, the Parties may establish appropriate measures to protect genetic resources, traditional knowledge and folklore.

China- Costa Rica FTA (2011)

Costa Rican law requires patent applications to be accompanied by a certificate of origin and prior consent.³⁷ Similarly, Chinese patent law requires the disclosure of source of the GRs in patent applications as a condition for inventions derived from the illegitimate acquisition or utilization of the Chinese GRs.³⁸ Costa-Rica China FTA, on the other hand, does not include a broad-reaching provision on disclosure. The brief provision in IP chapter is primarily about information exchange between the parties rather than robust substantive provision.

Box 12: China- Costa Rica FTA

Article 111: Genetic Resources, Traditional Knowledge and Folklore

- 1. The Parties recognize the contribution made by genetic resources, traditional knowledge and folklore to scientific, cultural and economic development.
- 2. The Parties acknowledge and reaffirm the principles and provisions established in the Convention on Biological Diversity adopted on 5th June 1992 and encourage the effort to establish a mutually supportive relationship between the TRIPS Agreement and the Convention on Biological Diversity, regarding genetic resources and the protection of traditional knowledge and folklore.
- 3. Subject to each Party's international obligations and domestic laws, the Parties may adopt or maintain measures to promote the conservation of biological diversity, share equitably benefits arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components in conformity with what is established in the Convention on Biological Diversity.
- 4. Subject to future developments of domestic laws and the outcome of negotiations in multilateral fora, the Parties agree to further discuss the disclosure of origin or source of genetic resources; and/or prior informed consent obligations in patent applications; and the grant of a patent for an invention that involves or relies on genetic resources, when such resources were acquired or exploited without complying the relevant domestic laws or regulations.

³⁷ Article 80 of Law no.7788 on Biodiversity (as last amended by Law No. 8686 of November 21, 2008).

³⁸ Article 25 and 26 Patent Law Amendment, December 27, 2008; entered into force October 2009.

China – Switzerland FTA (2014)

The Swiss Patent Act requires patent applicants to disclose the source of GRs and TK in their applications if the invention concerned is directly based on the resource or the knowledge³⁹. Chinese patent law includes similar provisions.⁴⁰ Consequently, the provision on GRs and TK places a greater emphasis on disclosure requirements and is more ambitious in scope than the other FTAs negotiated by China. It offers a language concerning the efforts needed to establish a mutually supportive relationship between the TRIPS and the CBD.

Box 12: China- Switzerland FTA ARTICLE 11.9

Genetic Resources and Traditional Knowledge

- 1. The Parties recognise the contribution made by genetic resources and traditional knowledge to scientific, cultural and economic development.
- 2. The Parties acknowledge and reaffirm the principles established in the Convention on Biological Diversity adopted on 5 June 1992 and encourage the effort to enhance a mutually supportive relationship between the TRIPS Agreement and the Convention on Biological Diversity, regarding genetic resources and traditional knowledge.
- 3. Subject to each Party's international rights and obligations and domestic laws, the Parties may adopt or maintain measures to promote the conservation of biological diversity and the equitable sharing of benefits arising from the use of genetic resources and traditional knowledge.
- 4. The Parties may require that patent applicants should indicate the source of a genetic resource and, if so provided by the national law, traditional knowledge, to which the inventor or the patent applicant has had access, insofar as the invention is directly based on this resource or this knowledge in accordance with domestic laws and regulations;
- 5. If a patent application does not meet the requirements of paragraph 4, the Parties may set a time limit by which the applicant must correct the defect. The Parties may refuse the application or consider it withdrawn if the defect according to this paragraph has not been corrected within the set time limit.
- 6. If it is discovered after the granting of a patent that the application failed to disclose the source or that intentionally false information was submitted, or other relevant laws and regulations were violated, the Parties may provide for appropriate legal consequences.

China- South Korea FTA (2015)

China-South Korea FTA does not include a specific provision on patent disclosure requirements. The provision on GRs, TK and folklore touches upon some of the issues revolving around GRs and TK without making a clear reference to disclosure requirements. The Parties acknowledge and reaffirm the principles established by the CBD and the Nagoya Protocol and encourage "the effort to enhance a mutually sup-

³⁹ Article 49 of the Amendment of Patent Law of June 2, 2007, RO 2008 2551 provides:

[&]quot;For inventions based on [GRs] or [TK] the patent application must contain information concerning the source:

⁽a) of the [GRs] to which the inventor or the applicant had access, when the invention is based directly on that resource;

⁽b) of [TK] of indigenous or local communities related to the [GRs] to which the inventor or applicant had access when the invention is based directly on that knowledge."

⁴⁰ See, footnote 45

portive relationship between the TRIPS Agreement and the Convention" regarding GRs and TK. They also agree to cooperate on issues related to patents and other IP rights that may have an influence on the implementation of the CBD subject to national and international law "in order to ensure that such rights are supportive of and do not run counter to the objectives of the Convention."

Box 13: China South Korea FTA

Article 15.17

Genetic Resources, Traditional Knowledge and Folklore

- 1. The Parties recognize the contribution made by genetic resources, traditional knowledge and folklore to scientific, cultural and economic development.
- 2. The Parties acknowledge and reaffirm the principles established in the Convention on Biological Diversity adopted on 5 June 1992 (hereinafter referred to in this Article as the "Convention") and respect the requirements in 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, especially those on prior informed consent and fair and equitable sharing of benefits. The Parties encourage the effort to enhance a mutually supportive relationship between the TRIPS Agreement and the Convention, regarding genetic resources and traditional knowledge.
- 3. Subject to each Party's international rights and obligations and domestic laws, the Parties may adopt or maintain measures to promote the conservation of biological diversity and the equitable sharing of benefits arising from the use of genetic resources and traditional knowledge.
- 4. Subject to future developments of multilateral agreements or their respective domestic legislations, the Parties agree to further discuss relevant issues on genetic resources.
- 5. The Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of the Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to the objectives of the Convention.

Other FTAs

Panama – Taiwan (Republic of China) FTA (2003)

Panama- Taiwan FTA is one of the first FTAs, which has specific provisions dealing with GRs and TK. The Parties explicitly commit to protect GRs and TK developed by indigenous people and local communities and ensure access to GRs shall accord a fair and equitable benefit sharing. The Parties also agreed that the granting of patents on inventions derived from material obtained from GRs or TK shall be subject to the conditions prescribed under relevant national and international laws and regulations.

The Parties clearly agreed to set up a special system for protection of TK and GRs and identified prior informed consent and fair and equitable sharing as the core elements of the system.

Box 14: Taiwan-Panama FTA(entered into force 1 January 2004) Article 16.07 Relation between Access to Genetic Resources and Intellectual Property

- 1. Each Party shall protect the access to its genetic resources and the traditional knowledge developed by indigenous people and local communities on the uses of the biological resources containing these genetic resources, against the indiscriminate use of biological diversity, as well as ensuring that the Party will participate in benefits derived from the use of its genetic resources.
- 2. Each Party shall accord a fair and equitable participation in the benefits derived from the access to its genetic resources and from the uses of its traditional knowledge and folklore expressions.
- 3. Each Party shall ensure that the protection accorded to the industrial <u>property shall safeguard its biological</u> and genetic heritage. Consequently, the licensing of patents on inventions developed from material obtained from such heritage or traditional knowledge shall be subject to the condition that this material was acquired according to relevant national and international laws and regulations.

Article 16.09 Applications

- 1. The Parties confirm the effective rights and obligations among them with respect to the procedures of observance in accordance with TRIPS.
- 2. The Parties recognize that the growing importance of IP protection in traditional knowledge and folklore, genetic resources, geographic indications, plant breeders and other related matters is critical to economic competitiveness in the knowledge-based economy and to sustainable economic development. The Parties, therefore, confirm that either Party which is not party to one or more of the multilateral agreements listed in Article 16.01 shall undertake with the best efforts to pursue affiliation, in due course, to the said agreements.

Thailand-New Zealand Closer Economic Partnership Agreement (2005)

Thailand – New Zealand Agreement one of the first trade agreements acknowledging Parties flexibility to introduce appropriate measures to protect traditional knowledge, GRs and folklore.

Box 15: Thailand-New Zealand Closer Economic Partnership Agreement Chapter 12: Intellectual Property

ARTICLE 12.5: Other Cooperation

- 1. Recognising that intellectual property rights can facilitate international trade through the dissemination of ideas, technology and creative works, the Parties, through their respective agencies responsible for intellectual property, shall:
 - (a) exchange information relating to developments in intellectual property policy;
 - (b) encourage and facilitate the development of contacts and cooperation between their respective agencies, educational institutions, organisations and other entities concerning the protection of intellectual property rights with a view to improving and strengthening intellectual property administrative systems in areas such as patents and trademarks;
 - (c) facilitate the sharing of information and cooperate on appropriate initiatives to promote awareness of intellectual property rights and Systems; and
 - (d) cooperate to enhance understanding in new areas of intellectual property such as traditional knowledge, genetic resources, and folklore, recognising that each Party may wish, consistent with its obligations under the WTO Agreement, to establish appropriate measures to protect traditional knowledge, genetic resources and folklore.

ASEAN-Australia and New Zealand Free Trade Agreement (2010)

ASEAN – Australia and New Zealand FTA includes a provision identical to the less ambitious and more ambiguous provision in China- New Zealand FTA. It does not necessarily mention patent disclosure requirements; however, it acknowledges Parties flexibility to establish measures to protect GRs, TK and folklore.

Box 16: ASEAN-Australia and New Zealand Free Trade Agreement Chapter 13: Intellectual Property

Article 8: Genetic Resources, Traditional Knowledge and Folklore

Subject to each Party's international obligations, each Party may establish appropriate measures to protect genetic resources, traditional knowledge and folklore.

Costa Rica-Singapore Free Trade Agreement (2013)

Costa Rica- Singapore FTA includes a very brief IP chapter with only six articles. In one of those six articles, the parties reaffirm the principles of the CBD and encourage a mutually supportive relationship between TRIPS and CBD. The provision confirms Parties flexibility to adopt or maintain measures to promote conservation of biological diversity, sustainable utilization of its components and fair and equitable participation.

Box 17: Costa Rica-Singapore Free Trade Agreement Article 13.3: Genetic Resources, Traditional Knowledge and Folklore

- 1. The Parties recognize the contribution made by the genetic resources, traditional knowledge and folklore to scientific, cultural and economic development.
- 2. The Parties acknowledge and reaffirm the principles and provisions established in the *Convention on Biological Diversity* adopted on 5 June 1992 94 and encourage a mutually supportive relationship between the TRIPS Agreement and the *Convention on Biological Diversity*.
- 3. Subject to each Party's international obligations and domestic laws, each Party may adopt or maintain measures to promote the conservation of biological diversity, the sustainable utilization of its components and the fair and equitable participation in the benefits arising from the utilization of genetic resources, traditional knowledge and folklore in conformity with what is established in the aforementioned *Convention*.

Multilateral FTAs

Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CTPP)

The Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), a multilateral free trade agreement formerly known as the Trans-Pacific Partnership (TPP). The TPP was negotiated between the U.S. and 11 Asia- Pacific Rim countries – Australia, New Zealand, Canada, Mexico, Japan, Chile, Peru, Singapore, Malaysia, Vietnam and Brunei Darussalam. U.S. President Donald Trump pulled the U.S. out of the deal in 2017. The remaining 11 members have rescued it almost intact, giving it a new name, the CPTPP.

During the early stages of the negotiations, Peru, New Zealand, Mexico and Singapore proposed a text on Traditional Knowledge, Traditional Cultural Expressions and Genetic Resources.⁴¹ The U.S. and Japan opposed the inclusion of any provision on TK and GRs in the IP Chapter. The final text on "Cooperation in the Area of Traditional Knowledge" has three components. It recognizes the relevance of IP and TK associated with GRs to each other and encourages Parties to cooperate "[...] to enhance the understanding of issues connected with TK associated with GRs [...]". It avoids making a reference to any basic principles such as prior informed consent or access and benefit sharing being discussed at the WIPO Intergovernmental Committee.

The third sub-article focuses on increasing the 'quality of patent examination' through prior art, third-party submissions, databases and cooperation in training of patent examiners. The provision does not include any binding and enforceable commitments. It does not require patent applicants to disclose information regarding any TK or GRs used in the development of the invention.

The text does not go beyond highly-qualified, non-obligatory and general statements on GRs and associated TK. It does not even recognize TK as an independent subject matter. Arguably, powerful/developed countries (U.S., Japan, Australia, Canada) have succeeded in restricting TK protection to a more aspirational and optional framework. ⁴²

⁴¹ Article QQ.E.23 {Traditional Knowledge, Traditional Cultural Expressions and Genetic Resources}, WikiLeaks release: October 16, 2014, available at https://wikileaks.org/tpp-ip2/tpp-ip2-chapter.pdf.

⁴² Hans Morten Haugen, "How Are Indigenous and Local Communities' Rights Over Their Traditional Knowledge and Genetic Resources Protected in Current Free Trade Negotiations?", Highlighting the Draft Trans-Pacific Partnership Agreement (TTPA), 17:3–4 J WORLD INTELLECT.PROP. 81,91 (2014), p.88-89

Box 18: Comprehensive and Progressive Agreement for Trans-Pacific Partnership Article 18.16

Cooperation in the Area of Traditional Knowledge

- 1. The Parties recognise the relevance of intellectual property systems and traditional knowledge associated with genetic resources to each other, when that traditional knowledge is related to those intellectual property systems.
- 2. The Parties shall endeavour to cooperate through their respective agencies responsible for intellectual property, or other relevant institutions, to enhance the understanding of issues connected with traditional knowledge associated with genetic resources, and genetic resources.
- 3. The Parties shall endeavour to pursue quality patent examination, which may include:
 - (a) that in determining prior art, relevant publicly available documented information related to traditional knowledge associated with genetic resources may be taken into account;
 - (b) an opportunity for third parties to cite, in writing, to the competent examining authority prior art disclosures that may have a bearing on patentability, including prior art disclosures related to traditional knowledge associated with genetic resources;
 - (c) if applicable and appropriate, the use of databases or digital libraries containing traditional knowledge associated with genetic resources; and
 - (d) cooperation in the training of patent examiners in the examination of patent applications related to traditional knowledge associated with genetic resources.

Conclusion

There is a promising trend that the value of patent disclosure requirements is increasingly being recognized in many domestic laws and international forums. While WIPO's Member States have been debating the possibility of introducing an international norm on patent disclosure requirement for more than a decade, more than 30 countries introduced some kind of disclosure requirements -either mandatory, voluntary or formality requirement- in national or regional laws.⁴³

Over the last decade we have seen a development towards the introduction of such provisions into the FTAs. A growing number of trade deals provide for provisions on patent disclosure related to GRs and TK. Yet, some of those agreements set surprisingly ambitious goals. Many FTA side letters (which are used as commitments between parties to continue deliberating on certain issues for the future) make references to the disclosure requirements. Although in many cases disclosure related provisions reflect existing obligations and lack binding legal effect, some of the best-endeavor clauses are important.

It is still premature to understand the impact of FTA provisions on disclosure requirements. Nevertheless, FTAs can play a functional role in articulating new legal obligations and diffusing disclosure requirements across borders. The demandeurs of disclosure requirements should consider using FTAs strategical-

⁴³ *See*, WIPO Disclosure Requirements Table, October 2017, available at http://www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic resources disclosure.pdf

ly to build norms around basic principles that signatories would accept. The FTAs among "like-minded" countries can play an important role in diversified and polarized landscape of IP. They may well offer opportunities for policy experimentation and create institutional laboratories to design and test disclosure requirements at a limited scale and among like-minded countries.

Since the need for patent disclosure requirements related to GRs and TK has been endorsed in many instruments, including the WIPO Draft Articles, it should be possible to develop a global norm around such principles.