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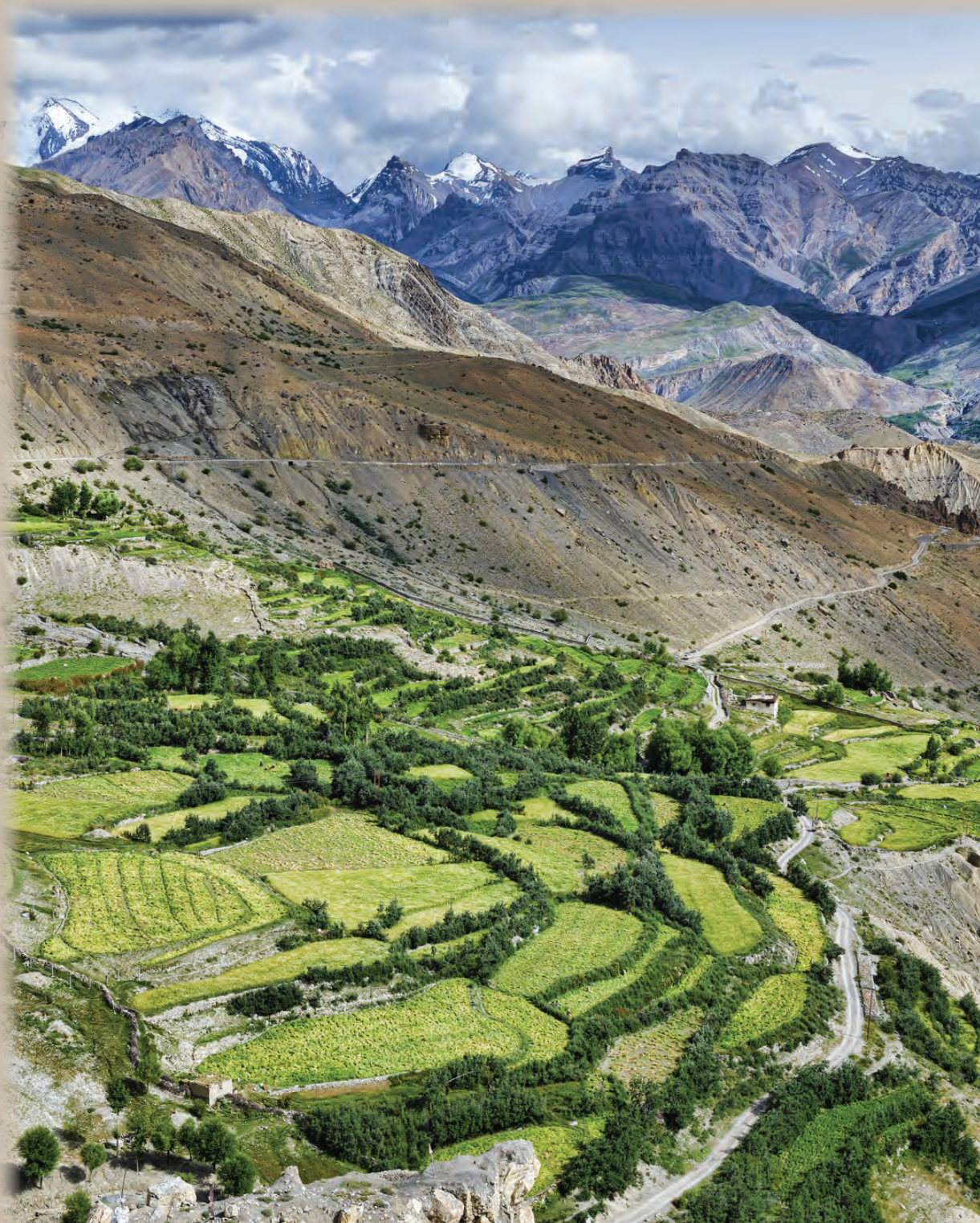
# Development Dimensions of Intellectual Property in Nepal:

## Transfer of Technology, Access to Medicines, Genetic Resources and Traditional Knowledge



UNITED NATIONS

**United Nations Conference on Trade and Development**

# Development Dimensions of Intellectual Property in Nepal

## Transfer of Technology, Access to Medicines, Genetic Resources and Traditional Knowledge

**United Nations**
**New York and Geneva, 2016**

**Note**

The Development Dimensions of Intellectual Property in Nepal: Patents and Access to Medicines, Genetic Resources/Traditional Knowledge, and the Transfer of Technology

1. Intellectual property. 2. Technology Transfer. 3. Access and Benefit Sharing. 4. Public Health. 5. Nepal

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# Table of Abbreviations

| | |
|---|---|
| **ABS** | Access and benefit sharing |
| **AIDS** | Acquired immunodeficiency syndrome |
| **ARIPO** | African Regional Intellectual Property Organisation |
| **API** | Active Pharmaceutical Ingredient |
| **CBD** | Convention on Biological Diversity |
| **CDIP** | Committee on Development and Intellectual Property |
| **DDIP** | Development Dimensions of Intellectual Property |
| **EPO** | European Patent Office |
| **GIs** | Geographical Indications |
| **GMP** | Good Manufacturing Practices |
| **GRs** | Genetic Resources |
| **GRs/TK** | Genetic resources and associated traditional knowledge |
| **HIV** | Human immunodeficiency virus |
| **ICTSD** | International Centre for Trade and Sustainable Development. |
| **IP** | Intellectual Property |
| **LDC** | Least Developed Country |
| **MoHP** | Ministry of Health and Population |
| **PIC** | Prior informed consent |
| **R&D** | Research and Development |
| **SMEs** | Small and medium enterprises |
| **TK** | Traditional knowledge |
| **TKDL** | Traditional Knowledge Digital Library |
| **TRIPS** | Agreement on Trade-Related Aspects of Intellectual Property |
| **UN** | United Nations |
| **UNCTAD** | United Nations Conference on Trade and Development |
| **UPOV** | International Convention for the Protection of New Varieties of Plants |
| **USPTO** | United States Patent and Trademark Office |
| **WHA** | World Health Assembly |
| **WHO** | World Health Organisation |
| **WIPO** | World Intellectual Property Organisation |
| **WTO** | World Trade Organisation |

## Executive Summary

*The recommendations of this report have already been provided to the Government of Nepal. The objective of this report is not only to formalize those recommendations, but also to disseminate the approach, findings and recommendations that have wider applicability to other Least Developed Countries (LDCs).*

UNCTAD originally developed this Report on the development dimension of intellectual property rights (DDIP) in response to a technical assistance request from Nepal. Part 1 of this Report outlines the major framework for intellectual property (IP) policy in Nepal. IP rights have differential impact on countries based on their respective levels of development, with LDCs being in a less advantageous position due to their limited absorptive capacity and technological base, among other limitations. In this context;

- The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) provides Nepal with transition periods for the implementation of the TRIPS Agreement until 2021 and for availability of pharmaceutical product patent and pharmaceutical test data protection until 2033. It also provides for inbuilt flexibilities for implementation, subject to the non-discrimination principles and the obligations under the Paris Convention and the Bern Convention.
- Further, the objectives of the various socio-economic policies of Nepal and related implementing acts and regulations, as well as institutions, may benefit from or conversely be influenced by IP rights. Striking an appropriate balance between the protection of IP and socio-economic objectives should be the key goal of IP legislation and implementation.

Considering its level of development, IP policy makers in Nepal needs to consider the importance of and the factors that facilitate indigenous learning activities and the adaptation of technologies, through incremental innovation in vital and promising sectors of the economy. Part 2 of the Report recommends a number of legislative, policy and practical steps to facilitate and enable the technological and innovation functions of IP protection. Part 3 of the Report examines the access to medicine regime of Nepal and recommends for Nepal to implement the transition period for the protection of pharmaceutical product patents and pharmaceutical test data that lasts until 2033. Part 4 of the Report analyses Nepal's access and benefit sharing regime, the interface between IP and biodiversity, and options for defensive and positive protection of genetic resources (GRs) and traditional knowledge (TK).

The recommendations of this Report on the framework for IP policy in Nepal and on each specific area examined have legislative and institutional dimensions that require capacity building, and, in some cases, additional studies to develop specific action plans for implementation. This Report serves as a good basis for identifying Nepal's priority needs for technical and financial cooperation.

Among the legislative reforms, the recommendation for the exclusion of pharmaceutical products from patentability and the protection of pharmaceutical test data can be prioritised, possibly without waiting for the full amendment of the 1965

Patent, Design and Trademark Act 2022 (Industrial Property Act). Other recommendations will require the IP Office to adopt and implement rules and procedures. Revisions to Nepal's Industrial Property Act should be made keeping in mind the ultimate objective of IP rights, in accordance with Article 7 of the TRIPS Agreement, to:

- *Ensure that IP laws contribute to innovation and technology transfer to vital sectors of the economy and facilitates indigenous learning and adaptation;*
- *Build mutual supportiveness of IP laws and laws and policies for the protection of GRs/TK, public health, others; and*
- *Ensure access to technological goods and services by the Nepalese public at large, including access to medicines and educational material by the use of TRIPS flexibilities.*

Finally, the IP system and IP policy will cover subject matter and laws/regulations that involve various Ministries. In the mid to long term, an effective institutional structure will need to exist in order to ensure effective coordination and policy coherence. Much of the analysis and recommendations of this Report are not limited to Nepal. LDCs and other developing countries face similar challenges in technology transfer, access to medicines, and the protection of GR and TK. Consequently, this Report may provide them with useful guidance.

## 1. Introduction: the Context of IP Policy Making and Development

UNCTAD developed this Report to provide advice on how to best design intellectual property (IP) laws in a balanced manner in response to a technical assistance request from the government of Nepal. The Report on Development Dimensions of Intellectual Property (DDIP) in Nepal focuses on:

1) Context and framework for IP policy, including institutional mechanisms, in Least Developed Countries (LDCs), such as Nepal;
2) IP and the transfer of technology;
3) Patents and access to medicines; and
4) IP and access to and benefit sharing arising out of the utilisation of genetic resources (GRs) and associated traditional knowledge (TK).

Much of the analysis and recommendations in this Report are not limited to Nepal. LDCs and other developing countries face similar challenges in technology transfer, access to medicines and the protection of GR and TK. UNCTAD's framework for analysis on the development dimension of IP rights involves:

1. identifying critical policy issues relevant to the use of IP to effectively leverage development prospects within regulatory frameworks reflective of specific socio-economic and cultural conditions;
2. the formulation of medium to long-term recommendations on how to make IP frameworks more coherent and transparent, and consistent with the country's identified economic and human development goals.

In carrying out advisory works, UNCTAD undertakes fact-finding missions and review of the laws and policies, and the socio-economic indicators.

Further consultations with stakeholders were undertaken on the first draft of the Nepal DDIP report and its recommendations. The final Nepal DDIP report and its recommendations were endorsed during a validation workshop on 12 November 2014 in Kathmandu, Nepal.

Accordingly, this Report (and where countries engage in similar exercise to address the development dimension of IP rights) began with mapping the socio-economic indicators, the international regime and domestic IP legislations of Nepal, followed by options to facilitate the technological and innovation functions of the IP system to address access to medicines and the mechanism for protection of GR and TK. The final part provides policy coordination, prioritising of recommendations and institutional reform.

### 1.1 Socio-economic Framework for IP Policy in Nepal

Nepal, with an estimated population of 31 million in 2012, is among the 48 least developed countries (LDCs) recognized by the United Nations.[1] Nepal is also among the countries with low human development, ranked 145th in the world.[2] Although the service sector, especially tourism, dominates Nepal's economy, the agriculture sector provides the most employment. The industrial base is largely in the textile, food, beverages and tobacco sectors. A single country, India, is the main destination of exports and imports to/from Nepal, followed by the United States as a distant second destination of exports and its neighbour to the north, China, as a distant second source of imports. [3]

Nepal's efforts to transform the economy towards industrialization are constrained by competition from regional manufacturing hubs, i.e., Bangladesh, China and India, and by the lack of access to the sea and the related high cost of transportation that arises from being a landlocked country. In 2005, WTO abolished quotas and other related trade restrictive measures imposed by developed countries on textiles and garments. The lifting of the quota undermined the exports of smaller LDCs such as Nepal and Lesotho, in favour of larger producer countries such as Bangladesh, China, and Viet Nam.[4] The Garment Association of Nepal reported that the country has suffered a decline of 90 percent in export of readymade garments between 2005 and 2010.[5]

In an effort to develop other promising sectors, the 2011 Industrial Policy of Nepal attempts to continue the economic transformation of the country. It identifies priority sectors to receive special investment incentives, including agriculture and forest products, energy, transportation, and manufacturing of chemical fertilizers and pharmaceuticals, as well as a number of traditional cottage industries.[6] The choice by Nepal to focus this Report on the relationship of intellectual property with access to medicines, biodiversity and technology transfer is clearly a reflection of this aspiration.

Private Nepalese enterprises are small both in terms of sales and employment.[7] They suffer from poor labour productivity, access to consistent electricity and access to finance, all of which affect their performance.[8] Only 3.8% of Nepalese enterprises export their products abroad, compared to 6.1% of Bangladesh firms, 8.6% of Bhutanese firms and 9.4% of Lao PDR's firms, all of which are similar LDCs in South/Southeast Asia.[9] While the low level of exports also reflects Nepal's isolation from the global market, it should be noted that Bhutan and Lao PDR are also landlocked. A World Bank survey of Nepalese enterprises further attests to the fact that little innovation occurs in the domestic private sector.[10]

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[1] UNCTAD, 2011a, 8.
[2] UNDP, *Human Development Report 2014*, New York.
[3] EIU, 2008, *Nepal,* 17-18; and EIU, 2012, *Nepal,* 6.
[4] See further, Adhikari, Ratnakar and Yumiko Yamamoto, 2007. The export of textile from China increased by 22.8% within one year following the lifting of the quota. More than 20% of textiles traded in 2005 originated from China.
[5] *The Kathmandu Post*, 5 July 2010.
[6] Nepal, 2011, Industrial Policy, schedule 7.
[7] World Bank, 2012, 95.
[8] *Ibid*.
[9] *Ibid*. 100
[10] *Ibid*. 101

The role of IP rights in an LDC economy has been the subject of various studies. Several studies confirm that IP rights have a differential impact on countries based on their level of development. With higher IP rights standards, technological products such as pharmaceuticals could be rendered expensive for the average consumer and may not be available in the local market at all if the correct IP regime is not in place. LDCs and other low-income countries with low absorptive capacity and weak economies have less potential to benefit from the strengthening of IP rights protection. [11] Empirical studies again suggest:

> that stronger [IP rights] may positively affect the volume of [foreign investment] and exports, particularly in countries with strong technical absorptive capabilities where the risk of imitation is high. When such risk is weak, particularly in the poorest countries, firms in developed countries do not seem to be sensitive to the level of protection in developing countries.[12]

The size of the technology gap that separates Nepal and other LDCs from more advanced economies makes learning a central factor for successful productivity and transformation of the economy.[13]

Yet, some form of IP protection is relevant for LDCs. Communities, producers and exporters can also utilize the trademark system, including collective marks, certification marks and geographical indications (GIs) to safeguard and improve existing production, and to add value to locally produced goods and services. Utility models – also known as "petty patents" that are granted to protect minor and incremental inventions – are also recognized as a tool to facilitate technological learning.[14]

Hence, IP policy in Nepal needs to consider the importance of and the factors that facilitate indigenous learning activities and the adaptation of technologies, through incremental innovation in vital and promising sectors of the economy.

## 1.2 International agreements and Nepal

The World Trade Organisation (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (the TRIPS Agreement), 1994, establishes international minimum standards for the protection of copyright and related rights, trademarks, GIs, industrial designs, patent, topographies of integrated circuits, and undisclosed information (trade secret, including pharmaceutical test data). It also provides minimum standards on the procedures for acquisition, maintenance and enforcement of IP rights. As one of the basic treaties, all WTO members are required to adhere to TRIPS standards unless specifically exempted.

All members of the WTO are bound by the non-discrimination principle consisting of the national treatment and most-favoured nation treatment rules under Articles 3, 4 and 5 of

[11] Branstetter, Foley, and Saggi, 2010.
[12] Hassan, Ohid and Diepeveen, 2010, xiv.
[13] UNCTAD, 2007, 103.
[14] Mackley, 1987.

the TRIPS Agreement. Article 7 of TRIPS provides the overall objectives of the protection of IP rights. Striking an appropriate balance between the protection of IP and the objectives of promoting innovation and dissemination of technology for the benefit of society at large is the key goal identified for IP protection. The preamble of the TRIPS Agreement recognises LDCs' needs for a maximum flexibility to help them build a sound technological base. In this regard, currently, Nepal benefits from:

1) *The LDCs Transition Period for TRIPS Implementation:* The full implementation of TRIPS by LDCs is currently subject to a transition period expiring 1 July 2021 — or until such a date on which they cease to be an LDC, whichever date is earlier.[15]

2) *The LDCs Transition Period for pharmaceutical products*: A separate transition period authorises LDCs to delay the implementation of obligations on patent and undisclosed information with respect to pharmaceutical products. In 2015, this transition period is extended unanimously by the WTO, until 2033 or until such a date on which they cease to be an LDC, whichever date is earlier. [16]

3) *Technology transfer:* Article 66.2 of TRIPS also obliges developed countries to maintain an incentive system for their institutions and private sector to transfer technology to LDCs.[17]

4) *Flexibilities in implementation of TRIPS:* Beyond the transition periods, various flexibilities exist within the provisions of the WTO. The TRIPS Agreement establishes the international minimum standards for IP rights that countries must "give effect" under their domestic laws (TRIPS, Article 1(1)). In giving effect to the provisions, the agreement also provides countries with a number of flexibilities to frame their IP laws in a manner that is appropriate to their levels of development and conducive to their socio-economic needs.[18] As an example, Article 27(1) of TRIPS requires the availability of patents for inventions that are "new, involve an inventive step and are capable of industrial application." Every member may reasonably set its own standards delineating what is new, what an inventive step consists of, and when an invention is capable of industrial application.

In this context, the WTO Ministerial Conference, held in November 2001, adopted the Doha Declaration on TRIPS and Public Health (14 November 2001) that reaffirms the rights of developing county members of the WTO to use the range of available flexibilities for the promotion of public health, including the use of compulsory licenses and parallel importation of patented products. The August 2003 Decision of the General Council of the WTO established the system for the exporting of pharmaceutical products produced under compulsory license for the benefit of an LDC or a developing country

[15] WTO, 2013, IP/C/64.
[16] WTO, 2015, IP/C/73.
[17] However, review of the implementation of the obligation found only one-third of the incentives reported by developed countries targets LDCs specifically (Moon, 2008, 5 and 6).
[18] UNCTAD, 2011b, 29-31

with limited or no pharmaceutical manufacturing capacity (hereafter the 'Paragraph 6 System').[19]

Hence, for Nepal's IP policy framework, the use of TRIPS flexibilities is a question of utilizing the transition periods and the flexibilities in the implementation of each provision of TRIPS. Until 2021, all current or upcoming IP legislation, practice of institutions and procedures for enforcement in Nepal should be extended to nationals of all WTO Member States. The only exception permitted is with respect to international treaties on the acquisition and maintenance of IP rights established under the World Intellectual Property Organisation (WIPO) auspices.[20] While these treaties facilitate the filing of international applications for acquisition and maintenance of IP rights, Nepal has not acceded to any of these WIPO treaties. Nepal is signatory of two substantive WIPO treaties: the Paris Convention on the Protection of Industrial Property and the Bern Convention on the Protection of Artistic and Literary works.[21] The TRIPS Agreement incorporates provisions of the Paris and the Bern Conventions by reference.[22]

The Paris Convention covers patents, trademarks, trade names, industrial designs, utility models, GIs, and protection against unfair competition, whereas the Bern Convention protects copyright works. Both Conventions provide for the principle of national treatment. The Bern Convention defines the economic and moral rights of copyright holders, performers, producers of phonograms and broadcasting organisations, and provides limitations on adopting exceptions to the rights conferred by copyright and related rights, known as the three-step-test (Article 9(2), Bern Convention).[23]

As a result, Nepal's benefit from the transition period for implementation of the TRIPS Agreement is constrained by its obligations under the Paris and the Bern Conventions. The more international treaties Nepal ratifies, the narrower its scope will be for utilising the transition period for the implementation of TRIPS and for utilising other available flexibilities. Nepal needs to assess the impact of any treaty before ratification.

Finally, the WIPO Development Agenda, adopted in 2007, contains several recommendations on the development dimension of IP rights. The Recommendations cover key development issues related to: technical assistance and capacity building, flexibilities, public domain, technology transfer, and access to knowledge. The WIPO Committee on Development and Intellectual Property (CDIP) regularly develops a work programme for the implementation of the recommendations. Nepal needs to actively participate in CDIP meetings in order to benefit more from technical assistance projects

[19] WTO, 2005, WT/L/641. The Protocol amending the TRIPS adopted in 2005 incorporated the Decision into TRIPS.

[20] The WIPO acquisition and maintenance agreements include "the Madrid Agreement (and Protocol) Concerning the International Registration of Marks, the Patent Cooperation Treaty, the Patent Law Treaty, and the Trademark Law Treaty." See, UNCTAD-ICTSD, 2005, 82.

[21] For the list of WIPO treaties, see WIPO, WIPO-Administered Treaties, available at http://www.wipo.int/treaties/en/.

[22] In its accession to the WTO, Nepal has avoided a definitive commitment as part of its accession commitments to accede to other WIPO treaties and the International Union for the Protection of New Varieties of Plants (UPOV)WTO, 2003, WT/ACC/NPL/16.

[23] The three-step-test under the Bern Convention require exceptions to copyright be limited to (i) certain special cases (ii) which do not conflict with a normal exploitation of the work, and (iii) do not unreasonably prejudice the legitimate interests of the rights holder.

under the WIPO Development Agenda. As part of the Development Agenda, WIPO adopted in 2013 the Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired, or Otherwise Print Disabled. Since Nepal is a signatory of the Bern Convention that defines the economic right of copyright holders, it makes sense to accede to the Marrakesh Treaty to improve coherence with its membership of the Convention on the Rights of Persons with Disabilities.

## 1.3 Nepal's IP Framework

The Interim Constitution of Nepal (2007) establishes the responsibility of the State to formulate "a common development concept for socioeconomic transformation and justice, and for rapid economic progress and prosperity of the country" (Article 33 (k), Interim Constitution). The prioritisation of the development of local technology and skill, and modernization of traditional knowledge (TK) provide a starting point to inform the elaboration of a national IP policy (Article 35, Interim Constitution).

The 2011 Industrial Policy of Nepal identifies the protection of IP rights as one of its main objectives. Currently, the Nepalese IP regime consists of the 1965 Patent, Design and Trademark Act 2022 (Industrial Property Act), as amended, and the 2002 Copyright Act 2059. The Competition Promotion and Market Protection Act, 2063 (2007), the Customs Act of 2007 and the Foreign Investment and Technology Transfer Act, 2049 (1992), as amended in 2001, all contain provisions relating to IP.

The Ministry of Industry leads the policy and legislative process on IP rights in Nepal. At present, there is an inter-Ministerial TRIPS Coordination Committee which is chaired by the Ministry of Commerce and Supplies. The Copyright Registrar's Office in the Ministry of Federal Affairs, established under the Parliamentary Affairs and Culture Constituent Assembly, administers copyright in Nepal as provided by the Copyright Rules 2061 of 2004. The Intellectual Property Office in the Ministry of Industry administers patents.

Nepal is currently undertaking a review of its Industrial Property Act.[24] Considering the tasks for administration of IP rights, the IP Office requires extensive capacity building measures in terms of facilities, human resources; operational rules and regulations.

Furthermore, the framework for the national IP system also depends on the strength of multiple institutions such as responsible entities for science, technology and innovation, agriculture, education and health, as well as law enforcement agencies, customs authorities and the judiciary.

The objectives of the various socio-economic policies of Nepal, such as the National Health Policy (1991), Biotechnology Policy (2006), Science and Technology Policy (2005), Industrial Policy (2011), National Agricultural Policy (2004), and related implementing acts and regulations, as well as institutions, may benefit or otherwise be influenced by IP rights. The stakeholders also vary considerably in terms of interest, size

[24] The description 'industrial property' is a legal term used under the Paris Convention covering patents, utility models, industrial designs, trademarks, service marks, trade names, indications of source or appellations of origin, and the repression of unfair competition. See, Paris Convention, Article 1.

and the ability to influence policy making. To a large extent, a combination of policies and regulations in health, education, science and innovation, trade and investment, taxation and government procurement can all play an important role in incentivizing innovation and building the technological base in Nepal.

## 2. Patents and Transfer of Technology

Nepal's low performance in global competitiveness and its LDC status are indicative of the current level of innovation capacity, availability of skilled human resource and the level of investments in research and development (R&D).[25] The trade patterns for Nepal also reflect the low technological input. The export revenue of Nepal largely originates from the textile, garment, woollen carpet industries and tourism sector.[26]

As stated in the previous section, the TRIPS Agreement provides LDCs with the maximum flexibility in domestic implementation of laws in order to enable them to create a sound and viable technological base. One of the key objectives of the protection of IP rights, as defined under the TRIPS Agreement, is the transfer and dissemination of technology. [27] The TRIPS Agreement, however, primarily focuses on establishing international standards for the protection and enforcement of IP rights, with a comparatively limited focus on technology transfer. Designing the appropriate technology transfer policy is therefore a key task for domestic laws.

Transfer of technology[28], for the purpose of this Report, is not limited to transactions between a provider (holder of a technology) and a recipient (user of technology), through trade, investment, technology transfer and IP licensing contracts or training services. It also includes circumstances where private and public enterprises engage in active learning of existing technology for adaptation and reverse engineering. The analysis in this Report is, though, limited to the IP rights aspects of technology transfer, while recognizing the role of flanking policies in the field of education, investment and science and innovation (among other policies) that also need to be in place to build a sound and viable technological base in Nepal.

### 2.1 Enabling the Use of Technological Information in IP Applications

Patents function as a means of communicating the latest state of the art and technological information covering inventions claimed for protection. Article 29 of TRIPS provides for:

(i) a mandatory obligation for countries to require patent applicants to disclose their inventions in a sufficient and complete manner; and

(ii) the option to require patent applicants to disclose the best mode to carry out the invention known to the inventor.

[25] World Bank, 2009, and World Economic Forum, 2012. Nepal has institutions dedicated to science and technology, including the Institute of Science and Technology, the Institute of Forestry, and the Institute of Agriculture and Animal Sciences at Tribhuvan University, among others. Other institutes of higher education include Kathmandu University and Pokhara University, as well as a number of medical and engineering colleges.

[26] EIU, 2012, *Nepal,* 6.

[27] As indicated in the previous Part, currently Nepalese IP laws do not define the objectives of IP protection.

[28] The Draft International Code of Conduct on the Transfer of Technology (UNCTAD, 1985), defines technology as the systematic knowledge for the application of a process that results in the manufacture of a product or the delivery of a service.

Similar disclosure requirements exist in applications for utility models, industrial designs and plant variety protection.[29] Provided the proper legal framework is in place, Nepalese researchers and industries may utilize information contained in IP applications for R&D, adaption of technology or manufacturing of products, such as pharmaceutical and agro-chemicals.[30]

To facilitate the use of technological information in IP applications, the first concern is the quality and sufficiency of the disclosure of the invention and the best mode in patent applications. If patent applicants disclose one possible method that can only be used by a highly skilled person, such disclosure could be less useful compared to a disclosure of the best method that enables an "ordinary" skilled person in the art, for example, a typical chemist or a biologist, to carry out an invention. Hence, a clear requirement in the patent law for sufficient and complete disclosure of an invention and a requirement to disclose the best mode to carry out the invention would be the first step to enable the technology transfer function inherent in the IP system. Such a requirement needs to be backed by a rigorous examination of patent applications by IP offices and the potential penalty for failure to comply with the disclosure requirement, including suspension of the examination of the patent or revocation.

Second, in developing countries with low information technology infrastructure, access to databases of patent and other IP rights applications designed to benefit local industry and researchers may be difficult. With limited history and limited numbers of IP applications, developing country IP offices may not have substantial data from which to draw information. Moreover, the scientific and business communities also may not be sufficiently aware of the availability of technological information contained in IP applications. To alleviate the access and awareness challenge, around 29 IP offices in developing countries, including the Philippines and Viet Nam in Asia, maintain dedicated technology information and support centres.[31] Basic services available through such centres include access to patent and non-patent (scientific and technical) resources and assistance in searching and retrieving technology information.[32]

Nepal needs to consider the development of an IP information database. Such a database can cover IP applications such as patents, utility models, industrial designs and plant breeders' rights, as well as trademarks filed anywhere in the world on a portal with links to databases elsewhere. Nepal could request WIPO to provide assistance in establishing an IP information database and related services within its IP Office.[33]

Since researchers may need to consult additional scientific and technical data, IP information database could be complemented with scientific publications. The

[29] National laws require applicants for plant variety protection to provide a detailed description of the plant variety to which the application relates, including the characteristics that distinguish the plant variety from other varieties, and any test growing carried out. See, Lesser, William H., 2007, 404.

[30] See for example, Sittig, Marshall, *Pharmaceutical Manufacturing Encyclopedia*, 3rd Edition, 2008, that describes manufacturing processes for approximately 1,300 pharmaceuticals utilizing process information from the patent literature, and references for other synthetic methods and pharmacology; and Swarbrick, James, 2006.

[31] See, WIPO website, Technology and Innovation Support Centers (TISCs).

[32] *Ibid*.

[33] See, WIPO, 2010, CDIP/3/INF/2/STUDY/VII/INF/1, for the project on Innovation and Technology Transfer Support Structure for National Institutions developed under the CDIP.

information contained in a pharmaceutical patent application, for example, needs to be complemented with scientific publications on clinical trials and additional research conducted on the pharmaceutical product. Access to copyright protected scientific publications and data is usually too costly for researchers in LDCs.

To solve the access problem, open access publication – a publication that provides access and reuse rights, such as those based on creative common licenses[34] – is emerging as a major standard of publication and improving access to scientific publications to researchers.[35] Governments in advanced countries are also now requiring researchers to publish results of government-funded research in a manner that facilitates access.[36] International organizations and non-governmental initiatives are providing free access to databases and web repositories. Examples include the Encyclopaedia of Life[37] and the Social Science Research Network.[38] The Food and Agriculture Organisation (FAO) maintains the International System for Agricultural Science and Technology (AGRIS) database for agricultural science and technology, as well as links to related data resources with content provided by more than 150 participating institutions from 65 countries, including Nepal's Agricultural Research Council.[39] Content is provided freely, unlike other databases that require a subscription. Moreover, research and educational tools, such as Open Source Software[40] – software developed by programmers participating in a collaborative project that ultimately is freely available for all users – are making a difference. These developments can benefit enterprises, university and government research centres in Nepal.

Finally, IP policies alone are not sufficient to facilitate technology transfer:

- Investment incentives, government procurement, and research grants can provide important incentives for firms to engage in technological adaptation.
- Open and collaborative research models can help local researchers and institutes exchange experience with developed country public and private research organisations. Considering Nepal's geography and rich genetic resources, access and benefit sharing agreements and other research related arrangements can be used to provide opportunities for researchers and institutions to participate and collaborate with developed country institutions; and

[34] Creative common license – a copyright license system in which the authors retain the copyright but grant others the license to copy, distribute, and make use of their work– is an alternative form of dissemination of works by institutions and individual authors. See, CreativeCommons, at http://creativecommons.org/licenses/

[35] *The Economist,* 27 September 2014.

[36] See, for example, the Bayh-Dole Act of the United States.

[37] See, global access to knowledge about life on Earth, at http://eol.org/. There also several databases under creative commons with respect to energy, genomics, disease research, and other scientific fields. See, CreativeCommons Data at http://wiki.creativecommons.org/Data, and Sage Bionetworks at http://sagebase.org/, for example.

[38] See, Social Science Research Network (SSRN), at http://www.ssrn.com/en/.

[39] See, FAO-Agris at http://agris.fao.org/.

[40] OSS Watch provides for a list of open source software. See, http://oss-watch.ac.uk/.

- Promoting university-industry linkages under education and science policies can also assist local firms to tap scientific and technological skills and resources.[41].

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*Recommendations*

1) *Ensure that the IP laws of Nepal require sufficient and complete disclosure of inventions to enable an ordinary skilled person to carry out the invention and the best mode to practice the invention. The IP Office should enforce compliance with the disclosure requirements. Failure to comply with the disclosure requirement should lead to suspension of consideration of the IP application, or if already granted, constitute grounds for revocation;*
2) *Consider the establishment within the IP office of a technology information and support centre and seek support from WIPO or with any other willing development partner.*
3) *The IP Office should take steps to increase awareness and to periodically disseminate information relevant to the private sector, students, university research centres and government agencies, on open access publications, open source software, and creative commons copyright licenses, with a focus on sectors of importance to Nepal.*
4) *Flanking policies such as procurement, investment incentives, access and benefit sharing agreements with respect to genetic resources and the like also offer opportunities for improving technology transfer to Nepal. Relevant Ministries, including the Ministry of Science, Technology and Environment, and the IP Office should be engaged when policies are made in promising sectors.*
5) *Nepal's IP Office should provide technical assistance on management, ownership and licensing of IP rights in university-industry research and development cooperation, government procurement and donor funded projects, in particular with a view to:*

    *a) develop guidelines for universities and government agencies on IP rights arising from publicly funded projects or procurements, including, for example, copyrights over textbooks published by the Ministry of Education or universities; new plant varieties and improved seeds developed by public research centres, design rights for public buildings, terms of license in government procurement of goods and services, etc.*

    *b) establish clear rules for the determination of ownership of IP rights between researchers and universities, as well as between universities and the private sector, suppliers and procurement agencies, and between private companies and their scientists;*

[41] University – industry linkage can take place in various forms including internships and fellowships by university researchers in industries, exchange of scientific personnel, and joint collaboration in specific research projects. Industry can directly finance university research projects. Government may also support industries and finance universities under a triangular collaboration. Entrepreneurial researchers may also establish their own spin off commercial entities. Greenhalgh, Christine and Mark Rogers, 2010, 95.

*c) ensure that IP rights arising from university-industry collaboration and government funding do not hinder access to technology and knowledge; and*

*d) organize periodical trainings on the management of IP rights for government entities, universities and researchers.*

## 2.2. Patent Examination: Balancing IP Rights and Technology in the Public Domain

Patents are granted after examination of whether the subject matter is eligible for patent protection; that it meets the patentability criteria (novelty, inventiveness and industrial applicability) and satisfies the conditions for patent applications, namely, the sufficiency of disclosure and the disclosure of best mode to carry out the invention. A rigorous examination of a patent application enriches the public domain – the subject matter not meeting the criteria for patentability is excluded from protection, and thus may be accessed and used by anyone without permission. It prevents the patenting of the building blocks of science and technology, and helps ensure fair competition in the market place.[42]

In this respect, patent examiners functions as the gatekeepers against patent claims for something that is not new, inventive or industrially applicable, and which should be available for access and utilisation by all. The existence of local capacity in the various fields of technology will influence the quality of search and examination of patent claims. In this respect, international practice varies. Smaller patent offices may rely on prior art search and examination reports prepared by other countries or international search reports, whereas a larger patent office may possess its own internal capacity for search and examination. The Patent offices of Belgium, Greece, and Turkey, for example, rely on the prior art 'search' by the European Patent Office (EPO).[43] Members of the African Regional Intellectual Property Organisation (ARIPO) rely on ARIPO search reports.[44]

Another important approach to patent examination has been to provide pre-grant opposition procedures. Pre-grant opposition provides the opportunity for third parties to submit information relevant to the patentability of the claimed invention. Such pre-grant opposition diversifies the sources of information and other experts' point of view with respect to the prior art, the patentability of the claimed invention and the sufficiency of the disclosure of the invention. For example, India has recently denied patents to various applications concerning pharmaceutical products by undertaking search and examination, and based on pre- and post-grant opposition procedures. Table 1 below provides some of the key decisions that concerns pharmaceutical patents to demonstrate the critical importance of search and examination, pre-grant and post-grant opposition.

[42] WIPO, 2011, CDIP/8/INF/3.

[43] The EPO will usually prepare three search reports: 1) an international search report, when it functions as the international search authority under the WIPO Patent Cooperation Treaty (PCT); 2) a European search report; and, finally, 3) a national search report where the patent application concerns any of the countries that designated EPO as their prior art searching authority.

[44] See ARIPO, 2006, Articles 15 and 18.

| **Table 1: Recent examples of patent claims rejected based on search and examination, pre and post grant opposition in India** | | |
|---|---|---|
| *Patent claimed* | *Grounds for rejection of patent claim* | *Procedures involved in the rejection of the patent claim* |
| Gilead Sciences patent claim concerning Tenofovir (ARV). | Known substance, new use of known substance, no improvements in the properties | Search and examination + pre-grant oppositions by generic manufacturers |
| Tibotec Pharmaceuticals concerning Darunavir (ARV). | Known substance, new use of known substance, no improvements in the properties | Search and examination + pre-grant oppositions by generic manufacturers |
| Novartis's patent claim on imatinib mesylate (Gleevec) – medicine for the treatment of cancer. | Known substance, new use of known substance, no improvements in the properties | Search and examination + pre-grant oppositions by civil society |
| Valganciclovir product patent | Known substance, new use of known substance, no improvements in the properties | Post-grant opposition generic manufacturers and civil society |
| Source: Compilation by UNCTAD, 2014. | | |

Beyond procedures, patent examination is also a question of capacity. Patent examiners need to be qualified experts in the technological fields, such as chemicals and pharmaceuticals, mechanical, electrical and other engineering fields, to determine the sufficiency of disclosure, the accuracy of the 'best mode' to carry out the invention, as well as the novelty and inventiveness of the claimed invention.

Nepal may not have the resources to maintain qualified patent examiners in all fields at present. To start, however, it can design measures to benefit from the expertise available in universities, research centres and government institutions. Nepal's IP Office can also benefit from cooperation with other IP offices in the region.

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*Recommendations*

6) *Nepal should provide pre-grant and post-opposition procedures to patent applications in its Industrial Property law.*

7) *The IP Office should consider cooperation with other IP offices in the region such as India and Thailand to help improve its capacity for patent examination.*

### 2.3. IP for the Diffusion of Technology through Incremental Innovation

Developing countries seek to put in place policies for building technological capacity. The successes of Japanese and South Korean manufacturers in importing foreign technology while developing their own industries are a reflection of, *inter alia*, IP policies that support technological diffusion.[45] The use of utility models by local companies is, for example, evidence of engagement in active technological learning, adaptation and incremental innovation. Utility models are predominantly used by local industries compared to regular patents (See Table 2, below). The novelty standard for utility models is what is known as 'relative novelty': the invention is new if it is not anticipated by prior art within the country, for example, within Nepal, even if it is known in other parts of the world. The inventiveness standard is also very limited: it should only not have been obvious *prima facie* for a person skilled in the art. The experience of Japan, with the continuous decline in the use of utility models from its peak in the 1980s in favour of patents, points to the suitability of these rights to promote incremental innovation at early stages of industrialization.[46]

Rival companies coming up with new industrial designs, utility models and trademarks tend to engage in more innovation and increasingly productivity.[47] Trade secret and protection against unfair competition also addresses the relationship between competitors in the domestic market.

**Table 2: Share of domestic applicants over the total number of utility models granted**

| *Country* | *2005* | *2006* | *2007* | *2008* | *2009* |
|---|---|---|---|---|---|
| Australia* | 87% | 85% | 84% | 82% | N/A |
| Brazil | 98% | 98% | 99% | 98% | N/A |
| China | 98% | 99% | 99% | 99% | 99% |
| Germany* | 83% | 83% | 82% | 82% | 82% |
| Korea | 98% | 98% | 98% | 98% | 98% |
| Japan | 80% | 80% | 81% | 81% | 82% |

*applications filed, as opposed to registered.
Source, DIPP, 2011, 14.

The TRIPS standards on utility models, industrial design, trade secrets (except for the protection of undisclosed pharmaceutical test data) and protection against unfair competition are minimal, thus leaving countries considerable leeway for variations in national implementation.[48] Since all categories of IP rights create temporary monopolies,

[45] Mackley, Carter, 1987; and UNCTAD-ICTSD, 2005, 264.
[46] Suthersanen, Uma, 2006, ICTSD and UNCTAD, Geneva, 18-19.
[47] Greenhalgh, Christine and Mark Rogers, 2010, 203.
[48] UNCTAD-ICTSD, 2005, 349 and 538. The TRIPS standards on utility models incorporate the Paris Convention standards including Article 4 (providing for right of priority), Article 5 (importation of products, failure to work, or insufficient working and compulsory license) and Article 11 (availability of protection).

the technology diffusion function of protecting incremental innovation is not a given outcome but an outcome dependant on the design of IP laws. Recently, Japan started the examination of utility model applications (while many other countries do not require examination of utility model applications at all) due to its shift to invention patents and the need to improve the quality of its utility models.[49]

While encouraging the use of utility models, Nepal may need to consider designing utility models in a manner that prevents undue patenting of technologies that exist abroad without technology transfer benefits. A strategy that helps to encourage the use, while controlling the abuse of, utility models is to require for payment of annual maintenance fees and subject the terms of protection for renewal. Utility model protection could be limited, for example, to 3-5 years, renewable once, provided that the holder proves the exploitation of the utility model through industrial application or manufacturing and has paid the maintenance fees annually.

Utility models are not normally subject to examination. Nepal, however, as a second strategy to control abuse of the system, can provide examination procedures where third parties object to grant of the utility model protection. Since utility models concern incremental innovation, they are also prone to litigation on the validity of the claims and potential infringement among small and medium enterprises. Nepal can also provide arbitration and mediation facilities within the IP Office for infringement and ownership disputes. The same can also apply to industrial designs and trademarks.

Trademark protection provides further incentive for competition and innovation among small and medium enterprises (SMEs) in the domestic and international market. In addition to product and service marks, countries can also provide protection for collective and certification marks. Certification marks identify the quality and nature of the product that meets certain pre-established standards. They are utilised as part of branding initiatives of products and services, including in tourism and international trade. Collective marks are available for both incorporated bodies and organisations of local communities. Nepal could consider a proactive policy to initiate, advocate and support the use of trademark in collaboration with local private sector associations, as well as farmer and community associations to enhance the competitiveness of local products and services.

Finally, protection against unfair competition, provided that it operates in a balanced manner, can also encourage competitors in the local market to come up with new products and services, ensuring quality and building the reputation of products and services. Nepalese SMEs competing in similar products and services within the domestic market may engage in unfair competition practice. Currently, there is no protection against unfair competition under the Nepalese Industrial Property Act (1965). Instead, the Competition Promotion and Market Protection Act, 2063 of 2007 provides some form of protection against unfair competition. At the international level, Article 10*bis* of the Paris Convention provides protection against any act of competition contrary to honest practices in industrial or commercial matters. Further principles are required in developing unfair competition law, especially to ensure that mere imitation does not

[49] Suthersanen, Uma, 2006, ICTSD and UNCTAD, Geneva, 36-37.

amount to unfair competition.[50] The availability of protection is important for SMEs in Nepal that continuously invest to improve the products and services they produce and the reputation they build.

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*Recommendations*

*8) To enhance the role of utility models in the diffusion of technology in Nepalese enterprises, Nepal may wish to consider:*

*a) subjecting utility model applications for examination when there is an opposition by third parties as to the validity of the utility model claim (i.e., a post-grant review procedure in order to reduce administrative burdens);*

*b) adjusting the terms of protection with due recognition of the need for working the invention. Nepal could provide, for example, 3 - 5 years of protection from the date of filing with the possibility of renewal for another 3 - 5 years on the condition that the applicant proves that the utility model has been worked during the initial period of protection; and*

*c) introducing utility model certificate maintenance fees to ensure due diligence, in the same way as maintenance fees are paid for patents, industrial designs and trademarks.*

*9) Nepal may wish to consider providing protection against unfair competition in accordance with Article 10bis of the Paris Convention as a check against passing off and ensuring a level playing field for competitors.*

*10) Nepal may wish to consider developing alternative dispute settlement procedures, including for mediation and arbitration involving IP disputes within the IP Office, private sector associations and other entities.*

*11) Government initiatives on IP strategies can facilitate further the use of IP rights for incremental innovation and dissemination of technologies. Nepal may wish to consider launching initiatives for trademarks in collaboration with local private sector associations, as well as farmer and community associations, including certification marks in the tourism, agriculture, medicinal herbs and traditional textile industries.*

## 2.4. The Use and Abuse of IP rights: Remedies and Technology Transfer

Once IP rights are granted, the manner in which the technology is exploited by the right holders would determine the technology transfer benefit arising from IP protection. According to Article 28 of the TRIPS Agreement, product patents confer the right to prevent third parties from the making, using, offering for sale, selling, or importing of the product for these purposes. Process patents confer the right to prevent third parties from

[50] Suthersanen, Uma, 2006, ICTSD and UNCTAD, Geneva, 33.

the act of using the process, and from the acts of using, offering for sale, selling, or importing the product obtained directly by that process for these purposes. Right holders may simply exploit the IP rights by themselves, such as by producing the product, supplying the services or using protected process inventions for the production of goods, or they can license third parties to exploit the IP right.

The manner of the exploitation of the rights conferred by patents can potentially undermine the innovation and technology transfer objective of the IP system. Procedures for compulsory licenses (the authorization given to work an IP right notwithstanding an absence of permission by the right holder), revocation and forfeiture of patents, as well as the regulation of anti-competitive practices can help to address the abuse of IP rights.

Importantly, the TRIPS Agreement does not provide substantive grounds for the issuance of compulsory licenses, revocation and forfeiture of patents and other IP rights, leaving these matters to be decided at the national level. The 2001 Doha Declaration on the TRIPS Agreement and Public Health has reaffirmed the freedom of WTO Members to determine the grounds for compulsory licenses.[51]

Although countries are free to determine the grounds for compulsory licenses, Article 31 of TRIPS imposes conditions in granting such compulsory licenses, including that the decision to grant compulsory licenses be based on the individual merits of each case; after unsuccessful effort to obtain voluntary license on reasonable commercial terms and within a reasonable period of time and that the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization. A compulsory license should be for use predominantly for the supply of the domestic market, and limited to the purpose for which it was authorized. When the compulsory license concerns enforcement of competition law, the conditions for prior-negotiation for voluntary licenses and the limit on the authorisation to be for use predominantly for the supply of the domestic market do not apply.

In its analysis of grounds for issuing compulsory licenses under national laws, WIPO identified broad categories consisting of the non-working of a patent; dependant patents; abuse of patent rights, e.g., refusing to deal with applicants for a license; public interest; and breach of competition law.[52] Based on national experiences, the grounds for compulsory licence can include:

- Non-working/insufficient working of the invention within 3 years from the grant or 4 years from the filing of the patent, where the reasonable requirements of the public or the relevant market have not been satisfied (Paris Convention);
- Excessive pricing: the patented invention is not available at a reasonably affordable price to the public or the relevant market;
- Anti-competitive licensing practices: including cases of excessive high royalty, unfair terms of license, for example, demanding competitor cease to compete in unrelated market; or terms deemed anti-competitive (TRIPS, Article 40). Cross licensing and patent pools designed to potentially divide the market, push prices upward and reduce competition can also be considered anti-competitive;

[51] WTO, 2001, WT/MIN(01)/DEC/2, 2001).
[52] WIPO, 2010, CDIP/5/4.

- Abuse of IP rights: Refusal to license or deal by a dominant player with competitors that affects access to an 'essential facility,[53] or the development of vital sectors, industry and international trade[54] and refusal to license that hampers the exploitation of dependant patents.[55] In the case of producing fixed dose combinations of medicines for HIV/AIDS treatment, for example, each patent covering the individual molecular compounds are essential to the manufacture of the combination products[56], and a refusal to license by one or more patent holders could be viewed as anti-competitive or an abuse of IP right;
- When laying down the minimum conditions for compulsory licenses, the TRIPS Agreement implicitly recognizes some grounds of compulsory licenses under Article 31, namely, national emergency or other circumstances of extreme urgency; to remedy a practice determined to be anti-competitive; and to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"). It should be borne in mind that the grounds for compulsory licenses, at the level of TRIPS compliance, need not be limited to natural or man-made emergencies or shortages of medicines.

Furthermore, practices of pharmaceutical companies in the registration or withdrawal from registration of medicines in a bid to prevent generic manufacturers from entering into the market relying on the approval of the originator's drug are deemed anti-competitive practice under European law.[57]

Some of the grounds for compulsory licenses can also be grounds for revocation of a patent. Under the European Patent Convention, for instance, revocation may take place when it is determined that:

(a) the subject matter of the patent is not patentable;
(b) the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art;
(c) the subject matter of the patent extends beyond the content of the application as filed.[58]

[53] The Competition Promotion and Market Protection Act, 2063 (2007) of Nepal does not specifically contain provisions on denial of access to an essential facility. The essential facilities doctrine imposes 'liability when one firm, which controls an essential facility, denies a second firm reasonable access to a product or service that the second firm must obtain in order to compete with the first.' See WIPO, 2010, CDIP/5/4, Annex I

[54] See WIPO, 2010, CDIP/5/4, Annex I for compulsory license laws across the world.

[55] A dependent patent is a patent that cannot be worked without falling within the scope of protection of another patent.

[56] From a therapeutic viewpoint, FDCs greatly reduce the number of pills a patient with HIV/AIDS must take.

[57] In *AstraZeneca v. European Commission and European Federation of Pharmaceutical Industries and Associations (EFPIA)*, 2012, the Court of Justice of the European Union ruled that an undertaking that makes representations to obtain exclusive rights to which it is not entitled infringes competition when such representations lead the public authorities into granting the rights, and that a dominant undertaking may not make use of regulatory procedure to hinder the market entry of new competitors unless there exists a legitimate interest or objective justifications.

[58] See, EPO, 2013, Article 100 and 101.

Finally, patents, utility models, trademarks and industrial designs can be forfeited due to failure to comply with procedures for maintenance of the IP right, in particular the failure to pay maintenance fees where required under the applicable law.[59] According to the Paris Convention, industrial property rights may also be forfeited where compulsory licenses fail to remedy the abuse, such as in cases of non-working and refusal to license.[60]

To sum up, the technology transfer function of IP rights should not be expected to occur simply by the grant of protection. The manner of exploitation of IP rights may affect the transfer of technology. Though Nepal may not have recent experience concerning abuse of patent rights and anti-competitive licensing practices, the ongoing revision of the Industrial Property Act can provide clear guidance on the implementation of procedures for compulsory licenses, as well as the revocation and forfeiture of IP rights, to address instances of the abuse of IP rights.

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*Recommendations*

*12) With respect to compulsory licensing, the IP law or regulations should make clear the grounds for issuing a compulsory license, procedures and the responsible authority for issuing such licenses, with a view to addressing the technological, public health and economic impacts of abuse of IP rights. Revisions to the Industrial Property Act should provide for grounds for forfeiture and revocation of patents.*

*13) Consider establishing a facility within the IP Office to make available information on the status of registered IP rights.*

*14) Nepal may wish to develop guidelines on a non-exhaustive list of practices that potentially amount to anti-competitive licensing practices. Based on the current practices of countries and Article 40 of TRIPS, anti-competitive practices and abuse of IP rights may consist of:*

*a) grant back clauses that require the licensee grants to the licensor the rights to any modifications and new technologies developed using the licensed technology;*

*b) limiting further R&D, adaptation or modifications, and preventing the use of other technologies by the licensee;*

*c) product tying, coercive packaging, conditions on sales of unrelated products, control of management, or otherwise extending the effect of the license beyond the IP rights covered;*

*d) restricting markets (geographically, quantitatively or qualitatively) and imposing a high resale price with the effect of limiting competition in the market; and*

*e) preventing the licensee from challenging the validity of the IP rights involved.*[61]

[59] The Paris Convention requires for forfeiture to take place only after a period of grace of not less than six months. See Article 5 bis (1) of the Paris Convention.
[60] *Ibid.*
[61] See also Abbott, Frederick M. 2006.

## 3. Patents and Access to Medicines

The interaction between patents and access to medicines occurs mainly in two ways. First, patents are designed to reward innovation by providing a temporary monopoly over medicines that meet the patentability criteria of novelty, inventive step and industrial application. Transnational R&D-based pharmaceutical companies undertake little R&D on diseases that predominantly affect people in developing countries, however. The World Health Organisation (WHO) Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (2008), recognize the limitations of patent incentives to address the public health problems of developing countries.

Second, where a medicine is protected by patent, the price of the medicine could be higher, unless the patent holder provides differential pricing or grants a license with favourable terms, taking into account the affordability of medicines. Higher prices of medicines affect the budget for government procurement and the out-of-pocket expenditure of consumers, and may prevent access to medicines.

Developing countries with low R&D investment, pharmaceutical manufacturing capacity, and an underdeveloped health financing system face critical challenges in ensuring access to medicines. In 2001, the WTO Ministerial Conference adopted the Doha Declaration on the TRIPS Agreement and Public Health.[62] The Doha Declaration reaffirms the right of WTO members to use, to the fullest extent, the TRIPS provisions that provide flexibility to protect public health. It also set out a work programme to address the problem of LDCs and other developing countries with limited or no pharmaceutical manufacturing capacity (the so-called *paragraph 6 system*). Nepal, when it acceded to the WTO in 2004, asserted in its Accession Protocol that:

> "… as a WTO Member, Nepal would be entitled to the flexibilities provided in the Doha Declaration on the TRIPS Agreement and Public Health."[63]

Given the transition period for the implementation of the TRIPS Agreement until 2021 and for providing pharmaceutical product patents and pharmaceutical data protection until 2033, Nepal is therefore free to strategically employ the full range of TRIPS Agreement flexibilities to ensure greater access to medicines. The following sections outline the key flexibilities after reviewing the current access to medicines regime for Nepal.

### 3.1 Nepal's Access to Medicines Regime

The Interim Constitution of Nepal (2007) provides that every citizen has the right to basic health services free of cost. However, the scope of the free health services is not determined by implementing laws. As Nepal is considering a new constitution, it remains to be seen the extent to which the right to basic health will be addressed in the outcome

[62] WTO, 2001, WT/MIN(01)/DEC/2, Doha.
[63] WTO, 2003, WT/ACC/NPL/16, 129.

document. In that regard, a number of developing countries such as Brazil have enshrined universal access and the right to health in their constitutions, and have used that as a basis for ensuring universal health insurance coverage.

There is currently no effective medicines price regulation in Nepal. The Consumer Protection Act requires the display of the retail price to improve transparency in pricing of medicines. In 2008, the total pharmaceutical expenditure in Nepal was estimated at NPR 13,089 million (US$ 187.64 million), resulting in a per capita expenditure of 485.41 NPR (US$ 6.96). Public expenditure by central government, local government, public insurance funds and parastatal companies accounts for 22.6% of the total pharmaceutical expenditure.[64] The out-of-pocket expenditure by Nepalese households, civil society and external development partners and the private sector covers the remainder.

Compared to all public and private sources, out-of-pocket expenditure takes the lion's share of the total health expenditure.[65] Most of the population must pay for their medicines out of pocket, as there is no effective health insurance system in place, which is typical of many developing countries. There is a public system whereby certain groups of people can receive medicines for free, including the very poor, children under the age of 5, pregnant women, the elderly and female community health volunteers.[66] Under the five-year health sector programme (2010-2015), a limited number of pharmaceuticals related to the treatment of malaria, Kala-azar, tuberculosis, HIV/AIDS, sexually transmittable diseases, and vaccines for children are available for free.[67]

Nepal's access to medicines regime consists of both pharmaceuticals and traditional medicine. According to a 2011 study by the Ministry of Health and Population (MoHP) and the WHO, there are 41 manufacturers of modern medicine, and 37 manufacturers of herbal preparations. The modern medicine manufacturers neither undertake R&D nor produce active pharmaceutical ingredients (APIs). They specialize in formulation manufacturing, mainly of simple generic medicines, including, but not limited to, Albendazole, Amoxicillin, Azithromycin, Ciprofloxacin, Fluconazole, Paracetamol, Ibuprofen, Hyoscine, Metronidazole and Ofloxacin. This should not come as a surprise considering the proximity of Nepal to India and China, both of which are global leaders in the manufacturing of APIs. Biologics, vaccines and more complex molecules tend to be imported, to a large extent from India and to a lesser extent from Bangladesh and China. Relatively few companies manufacture according to international quality standards.

Marketing of pharmaceuticals in Nepal is subject to registration and marketing authorization by the Medicines Regulatory Authority (MRA), Department of Drug Administration of MoHP. The marketing authorization is limited to licensed manufacturers – both domestic and international – that comply with Good Manufacturing Practices (GMP) with an additional licensing requirement for the importation of medicines produced abroad. GMP certification is mandatory to market medicine in Nepal.

[64] *Ibid.* 5
[65] Nepal MoHP, 2010, NHSP -IP 2, 45.
[66] *Ibid*.
[67] Nepal MoHP and WHO, 2011, 22.

However, not all local companies have secured their GMP certification.[68] Prescription by generic name is not mandatory. Medicines can be registered using brand names together with generic names (International Non-proprietary Names).[69] The National Medicines Laboratory undertakes monitoring of the quality of medicine distributed in the market. The Laboratory, however, lacks international accreditation.

The National Health Research Policy of Nepal (2006) aims at building national health research capacity and promoting research in the broad dimensions of public health, including biomedical, clinical, social sciences and health economics. The Nepal Health Research Council, established in 1991, provides support and regulates health related research in Nepal. Infectious diseases, reproductive health, children's health, indigenous medicine and non-communicable diseases are among its priorities. It has supported research on the quality of Ayurveda drugs and the documentation of century old codified and non-codified resources and practices of traditional healers (prior art). It has also started developing a Traditional Knowledge Digital Library (TKDL).

### 3.2 Local Pharmaceutical Manufacturing

Currently, the Association of Pharmaceutical Producers of Nepal has 50 pharmaceutical companies as its members, covering an estimated 40% of Nepalese pharmaceutical Market share. [70] Currently, 32 of local pharmaceutical companies are certified with GMP and others are in process of GMP certification.[71]

Since India has introduced pharmaceutical product patents in 2005,[72] Nepal could target pharmaceutical products introduced since 2005, especially those that are relevant in its public health system. As an example, a company in Bangladesh has already started producing the patented sofosbuvir - a treatment for hepatitis C - which is one of the most expensive drugs among those in the essential medicines list of the WHO. [73]

In 2008, Nepal requested for importation of the patented anti-cancer drug, *erlotinib*. In response, an Indian pharmaceutical company, Natco, unsuccessfully attempted to secure compulsory license in India to produce and export the medicine to Nepal. Due to the difficulty of securing a compulsory license to manufacture a patented product, NATCO entered into a licensing agreement with the patent holder of *sofosbuvir* for the manufacturing of the generic version of a *sofosbuvir* and *ledipasvir* combination, which was also launched in Nepal in 2015. Local pharmaceutical manufacturing is also affected not only by patents but also reliance on importation of API and other raw materials, largely from India.

[68] Nepal MoHP, 2010, NHSP -IP 2, 46. According to the Department of Drug Administration, only half of the pharmaceutical companies are certified with GMP as of mid-April, 2012 (Kantipur Publications Pvt. Ltd, 2012-04-05, 09:02).
[69] Nepal MoHP and WHO, 2011, 16
[70] Nepal started manufacturing only in the 1970s with a State-Owned Enterprise and one private pharmaceutical firm.
[71] Association of Pharmaceutical Producers of Nepal
[72] UNCTAD, 2011d.
[73] Hoen, 2015.

### 3.3 Transition Periods and TRIPS flexibilities

Currently, Nepal is required to implement only the TRIPS national treatment and MFN (Article 3-5) obligations until 2021. The 2021 transition period guarantees Nepal to continue applying existing IP laws that may derogate from or do not fully implement TRIPS provisions without the threat of legally-sanctioned trade retaliation. The transition period for the implementation of TRIPS obligations with respect to pharmaceutical products and pharmaceutical test data by LDCs lasts until 2033 or until they cease to be an LDC.

The benefits and costs of derogation from TRIPS depend on the standards of the existing IP laws of Nepal. As an example, under the 1965 Industrial Property Act, patents are subject to the novelty and industrial applicability criteria, but not to the inventiveness criteria. The lack of inventiveness criteria can lead to the grant of low quality patents. The Industrial Property Act also does not provide exclusion of naturally occurring substances and pharmaceutical products, and exceptions to patent rights and compulsory licensing.[74] The review of the Industrial Property Act, as a result, would be necessary for the full utilization of the TRIPS flexibilities. Table 4 below provides key TRIPS flexibilities in the context of pharmaceutical patent and their relevance for Nepal. The full list of flexibilities and implementation options are provided under UNCTAD's publication on "Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries: A Reference Guide", 2011. [75]

**Table 4: Public Health Flexibilities in the Implementation of TRIPS**

| | *TRIPS Flexibility* | *Remark* |
|---|---|---|
| 1. | Patentable subject matter and subject matter exclusion. | Allows domestic law to exclude naturally occurring substances, new use of known substances, diagnostics, therapeutic and surgical and other methods of treatment. |
| 2. | Patentability criteria. | Strict novelty and non-obviousness standard and broad scope of prior art have an effect on the quantity and quality of patents and the scope for generic production of pharmaceuticals. |
| 3. | Patent examination and opposition procedures. | Patent examination, pre and post grant opposition procedures can influence the overall quality of patents, and prevent erroneous grant of patents. |
| 4. | Research exception. | Allows researchers to undertake research on or with the patented technology to improve the technology or use the technology as a research tool. |
| 5. | Regulatory exception (Bolar | Allows generic manufacturers to research on patented pharmaceutical products and submit their application for |

[74] There are also various gaps and problems under the 1965 Act. It does not clearly define the rights of patentees. The protection of patents lasts 21 years in total compared to 20 years under TRIPS.

[75] UNCTAD, 2011(b). Other important work in this respect includes UNDP, 2010. The table is developed based on UNCTAD's reference guide on "Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries."

| | | |
|---|---|---|
| | Exception). | marketing authorization before the expiration of the patent. |
| 6. | Parallel importation. | Allows generic manufacturers to source API and other inputs, or health authorities to authorize importation of pharmaceuticals from wherever the products are placed in the market with the consent of the patent holder. |
| 7. | Government/Public Use. | Enables the government to use a patented technology for non-commercial purposes, without the consent of the patent holder. |
| 8. | Compulsory License. | When negotiation for license fails, third parties can be authorised to exploit the patent without the consent of the patent holder. Such licenses may also be granted to remedy anti-competitive practices, even in the absence of a prior-negotiation. |
| 9. | Compulsory Licenses for Export/Import (30 August 2003 Decision). | A special regime that permits the export of pharmaceuticals produced under compulsory license for the benefit of a developing country or LDC Member with no or limited manufacturing capacity. |
| 10. | Control of anti-competitive licensing practices. | Allows countries to address anti-competitive licensing practices and abuses of patent rights that may unduly affect licensees and consumers. |
| 11. | Fair and equitable procedures for the enforcement of IP rights | Procedures and remedies for IP enforcement need to be fair, equitable and proportional. No obligation to provide criminal procedures and special border measures to enforce patents, as well as to issue injunctions in cases of government use and compulsory license, or even in other cases. |
| Source: Compilation by UNCTAD, based on UNCTAD, 2011(b). | | |

As indicated under Table 4 there are several TRIPS flexibilities in the context of pharmaceutical patent that Nepal can incorporate under its domestic law. Since legislative revision takes time, Nepal can initiate the process to exclude pharmaceutical product patent until 2033 or until the country graduates from its LDC status, separate from the revision of the entire Act.

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*Recommendations*

*15) Consider the exclusion of pharmaceutical product patents until 2033 or until the country graduates from its LDC status.*

*16) Review the Industrial Property Act in order to ensure that Nepal fully benefits from the flexibilities provided under the TRIPS Agreement in defining patentable subject matter, including disclosure of the best mode to carry out the invention, establishing narrow patentability criteria and introducing patent examination and opposition procedures to avoid bad quality patents.*

*17) Ensure that provisions in the new Industrial Property law include, with respect to patents, a broad research exception, regulatory review (Bolar) exception, medical treatment exception, enabling clauses for parallel importation of medicines and raw*

*materials, enabling clauses for the use of compulsory licenses/government use licenses, and provide legal mechanisms for the control of anti-competitive practices, as well as fair and equitable procedures for the enforcement of IP rights. See also Recommendations 1.1, 1.5, 1.12 and 1.14.*

18) *Nepal should request technical assistance in the elaboration of regulations and guidelines for the above where necessary, as well as for the establishment of a fully automated, modern and comprehensive IP infrastructure that supports these new policies.*

19) *Nepal should maintain the exclusion of the protection of pharmaceutical/clinical test data under the 1965 Act until 2033 or* until the country graduates from its LDC status.

### 3.4 Enabling the Use of TRIPS flexibilities

Although incorporating TRIPS flexibilities under domestic laws is an important step, private firms, research centres and universities can benefit from additional support that enable the use of the opportunities presented by the flexibilities, such as exclusion of pharmaceutical products.

Measures to enable the use of TRIPS flexibilities, especially the exclusion of pharmaceutical products, are beyond IP laws. Ideally, firms could invest to benefit from the market opportunity, as in the case of Bangladesh, where a local pharmaceutical company started producing patented medicines or as in the case of Uganda, where the government attracted an Indian generic manufacturer to invest and produce patented pharmaceutical products.[76] However, in the context of small firms in Nepal, it would be necessarily to provide additional incentives and support for firms that engage in pharmaceutical production in general and essential medicines in particular. The incentives could include:

- Tariff and VAT free imports or purchases from domestic suppliers of raw materials and equipment;
- Preference in government procurement;
- Concessionary loan for investment, expansion and operation;
- Income tax exemption linked with milestones, such as production of essential medicines, and introduction of products new to the country.

The previous Section has outlined in detail options to encourage technology transfer and research. The IP Office may need to follow up as part of its services to provide technological information and innovation support, as provided under recommendations 1.2, 1.4 and 1.7 in the previous Section of this Report.

[76] See, CIPLAQCL, Vision | Mission | History, available at http://www.ciplaqcil.co.ug/about-us/historymissionvision/.

## 4. Patents and Access to Genetic Resources and Benefit Sharing Arising from their Utilization

The objectives of the Convention on Biological Diversity (CBD), 1992, are the preservation of biological resources and ensuring their sustainable use.[77] The CBD establishes the sovereign right of states over the exploitation of their genetic resources (GR). It provides an Access and Benefit Sharing (ABS) regime as implemented by the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol), 2010, based on the principles of prior informed consent (PIC) and fair and equitable benefits sharing.

The UN Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO) maintain two additional special regimes designed to support access and benefit sharing of certain GRs. The International Treaty on Plant Genetic Resources for Food and Agriculture (FAO Treaty) of 2010 provides a multilateral system for access to plant GRs and benefit sharing.

The World Health Assembly adopted in May 2011 a resolution on the sharing of influenza viruses and access to vaccines and other benefits. While not a treaty as such, the 'Pandemic Influenza Preparedness Framework' of the resolution includes as annexes standard material transfer agreements (SMTAs) for the sharing of pathogens with entities that are first, part of the WHO network for influenza monitoring, and second, for entities outside of that network, including between private companies.[78]

### 4.1 Nepal's ABS regime and the interface between IP and Biodiversity

The geography of Nepal represented by a vast altitude variation contributes to its status as a hotspot for diversity. Nepal also has 61 ethnic groups/communities and over 100 languages and dialects, many of whom have particular relationships with the plant and animal GRs in the vicinity of where they live.[79]

The Genetic Resources Bill of Nepal is currently being drafted. However, several laws are already in place governing the protection, access and utilization of GRs and associated traditional knowledge (GRs/TK). These laws include acts and regulations on seeds, forests and for the conservation of national parks and wildlife.[80] Nepal's non-timber forest products include 2000 plants that are reported to have medicinal properties. The other dominant use of plant resources concern aromatic plants, *lokta* paper, resin and turpentine, sal seed, *katha* and *cutch*, *sabai* grass, bamboo and rattan. High altitude products are thought to have significant market value. A study by Banjade, M. Ram and Naya S. Paudel (2008), demonstrates that a significant portion of trade in non-timber forest products involves only raw material exports of largely medicinal and aromatic

[77] See CBD, 1992, preamble, Article 1, and Article 15.
[78] WHO, 2011, Resolution 64.5.
[79] Tiwari, Sagendra, 2003.
[80] Nepal, 2009, 82. Relevant policies and laws include: Agriculture Biodiversity Policy, 2006, Climate Change Policy, 2011, Seed Act, 1998 and Forest Act, 1993.

plants, and some are still in the illicit trade.[81] Medicinal plants are among the main exports of Nepal, largely to India.

The relationship between GRs/TK and IP rights may start with the conclusion of an ABS agreement (also known as Material Transfer Agreements or MTAs). Both the CBD and Nagoya Protocol recognize the role of research collaboration and, where appropriate, undertaking the research in the country providing GRs/TK, but do not provide guidance on ownership of IP rights arising from the results of R&D. The FAO Treaty attempts to govern IP rights issues by preventing recipients of certain plant GRs from claiming IP rights over those resources 'in the form received'.[82] Since the grant of patents and plant varieties is based on the criteria of novelty, among others, the restriction on IP rights over plant GRs in the form they were received does not necessarily prevent patenting or acquisition of protection for new varieties, novel products and processes developed using the GRs.

The WHO Resolution elaborates on research collaborations for the sharing of certain pathogens. Recipients of pathogens within the WHO network are obliged to actively seek the participation of scientists from the originating laboratories, especially those in developing countries, and participating entities are required to refrain from seeking any IP protection over vaccines and other treatments made using the underlying materials.[83]

Other than the FAO Treaty and WHO Resolution, there are various options for Nepal to design research collaborations, IP and benefit sharing clauses under ABS agreements. A one-size fits all approach and predetermined terms and conditions for research and benefit sharing is difficult to achieve. R&D collaboration, IP rights and benefit sharing clauses need to be crafted depending on the purpose (commercial or non-commercial), the status of the recipient, such as local or foreign university, SMEs, transnational corporations, or the objective of the search, such as public health and agriculture. In this regard, in drafting ABS agreements, the IP Office will need to provide inputs.

The Nagoya Protocol already recognizes both monetary and non-monetary arrangements to facilitate ABS agreements. Monetary benefits may include access fees, milestone payments, royalties and license fees in case of commercialization or contribution to trust funds for conservation, sustainable use and research on GRs. ABS partners can also establish joint venture, or agree on joint ownership of IP rights. Non-monetary benefits consist of a broad set of options. Sharing of R&D results, research collaboration, participation of scientists from the provider country in the R&D and transfer of technology are enumerated as possible benefits under the CBD. Capacity building, both institutional and human resource, including education and training, access to scientific information relevant to the conservation and sustainable use of biological diversity, such as biological inventories and taxonomic studies can also form part of the fair and equitable benefit sharing.

[81] Banjade, M. Ram and Naya S. Paudel, 2008.
[82] See Article 12 of the International Treaty on Plant Genetic Resources for Food and Agriculture, 2001.
[83] Assuming that pathogens are covered under the Nagoya Protocol, this requirement to refrain from patenting would be stricter than the standards as required by the Nagoya Protocol.

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*Recommendations*

20) *The IP Office should have the capacity to provide inputs into negotiations for ABS contracts between providers of GRs/TK of Nepal and domestic or foreign recipients, to ensure, to the extent possible, collaboration and R&D with Nepalese scientists, to encourage R&D to take place within Nepal and crafting the appropriate IP clause. Contracts should contain clauses that ensure benefit sharing by Nepal and its indigenous and local communities.*

## 4.2 Prevention of Bio-piracy and Misappropriation

Article 16(5) of the CBD recognizes the influence of patents and other IP rights on the promotion of its objectives and requires that countries cooperate to ensure that such rights are supportive of, and do not run counter to, its objectives. Patents play an important role as an incentive for researchers to enter into arrangements for ABS and to protect their economic interests. In the absence of ABS, however, patents simply enable the utilization of GRs for the benefit of the applicant alone conferring on them the right to exclude others from its use, potentially leading to bio-piracy and misappropriation. Although countries may develop an efficient access regime for GRs/TK, there remains a question as to how countries can ensure that the GRs/TK transferred do not end up being patented or, if patented, how the benefits are shared.

Defensive protection has emerged as a key element of the strategy to facilitate fair access and use of GRs/TK in accordance with the CBD/Nagoya Protocol, as well as national policies for the conservation of biodiversity. Such defensive protection can include a requirement for mandatory disclosure of the origin of GRs/TK in applications for patents, utility models and plant variety protection, as well as TK digital libraries (TKDLs) and interventions in the pre-grant and post-grant opposition of patents filed abroad. The principles behind defensive protection of TK associated with GRs also apply to the protection of TK in general, even when not associated with GRs.

### *1) The Mandatory Disclosure Requirement*

A mandatory disclosure requirement on the source and origin GRs/TK and compliance with the ABS laws ('disclosure requirement', hereinafter) can be included in patent, utility model and plant variety laws. Countries may also require a more robust disclosure by recipients of GRs/TK under an ABS agreement to cover not only patent, utility model and plant variety applications, but also in any communication by the recipient with respect to the GRs/TK with third parties. Developing countries proposed at the WTO for such a mandatory disclosure requirement for patent applications (See Box 1 below for the proposal). The proposal covers the use of GRs, TK associated with GRs and all other TK.

**Box 1: TRIPS, Article 29: Conditions on Patent Applicants**

**Draft Article 29*bis***

Disclosure of Origin of Genetic Resources and/or Associated Traditional Knowledge

2. Where the subject matter of a patent application involves utilization of genetic resources and/or associated traditional knowledge, Members shall require applicants to disclose: (i) the country providing such resources, that is, the country of origin of such resources or a country that has acquired the genetic resources and/or associated traditional knowledge in accordance with the CBD; and, (ii) the source in the country providing the genetic resources and/or associated traditional knowledge. Members shall also require that applicants provide a copy of an Internationally Recognized Certificate of Compliance (IRCC). If an IRCC is not applicable in the providing country, the applicant should provide relevant information regarding compliance with prior informed consent and access and fair and equitable benefit sharing as required by the national legislation of the country providing the genetic resources and/or associated traditional knowledge, that is, the country of origin of such resources or a country that has acquired the genetic resources and/or associated traditional knowledge in accordance with the CBD.

3. Members shall publish the information disclosed in accordance with paragraph 2 of this Article jointly with the publication of the application or the grant of patent, whichever is made first.

4. Members shall put in place appropriate, effective and proportionate measures so as to permit effective action against the non-compliance with the obligations set out in paragraph 2 of this Article. Patent applications shall not be processed without completion of the disclosure obligations set out in paragraph 2 of this Article.

5. If it is discovered after the grant of a patent that the applicant failed to disclose the information set out in paragraph 2 of this Article, or submitted false and fraudulent information, or it is demonstrated by the evidence that the access and utilization of genetic resources and/or associated traditional knowledge violated the relevant national legislation of the country providing genetic resources and/or associated traditional knowledge, that is, the country of origin of such resources or a country that has acquired the genetic resources and/or associated traditional knowledge in accordance with the CBD, Members shall impose sanctions, which may include administrative sanctions, criminal sanctions, fines and adequate compensation for damages. Members may take other measures and sanctions, including revocation, against the violation of the obligations set out in paragraph 2.

**Source:** WTO, 2011, TN/C/W/59.

Currently, Nepal does not provide mandatory disclosure of GRs/TK in patent applications. Many developed countries including Belgium, Denmark, New Zealand, Norway, Romania, Sweden and Switzerland have already adopted a disclosure requirement or closely related standards. Patent applicants are therefore increasingly likely to face the disclosure requirement when applying for patents at home and abroad.

The amendment of TRIPS to introduce a disclosure requirement is not yet agreed among WTO Member States.[84] Currently, WIPO is also considering the relationship between GRs/TK and patents. The proposals include a disclosure requirement. The adoption of the disclosure requirement in Nepal will thus contribute to the development of the global standard.

### *2) The Role of a Traditional Knowledge Digital Library and an IP Office*

Two additional approaches can play a role in preventing bio-piracy and misappropriation of GRs/TK. The first is the approach of India by developing a traditional knowledge digital library (TKDL) and providing direct access to its content for foreign patent examiners.[85] Foreign patent offices that are able to access TKDL can receive information on prior art embodied in the TK in determining the novelty and inventiveness of claimed patents. The second approach involves IP offices actively identifying potential cases of bio-piracy and misappropriation in patent applications abroad, and providing information to the country concerned. Peru, for example, has been studying and identifying cases of bio-piracy in patent applications and making available the relevant information to foreign patent offices. These approaches need not be mutually exclusive.

Nepal is at the initial stages of developing a TKDL. TKDL documents TK as prior art for patent examiners, but also ensures its preservation and further development. Nepal can provide an institutional framework that utilizes TKDL and other information selectively to combat bio-piracy and misappropriation abroad. As an example, the Peruvian IP office chairs a National Commission against Biopiracy charged with developing dossiers that are made available to patent offices in other countries, to assist them in conducting a thorough examination of patent applications that contain GR and related TK.[86] The National Commission against Biopiracy prioritized 35 Peruvian GRs of significant utility and potential value. It has prepared dossiers on these resources and sent various studies on potential cases of "biopiracy" and prior art to WIPO and IP offices of Japan, Korea and France. So far the submissions of the National Commission against Biopiracy have contributed to decisions to reject, abandon or withdraw nine controversial patent claims utilizing Peruvian GRs/TK.

Patent offices are normally equipped to study patent applications, compile patent files that help other domestic institutions and foreign IP offices to analyse the risk of biopiracy. Under the Peruvian approach, decision making on when and what to disclose is at the national level and done on a case-by-case basis, whereas the Indian approach provides foreign patent offices direct access to TKDL. For Nepal, the issue not only concerns controlling the potential disclosure of TK but also the institutional capacity for monitoring potential cases of biopiracy in foreign patent applications.

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[84] International Convention for the Protection of New Varieties of Plants (UPOV), however, has ruled out including a mandatory disclosure requirement for plant varieties in 2005. See Dutfield, Graham, 2011, 15.

[85] See, India, Council of Scientific and Industrial Research (CSIR), TKDL. Available at http://www.tkdl.res.in/.

[86] See, WTO, 2007, IP/C/W/493.

*3) Other IP rights issues relevant to the defensive protection of GRs/TK*

The mandatory disclosure requirement and TKDL are two key aspects of defensive protection of GRs/TK. However, there are a number of other applications of IP right that can lead to bio-piracy and misappropriation.

a) Orally Disclosed Prior Art: A patent law that does not recognize orally disclosed prior art, such as non-codified TK, as part of the prior art will potentially facilitate bio-piracy and misappropriation of GRs/TK. This will be important for indigenous and local communities that transmit their practices through oral tradition, rather than in written form.

b) Erroneous Grant of Patents: Decisions on the patentability of a claimed invention or eligibility for a plant breeders' right that utilises GRs/TK involves analysis of a complex set of claims and interpretation of prior art. The patent system may not address the problem of bad patents and other IP rights by law alone. In practice, prior art may not always be available or interpreted correctly even when it is available. A good example is the gap for correct interpretation of traditional medicinal knowledge that uses different terminologies than modern pharmaceutical science. The erroneous grant of patents and plant varieties will remain a particular challenge for the protection of GRs/TK.

A number of developing countries and civil society have been active in directly engaging in post-grant challenges or re-examination of patents that utilize GRs/TK in foreign jurisdictions. In 2008, the International Center for Tropical Agriculture (CIAT) based in Colombia successfully challenged a patent granted in the United States on a variety of enola yellow beans on behalf of Mexican farmers.[87] An international action group initiated by representatives of Indian farmers also successfully challenged a European patent granted with respect to extracts from the neem tree.[88]

This approach can be expensive and time consuming. In the case of enola yellow beans, the Mexican farmers were blocked from exporting their beans until a final decision was reached nine years after the grant of the patent.[138] In the context of Nepal, the issue is not only how it can fight foreign patents on its GRs/TK, but also if its own patent law provide opportunities to scrutinize patent application. *Recommendation 1.6* has proposed to introduce pre-grant procedures.

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*Recommendations*

*21) Nepal should consider introducing in its patent legislation mandatory disclosure in all cases where subject matter of a patent application involves the utilization of GR and associated TK. The disclosure should, at the minimum, include the name of the country providing the resource and/or TK, that is, the country of origin of such resources or a country that has acquired the GRs and/or associated TK.*

[87] USPTO Board of Patent Appeals and Interferences, 2008.
[88] EPO, Boards of Appeal of the EPO, 2005.

*a) Nepal should consider adopting a similar requirement for plant variety protection; and*

*b) Nepal should also consider, through its ABS legislation, for ABS contract to include a requirement for the recipient of Nepalese GRs/TK to disclose and indicate Nepal as the provider country of the GR/TK in all its communications. Such a requirement allows better dissemination of information on Nepalese GRs/TK transferred under ABS contract to all third parties, including partners of the recipient, scientists, government regulatory agencies, funds, banks and investors financing the R&D.*

22) *Nepal should provide patent applicants with the opportunity to correct erroneous or incomplete disclosure of the GRs/TK as a matter of due process. The revised Industrial Property law should also clarify the manner of compliance with the disclosure requirement and any relationship with the national ABS law, especially with respect to enforcement measures such as criminal procedures for fraudulent disclosure, failure to comply with PIC and benefit sharing arrangements.*

23) *The IP Office should have the capacity to monitor the use of selected GRs/TK from Nepal in foreign patent applications and coordinate with foreign patent offices and civil society to challenge potential cases of bio-piracy and misappropriation abroad. The list of GRs/TK to be monitored should be worked out with the national ABS focal point and with the participation of indigenous and local communities.*

24) *To the extent of the prevalence of non-codified TK, Nepal may need to consider including in the definition of prior art all information disclosed both in writing and orally.*

### 4.3 Positive Protection: Options for S*ui Generis* Protection of TK

Whereas defensive protection aims at preventing misappropriation of TK by IP claimants, *sui generis* protection promotes protection of TK inventions by local or indigenous communities. The protection of TK in developing countries is influenced by the implementation of the CBD and the Nagoya Protocol, in a manner that deals with TK to the extent it is associated with GRs, but not all TK. Unlike CBD, a *sui generis* regime will cover all TK, whether it is or is not associated with biodiversity or form part of ABS agreements. It can cover forestry, fishing, farming, food and beverage processing and traditional medicinal knowledge that may not use biodiversity and other fields where TK is utilized.

Two regional organizations, the Pacific Islands Forum,[89] and ARIPO have specialised laws on the protection of TK. The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) is currently

[89] The Pacific Islands Forum represents countries in the Pacific region.

undertaking negotiations for the development of international instruments on the protection of TK and GRs. [90] The negotiation is divided into three themes:

1) Protection of TK, innovations and creativity – the latest document provides draft articles, principles and objectives for the protection of TK;[91]
2) The protection of cultural expressions (expressions of folklore) – the latest document provides draft articles, principles and objectives for the protection of traditional cultural expressions;[92] and
3) IP and GRs – the latest negotiation document (February 2015) proposes a disclosure requirement and other defensive protection mechanisms.[93]

The negotiation in WIPO and existing legislation in developing countries and regional bodies are useful evidence of what countries are considering as the scope of protection of TK. Without prejudice as to the final outcome of the WIPO negotiations, the proposed rights of TK holders in WIPO negotiations comprise PIC and fair and equitable benefit sharing principles, similar to the CBD. Beyond PIC and fair and equitable benefit sharing, a more robust system of protection exists in *sui generis* protection mechanisms focused on the traditional medicine that includes rights similar to those granted under the IP system.[94]

Among the different forms of TK, WIPO negotiations on the protection of traditional cultural expressions or folklore appears to be in an advanced stage and can be the basis for the protection of traditional cultural expressions of Nepal. According to the current draft, traditional cultural expressions holders should have the exclusive rights to authorize the fixation; reproduction; public performance; translation or adaptation; making available or communicating to the public; distribution; and any use for commercial purposes, other than their traditional use.[95]

A different category of the *sui generis* system concerns the notion of 'farmers' rights' developed under the FAO Treaty. The FAO Treaty recognizes 'farmers' rights' as arising from the contributions of farmers in conserving, improving, and making available plant GRs. The purpose is to ensure full benefits to all farmers and to support their contributions.[96] The problem, however, has been defining what exactly 'farmers' rights' consists of and how it can be implemented in a meaningful way. Current laws, especially the African Model that details the rights, often include:

- Rights arising from customary law of each community and country;
- Community variety with special attributes to be protected by a certification conferring the exclusive rights to multiply, cultivate, use or sell the variety, or to

[90] More information available at WIPO, The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, available at: http://www.wipo.int/tk/en/igc/ .
[91] See, WIPO, 2013, *WIPO/GRTKF/IC/25/6.*
[92] See, WIPO, 2013, *WIPO/GRTKF/IC/25/4*.
[93] See, WIPO, 2014, *WIPO/GRTKF/IC/26/4.*
[94] Thailand's protection of Thai Traditional Medicine is one important examples of *sui generis* protection See WIPO, 2003, WIPO/GRTKF/IC/5/INF/4, p. 3-4, PRC State Council Decree No. 106 and Thailand, Act on Protection and Promotion of Traditional Thai Medicinal Intelligence, 1999.
[95] See, WIPO, 2013, *WIPO/GRTKF/IC/25/4*.
[96] FAO, 2001, ITPGRFA, Article 9 and FAO, 1989, Resolution 5/89 Annex 2.

license its use. Certification of sustainable use of biodiversity and fair trade marking are also proposed;
- CBD requirements, for PIC and fair and equitable benefits sharing, are often included as farmers' rights.
- A broad statement for the protection of TK associated with farmers' rights is also common.[97]

Nepal has identified a *sui generis* system of protection for TK as one of its goals under the CBD implementation programme.[98] Nepal has a reasonably good experience in the administration and marketing of non-timber products under its current laws. Nepal also has institutions and laws governing seeds.[99] Since Nepal's Genetic Resources Bill implements the CBD, it can be expected that it may not extend the PIC principle to TK that is not associated with GRs and provide farmers' rights. Hence, the first task for Nepal on the protection of TK is to extend the PIC and fair and equitable principles to all TK, whether associated with GRs or not. The PIC requirement assumes that TK holders have the right to refuse or prevent third parties from accessing the TK. Further, under the relevant laws and building on its experience, it is possible to consider the recognition and protection of farmers' rights.

A *sui generis* system of protection is without prejudice to the avaibility of protection within the IP system for TK whenever appropriate. In this sense:

- Inventions within TK can be subject matter of patent protection or utility model protection if they meet the patentability criteria. In both patents and utility model protection, the peculiarities of TK, such as traditional medicine, pose a challenge for patent examiners. The examination of the patentability of claimed formulations and devices would be a difficult task unless the IP office has expertise in TK. Often there are no articles published in scientific journals detailing the prior art. Hence, Nepal needs to consider accommodating the special situation of protection of inventions within or using TK by patents and utility models through rules and examination guidelines.
- TK can be non-codified, hence not known by third parties or codified but not disclosed to third parties. TK maintained among practitioners or within a community could be considered a trade secret where the practitioners or the communities take reasonable steps to protect the knowledge as a trade secret.
- Protection against unfair competition provides an additional legal means for traditional medicine practitioners. Registered practitioners can take legal actions against all acts of competitors that create confusion with their name, traditional medicinal products, as well as mislead the public as to the nature, the manufacturing process, or the quantity or use of the products (See Article 10bis, Paris Convention for the Protection of Industrial Property). Such protection safeguards the reputation of the businesses and products, but not the products themselves.

[97] See for example, Organization of African Unity, 2000.
[98] Nepal, 2009, Ministry of Forests and Soil Conservation, 26.
[99] The relevant laws include Plant Protection Act 1972 (Amendment), Plant Protection Regulation 1975 (Amendment), and Seed Act 1998 (First Amendment)

- Collective and certification trademarks and geographical indications (GIs) can also assist communities to develop and market products based on their GRs and TK.

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*Recommendations*

*25) Nepal should consider providing within the Genetic Resources Bill or under separate legislation protection for all categories of TK based on PIC and fair and equitable benefit sharing principles.*

*26) Considering developments in the protection of traditional cultural expressions in current WIPO negotiations, Nepal may wish to consider developing legislation for the protection of traditional cultural expressions, and may wish to request technical assistance in elaborating a draft text. Nepal should consider sending representatives from the capital to WIPO negotiations.*

*27) Nepal should consider granting legal status for farmers' and local plant varieties as part of protection of TK or as part of Nepal's plant variety protection law.*

*28) The IP Office should consider developing specific rules and guidelines with respect to inventions that contain TK, to address, among others:*

- *Exclusion from patentability of traditional medicinal practices that are methods of treatment;*
- *Subject matter of TK for protection under patents to be limited to new formulations of herbal compositions and other non-plant Nepalese traditional medicines, as well as new preparations and methods of formulation of Nepalese traditional medicines;*
- *Clarification of minor and incremental inventions in TK-related inventions that potentially meet qualifications for utility model protection; and*
- *Working procedures with the national ABS authority to ascertain if the PIC requirement has been met, where the invention is claimed by a recipient of TK.*

*29) Nepal should consider the use of trademarks in general, and collective marks, certification marks and GIs as additional measures to promote and protect TK. For this purpose, Nepal may seek international cooperation to undertake studies on potential products, and to establish the administrative structure to manage the marks in consultation with stakeholders.*

## 5. Policy Coordination, Priority Action areas and Institutional Reform

As discussed in Part I, IP policy interacts with various socio-economic policies of Nepal and involve a diverse range of interest groups. Beyond legislative reforms, the utilization of TRIPS flexibilities also relies on other flanking policies in investment, education, science and technology and government procurement. To ensure that IP laws are implemented and enforced in a manner consistent with the objectives of Nepal's socio-economic policies, it is paramount to provide in its IP legislation a clear determination of the objectives of IP protection as provided under Article 7 of the TRIPS Agreement (See recommendation 4.1).

This Report suggests two avenues to address coordination and consistency among IP, development and specific socio-economic polices. First, to develop the capacity for implementation of the policy objectives for the protection of IP rights in Nepal, the existing high level TRIPS Coordination Committee should be converted into a permanent National IP and Knowledge Transfer Committee. Second, the existing IP registration office in the Ministry of Industry should be upgraded into a permanent and independent Intellectual Property Office with proper funding. Suggestions for the functions and responsibilities of the National IP and Knowledge Transfer Committee and IP Office are provided under recommendation 4.2. Technical assistance could be requested to assist in the upgrading of the IP Office.

With respect to staffing of the IP Office, consideration should be given to maintaining a core staff in order to build expertise, rather than rotating civil servants through the Office. Given the inter-ministerial expertise required if IP examination and registration of various rights including plant variety protection, patents, copyrights, trademarks, geographic indications and the maintenance of TK databases are housed under one roof, the core staff may be supplemented by secondments from relevant Ministries that have been mandated to implement the respective laws and regulations covering these respective IP instruments.

### 5.1 Capacity Building

Nepal's IP Office would need trained staff and adequate infrastructure in order to implement its responsibilities. With respect to external stakeholders, the goal should be to establish an IP training institute under the IP Office, which could conduct stakeholder training across the country. Nepal could avail itself of technical assistance provided by the WTO and its Members as well as international organizations such as WIPO, UNCTAD and the South Centre.

Meanwhile, given the present low level of capacity and awareness of IPRs and TRIPS in Nepal, consideration should also be given to provide the Ministry of Commerce and Supplies, as the focal agency for TRIPS issues, with resources to organize capacity building for public and private sector stakeholders in Nepal.

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*Recommendations*

30) *Nepal's IP and knowledge transfer policies should reflect the objectives of IP rights protection in accordance with Article 7 of the TRIPS Agreement, in particular to:*

- *Ensure that IP laws contribute to innovation and technology transfer to vital sectors of the economy, and facilitate indigenous learning and adaptation;*
- *Building mutual supportiveness of IP laws and laws for the implementation of protection and conservation of biodiversity, and traditional knowledge, among others; and*
- *Ensure access to technological goods and services by the Nepalese public at large, including access to medicines and education materials through the strategic use of available TRIPS flexibilities.*

31) *Improve the institutional framework and mandate on national IP policy and knowledge transfer, and for this purpose:*

- *Upgrade and make effective the existing high level TRIPS Coordination Committee into a permanent National IP and Knowledge Transfer Committee, with responsibilities including:*
    - *Providing a coordination mechanism for the government of Nepal on IP policy and ensuring that Nepal's policies and priorities are reflected consistently in international negotiations, taking into account the number of multilateral, regional and bilateral instruments and players on IP rights;*
    - *Providing a platform for regular periodical exchange of views among government agencies, civil society and the private sector;*
    - *Establishing and maintaining relationships with regional and international stakeholders on key priorities of Nepal, for example, in negotiations for the protection of, inter alia, TK, GIs and traditional cultural expressions;*
    - *Undertaking a review of national laws and regulations, directives and practices, and making recommendations to improve policy coherence in the protection and enforcement of IP rights, and TK, including in areas such as GIs, commercial licenses and government use; and*
    - *Maintaining a platform for undertaking and dissemination of empirical and interdisciplinary studies by Nepalese researchers on the functioning, pros and cons of the IP system in economic, legal, management and relevant scientific fields.*
- *Upgrade the existing IP registration office to a fully empowered and independent IP Office, with responsibilities including:*
    - *Undertaking examination, registration and administration of IP rights;*
    - *Developing and maintaining rules and guidelines for the implementation of its responsibilities under relevant laws and regulations;*

- *Providing training for policy making entities, implementation and enforcement agencies, state-owned enterprises, procurement agencies, the judiciary and the private sector;*
- *Developing and maintaining a technology information and support centre (TISC) (see Recommendation 1.2);*
- *Providing assistance on the management, ownership and licensing of IP rights in university-industry research and government-funded projects (see Recommendations 1.3 and 1.7); and in the negotiations for transfer and benefit sharing arising from the utilisation of Nepalese GRs and TK (see Recommendation 3.1);*
- *Establishing and maintaining alternative IP dispute settlement facilities, such as conciliation, mediation and arbitration (see Recommendation 1.10);*
- *Encourage the branding and promotion of Nepalese traditional and agricultural goods (see Recommendations 1.13 and 3.10); and protecting Nepalese GRs/TK from bio-piracy/misappropriation (see Recommendation 3.4);*
- *Serving as the Secretariat of the National IP and Knowledge Transfer Committee; and*
- *Establishing an IP training institute and organizing periodically awareness-raising workshops on IP with stakeholders across Nepal, in conjunction with national universities (see Recommendation 4.4).*

32) *Nepal should ensure that both the IP Office and the National IP and Knowledge Transfer Committee are adequately staffed and funded, and receive the necessary training to carry out their functions.*

## 5.2 IP Enforcement and Awareness

The legal and institutional mechanisms for IP need to be reinforced by greater awareness of IP in general, as well as measures to ensure the enforcement of laws and regulations, in particular. IP protection mean very little if Nepal is unable to respect the boundaries of granted IP rights, understand how they could benefit from IP rights and take advantage of what is available in the public domain. The 2012 UNCTAD fact-finding mission to Nepal revealed that the general awareness of IP rights remains minimal at present beyond a limited circle of direct stakeholders researchers, inventors and artists. Local movie production studios and musicians identified copyright piracy as a serious challenge to their IP-based business model.

In many respects, awareness will be an important means to improve enforcement of IP rights. Universities and the IP office can offer courses and capacity building programme on IP. In the absence of a critical mass of qualified staff to teach courses, Nepal may wish to request technical assistance for the training of trainers.

The IP owner have the primary responsibility to seek to enforce their right against the infringing party through the legal means provided under Nepal law, rather than automatically expecting the IP Office to take action on their behalf. In many developing countries including Nepal, however, the judicial mechanisms are ill-equipped to handle IP cases when they are brought. Therefore, both judges' trainings in IP and establishing arbitration, mediation and conciliation facilities will be needed to ensure that IP cases are heard, understood and adjudicated fairly in Nepal.

IP rights being private rights is that in some instances, IP laws will need to draw the line as to what would constitute a criminal violation of IP rights. Not all IP violations may amount to a criminal violation, which generally requires the wilful intent to commit a criminal act or omission, such as wilful counterfeiting of medicine, and copyright piracy. The lines where violators will be subject to administrative fines or jail time needs to take account of due process of law and standards of fairness, as well as instances where the owner of a right should be expected to take enforcement measures him or herself. These lines need to be clearly delineated in the IP laws.

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*Recommendations*

*33) National universities should be supported in offering IP courses, both with financial and academic resources.*

*34) As IP rights are in principle private rights, judges should be trained to adjudicate disputes in IP-related issues. Nepal should also offer the possibility of alternative dispute resolution for IP-related disputes (see Recommendations 1.10 and 4.2).*

*35) National legislation should clearly delineate the boundaries of criminal cases and civil cases related to IP, where action should be the primary responsibility of public authorities in the case of the former, and initially the responsibility should rest with the right owner to enforce their rights in the case of the latter.*

## 5.3 Prioritising action areas

Taking into account the financial, administrative and economic constraints of Nepal, prioritisation of recommendations and action plans would be necessary. The majority of the recommendations require legislative reform, in particular the revision of the current Industrial Property Act (1965) and for an IP office, once established, to adopt and implement rules and procedures. Since the recommendations are adopted by the stakeholders, the main remaining task would be securing the approval of the legislative assembly. In this regard;

1. Nepal may need to consider as a priority the implementation of the transition period for pharmaceutical product patent and pharmaceutical test data protection, pending the finalisation of the revision of the Industrial Property Act, since the use of the transition period is time bound.

2. The ongoing revision of the Industrial Property Act is the major action area to address recommendations 1, 5, 8-10, 12, 14, 15-17, 19, 21, 22, 24, 30, 31 and 35. Institutional reform concerning the IP Office stipulated under recommendation 32, adoption of rules and regulations identified under recommendations 18 and 28 can also begin only once the IP office is established by the revised Industrial property Act. As a result, the second priority would be to finalise the revision of the Industrial Property Act. Equally, recommendations 4 and 25-27 identify legislative and policy formulation outside the Industrial Property Act and should be considered as second priority.
3. The implementation of recommendations 2 and 3 concerning the establishment of a technology transfer and innovation support centre and related services depends on the availability of financial and technical assistance from WIPO and other partners.
4. Recommendations 7, 11, 13, 20, 23, and 29 concerning the role of the IP Office in technology transfer and the protection of GRs/TK, and recommendations 6, 33 and 34 concerning capacity building measures require further action plans to determine the scope and duration of activities.

Nepal should seek technical assistance for the formulation of laws for the protection of traditional cultural expressions, *sui generis* protection TK, as well as for undertaking additional studies, in particular by submitting its financial and technical assistance need to development partners. Nepal needs further technical assistance from WIPO to establish the technology and innovation support centre and to develop strategies for university-industry linkages.

In the mid to long term, an effective institutional structure will need to exist in order to ensure effective coordination and policy coherence. Once the IP Office is established, Nepal could seek to implement capacity building programmes, develop rules and procedures, and mechanisms for policy coordination.

## Conclusion

This Report examines IP and transfer of technology, patents and access to medicines, and IP and access to GRs/TK, and sharing of benefits arising from their utilisation - three issues that currently emerged as critical questions of the IP system of many developing countries. The three issues are also linked to the basic purpose of IP laws in achieving the balance between the economic interests of IP rights holders, and the benefit for the society at large and managing the interface between biodiversity conservation and IP rights protection. The socio-economic context of Nepal and its current policies provide the framework for the analysis of the three issues.

As an LDC, Nepal benefits from the transition period for the implementation of TRIPS and protection of pharmaceutical products. As one of the major biodiversity hotspots of the world, Nepal requires the norms that govern the relationship between the protection of IP rights as an incentive for innovation and the protection of biodiversity that meets the expectations of TK holders and sustainable use of its GRs. As an LDC and with an economy dominated by primary sectors, Nepal's needs in terms of transfer of technology should also influence its IP policy.

This Report identifies several recommendations for updating the Industrial Property Act of Nepal so that available flexibilities are fully utilized to support important development objectives.

The list of recommendations at the end of each section is not, however, exhaustive as changes in the IP regime alone will not ensure that biopiracy does not occur, or that there will be greater access to medicines. The Report does, however, identify recommendations that can be addressed under capacity building and other actionable measures to improve the utilization of the IP rights system for the socio-economic benefit of Nepal, particularly in relation to technology transfer, and the use of GIs and trademarks for promotion of GRs/TK in Nepal. Nepal may wish to request the donor community to address these needs in the near future, using mechanisms such as the Enhanced Integrated Framework, the WIPO Development Agenda or the WTO TRIPS Council.

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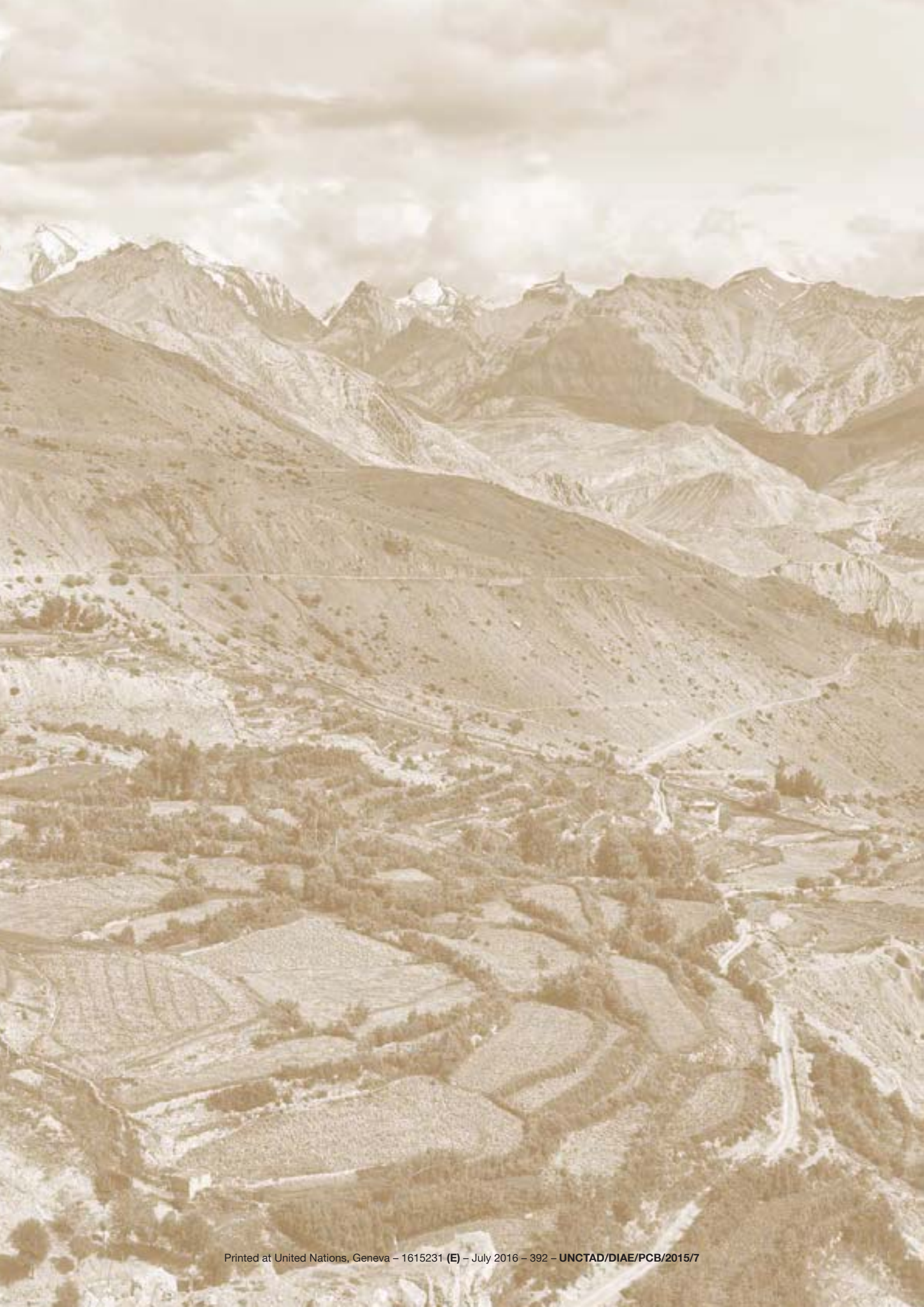

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