



TOWARDS AN EFFECTIVE AND PRACTICAL VERIFICATION AND
TRANSPARENCY MECHANISM ON THE UTILIZATION OF
GENETIC RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE IN
VIET NAM'S INTELLECTUAL PROPERTY SYSTEM



© 2020, United Nations Conference on Trade and Development

This work is available open access by complying with the Creative Commons licence created for intergovernmental organizations, available at <http://creativecommons.org/licenses/by/3.0/igo/>.

The findings, interpretations and conclusions expressed herein are those of the authors and do not necessarily reflect the views of the United Nations or its officials or Member States.

The designation employed and the presentation of material on any map in this work do not imply the expression of any opinion whatsoever on the part of the United Nations concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

This publication has not been formally edited.

UNCTAD/DITC/TED/INF/2020/4

Contents

Acronyms and abbreviations	iv
Acknowledgements	iv
1. INTRODUCTION	1
2. INTERNATIONAL RULES ON ACCESS AND BENEFIT SHARING AND DISCLOSURE OF ORIGIN.....	2
3. VIET NAM'S LEGAL REGIME FOR ACCESS AND BENEFIT SHARING	4
4. VIET NAM'S INTELLECTUAL PROPERTY POLICIES AND ITS LIMITATIONS.....	5
5. RECOMMENDATIONS	8
6. IMPLEMENTATION OF THE NEW RULES.....	10
7. CONCLUSION.....	11
8. ANNEX: LIST OF INTERVIEWEES, UNCTAD MISSION (30–31 MAY, 2019).....	13
References	14
Notes.....	14

Tables

Table 1: Statistics of patent applications of genetic resource-related invention and utility solution (IPC: C12N, A61K35, A61K36, A61K37, A61K38, A61K39, A01H, C07K, A01K)	6
---	---

Acronyms and abbreviations

ABS	Access and benefit-sharing
ATK	Associated traditional knowledge
BCA	Biodiversity and Conservation Agency, Viet Nam
CBD	Convention on Biological Diversity
IGC	Intergovernmental Committee on Intellectual Property on Genetic Resources, Traditional Knowledge and Folklore
ILCs	Indigenous and local communities
IP Viet Nam	National Office of Intellectual Property of Viet Nam
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
MAT	Mutually agreed terms
MARD	Ministry of Agriculture and Rural Development, Viet Nam
MOH	Ministry of Health, Viet Nam
MONRE	Ministry of Natural Resources and the Environment, Viet Nam
MOST	Ministry of Science and Technology, Viet Nam
PIC	Prior informed consent
PVP	Plant variety protection
TRIPS Agreement	Agreement on the Trade-related Aspects of Intellectual Property Rights
UNCED	United Nations Conference on Environment and Development
UNCTAD	United Nations Conference on Trade and Development
UPOV	International Convention on the Protection of New Varieties of Plants
WIPO	World Intellectual Property Organization

Acknowledgements

This study was prepared by Nguyen Thi Thanh Ha, Consultant for the BioTrade Initiative of the Trade, Environment, Climate Change and Sustainable Development Branch of UNCTAD.

The study has greatly benefited from peer reviews and substantive inputs by: Kiyoshi Adachi, Legal Officer, Intellectual Property Unit, Division on Investment and Enterprise (DIAE), David Vivas Eugui, Legal Officer and Frederic Perron-Welch, Consultant, Trade, Environment, Climate Change and Sustainable Development Branch (TED) of UNCTAD. Desktop formatting was done by Rafe Dent of UNCTAD.

UNCTAD gratefully acknowledges the support of the Swiss State Secretariat for Economic Affairs SECO in the development of this study under the Global BioTrade Programme: Linking trade, biodiversity and sustainable development.

For further information on UNCTAD's BioTrade Initiative please consult the following website: <http://www.unctad.org/biotrade> or contact us at: biotrade@unctad.org.

28 October 2020

1. INTRODUCTION

This study was prepared in response to a request for technical assistance to the United Nations Conference on Trade and Development (UNCTAD) by Viet Nam's Biodiversity Conservation Agency (BCA) for guidance and proposals to implement a disclosure of origin requirement for genetic resources under the country's intellectual property laws and regulations.

The study is based on both original research and interviews conducted during a fact-finding mission in Hanoi, Viet Nam on 30–31 May 2019 by UNCTAD's local consultant, Ms. Nguyen Thi Thanh Ha, and

Mr. Kiyoshi Adachi, a Legal Officer with UNCTAD's Intellectual Property Unit, Division on Investment and Enterprise. The list of individuals interviewed during the fact-finding mission is contained in the Annex to this study.

UNCTAD is grateful to the support given by BCA to the organization of the fact-finding interviews. The study takes on board comments from BCA and the National Office of Intellectual Property of Viet Nam (IP Viet Nam), and was presented in draft form at the Second Regional Coordination Workshop on BioTrade and Access and Benefit Sharing in the Mekong Region on 4–5 December 2019, in Hanoi, Viet Nam.

2. INTERNATIONAL RULES ON ACCESS AND BENEFIT SHARING AND DISCLOSURE OF ORIGIN

The Convention on Biological Diversity (CBD) is a multilateral environmental treaty that was opened for signature at the 1992 United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro, Brazil. Viet Nam ratified the Convention on Biological Diversity in 1994 and became a Party in early 1995. A unique feature of the treaty is that, in addition to its objective of conserving the world's biodiversity and ecosystems, which involve a plethora of animal, plant and microbial species, there were provisions dedicated to ensuring that parties to the treaty used their biological resources in a sustainable manner, and on the fair and equitable sharing of benefits arising out of the utilization of genetic resources.

With respect to the sharing of benefits arising out of the use of genetic resources, numerous clauses in the CBD attempt to address the issue of misappropriation of genetic resources (sometimes also known as 'biopiracy'). While not a defined term under the CBD, misappropriation occurs when an individual or firm takes genetic resources from a country or uses associated traditional knowledge (ATK), and develops a technology therefrom without having obtained permission and/or without sharing benefits derived from the commercialization of the product. The full extent of misappropriation globally is not known, but a number of studies have detailed examples of such misappropriation (see, for example, Mgbeoji, 2006; Robinson, 2010), including through the use of intellectual property rights.

The clauses in the CBD established some of the basic notions that shape national practices on what would be considered appropriate when accessing and using genetic resources (Article 15, CBD). Genetic resources fall under the sovereignty of States (Article 3, CBD). The authority to determine conditions of access thus rests with the national government. Where national legislation prescribes, it may also lie with indigenous and local communities (ILCs). Where national governments require authorization for access, genetic resources can only be accessed with prior informed consent (PIC) of the Party providing such resources, and benefits arising from the utilization of genetic resources and their commercialization must

be shared in a fair and equitable way with the provider under mutually agreed terms (MAT). This system is commonly known as access and benefit-sharing, or ABS.

As the CBD's provisions on ABS were considered to be insufficiently binding, extensive negotiations among Parties led in 2010 to the adoption of a new treaty under the auspices of the CBD – the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization (Nagoya Protocol). The Nagoya Protocol aims to establish greater legal certainty around ABS, defining how PIC and MAT can be operationalized (Articles 5 and 6), rules relating to ATK (Article 7), compliance and monitoring (Articles 15, 16 and 17), and an international clearing house system – the ABS Clearing-House Mechanism – to support transparency and compliance. Taken together, the CBD and the Nagoya Protocol provide guidance to countries in the development of their national ABS legislation, regulations and policies. The Nagoya Protocol came into effect for both Viet Nam and globally on 12 October 2014. As of 9 December 2019, there are 196 Parties to the CBD, and 123 ratifications of the Nagoya Protocol (120 Parties and 3 accessions entering into force in December 2019/ January 2020).

Over time, it became clear that stand-alone ABS laws and policies are not sufficient to address the problem of the misappropriation of genetic resources and ATK (UNCTAD, 2014). As noted above, misappropriation was occurring through the intellectual property systems through which exclusive rights were being granted to those who had developed commercial products from accessed genetic resources and ATK, absent the authorization to do so. Article 16(5) of the CBD recognizes the influence of patents and other intellectual property rights, such as those covering new varieties of plants (PVP), on the promotion of CBD objectives. As such, it requires that countries cooperate to ensure that intellectual property rights are supportive of, and do not run counter to, CBD objectives.

Moreover, Article 17 of the Nagoya Protocol provides that Parties shall take measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources, including designating effective checkpoints to collect or receive, as appropriate, relevant information regarding the utilization of genetic resources at, *inter alia*, any stage of research, development, innovation, pre-

commercialization or commercialization. Given that misappropriation occurs through the intellectual property system, and States have an obligation to monitor the utilization of genetic resources within their jurisdictions, intellectual property offices are sometimes designated as checkpoints in the implementation of the Nagoya Protocol (Chiarolla, 2019). In the Asia region, Bhutan is a recent example of a country that has designated their intellectual property office as such as checkpoint.¹

Discussions have taken place in various intergovernmental forums to attempt to harmonize the international intellectual property system with the ABS system, and have generally centered on the desirability of a mandatory disclosure of source/origin requirement in patent law. This requirement would oblige applicants for intellectual property rights to disclose the source/origin of genetic resources and/or ATK when they are used in the subject matter of the intellectual property right. Such disclosure would allow interested parties to begin to trace the origins of a genetic resource and/or ATK to establish whether domestic PIC and MAT requirements have been met.

At the Council for the Agreement on Trade-related Aspects of Intellectual Property Rights (the TRIPS Council), developing countries tabled a proposal to amend the TRIPS Agreement to require disclosure of source/origin. Developing countries argued that the disclosure requirement in Article 29 of the TRIPS Agreement is incomplete without the disclosure of source/origin of genetic resources and/or ATK. In order to remedy this, a legal obligation establishing a mandatory disclosure requirement in patent applications would contribute to preventing both misappropriation of genetic resources and the grant of erroneous patents, and also enhance transparency about the utilization of genetic resources and/or ATK.²

The TRIPS Council has, however, been unable to agree upon such an amendment to the TRIPS Agreement.

Similar discussions at the negotiations leading up to the Nagoya Protocol and in the World Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property on Genetic Resources, Traditional Knowledge and Folklore (IGC) have been equally contentious and have not yet led to any legally binding outcome.

It should be noted that disclosure is not a novel idea. It is, rather, part of the social contract underlying the grant of exclusive rights over an invention, utility model or new plant variety, where the technology is disclosed so that others may experiment and build on it for the sake of innovation and technological progress. With respect to patents, TRIPS, Article 29(1) stipulates that:

Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of application.

The standoff on making disclosure of origin/source a mandatory requirement under international law is generally between user countries in the developed world who argue that such a requirement could amount to adding a supplemental condition beyond novelty, inventive step and industrial application to patentability and that the current text of Article 29(1) is sufficient for assessing patentability criteria; and countries of origin/source, like Viet Nam and a number of other countries in Southeast Asia with substantial biodiversity, which would wish to see a requirement codified at the international level. The impasse on an international requirement for disclosure of origin is unlikely to be resolved in the near future.

3. VIET NAM'S LEGAL REGIME FOR ACCESS AND BENEFIT SHARING

As a result, a number of countries and regional organizations (approximately 25 countries and 2 regional organizations) have not waited for an international consensus on disclosure of origin to introduce changes to their laws, regulations and policies (Chiarolla, 2019), including Viet Nam. The 2008 Law on Biological Diversity sets out the basic requirements on PIC for access to genetic resources and benefit sharing with related parties based on MAT. In light of its accession to the Nagoya Protocol in 2014, Viet Nam promulgated a Decree in 2017 (59/2017/ND-CP) setting out in detail the ABS requirements of the 2008 Biodiversity Law.

Notably, Articles 14.3 and 23.3 of the Decree provide for the obligation to disclose the source and geographical origin in the course of applying for intellectual property rights resulting from the utilization of genetic resources. It provides, in relevant part:

Article 14. Change of intent; transfer of genetic resources to a third party; and registration for intellectual property rights for innovative results based on using genetic resources.

3. Registration for intellectual property rights over creation resulting from the utilization of genetic resources and its derivatives must state clearly the source and origin of accessed genetic resources, and comply with Clause 2, Article 22 of this Decree.

Article 23. Sharing of non-monetary benefits

3. The source and geographical origin of the accessed genetic resources shall be clearly stated when announcing any results of the scientific research or when applying for intellectual property rights over any creation resulted from using such genetic resources.

These articles contain no particular requirement for disclosure of ATK, and are therefore limited to genetic resources. However, it does apply to all forms of intellectual property rights resulting from the utilization of genetic resources and their derivatives, meaning that the scope of this obligation goes beyond patent law.

4. VIET NAM'S INTELLECTUAL PROPERTY POLICIES AND ITS LIMITATIONS

Even before Article 14 of the Decree above was adopted, Viet Nam already had a requirement for disclosure of origin for genetic resources and ATK. Disclosure of origin for patents is currently governed in Viet Nam by Article 102(2) of the Law on Intellectual Property of 29 November 2005 and paragraph 23.11 of Circular 01/2007/TT-BKHCHN, promulgated by the Ministry of Science and Technology (MOST) on 14 February 2007.

The text of the former stipulates the mandatory disclosure required in applications for protection of inventions, which states that:

2. The description of invention must satisfy the following conditions:

- a). Fully and clearly disclosing the nature of the invention to the extent that such invention may be realized by a person with average knowledge in the art;*
- b). Briefly explaining the accompanied drawings, if it is required to further clarify the nature of the invention;*
- c). Clarifying the novelty, inventive step and susceptibility of industrial application of the invention.*

The text of the latter is where the mandatory disclosure is spelled out, and reads:

23.11. Additional provisions applicable to applications for registration of inventions concerning genetic resource or traditional knowledge

Apart from the general requirements for invention registration applications specified at Points 23.1 thru 23.7 of this Circular, an application for registration of an invention concerning genetic resource or traditional knowledge must also contain documents explaining the origin of the genetic resource and/or traditional knowledge accessed by the inventor or the applicant, if the invention is directly based on that genetic resource and/or traditional knowledge. If the inventor or the applicant cannot identify the origin of the genetic resource and/or traditional knowledge, he/she shall so declare and bear responsibility for the truthfulness of his/her declaration.

The decision to introduce a disclosure of origin requirement both in its Circular 01/2007/TT-BKHCHN and in Decree 59/2017/ND-CP – is appropriate as there are increasing numbers of patent and utility model applications that are based on some type of genetic resource, particularly in fields such as health products. According to data from IP Viet Nam, such applications have exceeded 200 since at least 2009, with most of the applications originating from foreign jurisdictions (Table 1, below). In addition, like many other Asian countries, traditional medicine is practiced widely in Viet Nam, and many of the plants and animals used in its practice are often candidates for the development of a range of health/pharmaceutical products.

How Circular 01/2007/TT-BKHCHN interacts with the disclosure requirement in the intellectual property law is not entirely clear. At one level, it could be interpreted as a guide to what would constitute the full and clear disclosure of an invention in a patent application, an interpretation that would seem to be consistent with the text of the Circular itself (paragraph 7.2). However, in practice, in interviews with staff at the National Office of Intellectual Property in May 2019, it was explained that, to date, it has not once invoked paragraph 23.11 of the Circular to require supplemental information. Even if there were an instance where they could request the disclosure, it was explained that the only thing a prospective applicant would need to do is to declare that s/he is unaware of the origin of the genetic resource or traditional knowledge. The application would then be accepted at the formality check level, and would move to substantive patent examination.

Compounding this problem is that the intellectual property law does not provide any grounds for invalidating patents where disclosure of origin of genetic resources and ATK has not been made. The conditions for invalidation of intellectual property titles is set out in Article 96 of the intellectual property law, and provides:

Article 96. Invalidation of Protection Titles

1. A Protection Title shall be entirely invalidated in the following cases:

- a). The applicant for registration neither has right to registration nor has been assigned such right (with regard to inventions, industrial designs, layout-designs and marks);*
- b). The subject matter of industrial property failed to satisfy the protection conditions at the grant date of the Protection Title.*

Table 1. Statistics of patent applications of genetic resource-related invention and utility solution (IPC: C12N, A61K35, A61K36, A61K37, A61K38, A61K39, A01H, C07K, A01K)

Year	Genetic resource-related invention		Genetic resource-related utility solution		Genetic resource-related invention and utility solution		Invention and utility solution
	Total	Viet Nam	Total	Viet Nam	Total	Viet Nam	Total
1995	20		0		20	0	748
1996	38		2		40	0	1,092
1997	66		6		64	0	1,333
1998	40		2		42	0	1,139
1999	51		0		51	0	1,202
2000	88	2	3	2	91	4	1,340
2001	83	2	2	2	85	4	1,368
2002	83	3	4	4	87	7	1,314
2003	75	4	5	5	80	9	1,342
2004	115	8	0	0	115	8	1,601
2005	135	5	17	17	152	22	2,201
2006	117	12	5	5	122	17	2,411
2007	168	10	2	2	170	12	3,080
2008	184	3	4	4	188	7	3,484
2009	192	11	8	8	200	19	3,143
2010	197	12	9	8	206	20	3,882
2011	230	12	15	14	245	26	3,995
2012	220	14	17	15	237	29	3,960
2013	256	19	17	17	273	36	4,169
2014	241	14	17	17	258	31	4,447
9/2015	170	14	13	12	183	26	3,389

Source: National Office of Intellectual Property, 2019

2. A Protection Title shall be partly invalidated if that part failed to satisfy the protection conditions.

In practice, the grounds for patent invalidation are confined to where the applicant had no right to apply for the patent in the first place (i.e., patent eligibility), and challenges based on the substantive requirements of patentability (i.e., not having met the conditions of novelty, inventive step and industrial applicability).

With respect to PVP, Viet Nam promulgated amendments to its intellectual property law in 2009 (Law No. 36/2009/QH12) and an implementing Decree 88/2010/ND-CP of 16 August 2010 in order to conform domestic PVP protection laws to the International Convention on the Protection of New Varieties of Plants (UPOV), 1991, to which it was obliged to join as a condition for its bilateral trade agreement with the United States. It was confirmed in interviews with the Ministry of Agriculture and Rural Development

(MARD) that Viet Nam has no immediate plans to accede to the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), which establishes a multilateral ABS system for a number of important agricultural crops and contains certain limitations on seeking intellectual property rights over material received from the system.³ Viet Nam's plans may change in the future.⁴ Neither the intellectual property law, as amended, nor Decree 88/2010/ND-CP contain any requirement for disclosure of source or origin, or of ATK, in applications for protection of new plant varieties.

What the above analysis shows is that, for patents, while there is a requirement in Viet Nam for disclosure of origin or source in patent applications on paper, the absence of effective enforcement mechanisms renders the requirement ineffective. For PVP, laws and regulations contain no obligation to disclose the origin or source of genetic resources, or ATK.

5. RECOMMENDATIONS

IP Viet Nam has indicated that clear guidance is needed to enforce the requirement to disclose origin and source as envisaged under Circular 01/2007/TT-BKHCHN. The following changes in legislation and regulations are suggested (in *red italics* for additions and in *strike-out/blue italics* for deletions).

With respect to patents, Article 102 of the intellectual property law should be amended to empower the Government or the MOST to provide for specifications on the required disclosure, as recommended below. This will have the effect of directly linking the Government Decrees or the MOST Circulars with the intellectual property law. Keeping the link with the disclosure of origin requirement within the ambit of Article 102 strengthens the argument that the disclosure requirement is not an additional substantive requirement for patentability, but is linked to the fulfillment of the patent applicant's obligations to meet the requisite formalities to have the patent application examined.

Article 102. Requirements for Invention Registration Applications

1. Documents identifying the invention claimed for protection in an invention registration application shall include a Specification of invention and an Abstract of invention. Specification of invention consists of a Description of invention and a Scope of protection of invention.
2. The Description of invention shall fulfill the following conditions:
 - a). To sufficiently and clearly disclose the nature of the invention to the extent that such invention may be carried out by a person having ordinary knowledge in the art;
 - b). To briefly explain the drawings, if it is required to further clarify the nature of the invention; and
 - c). To clarify the novelty, inventive step and susceptibility of industrial application of the invention.
3. The Scope of protection of invention shall be expressed in the form of a combination of those technical features necessary and sufficient to identify the scope of the rights to that invention, and must be in line with the Specification of invention and drawings.

4. *The Abstract of invention shall disclose the essential features of the nature of the invention.*

5. *Ministry of Science and Technology shall provide specifications of what will need to be included in the description of an invention and in the abstract of invention.*

Paragraph 23.11 of Administrative Circular 01/2007/TT-BKHCHN should be amended to clarify the scope of the disclosure requirement, as follows:

23.11. Additional Provisions Applicable to Applications for Registration of Inventions concerning Genetic Resources or Traditional Knowledge

Apart from the general requirements for invention registration applications specified at Points 23.1 thru 23.7 of this Circular, *regarding* an application for registration of an invention *directly based on concerning* genetic resource or traditional knowledge *the Description* must also *describe contain documents explaining the origin of* the genetic resource and/or *associated* traditional knowledge accessed by the inventor or the applicant, *as well as their source or geographical origin* if *the invention is directly based on that genetic resource and/or traditional knowledge the source or geographical origin is essential technical feature of the invention.* ~~*If the inventor or the applicant cannot identify the origin of the genetic resource and/or traditional knowledge, he/she shall so declare and bear responsibility for the truthfulness of his/her declaration.*~~

The amendment aligns the disclosure requirement with the language of the CBD and the Nagoya Protocol, in that it covers both accessed genetic resources and ATK. The disclosure is triggered only, however, where the invention is directly based on the genetic resource or ATK, and is an essential technical feature of the invention.

Finally, an amendment to Article 96 of the intellectual property law is suggested to enable IP Viet Nam to invalidate granted titles to patents that did not comply with the disclosure requirement.

Article 96. Invalidation of Protection Titles

1. A Protection Title shall be entirely invalidated in the following cases:
 - a). The applicant for registration neither has right to registration nor has been assigned such right (with regard to inventions, industrial designs, layout-designs and marks);

b). *The subject matter of industrial property failed to satisfy the protection conditions at the grant date of the Protection Title.*

c). *Evidence is provided that the specification of invention failed to satisfy the requirements as stipulated in Article 102 of this Law and detailing provisions in the relevant Decrees and Circulars.*

2. *A Protection Title shall be partly invalidated if that part failed to satisfy the protection conditions.*

With respect to plant variety protection, the procedures for the registration of PVP rights are set out in Decree 88/2010/ND-CP, which designates MARD as the authority in charge of managing Viet Nam's system of PVP rights. It is suggested to amend Article 174.1 of the intellectual property law as follows:

Article 174. Protection registration applications

1. *A protection registration application comprises the following documents:*

- a). *A declaration form for registration made according to a set form;*
- b). *Photos and technical declarations made according to a set form;*
- c). *Power of attorney, where the application is filed through a representative;*
- d). *Documents evidencing the registration right where the registrant is a transferee of the registration right;*
- e). *Documents evidencing the priority right, where the application contains a claim for enjoying the priority right;*
- f). *Vouchers of payment of fees and charges; and*
- g). *Where registration of a plant variety is sought that has been developed from genetic resources obtained from Viet Nam, evidence of compliance with applicable laws and*

regulations on access and benefit sharing from genetic resources.

While awareness of ABS requirements is still low at the MARD, making it clear that obtaining PVPs will require disclosure of geographical origin and source will put applicants on notice that their applications will be scrutinized for proper disclosure.

As in the case of patents, a mechanism is needed to ensure that MARD will be able to invalidate PVP rights that have not complied with Viet Nam's ABS law. This can be addressed through the following amendment to Article 171 of the intellectual property Law.

Article 171. Invalidation of Plant Variety Protection Title

1. *The Plant variety Protection Title will be invalidated in the following circumstances:*

- a). *The applicant who does not have the right to file application, except where the right over a plant variety has been assigned to the holder of the registration right;*
- b). *The protected variety did not meet the conditions for novelty or distinctness at the time of granting the plant variety Protection Title;*
- c). *The protected variety did not meet the conditions for uniformity or stability if the plant variety protection certificate is granted on the basis of technical test results which were supplied by the registrant; and*
- d). *Evidence is provided that the plant variety failed to satisfy the requirements as stipulated in Article 174 of this Law and detailing provisions in the relevant Decrees and Circulars.*

In addition, policy makers may wish to consider amending the penalties for violations of the IP law to include cases of willfully misleading or false declarations on disclosure of origin, applicants shall be subject to possible measures against administrative violations, including fines and possible sanctions, as determined by competent authorities.

6. IMPLEMENTATION OF THE NEW RULES

The changes contemplated above will have the effect of requiring genetic resources and ATK data into the IP Viet Nam databases, enabling searches. This will, in turn, assist Viet Nam in discharging its obligation to ensure compliance with CBD/Nagoya Protocol PIC and MAT requirements. Optimally, however, a database of local genetic resources will go a long way towards assisting all stakeholders in preventing misappropriation of genetic resources and ATK. The establishment of a comprehensive database is, however, both costly and time consuming. While countries such as India have successfully established such a database with respect to their traditional medicines, many developing countries have found creating and maintaining a usable database to be a challenge.

In the meantime, however, BCA could provide IP Viet Nam with a list of priority genetic resources that are indigenous to Viet Nam and have potential commercial application, indicating the products and sectors where they believe each resource to have commercial application. This list could be published as a notification jointly by BCA and IP Viet Nam, subject to the following procedures. During formal examination, if an application for patents contains a reference to these genetic resources and ATK the examiner will need to make an assessment whether the application requires disclosure of origin in accordance with Circular 01/2007/TT-BKHCHN. In the event that disclosure of origin is required (i.e., the

genetic resource is an essential part of the invention over which a patent is being claimed rather than, for example, cited as a reference), then the examiner needs to assess whether sufficient disclosure of origin has been made. At this point in time, the examiner should alert BCA that a patent application has been filed that contains a priority genetic resource.

If there has been no or insufficient disclosure of origin, the examiner should request the applicant to amend the patent application to comply with the Circular. The formal examination of the patent application should be stayed until the disclosure is made. In the event that a patent applicant claims that s/he is unaware of the origin or source of the genetic resource, formal examination of the application shall be stayed until such time as BCA can provide an opinion that the genetic resource concerned was unlikely to have been obtained in contravention of Viet Nam's Access and Benefit Sharing Decree 59/2017/NB-CP.

Finally, BCA should take the lead in setting up and operating an *Inter-agency Benefit Sharing support system*, in the model of a hub (BCA), sub-hubs (IP Viet Nam and PVP office) and spokes (genetic resources administration authorities under MARD and Ministry of Health (MOH)), with an aim to ensure access to and propagation of intellectual property information related to genetic resources/ATK and their source and geographical origin for the public, particularly beneficiaries of genetic resources/ATK. This policy need not to be regulated by legal instruments, but should be a task assigned by the Government or agreed among related Ministries (i.e. Ministry of Natural Resources and the Environment (MONRE), MOST, MARD and MOH).

7. CONCLUSION

A requirement to disclose the origin of genetic resources and ATK in a patent or PVP application is a tool used by a number of countries as a defensive measure to combat misappropriation. While such a measure would not necessarily prevent patenting in foreign jurisdictions, foreign jurisdictions can search patent applications globally to ascertain patentability, while also providing ABS authorities with important leads to determine compliance with domestic ABS laws and policies. It would also help ensure that patents filed in Viet Nam demonstrate compliance with domestic PIC and MAT requirements. In Southeast Asia, such a system is already in place in Indonesia and the Philippines.

In order to be effective, however, a disclosure requirement needs to be enforceable, i.e., there needs to be consequences for non-disclosure/non-compliance. The principal weakness of Viet Nam's existing disclosure requirement to date has been that the intellectual property legislation and regulations did not specify what the consequences were for an absence of disclosure. Under the present system, a statement that an applicant was unaware of the origin of any genetic resource used in an invention would suffice to move an application from a formality review to substantive examination. The proposed amendments to the above laws and decrees above seek to address this shortcoming.

In the longer run, there will clearly need to be a systemized line of communication between IP Viet Nam and BCA for the disclosure system and, more broadly ABS, to work effectively. While the availability of searchable databases will help in this effort, the creation and maintenance of such databases is challenging for many developing countries. There are measures that could be taken in the short run, nonetheless, such as for BCA to identify key indigenous genetic resources that have commercial potential and to share that with IP Viet Nam. Such actions could be important building blocks for eventually having a stronger and more comprehensive ABS system, including the designation of appropriate checkpoint agencies.

Key Recommendations

1. Article 102 of the intellectual property law should be amended to empower the Government or the MOST to provide for specifications on the required disclosure:

102(5). Ministry of Science and Technology shall provide specifications of what will need to be included in the description of an invention and in the abstract of invention.

2. Paragraph 23.11 of Administrative Circular 01/2007/TT-BKHCHN should be amended to clarify the scope of the disclosure requirement:

Apart from the general requirements for invention registration applications specified at Points 23.1 thru 23.7 of this Circular, regarding an application for registration of an invention directly based on ~~concerning~~ genetic resource or traditional knowledge the Description must also ~~describe contain documents explaining the origin of the~~ genetic resource and/or ~~associated~~ traditional knowledge accessed by the inventor or the applicant, as well as their source or geographical origin ~~if the invention is directly based on that genetic resource and/or traditional knowledge~~ the source or geographical origin is essential technical feature of the invention. ~~If the inventor or the applicant cannot identify the origin of the genetic resource and/or traditional knowledge, he/she shall so declare and bear responsibility for the truthfulness of his/her declaration.~~

3. Article 96 of the intellectual property law should be amended to enable IP Viet Nam to invalidate granted titles to patents that did not comply with the disclosure requirement:

1. A Protection Title shall be entirely invalidated in the following cases:

...

c) Evidence is provided that the specification of invention failed to satisfy the requirements as stipulated in Article 102 of this Law and detailing provisions in the relevant Decrees and Circulars.

4. With respect to plant variety protection, Article 174.1 of the intellectual property law should be amended as follows:

1. A protection registration application comprises the following documents:

...

g) Where registration of a plant variety is sought that has been developed from genetic resources obtained from Viet Nam, evidence of compliance

with applicable laws and regulations on access and benefit sharing from genetic resources.

5. A mechanism to invalidate PVP rights that have not complied with Viet Nam's ABS law can be addressed through the following amendment to Article 171 of the intellectual property law:

1. The Plant variety Protection Title will be invalidated in the following circumstances:

...

d) Evidence is provided that the plant variety failed to satisfy the requirements as stipulated in Article 174 of this Law and detailing provisions in the relevant Decrees and Circulars.

6. Policy makers may wish to consider amending the penalties for violations of the IP law to include cases of willfully misleading or false declarations on disclosure of origin, applicants shall be subject to possible measures against administrative violations, including fines and possible sanctions, as determined by administrative competent authorities.

7. BCA should take the lead in setting up and operating an Inter-agency Benefit Sharing support system, in the model of a hub (BCA), sub-hubs (IP Viet Nam and PVP office) and spokes (genetic resources administration authorities under MARD and MOH).

8. ANNEX

List of interviewees, UNCTAD mission (30–31 May, 2019)

	Organization	Individual	
1	IP Office	Leader in charge of Patent	- Deputy Director General Phan Ngan Son
2		- Administrators in charge of Biological Patent	- Patent Examination Center Deputy Director Nguyen Thanh Tu and staff
		- Staff in charge of Legal and Policy Affairs	- Legal and Policy Affairs Division Staff
3	Plant Variety Protection Office	- Leader of PVP Office Department of Crop Production	Director Nguyen Thanh Minh
4	Genetic Resources Management Authorities under Ministry of Agriculture and Rural Development	- Department of Livestock Production	Invited by PVPO
		- Department of Sea Products - Science and Technology Division	
5	Genetic Resources Management Authorities under Ministry of Health	- Traditional Medical and Pharmaceutical Administration	Invited by BCA
		- Pharmaceutical Material Institute	
6	BCA/ Ministry of Natural Resources and the Environment	- To be determined by BCA	Invited by BCA

References

- Chiarolla, Claudio. *Intellectual Property from a Global Environmental Law Perspective: Lessons from Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge* Transnational Environmental Law 8:3 (2019), pp. 503–521.
- Mgbeoji, Ikechi. *Global Biopiracy: Patents, Plants and Indigenous Knowledge*. Vancouver, BC: UBC Press, 2006.
- Robinson, Daniel F. "Patent-Related Biopiracy Cases. *Confronting Biopiracy: Challenges, Cases and International Debates*. (pp. 67-76). United Kingdom: Earthscan, 2010.
- UNCTAD. *The Convention on Biological Diversity and the Nagoya Protocol: Intellectual Property Implications – A Handbook on the Interface between Global Access and Benefit Sharing Rules and Intellectual Property*. New York and Geneva: United Nations, 2014.

Notes

- 1 Notified to the CBD Secretariat's ABS Clearing-House on 11 May 2018 following a national consultation.
 - 2 Draft Decision to Enhance Mutual Supportiveness between the TRIPS Agreement and the Convention on Biological Diversity, TN/C/W/59 19, April 2011, WTO, https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/4_tncw59_e.pdf.
 - 3 ITPGRFA, Art 12.3(d): *Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System.*
 - 4 Letter 116/ICD-MARD of 23 April 2019 requests FAO's technical support for a study on the requirements and implications and process for Viet Nam joining the ITPGRFA.
-