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Impacts of LDC Graduation on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in Cambodia, Djibouti, Senegal and Zambia

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Impacts of LDC Graduation on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in Cambodia, Djibouti, Senegal and Zambia

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Abstract: Least developed countries (LDCs) benefit from specific flexibilities under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), including an extended transition period for implementation of the agreement. These flexibilities cease to apply when countries graduate from the LDC category. Cambodia, Djibouti, Senegal and Zambia are among the countries that have recently started the graduation process, which consists of a series of stages over several years and involves analysis of quantitative and qualitative information, including the expected impacts of graduation. In that context, this study analyses the policy and developmental implications for these countries of no longer benefitting from the LDC-specific provisions of the TRIPS Agreement. The study finds that the countries under analysis do not make full use of the LDC-specific flexibilities, with exceptions particularly in the area of pharmaceuticals in Cambodia. After graduation, countries would still be able to apply a number of flexibilities and policy space available under TRIPS that are not exclusive to LDCs, but this would require legislative action and capacity-building. For the most part, however, these countries lack the necessary conditions to be able to benefit from stronger standards of IP protection that are absent in the LDCs. The paper concludes with recommendations for countries as they prepare for graduation.

JEL Classification: F13; F68.

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1. Introduction

This study presents an assessment of the possible impacts of implementation of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) upon the graduation of Cambodia, Djibouti, Senegal and Zambia from the least developed country (LDC) category. These countries, along with Comoros, met the criteria for LDC graduation for the first time at the periodic review of the LDC category undertaken by the Committee for Development Policy of the United Nations (CDP) in 2021.[1] If they meet the criteria again in 2024, they may be recommended for graduation. As part of its assessment, the CDP will consider several inputs, including an assessment of the impacts of graduation by the UN Department of Economic and Social Affairs (DESA). In this context, this study will analyse the policy and developmental implications, for Cambodia, Djibouti, Senegal and Zambia, of losing access to the LDC-specific provisions of the TRIPS Agreement, in order to inform the CDP's decision and the respective governments of the prospective graduating LDCs that are WTO members as they prepare for graduation. Comoros is not included in the scope of this study as it is not a WTO member.

A fundamental transformation brought about in global standards of intellectual property (IP) protection after the adoption of the TRIPS Agreement in 1994 was that all WTO members had to provide different forms of IP protection as mandated in the TRIPS Agreement. All WTO members had to grant patent protection in all fields of technology without discrimination for a minimum term of 20 years. Hence, WTO members could no longer exclude certain technology sectors like pharmaceuticals from the scope of patent protection or grant lesser terms of protection, which had been a common practice among countries that had developed a strong pharmaceutical industry. There are multiple examples of how industrialized countries developed pharmaceutical and other industries in the absence of patent protection.[2]

To enable them to prepare and gradually work towards the implementation of the TRIPS Agreement, developing countries were generally allowed to delay the application of the agreement for a period of five years. In addition, developing countries that did not extend patent protection to certain areas of technology, such as pharmaceuticals, could delay application of the provisions relating to patents in these areas of technology for an additional period of five years. LDCs were granted special longer transition periods, of 10 years, extendable upon a duly motivated request to the TRIPS Council by any LDC member. The general transition period for LDCs has been extended three times by the TRIPS Council, most recently until 1 July

1 United Nations, *Committee for Development Policy: Report on the Twenty-Third Session (22-26 February 2021)*, Economic and Social Council, Official Records, 2021, Supplement No.13, E/2021/33, p.20. Available from https://documents-dds-ny.un.org/doc/UNDOC/GEN/N21/070/41/PDF/N2107041.pdf?OpenElement.

2 See Carlos M. Correa, "Intellectual Property: How Much Room is Left for Industrial Policy?", United Nations Conference on Trade and Development, Discussion Paper No.233, October 2015, UNCTAD/OSG/DP/2015/5, pp.1-2. Available from https://unctad.org/system/files/official-document/osgdp20155_en.pdf.

2034. The LDC-specific transition period for pharmaceutical products has been extended twice and is currently available until 1 January 2033.[3] When countries graduate from the LDC category, these transition periods no longer apply. Graduated countries that are WTO members are obligated to implement all the provisions of TRIPS.

3 WTO, "Responding to least developed countries' special needs in intellectual property." Available from https://www.wto.org/english/tratop_e/trips_e/ldc_e.htm.

2. WTO TRIPS Agreement and its Flexibilities

While the TRIPS Agreement has led to some degree of harmonisation of national IP laws, it is not a uniform law on IP. Though the Agreement establishes minimum standards, it does not obligate WTO members to adopt broader standards. The TRIPS Agreement leaves room for all WTO members to implement its provisions in different manners, to legislate in areas not subject to the minimum standards under the Agreement, and to develop legal interpretations of the provisions in order to determine the scope and content of the applicable obligations. The actual policy space available under TRIPS – beyond the areas not covered by the Agreement – depends on the interpretation of its provisions. The diversity of legislative options available through such interpretation are referred to as "TRIPS flexibilities".[4]

The term "flexibility" itself is used with a different connotation in article 66.1 of the TRIPS Agreement, specifically in relation to LDCs. Article 66.1 states that, "In view of the special needs and requirements of the least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than articles 3, 4, and 5, for a period of …" (emphasis added). Essentially, this provision acknowledges that certain aspects of the TRIPS Agreement may not be compatible with the social and economic circumstances of LDCs, which need policy space and flexibility to address their development challenges and to create a viable technological base. The special status of LDCs is also acknowledged in the preamble of the TRIPS Agreement, which recognizes "… the special needs of least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base."

The negotiators of the TRIPS Agreement were mindful of the special needs of LDCs and the unique challenges these countries faced in the process of technological catch-up as latecomers to technological development. It was recognized that intellectual property rights (IPRs) cannot be effective as an incentive mechanism in the absence of a sound and viable technological base. In order to be effective, IPRs need to apply in a context where there is a significant market, sufficient capital, qualified personnel at the firm level, innovation-oriented entrepreneurs, as well as a solid scientific and technological base. LDCs need access to appropriate technology and to be able to effectively use such technology in the local context. This requires sufficient levels of absorptive capacity, or the ability to assimilate and adopt technological know-how. These primary conditions for benefiting from stronger

4 Carlos M. Correa, "Interpreting the Flexibilities Under the TRIPS Agreement", in Carlos M. Correa and Reto M. Hilty (eds.), *Access to Medicines and Vaccines* (Springer, Cham, 2021). Available from https://doi.org/10.1007/978-3-030-83114-1_1.

BOX 1

Flexibilities Derived from TRIPS

1. Flexibility in the choice of patentability criteria, including for chemical entities and biologics. WTO members have considerable policy space to define what an 'invention' is and to apply rigorous standards of patentability to avoid the grant of patents that, without making a genuine technical contribution, may distort market competition.
2. Compulsory license. Widely recognized in the legislation of developed and developing countries—and granted since the adoption of the TRIPS Agreement by administrations or courts in countries such as Thailand, Ecuador, Indonesia, India, United States, Italy, and Germany, compulsory licenses may be necessary to correct market distortions (abuses of market power, unfair pricing, refusal to license, etc.).
3. Government use authorization. In many cases governments may decide, consistently with the TRIPS Agreement, to use patented inventions for non-commercial purposes, such as for ensuring the supply of essential medicines.
4. Compulsory licenses for the supply of medicines to countries with a lack of or insufficient manufacturing capacity. Compulsory licenses exclusively for the export of medicines can be granted under the amendment introduced to the TRIPS Agreement in 2017 and the waiver adopted by the WTO in 2003.
5. Test data protection. The TRIPS Agreement (Article 39.3) requires WTO members to protect test data against unfair competition, which does not create exclusive rights. The Agreement is complied with if legislation on unfair competition is implemented to protect such data.
6. Parallel importation. Importing protected medicines from any country where they can be purchased cheaper than locally is consistent with the TRIPS Agreement.
7. Pre- and post-patent grant opposition. Patent office procedures for granting patents provide for the possibility for third parties to contribute to the examination process through 'observations' or 'oppositions,' whether before or after the grant of a patent, or both.
8. Use of competition law to address the misuse of IPRs. Competition law may be applied to correct market distortions created through the abuse of IPRs.
9. Bolar exception. 'Bolar exceptions' (allowing the use of a patented medicine for the purpose of conducting research and tests for regulatory approval for generic medicines) are important to accelerate the entry of generic products and promote a dynamic market for medicines.
10. Research or experimentation exception. This exception allows research to be conducted by third parties on patented inventions, for instance, to improve on them or derive new inventions.
11. Disclosure requirement, particularly for biologics. The full and precise disclosure of an invention is crucial for the patent system to perform its informational function. This is particularly relevant for biologicals, which cannot be described in the same way as medicines produced by chemical synthesis.
12. Flexibilities in enforcement of IP. Measures to enforce IPRs, such as reversal of the burden of proof, determination of infringement by equivalence and damages, and border measures, if overly broad, may distort competition by discouraging or preventing market entry and the availability of generic medicines. Provisional injunctions need to be cautiously granted so as not to distort the market dynamics, generally after giving the alleged infringer an opportunity to articulate their defense. Permanent injunctions may be denied for public health reasons under certain circumstances.
13. Security exception. Compliance with obligations under the TRIPS Agreement can be suspended, inter alia, in cases of emergency in international relations, such as in the case of a pandemic (Article 73 (b) of the Agreement).

Source: South Centre, Public Health Related Flexibilities in the TRIPS Agreement. Available from https://ipaccessmeds.southcentre.int/wp-content/uploads/2018/12/Public-Health-Related-Flexibilities-in-the-TRIPS-Agreement.pdf.

standards of IP protection are absent in the LDCs. Strong IP protection in such a context can stifle technological learning and severely impede the development of a technological base.[5] As noted by United Nations Conference on Trade and Development (UNCTAD):

"In the case of LDCs, learning will principally revolve around absorbing already existing techniques and adapting them to specific local conditions, namely by imitation. ... in most cases of imitation some kind of "reverse engineering" will be essential based on a variety of skills and activities which would support a purposive search for relevant information and its development through effective interactions within and among firms and other institutions familiar with knowledge acquired from abroad. In that respect, strong IPR protection is likely to hinder rather than facilitate technology transfer and indigenous learning activities in the early stages of industrialization."

However, the term "TRIPS flexibilities" not only includes the exemption for LDCs from implementation of the provisions of the TRIPS Agreement under article 66.1, but also encompasses possible variations in the manner in which the provisions of the TRIPS Agreement are interpreted and implemented by the countries that are subject to them.[6] Some of the flexibilities that can be derived from the express and implied terms of the TRIPS Agreement are described in Box 1. These flexibilities will continue to be available to LDC members of the WTO after graduation, when the LDC-specific flexibilities will end. A major question for LDCs to consider in the context of graduation is whether they have the legal and institutional capacities to make use of these flexibilities to mitigate the loss of the LDC-specific flexibilities.

5 UNCTAD, LDC Report 2007. P.103.

6 Correa, *supra* note 4.

3. Impact of Loss of LDC-specific Flexibilities and TRIPS Implementation

This section analyses the extent to which the LDC-specific TRIPS flexibilities have been used by the four prospective graduating countries that are WTO members, the major manufacturing industries that could be impacted due to the loss of the flexibilities and introduction of patent protection, and the legal and institutional capacities to mitigate the impact of such loss through the use of other available TRIPS flexibilities.

A graduated LDC will be required to 1) extend patent protection to all fields of technology including pharmaceutical products and processes, for a minimum term of 20 years; and 2) notify the WTO of its intention to use the special compulsory licensing system under article 31bis of TRIPS to demonstrate that it has insufficient pharmaceutical manufacturing capacity and thereby import medicines under a compulsory license for export issued by an exporting country.

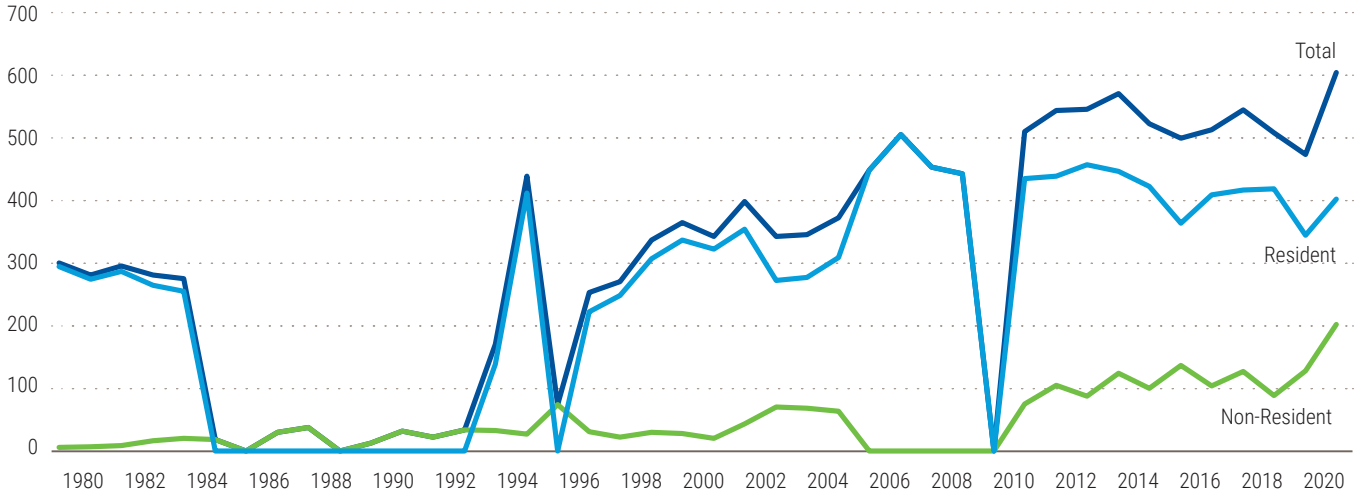
Additionally, developed country members of WTO will no longer be under any obligation in terms of article 66.2 of TRIPS. Article 66.2 requires developed country members to "... provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least developed country members in order to enable them to create a sound and viable technology base." An analysis of reports on the implementation of this obligation, submitted by developed countries from 1999 to 2007, found that most policies and programmes reported as incentives provided to encourage transfer of technology "either poorly targeted, or did not at all target LDCs."[7] Even after applying a broad understanding of technology transfer to include incentives such as scholarships for technical education of beneficiaries from LDCs, the report found that "... many of the programmes or policies either were not technical in nature or did not include a transfer component."[8] Analysis of developed country submissions on implementation of article 66.2 that cite the four LDCs that are the subject of this study shows a similar trend. For example, an overview of 183 reports that mention Cambodia shows that most do not refer to specific incentives provided to incentivize firms or institutions to transfer technology to Cambodia. Rather, they refer to forms of technical assistance provided, that are not contingent on LDC status.

7 Suerie Moon, "Does TRIPS Art. 66.2 Encourage Technology Transfer to LDCs? An Analysis of Country Submissions to the TRIPS Council (1999-2007), Policy Brief No.2, ICTSD, December 2008, p.5. Available from https://unctad.org/system/files/official-document/iprs_pb20092_en.pdf.

8 Ibid.

Figure 1

Patent applications filed in OAPI, 1980-2021 (number of applications)



Source: WIPO IP Statistics Database.

3.1. Senegal

Senegal has been a member of the WTO since its establishment. It is also a contracting party to the Bangui Agreement Instituting an African Intellectual Property Organization[9] and thereby a member of the African Intellectual Property Organization (OAPI). The Bangui Agreement constitutes the main IP law of the country since it has the force of national law in OAPI member States. This means that the utilization of the TRIPS flexibilities, including LDC specific flexibilities, by a country that is an OAPI member State is shaped by, if and how the Bangui Agreement allows the use of such flexibilities. However, the 1999 Act of the Bangui Agreement had no provision giving effect to the LDC-specific TRIPS flexibilities for OAPI member States that are LDCs.[10] Hence, Senegal could not benefit from the transition periods under article 66.1 of TRIPS. Since the entry into force of the revised 2015 Act of the Bangui Agreement in 2022, it is possible for LDC member States of OAPI to implement the TRIPS transition period specifically in respect of pharmaceutical products until 1 January 2033 or LDC graduation.[11] Thus, Senegal can currently implement the TRIPS transition period in respect of pharmaceutical products and exclude the same from patent protection and protection of confidential (undisclosed) information as required under TRIPS. However, Senegal has not adopted any measure implementing a transitional exclusion in respect of pharmaceutical products. Patent protection is thus available in Senegal through the OAPI in all fields of technology, including pharmaceutical products.

Patent grants in Senegal are based on grants by the OAPI office. According to the World

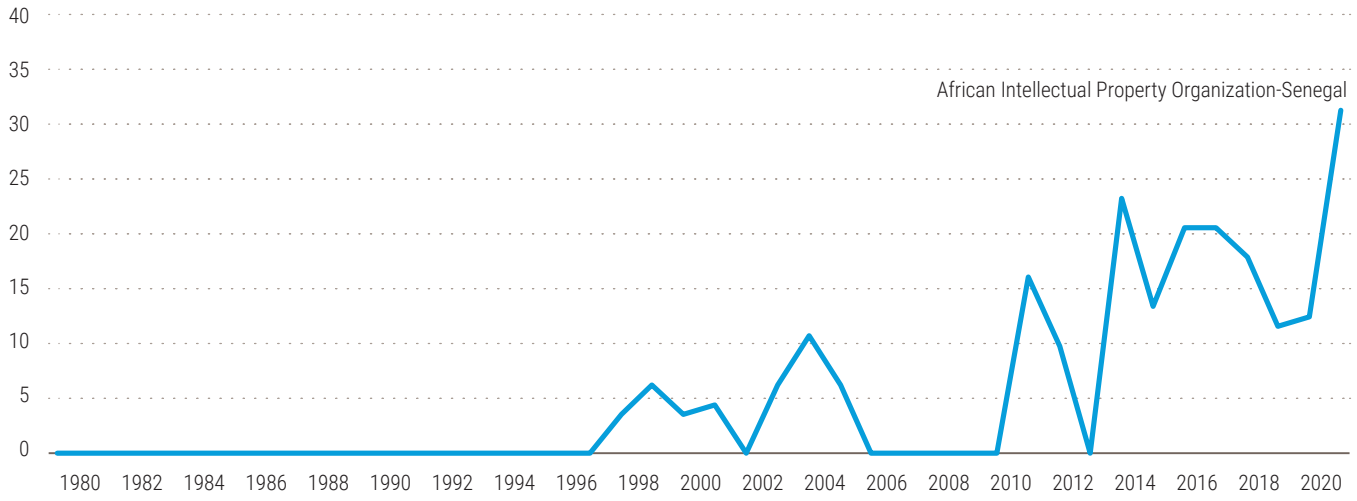
9 The Bangui Agreement was adopted in 1977 to establish the OAPI as a regional IP office for the Francophone African countries with regard to patents, trademarks, copyright. The Bangui Agreement was revised in 1999 to make it consistent with the requirements of international intellectual property treaties including the TRIPS Agreement. It was further revised in 2015 considering, among others, the role played by intellectual property in achieving economic and social development, introducing provisions utilizing some of the flexibilities available under the TRIPS Agreement. The revised 2015 Act of the Bangui Agreement entered into force in January 2022.

10 Yousuf A. Vawda and Bonginkosi Shozi, *Utilizing Public Health Flexibilities in the Era of COVID-19: An Analysis of Intellectual Property Regulation in the OAPI and MENA Regions* (Research Paper No.141, South Centre, Geneva, 2021), p. 5. Available from https://www.southcentre.int/research-paper-141-november-2021/.

11 Article 46, Bangui Agreement (Act of 2015). Available from http://www.oapi.int/Ressources/accord_bangui/2020/anglais.pdf.

Figure 2

Patent applications of Senegalese origin filed in OAPI, 1980-2021 (number of applications)



Source: WIPO IP Statistics Database.

Intellectual Property Organization (WIPO) statistics, the overall number of patent applications of Senegalese origin through the OAPI office is modest. The majority of patent applications filed through OAPI are of foreign origin. Two hundred and forty-four patent applications filed in OAPI between 1981-2021 were of Senegalese origin, comprising 1.9 per cent of patent applications filed in OAPI during this period. Of these, only 54 applications have resulted in a grant, with a grant rate of approximately 25 per cent. Most of the patent applications originating from Senegal have been filed after the adoption of the revised Bangui Agreement in 1999.

It should be noted that though OAPI acts as the patent office for all its member States including Senegal, it does not carry out substantive examination of patent applications and acts essentially as a registration office.[12] Patent search and examination functions are outsourced by OAPI to WIPO and the European Patent Office (EPO).[13]

Pharmaceuticals, chemicals and biotechnology comprise the leading technology sectors in terms of overall patents granted by OAPI. The overwhelming majority of patents granted on pharmaceuticals, and related sectors of organic chemistry, macromolecular chemistry and polymers, and biotechnology belong to patentees from developed countries such as the United States, France, Germany, the United Kingdom, Belgium, and other European countries. More than 1,000 patents granted in these technology sectors are owned by patentees from these countries, while patents of Senegalese origin in the pharmaceutical and biotechnology sectors have been low in absolute terms. Between 2000 and 2021, only five patents in pharmaceuticals and one patent in the biotechnology sector have been granted by OAPI, out of a total of 35 granted patents of Senegalese origin across all technology sectors. This clearly shows that there is overall dominance of developed country patentees.

The patents granted by OAPI are in force in Senegal as well. The 2015 Act of the Bangui

12 Vawda and Shozi, *supra* note 10, p.6.
13 See Carolyn Deere, The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries (Oxford University Press, 2009), p.251.

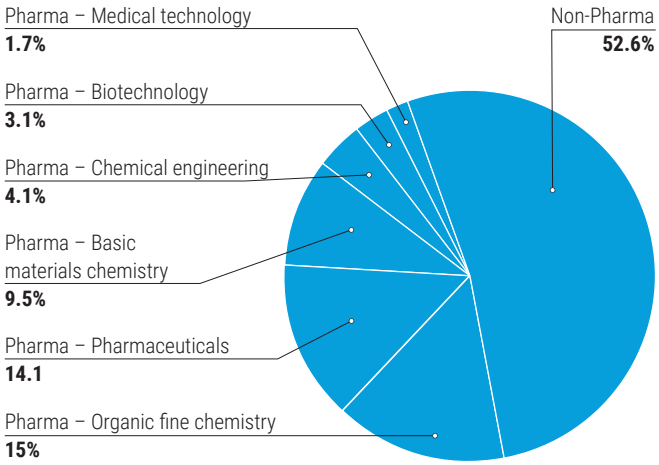
Agreement which entered into force in 2022 also grandfathers patents granted under the 1999 Act which are in force in a member State.[14] According to the MedsPaL database[15], a number of patents have been granted and will be in force for Senegal on pharmaceutical products during the current decade. These include patents on antiretroviral drugs, drugs for the treatment of tuberculosis, diabetes, cancer, COVID-19, and others. In this context it is important to note that although Senegal could not exclude pharmaceutical products from patent protection under the 1999 Act of the Bangui Agreement, in 2006 Senegal waived patent protection for antiretroviral drugs through a procurement letter allowing the procurement of generic antiretroviral drugs. However, Senegal has not adopted domestic legislation to make the LDC transition period self-executing. The 1999 Act of the Bangui Agreement did not allow this, and though the revised 2015 Act of the Bangui Agreement allows LDC member States to exclude pharmaceutical products from patent protection, domestic legislation implementing such exclusion has not been adopted.

Given that the pharmaceuticals sector has received most applications and grants in Senegal through OAPI, and patenting activity in this sector shows a consistent trend over the medium to long term, it can be assumed that this trend will continue after LDC graduation. It will be important to look at the implications of this trend in the context of the emphasis being placed on the development of the local pharmaceutical industry by the government in Senegal.

The three biggest industrial sectors in Senegal are electricity, water and gas industry followed by the construction industry and the chemical industry (including pharmaceuticals).[16] In the context of the Plan for an Emerging Senegal

Figure 3

Patents granted by OAPI in different technology sectors from1980-2021 (percentages)



Source: WIPO IP Statistics Database.

(PES) infrastructure, urban development, energy, and health have been identified as priorities of the Vision 2019-2024.[17] Of these sectors, patenting activity is the highest in the chemicals and pharmaceutical industry, as noted above. The extent of patents granted on pharmaceutical products is very significant and can create entry barriers for generics in this sector. This challenge will remain for Senegal even after graduation.

It will be important for Senegal to be able to use the maximum available policy space in the context of TRIPS implementation to complement and support its policy objective of developing a strong local pharmaceutical industry. While the LDC-specific flexibilities such as the TRIPS transition period will not be available for Senegal to facilitate the development of a local pharmaceutical industry after graduation, Senegal could still make use of the other available TRIPS flexibilities.

14 Article 44, Bangui Agreement, Act of 2015.

15 MedsPaL: The Medicines Patents and Licensing Database. Available from https://www.medspal.org/?page=1.

16 Fatou Cisse, *et. al.*, "Learning to Compete; Scoping paper on industry in Senegal", Working Paper No.26, Brookings Institute, African Development Bank and UNU-WIDER, p.11. Available from https://www.brookings.edu/wp-content/uploads/2016/07/L2C_WP26-1.pdf.

17 See UNIDO, "Senegal: Programme for Country Partnership (PCP): Annual Report 2021". Available from https://www.unido.org/sites/default/files/files/2022-10/Senegal-PCP-AR2021_0.pdf.

While the 1999 Act of the Bangui Agreement significantly restricted the scope of implementing TRIPS flexibilities, the revisions under the Act of 2015 allows OAPI member States to make use of a number of TRIPS flexibilities in addition to the LDC transitional exclusion for pharmaceutical products. Thus, after January 2022, member States of OAPI can issue compulsory licenses or government use authorizations by an administrative order of a competent Minister where such authorization is deemed necessary in the national interest, including economic needs, public health, and national security of the country. The patentee cannot raise the defense of legitimate reasons for failure to work the invention in such cases. The 2015 revision also allows OAPI member States to apply a Bolar exception, undertake parallel importation by applying an international regime of exhaustion of patent rights, and allow pre-grant and post-grant opposition of patent applications.

The Bangui Agreement allows the national laws of each member State of OAPI to co-exist with it if they are not contrary to the provisions of the agreement.[18] OAPI member States like Senegal could adopt national laws in the field of patents to give effect to the TRIPS flexibilities consistent with the provisions of the revised 2015 Act. In order to make full use of the TRIPS flexibilities insofar as the 2015 Act of the Bangui Agreement allows, Senegal will have to put in place the legal and institutional arrangements necessary to implement such flexibilities. For example, Senegal could adopt legislation to operationalize the transition period available for pharmaceutical products until its graduation. Domestic law and regulations could also be adopted to expand the grounds on which a compulsory license can be granted, including public health and anti-competitive grounds, and to institute streamlined and user-friendly administrative procedures for the grant of compulsory licenses.[19]

While the revisions under the 2015 Act of the Bangui Agreement are a step in the right direction, the Bangui Agreement continues to restrict the scope of TRIPS flexibilities in other ways. OAPI continues to grant patents based on a formality examination only by relying primarily on the work of the EPO. Discussions are ongoing between OAPI and EPO to conclude a validation agreement that would provide EPO applicants with direct access to patent protection in OAPI member States.[20] This would imply a proliferation of patents of foreign origin in the OAPI member States. Therefore, it will be important for OAPI member States, including Senegal, to pursue further reforms to introduce substantive patent examination by OAPI as a requirement to thoroughly assess the merits of all patent applications, particularly for pharmaceutical and related products and processes.[21]

3.2. Cambodia

Cambodia became a member of the WTO through accession in 2004. The terms of Cambodia's accession to the WTO, as laid down in the Accession Protocol and the Working Party report on Cambodia's accession, indicate that Cambodia is committed to apply the TRIPS Agreement no later than 1 January 2007.[22] The Working party report states that Cambodia had requested that the Working Party grant a transitional period until 1 January 2007 to obtain technical assistance and equip the administration to implement fully the obligations of the TRIPS Agreement. Cambodia confirmed it would undertake the following commitments during the transition period:

18 Article 5, Bangui Agreement, Act of 2015.
19 ibid.
20 EPO, "Bilateral heads of office meeting with OAPI", 29 March 2022. Available from https://www.epo.org/news-events/news/2022/20220329.html.
21 Vawda and Shozi, *supra* note 10, p.15.
22 See generally WTO, Accessions-Cambodia, "What Cambodia has promised". Available from https://www.wto.org/english/thewto_e/acc_e/factsheet_cambodge_e.htm.

1. to fully apply Articles 3, 4 and 5 of TRIPS that provide for, inter alia, national treatment and MFN treatment under current legislation in place;
2. to ensure that any change made in its laws, regulations and practice during this period would not result in a lesser degree of consistency with the provisions of the TRIPS Agreement that existed on the date of accession;
3. to not grant patents, trademarks, or copyrights, or marketing approvals for pharmaceuticals or agricultural chemicals inconsistent with the provisions of the TRIPS Agreement;
4. to ensure that existing rates of infringement would not significantly increase and any infringement of intellectual property rights would be addressed immediately in cooperation with the assistance from affected right holders;
5. to protect against unfair commercial use of undisclosed test or other data submitted in support of applications for marketing approval of pharmaceutical or agricultural chemical products which utilize new chemical entities, by providing that no person other than the person who submitted such data may, without the permission of the latter person, rely on such data in support of an application for product approval for a period of at least five years from the date on which Cambodia granted marketing approval to the person that produced the data;
6. Prior to the issuance of marketing approval of any pharmaceutical and agricultural chemical products, the relevant Ministries in Cambodia will determine the existence of a patent covering a product for which an application for marketing approval had been filed by a party other than the patentee, and will not approve such application for marketing approval until the date of the expiration of such patent.[23]

Some of these commitments clearly restricted the scope of the LDC-specific flexibilities available under TRIPS in the sense that Cambodia committed to apply the provisions of TRIPS fully from 1 January 2007, even though LDCs had an extendable transition period under article 66.1. Cambodia also agreed to introduce TRIPS plus standards of protection, including commitments to apply data exclusivity for a period of 5 years (which is not an obligation under TRIPS), as well as to introduce patent linkage for marketing approval of drugs (also not a requirement under TRIPS).

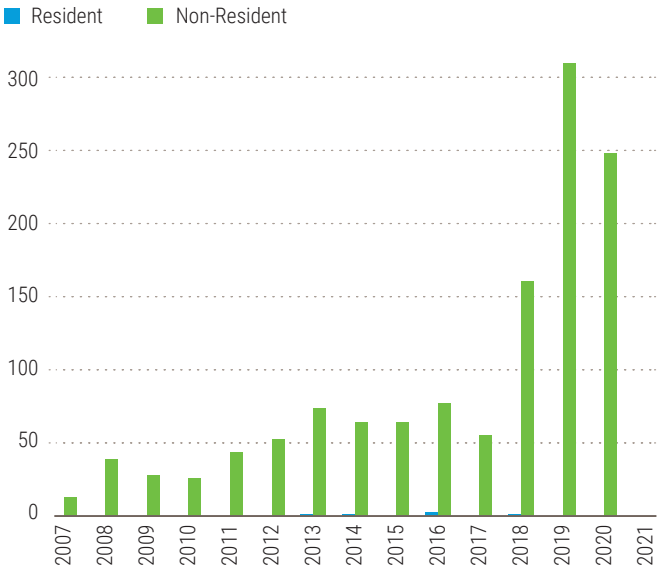
In 2003 Cambodia adopted the Law on Patents, Utility Models and Industrial Designs. This law extends patent protection to all fields of technology except pharmaceutical products, which were excluded from patent protection until 1 January 2016 in accordance with the Doha Declaration on TRIPS and Public Health. In 2017 Cambodia adopted an amendment to the patent law extending this transition period to 1 January 2033 in accordance with the WTO Ministerial Decision to the same effect. Cambodia has made use of the LDC-specific TRIPS transition period only for pharmaceutical products by excluding such products from being granted patents during the transition period. Pharmaceutical products cannot be currently patented in Cambodia.

The absence of patent protection for pharmaceutical products in Cambodia has facilitated greater competition among generic versions of medicines that are protected by patents and has enabled Cambodia to make significant progress in promoting access to affordable medicines. However, Cambodia has been able to do this through the importation of generic medicines and not local production. Diminished generic competition in developing countries that have been the source of generic imports for Cambodia remains a major challenge. In this context loss of the transition period

23 WTO document WT/ACC/KHM/21, 15 August 2003. Available from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/ACC/KHM21.pdf&Open=True.

Figure 4

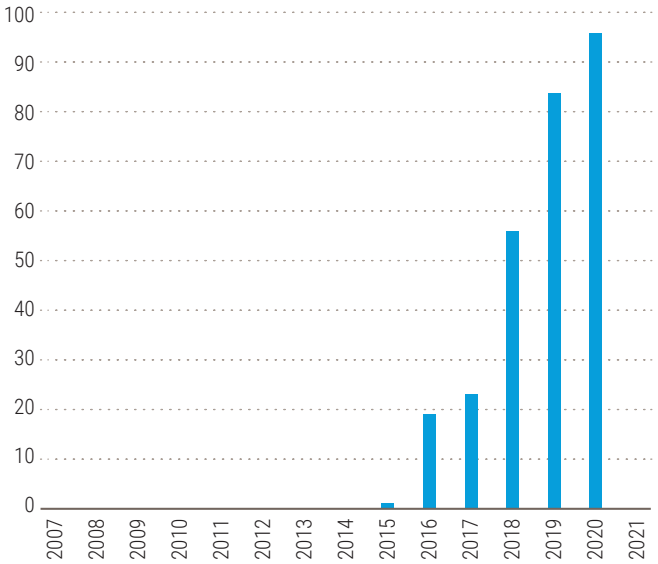
Patent Filing in Cambodia, 2007-2020 (number of resident and non-resident applications)



Source: WIPO IP Statistics Database.

Figure 5

Patents Granted in Cambodia, 2007-2020 (number of patents granted)



Source: WIPO IP Statistics Database.

upon graduation and consequent extension of patent protection to pharmaceutical products could restrict the scope for generic competition within Cambodia for both imported or locally manufactured generic medicines.[24]

Industrial development was given policy priority by the government since the 1990s. The textiles industry is the largest industrial sector in Cambodia. However, this sector is currently not excluded from patent protection in Cambodia.

In this context it is interesting to look at the extent of the current patenting activity in Cambodia. The WIPO IP Statistics Database shows that the current level of patenting activity in Cambodia is low. A total of 1,273 patents have been filed in Cambodia, out of which only 7 are resident patent applications. Of these, only 279 patents have been granted. All granted patents (which include all technology sectors except pharmaceuticals) are of foreign origin. Disaggregated data on the technology sectors with patenting activity in Cambodia is not available from the WIPO database.

However, the impact may be significant when patent protection is introduced in the pharmaceutical sector upon graduation. Upon graduation, the transitional exclusion for pharmaceutical products will not be possible in Cambodia. Hence, patents will have to be granted in respect of pharmaceuticals. Even though Cambodia has excluded pharmaceutical products from the scope of patent protection, it has established a "mailbox system" wherein pharmaceutical patent applications can be filed during the transition period, despite the country having no obligation under TRIPS to provide a mailbox system. These applications are to be examined, and could result in grant of patent protection, when the transition period ends upon graduation. In accordance with Rule 48 of the 2019 Prakas[25] on Management and Procedures for the

24 Phinh Sovath, "A Contextual Framework for Designing and Implementing Laws and Policies to Promote Access to Medicines in Cambodia". Available from https://www.wto.org/english/tratop_e/trips_e/colloquium_papers_e/2015/chapter_3_2015_e.pdf.

25 Prakas means an official proclamation or declaration.

Grant of Patents and Utility Model Certificates issued by the Ministry of Industry and Handicraft, the patent applications in the mailbox will be opened for examination after the expiry of the LDC transitional period. Therefore, not only new patent applications filed after the end of the transition period, but patent applications filed in the mailbox during the transition period will be eligible for a grant of patent.

Cambodia has also acceded to multiple patent treaties designed to expedite the granting of patents, implying that the grant of many of the applications in the mailbox could be on the basis of validation of corresponding patents granted by other national patent offices. These include a validation agreement that Cambodia has concluded with the EPO, which entered into force on 1 March 2018, allowing validation of any patent granted by the EPO from this date and automatically recognizing pharmaceutical patents granted by the EPO. These patents would enter into force immediately upon the end of the TRIPS transition period for LDCs in respect of pharmaceutical products.[26] It is important to note, from the figures on patent filings and grants in Cambodia, that there has been a significant increase in the number of patent filings and grants since 2018, the same year that the validation agreement with EPO came into force.

While the size of the pharmaceutical industry is small, the pharmaceutical market is expected to grow moderately, according to a forecast by Fitch solutions.[27] According to a WIPO study of ASEAN countries including Cambodia, firms view the impact of IP in pharmaceuticals as likely to induce more competition from foreign multinational firms, higher cost of access to technology, higher R&D costs and a compulsion to move to new products to avoid IP infringement.[28] Generally, these impacts are viewed to be significantly high in Cambodia given its low technology base. As Cambodia has used the TRIPS transition period for LDCs in the case of pharmaceuticals by excluding pharmaceutical products from patentability during the transition period, the introduction of patent protection on pharmaceuticals after graduation is expected to have significant impacts on the pharmaceutical industry in the country.

According to the MedsPaL database, a number of pharmaceutical patent applications have been filed in Cambodia, and there are corresponding grants of those applications filed with the European Patent Office.

In 2015 Cambodia adopted a law on compulsory licensing for public health with the objective of enhancing access to pharmaceutical products by granting compulsory licenses for production, export and import of pharmaceutical products in cases of national emergency, extreme urgency, public non-commercial use, or any other public health circumstances defined by the Ministry of Health. This law also allows Cambodia to grant a compulsory license for exporting to an eligible importing country in terms of Article 31bis and the Annex to the TRIPS Agreement. The application of this law was suspended during the transition period that ended in 2021. It is unclear if the law has come into effect since or continues to be suspended given the current extension of the transitional period. As pharmaceutical products are not eligible for patent protection in Cambodia currently, the need to use a compulsory license to facilitate access to a patented medicine has not arisen. However, a law on compulsory licensing will be an important legal tool to safeguard public health in relation to pharmaceutical

26 EPO, "Validation of European Patents in Cambodia (KH) with effect from 1 MARCH 2018". Available from https://www.epo.org/law-practice/legal-texts/official-journal/information-epo/archive/20180209.html.

27 FitchSolutions, "Economic Growth and Political Stability In Cambodia Will Facilitate Moderate Pharmaceutical Market Growth in 2023", 28 December 2022. Available from https://www.fitchsolutions.com/pharmaceuticals/economic-growth-and-political-stability-cambodia-will-facilitate-moderate-pharmaceutical-market-growth-2023-28-12-2022.

28 WIPO-ASEAN Study, "The Strategic Use of Intellectual Property to Enhance Competitiveness in Select Industries in ASEAN", World Intellectual Property Organization. Available from https://www.wipo.int/edocs/pubdocs/en/intproperty/953/wipo_pub_953.pdf.

patents that will have to be granted in Cambodia after graduation.

The 2015 law on compulsory licensing for public health seems to limit the scope of compulsory licensing to the system under article 31bis because it mandates the Ministry of Commerce to notify the WTO General Council in accordance with the requirements under the Annex to the TRIPS Agreement when an importation occurs under a compulsory license. However, it is possible for any WTO member to import under a compulsory license under article 31 of TRIPS without resorting to the procedure under article 31bis. For instance, a pharmaceutical product could be legitimately imported under a compulsory license from a country where a generic product is legitimately placed in the market without infringing a patent, and thus without the need for a special compulsory license for export by that country.

In light of the law on compulsory licensing for public health, Cambodia would need to issue notifications to the TRIPS Council of its intention to use the system as an importer, as well as a notification specifying the names and expected quantities of the products needed, confirming that it has insufficient or no manufacturing capacity in the pharmaceutical sector for the products in question, and confirming the grant or intention to grant a compulsory license in accordance with article 31 and 31bis of TRIPS where the pharmaceutical product is patented in its territory. These reporting requirements will challenge the limited capacities of the government of Cambodia to fulfil them, and stymie speedy response to public health emergencies for which these measures are meant. The complexity of using the system that has generally plagued WTO members will be accentuated for an LDC after graduation.

In the light of this analysis, it can be concluded that the biggest impact of the loss of the LDC-specific TRIPS flexibilities in the context of Cambodia will be in the pharmaceutical sector, as this is the only sector in respect of which Cambodia has tried to use the LDC-specific flexibility of the transition period for pharmaceutical products. Cambodia is likely to experience an immediate and significant increase in the number of pharmaceutical patent grants in respect of the pharmaceutical patents filed in the mailbox. However, it should be noted that Cambodia has no obligation under TRIPS to extend patent protection to applications filed under a mailbox system and it would be legitimate to adopt measures excluding patent grants to applications in the mailbox upon the end of transition period after graduation. It will be TRIPS consistent if Cambodia were to adopt measures allowing grant of patents on pharmaceutical products and process only in respect of applications filed after the end of the transition period.

Cambodia is also likely to experience an increase in filings of new pharmaceutical patent applications, including secondary patent applications that could extend the term of granted patents, or applications in the mailbox which may be nearing the end of their stipulated term. The increase in the number of pharmaceutical patents, facilitated through validation of corresponding patent grants by other national patent offices, together with the provision of TRIPS plus protection of data exclusivity and recognition of patent linkage in respect of marketing authorization of drugs, could create significant entry barriers for competing generic pharmaceutical products either through importation or local production, and adversely impact public health. According to the Health Sector Strategic Plan 2016-2020, ensuring timely delivery of quality assured medicines at affordable cost is a strategic priority for Cambodia. However, Cambodia has very limited local production of pharmaceuticals and imports 90 per cent of its pharmaceuticals to meet domestic demand. The absence of patent protection for pharmaceutical products in Cambodia provides the opportunity for Cambodia to import generic drugs from other countries. This freedom to import generic drugs will be lost if patents are granted on pharmaceutical products in Cambodia after graduation.

Another issue is capacity to implement TRIPS and grant patent protection based on robust patent examination. WIPO IP statistical data for Cambodia shows that between 2016 and 2021 the Cambodian IP office had 4 patent examiners. This implies that upon graduation, Cambodia will continue to have very limited capacity. It will be critical for Cambodia to expand its patent examination capacity in the lead up to graduation, particularly in respect of pharmaceutical patent claims, and reduce the dependency on patent grants through validation of grant decisions taken by foreign patent offices. Patent cooperation and validation agreements with foreign IP offices should be revised to particularly exclude pharmaceutical patent claims from their scope. At the same time, Cambodia should amend its domestic law and implementing regulations to eliminate TRIPS plus provisions that extend patent linkage and data exclusivity in respect of pharmaceutical products.

3.3. Djibouti

Djibouti is an original member of the WTO. Until 2009 it did not have an IP law. This situation was consistent with the transition period that is accorded to LDCs under article 66.1 of TRIPS. Since the adoption of the main IP law – Law No. 50/AN/09/6L of 19 July 2009 – patent protection is available in Djibouti in all fields of technology. Hence, currently Djibouti does not make use of the TRIPS transition periods available to it as an LDC, even for pharmaceutical products.

The economic growth of Djibouti is largely driven by revenues generated from ports and military bases rented to foreign contingents, taking advantage of Djibouti's strategic location as a maritime trade hub. The structure of Djibouti's economy is dominated by the services sector, particularly port activities and finance, which account for more than three quarters of GDP. Productivity in the agricultural sector is very low due to high vulnerability to climatic variations, lack of water resources and scarcity of arable land. Djibouti has a narrow production base and is heavily reliant on imports. The manufacturing value-added (MVA) of Djibouti is comparatively much lower than other prospective graduating LDCs (Cambodia, Senegal and Zambia).[29] There is no significant manufacturing cluster in Djibouti. Industrial manufacturing capacity is limited to basic metal product manufacturing. For instance, in 2019 the largest manufacturing product exports were razor blades, railway locomotive parts and machine parts.[30] However, the development of the manufacturing sector has not received policy priority. Rather, the major focus of the medium-term strategy for economic development is to make Djibouti a trade and logistics hub, and develop a modern regional financial centre.

Djibouti faces a generalized HIV epidemic and has high prevalence rates of TB and TB/HIV co-infection. The National Health Development Plan 2013-2017 (PNDS) was adopted to pursue the objective of ensuring universal access to quality health services to meet the needs of the population, and improve the availability, accessibility and rational use of medicines. Reduction of the prevalence of HIV and TB, and strengthening of the fight against communicable and non-communicable diseases and epidemiological surveillance, are identified as priorities in the PNDS. The Plan also identifies the insufficient supply of essential drugs as a major problem and makes defining an adequate policy for the acquisition and supply of drugs a priority. Djibouti also adopted a National Pharmaceutical Policy which is to be implemented by the Department of Medicine, Pharmacy and Laboratories (DMPL). Djibouti is primarily dependent on the import of pharmaceutical products.

29 The MVA as a percentage of GDP for Djibouti is 4%. In comparison, the MVA for Cambodia, Senegal and Zambia are 18%, 15% and 9% respectively. The World Bank, Manufacturing Value Added (% of GDP). Available from https://data.worldbank.org/indicator/NV.IND.MANF.ZS.

30 Fitch Solutions, "Manufacturing in East Africa: Djibouti". HKTDC Research, 19 August 2019. Available from https://research.hktdc.com/en/article/MzU3MDQ2NDg4.

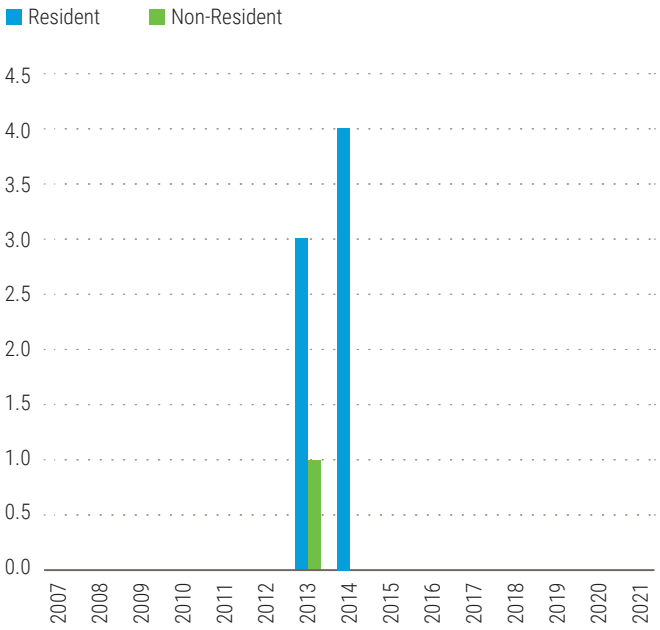
Therefore, despite being in the graduation process, Djibouti lacks a sound and viable technological base. It will also remain vulnerable to climatic variations and external shocks due to its predominant reliance on servicing trade flows from other countries. In the health sector, it remains vulnerable to the HIV epidemic along with the high prevalence of tuberculosis. It remains almost fully dependent on the importation of the necessary technologies to address these vulnerabilities. Hence, the fundamental conditions that are meant to be addressed through LDC-specific TRIPS flexibilities will continue to exist in Djibouti even after graduation. WIPO statistics show that patenting activity in Djibouti is extremely low. A total of 7 patent applications were filed between 1980 and 2021, and no patent application has been filed since 2014. All but one of these applications are of foreign origin. Information on patent grants in Djibouti is not available in the WIPO IP Statistics database. However, given that Djibouti does not undertake an examination of filed patent applications unless opposed within the stipulated period, it is possible that all of these applications have been granted unopposed. The MedsPaL database also shows no patent applications on pharmaceutical products covered in the database as filed in Djibouti.

The very low level of patenting activity in Djibouti, even though the TRIPS transition period has not been implemented, is reflective of the fact that Djibouti does not have the technological base to pose a competitive challenge to technology holders, which they would try to safeguard through patent protection.

Due to the high level of import dependence for industrial products, it will be important for Djibouti to ensure that it has the necessary legal and policy tools to facilitate affordable access to imported products such as agricultural technologies, manufacturing technologies and health technologies. If the low level of patenting activity prevalent in Djibouti continues after graduation, it will be possible for Djibouti to import generic technologies. However, if the patenting activity increases significantly, it could impact the ability of Djibouti to import generic technologies in those sectors.

Figure 6

Patent filing in Djibouti, 2009-2021 (number of resident and non-resident applications)



Source: WIPO IP Statistics Database.

To mitigate any adverse impact of increased patenting activities (if required) on access to such technologies, it will be important for Djibouti to have the legal provisions in its industrial property law that would allow it to make full use of the TRIPS flexibilities to that end. In this regard, it will be important for Djibouti to put in place a system of robust substantive patent examination. Djibouti allows the grant of patents without substantive examination if the patent applications filed are not opposed within a period of three months after the publication of the patent application.[31] Substantive examination of patent application is regarded as a gatekeeping

31 Article 46, Law No.50/AN/09/6 L On the Protection of Industrial Property. Available from https://www.wipo.int/wipolex/en/text/260854.

function that prevents the grant of frivolous patents. As Djibouti only conducts a formality examination to review that all the requirements under the patent application form have been complied with, there remains the possibility that granted patents in Djibouti may not meet the substantive patentability criteria. Currently, Djibouti receives very few patent applications. It would therefore need less examiners to conduct substantive examination of these applications. Hence, instituting a substantive examination system may not be very cost intensive.

The industrial property law of Djibouti also does not contain any provision making use of the exceptions to patents rights that are permissible under Article 30 of the TRIPS Agreement. The flexibility to apply exceptions to patent rights that are consistent with Article 30 of TRIPS is available to all WTO members. Hence, this flexibility will continue to be available to Djibouti after graduation. Djibouti can, therefore, amend the industrial property law to introduce the research exception and the Bolar or regulatory review exception.

Besides initiating a system of substantive patent examination, Djibouti should also make use of the other available TRIPS flexibilities. Parallel importation of patented products may be particularly important for Djibouti in view of its import dependence. The industrial property law of Djibouti adopts an international regime of exhaustion of patent rights such that the patent rights do not extend to acts "relating to products that have been introduced into the commerce of any country by the owner or another person authorized by the right holder or with economic ties to that patent owner."[32] In this regard, it will be important for Djibouti to clarify that this exception to the patent right will apply even in situations where the product is put in the relevant market through legitimate means such as under a compulsory license.

The industrial property law provides that a competent court may grant a compulsory license for a patent three years after the patent was granted or four years after the date the patent application was filed. This course of action may only be followed if the patent holder exercises their right in an "abusive" manner and where national security, health or nutritional concerns, or the development of vital sectors of the economy so require. However, the authorities have never had recourse to compulsory licensing in Djibouti.

The industrial property law also allows the use of a compulsory license for exports in accordance with article 31bis of TRIPS. It also states that where a medicine is imported into Djibouti pursuant to an ex officio license issued by the exporting country and remuneration has been paid in the exporting country, there would not be any payment of remuneration in Djibouti.[33] These provisions have not been applied in practice. However, the industrial property law seems to limit the scope of this provision to the medicines exported to Djibouti under a government use authorization in the exporting country. Article 31 bis of TRIPS allows exportation under a compulsory license to countries with insufficient manufacturing capacity and LDCs. It does not require that such exportation can only happen if an ex officio or government use authorization is issued. For instance, if an exporting country were to grant a compulsory license to a generic company to manufacture and export a patented drug to Djibouti upon payment of a royalty to the patentee, then a royalty for the same product cannot be required in Djibouti on the grounds that the authorization in the exporting country was not a government use or ex officio authorization. It would be sufficient for the industrial property law to state that, where a medicine is imported into Djibouti under a compulsory license or government use authorization in accordance with article 31

32 Article 55. Law No.
33 Article 69, ibid.

bis, and royalties are payable in the country of export, no royalty would be payable for the same product in Djibouti.

As an LDC member of WTO, Djibouti does not need to notify the TRIPS Council if it intends to make use of article 31bis. After graduation, if Djibouti intends to use article 31bis, it will have to notify the TRIPS Council. This will not impact the substantive challenges that all eligible WTO members face in making use of the system.[34]

3.4. Zambia

Zambia has been a member of the WTO since its establishment on 1 January 1995. Therefore, Zambia had the opportunity to use the TRIPS transition period for LDCs till 2005 under article 66.1, and its subsequent general extensions, as well as the special extensions of the transition period in respect of pharmaceutical products. These two extended transition periods are currently available for Zambia. Similarly, like other LDC members of the WTO, Zambia can also use the special compulsory licensing system under article 31 bis to import medicines under a compulsory license for export without notifying the TRIPS Council.

Zambia's main patent law is the Patents Act of 2016. There is no provision in the law excluding patent protection as per TRIPS standards generally or specifically for pharmaceuticals in accordance with the transition periods that have been granted to LDCs by the WTO TRIPS Council. There is also no provision implementing article 31 bis of TRIPS. Rather, the patent law specifically limited the use of compulsory licenses only for domestic purposes.[35] In 2004, Zambia issued a compulsory license for the antiretroviral combination of lamivudine, stavudine and nevirapine.[36]

Patenting activity in Zambia was significant from 1980 to 2021 but the trend of patent filing in the Zambian patent office has been declining. WIPO statistics show that a great majority (87 per cent) of the patent applications are of foreign origin. The patent filing trend has declined since 1996 and has remained similar since the adoption of the patent law in 2016. Almost half of the patent applications filed in the Zambian patent office since 2005 are resident applications.

Patent applications can be filed with the Zambian Patents and Companies Registration Agency (PACRA) which has the statutory powers to undertake substantive patent examination of applications filed. However, the patent law allows the patent office (PACRA) to refer a patent application to an International Examination Authority under the Patent Cooperation Treaty for a patentability search. The patent law also allows for the grant of a patent in Zambia based on a patent grant by the African Regional Intellectual Property Office (ARIPO) in accordance with the Harare Protocol on Patents and Designs. Patents granted by ARIPO take effect as patents granted by national offices of contracting parties to the Harare Protocol, if the patent application designates those States therein, unless the decision of the ARIPO is rejected by the national office within 6 months. So far, no patent granted by ARIPO has been opposed by a national office of a contracting party.

According to WIPO figures, the Zambian IP office had only 2 patent examiners as of 2020. This suggests that while Zambia allows the grant of patents in all fields of technology, it has very limited capacity to conduct rigorous substantive patent examination. According to a South Centre study, in addition to the regional patents granted by ARIPO, most national IP offices of

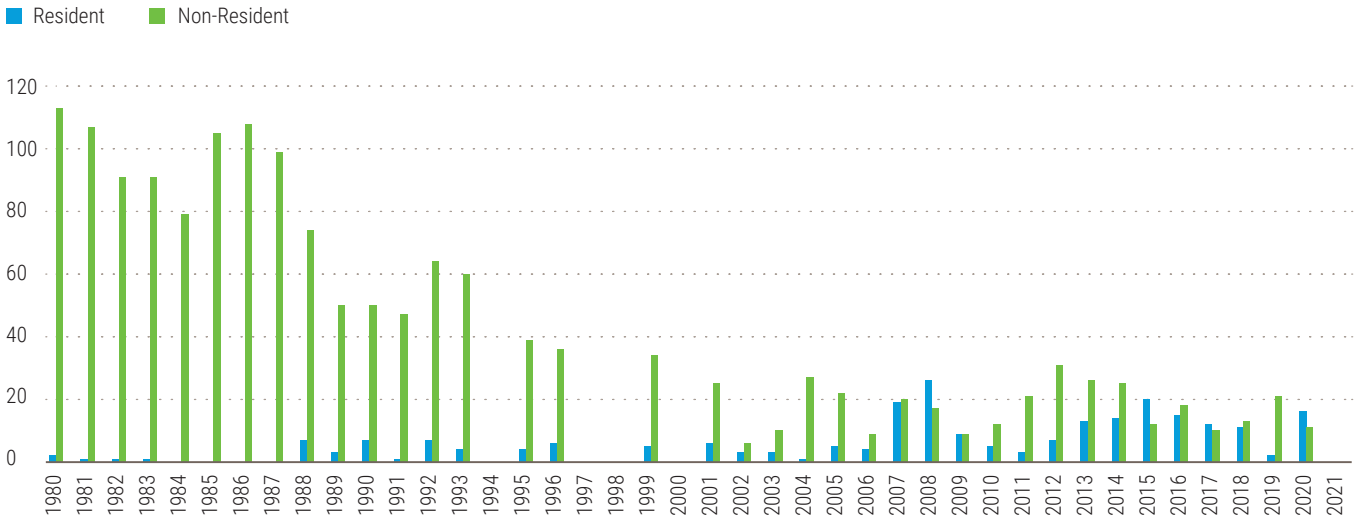
34 Carlos Correa, "Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?", Policy Brief No.57, January 2019, South Centre, Geneva. Available from https://www.southcentre.int/wp-content/uploads/2019/01/PB57_Will-the-Amendment-to-the-TRIPS-Agreement-Enhance-Access-to-Medicines_EN-1.pdf.

35 Section 99 (9), The Patents Act, 2016 (Act No.40 of 2016). Available from https://www.wipo.int/wipolex/en/text/481205.

36 https://unctad.org/system/files/official-document/ictsd-tralec2006d3_en.pdf

Figure 7

Patent filing in Zambia, 1980-2021 (number of resident and non-resident applications)



Source: WIPO IP Statistics Database.

ARIPO member States rely on the ARIPO office for substantive examination, and often send applications directly filed in their national offices to the ARIPO office for examination.[37]

The majority of patent applications are of foreign origin and are filed through the Patent Cooperation Treaty (PCT) route.[38] Between 1980 and 2021, a total of 1,835 patent applications have been filed in the Zambian patent office. Besides these patent applications filed in the Zambian office, 13,684 patent applications were filed in the ARIPO office between 1982 and 2021. Between 2003 and 2013, the ARIPO granted 345 patents relating to pharmaceuticals with Zambia as a designated State in the patent application.[39] As of 2021, 83,829 patents, across various technology sectors, were in force in Zambia. It is noteworthy that the number of patent applications filed in the Zambian patent office has been declining, while the number of applications filed in ARIPO has been increasing. This suggests that patent grants by ARIPO are the primary route through which patents in force in Zambia are granted.

The National Industrial Policy 2018 seeks to promote sustainable economic growth through industrialization. It has identified eight manufacturing sub-sectors as priority drivers of industrialization: food processing, textile garments, engineering products, wood and wood products, leather and leather products, mineral processing and products, pharmaceuticals and the blue economy.[40] In this context it is important to see which technological sectors have the largest levels of patent grants. Information on patents granted in different technology sectors in Zambia is not available from WIPO figures. Figure 9 shows patents granted in different technology sectors by ARIPO since Zambia became a member of the Harare Protocol in 1986.

A search of patents granted by technology sectors by ARIPO from 1986 to 2021 shows that the most

37 Sangeeta Shashikant, "The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for Access to Medicines", Research Paper No. 56, South Centre, November 2014, p.20. Available from https://www.southcentre.int/wp-content/uploads/2014/11/RP56_The-ARIPO-Protocol-on-Patents_ENI.pdf.

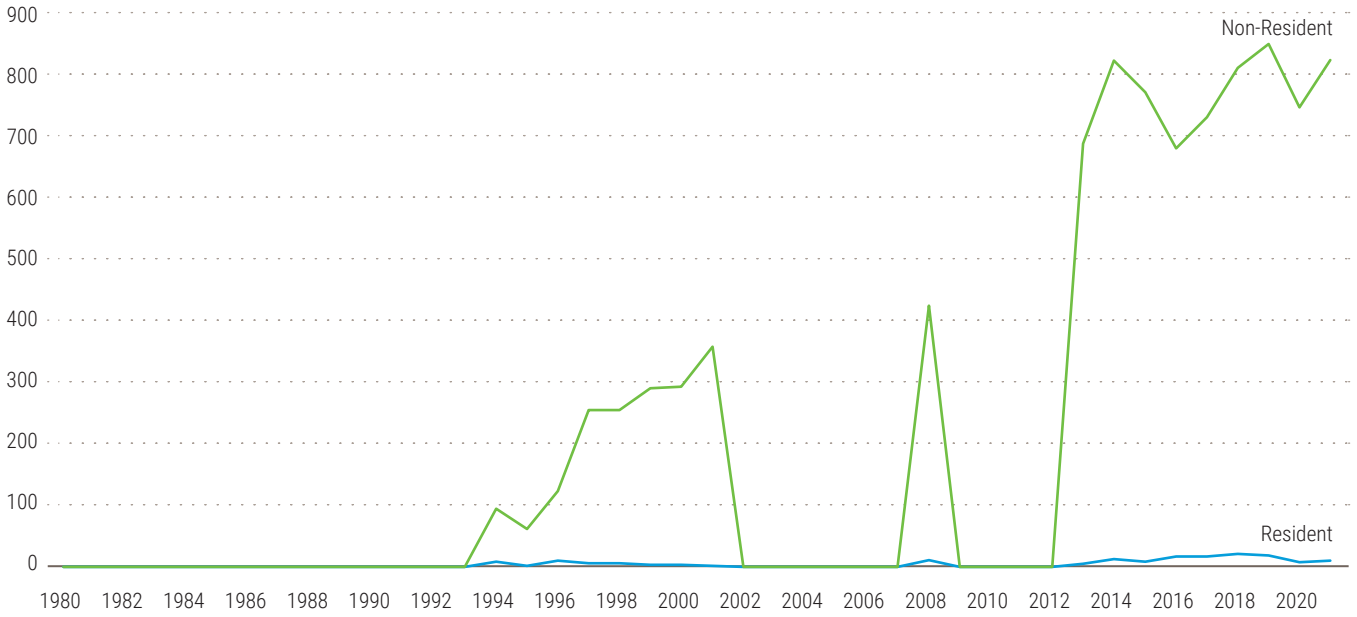
38 The Patent Cooperation Treaty provides a uniform system administered by WIPO for filing patent applications in multiple territories through a single application.

39 ibid, p.16.

40 Republic of Zambia, National Industrial Policy 2018. Available from https://www.zda.org.zm/wp-content/uploads/2020/09/National-Industrial-Policy.pdf.

Figure 8

Patent applications filed in ARIPO, 1980-2021 (number of ARIPO member resident and non-resident applications)



Source: WIPO IP Statistics Database.

dominant technology sectors in terms of patent grants in ARIPO members are pharmaceuticals, organic fine chemistry (associated closely with pharmaceuticals), and basic materials chemistry (also related closely to pharmaceuticals) with the share of 19.8, 15.3 and 8.8 per cent out of total technologies in which the patents are granted. While the overall patent filing in Zambia declined after 2005, grant of patents in these technology sectors has increased during this period, with pharmaceuticals being the largest technology sector in terms of patents granted by ARIPO between 2005 and 2021. None of these patents seem to be of Zambian origin. Thus, the biggest impact of patenting activity in ARIPO is on the chemicals and pharmaceuticals sector, which comprises almost 37 per cent of all granted patents by ARIPO. The MedsPaL database shows a number of patents have been granted in Zambia on antiretroviral drugs, as well as drugs for treatment of TB, COVID-19, and URT.

A primary challenge for Zambia, given the proliferation of premature deaths due to HIV-AIDS, malaria, and tuberculosis, is facilitating affordable access to essential medicines. HIV-AIDSrelated complications are the second principal cause of death in Zambia, after malaria. The demand for more and cheaper antiretrovirals (ARVs) is high. There are 10 registered pharmaceutical manufacturing companies in Zambia, seven of which are undertaking full manufacturing while three are involved in repackaging of finished pharmaceutical products. The seven manufacturing companies are mostly engaged in the production of generic small and large volume parenteral, oral solid dosage forms, liquid dosage forms, powders, external preparations and medical supplies. It is estimated that local production represents between 10–15 per cent of the demand for pharmaceuticals in Zambia. Most of these manufacturing companies are engaged in the manufacturing of basic pharmaceutical formulations (finished medicines). The majority of essential health drugs are still being imported. In 2022 the Zambian Government launched the

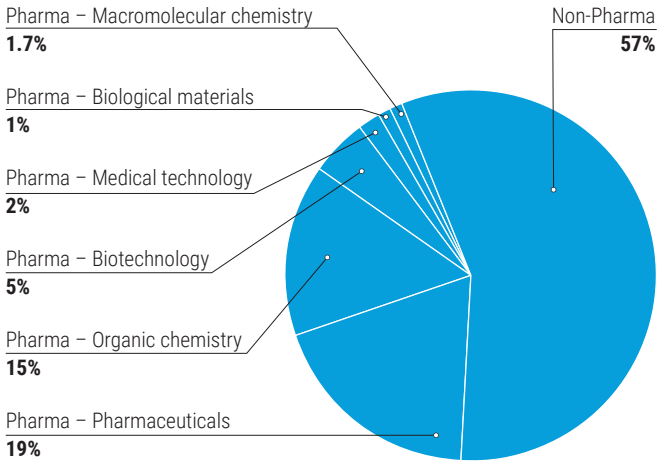
Zambia Pharmaceutical Manufacturing Initiative with the objective of strengthening local pharmaceutical manufacturing.[41]

In this context, the major impact of the loss of LDC-specific flexibilities will be with regard to the development of the local pharmaceutical industry, given that the majority of the LDC-specific flexibilities are related to the pharmaceutical sector. If the transition period for LDCs were to be available after graduation, Zambia could have excluded the pharmaceutical sector from the scope of patent protection and support the development of the local pharmaceutical industry. Even in the case of pharmaceutical patents granted by ARIPO, if the LDC specific transitional waiver had been applied by Zambia, it could have refused to recognize the patent grant decisions by ARIPO within the stipulated time frame for such notification provided in the Harare Protocol. However, following graduation Zambia will have to pursue the objective of development of a local pharmaceutical industry while providing patent protection to foreign pharmaceutical companies. It will also not be able to reject any pharmaceutical patent granted by ARIPO merely on the ground that such patents are excluded from the scope patent protection.

Although Zambia does not exclude pharmaceutical products from patent protection as an LDC, and it will not be able to do so after graduation, it adopts a strict approach towards patenting of pharmaceutical products and excludes "new uses of a known product, including second use of a medicine" from patentability.[42] Such exclusion of a type of pharmaceutical product can be done even after LDC graduation. However, a major impediment in application of this strict

Figure 9

Patent grants by ARIPO in different technology sectors from 1986-2021 (percentage of patents granted)



WIPO IP Statistics Database.

standard by Zambia could arise in the context of patents on pharmaceutical products granted by ARIPO. A review of the type of patents granted by ARIPO shows that ARIPO is open to granting secondary patents,[43] contrary to the strict approach provided in the Zambian law.

Therefore, while approaching LDC graduation, Zambia should strengthen the patent examination capacity in its intellectual property office so that it is able to apply rigorous standards in examining patent applications and adopt examination guidelines in specific technology sectors such as pharmaceuticals, where patenting activity can create entry barriers for local generic pharmaceutical manufacturers. In this regard, Zambia could also pursue reforms in the examination standards pursed by ARIPO.

41 Xinhua, "Zambia to boost manufacturing of pharmaceutical products", 20 October 2022. Available from https://english.news.cn/20221021/8796767b9d7e4c779c57b3e960bcf1f1/c.html#:~:text=Launched%20under%20the%20theme%20%22Strengthening,dependence%20on%20imported%20pharmaceutical%20products.

42 Section 17 (e).

43 Sashikant, *supra* note 23.

4. Conclusions and Recommendations

In the context of the prospective graduation of Cambodia, Djibouti, Senegal and Zambia from the category of least developed countries and the implications of the consequent loss of the flexibilities specifically available to LDCs under the WTO TRIPS Agreement, this study has found that none of the LDCs that are the focus of this study have made use of the general transition period available under article 66.1 of TRIPS. Moreover, among these countries, only Cambodia has made use of the transition period waiving obligations to extend patent protection and protection of undisclosed information for pharmaceutical products as stipulated in the TRIPS Agreement until 1 January 2033. This means that even before their graduation, all these LDCs grant patent protection in all fields of technology as mandated under article 27.1 of TRIPS, apart from Cambodia which excludes pharmaceutical products from patent protection. The extent of patenting activity in these countries, except for the pharmaceutical sector in Cambodia, will remain much like it is at present after graduation from the LDC category.

Besides the transition period available to LDCs, another consequence of graduation in terms of LDC-specific provisions in TRIPS will be the end of any obligation under article 66.2 of TRIPS for developed countries, to provide incentives to enterprises or institutions in their territories for transfer of technology to LDCs. However, current reporting of implementation of this obligation by developed countries shows that many of the initiatives or schemes reported in the various submissions made to the TRIPS Council in this regard are not specific to LDCs. Indeed, many non-LDC developing countries are also beneficiaries of the reported initiatives. Moreover, most of the reported initiatives are not specific incentives aimed at firms or institutions in developed countries to transfer proprietary technologies to LDCs, but are broader technical assistance and capacity-building activities for individuals and institutions from developing countries and LDCs. Article 66.2 of TRIPS has not been appropriately implemented by developed countries and hence its continued non-availability to LDCs will not have any different implications for LDCs.

With regard to the flexibility available to LDCs to use article 31 bis of the TRIPS Agreement to import a patented medicine or vaccine without having to notify its intent to use the system, the implication of the loss of this flexibility will be minimal. An LDC desirous of using the system to import medicines can issue a general notification of its intention to use the system to comply with this requirement. In practical terms, if a graduated LDC seeks to use the system, it will have to overcome the systemic impediments that have led to only one instance of use of the system since its inception.

Therefore, the most significant impact for these LDCs will be in those sectors where there is a high level of patenting activity. The TRIPS transitional waiver under article 66.1 would have allowed the respective LDCs to exclude technology sectors where there is high patenting activity by foreign patentees for the development of local manufacturing in those sectors. Most of the LDCs have not applied the transitional waivers. Patent applications and grants of foreign

origin predominate across technology sectors in the countries under analysis. The highest levels of patenting activity with a dominance of foreign patentees are in the chemicals and pharmaceuticals sector in Senegal and Zambia, based on data on patent applications and grants by the OAPI and ARIPO of which Senegal and Zambia respectively are members.

The dominance of foreign patent applications and grants in the pharmaceuticals sector shows that the most significant impact in terms of patenting activity in Senegal and Zambia will be in the pharmaceutical sector. In both countries, development of a strong and competitive local pharmaceutical industry has been identified as a matter of policy priority. However, the existence of patents held by foreign firms can enable the patentees to create entry barriers for local generic manufacturing.[44]

Even though Cambodia has made use of the TRIPS transition period to exclude pharmaceutical products from the scope of patent protection, it has still allowed the filing of patent applications on pharmaceutical products during the transition period under a mailbox system. However, there is no obligation under TRIPS for any LDC making use of the transition periods to establish a mailbox system. The MedsPaL database indicates that a number of patent applications on pharmaceutical products have been filed in Cambodia. These applications could lead to a patent grant soon after the end of the transition period upon the graduation of Cambodia.

Among all the focus countries, Djibouti has the lowest scale of patenting activity even though it has not used the TRIPS transition period for LDCs. This is reflective of the low technological base of Djibouti to address which flexibilities, such as the transition period is provided in the TRIPS Agreement. While this flexibility will be lost upon the graduation of Djibouti, it will continue to have the challenge of overcoming a low technological base. This challenge will be compounded by the lack of flexibility to adjust the level of IP protection after graduation.

A common challenge for all the countries in focus in this study is that they have very limited capacity to undertake rigorous patent examination. Djibouti does not conduct substantive examination of patent applications unless the grant of patent is opposed after publication of the application. Cambodia has allowed grant of patents through validation of corresponding patents granted by foreign patent offices and has entered into validation agreements with foreign patent offices, such as the European Patent Office. Senegal and Zambia rely on patent examination undertaken by OAPI and ARIPO, which themselves have very limited examination capacity. OAPI also does not conduct substantive examination but grants regional patents by relying on search and examination results of corresponding applications by EPO, and is also negotiating a validation agreement with EPO. This limited capacity increases the likelihood of proliferation of patents applied for, which can curtail the freedom to operate for local industries in technology sectors covered by granted patents, such as pharmaceuticals.

In order to mitigate the loss of the currently available policy space under TRIPS after their graduation, which will compel these countries to extend patent protection to pharmaceutical products, it is imperative that in preparation for graduation they ensure they have the legal provisions in their national laws and regulations to make full use of the flexibilities under TRIPS that will continue to be available to them. The following suggestions are made in respect of the focus countries in this study in this regard.

44 See Richard Gerster, "Patents and Development: Lessons from the Economic History of Switzerland". Available from http://www.gersterconsulting.ch/docs/TWN_Patents_and_Development.pdf.

4.1. Cambodia

While Cambodia allows filing of mailbox applications for pharmaceutical patents currently, there is no obligation on Cambodia under TRIPS to grant patent protection to such applications at the end of the transition period. Therefore, in the period leading to her graduation, Cambodia should consider adopting appropriate legal amendments or other measures to exclude grant of patents on the basis of mailbox applications and limit the grant of patents only to new applications filed after the end of the transition period.

Cambodia is also likely to experience a surge in new pharmaceutical patent applications, including applications for second use claims over patent applications in the mailbox that are nearing the end of their term from the priority date. To deal with the possible surge in such applications, Cambodia should utilise the period leading to graduation to expand its patent examination capacity with regard to pharmaceutical products and processes, and adopt examination guidelines that apply a strict approach towards grant of secondary patents, consistent with the TRIPS Agreement.

Cambodia should also reduce its dependency on patent grants through the validation of grant decisions taken by foreign patent offices. Accordingly, Cambodia should revise patent cooperation or validation agreements with such foreign patent offices and at least exclude pharmaceutical patent claims from the scope of such agreements.

4.2. Djibouti

Djibouti does not make use of the TRIPS transition period and allows the grant of patents in all fields of technology. However, the level of patenting activity is very low and it is likely to remain so at the time of LDC graduation. Djibouti does not undertake substantive examination of patent applications unless an application is opposed by a third party. Leading up to graduation, Djibouti should seek to build its patent examination capacity in order to apply a policy of substantive examination of all patent applications. Technical assistance in this regard may be requested from relevant intergovernmental organizations that provide such support to developing countries to establish and expand their patent examination capacities. Djibouti should also consider revising its industrial property law to make use of certain flexibilities that are not included in the scope of the existing law, e.g., research exception, regulatory review (Bolar) exception.

4.3. Senegal

Senegal's intellectual property law and policy is determined by the provisions of the revised Bangui Agreement, and the grant of patents made thereunder by the regional patent office, OAPI. Senegal will need to make full use of the TRIPS flexibilities that will continue to be available to it as a WTO member after its graduation. However, the scope of application of such flexibilities will be determined by the provisions of the revised Bangui Agreement and the patent examination practices of OAPI. The entry into force of the 2015 Act of the Bangui Agreement allows OAPI members, including Senegal, to take advantage of a number of TRIPS flexibilities. Senegal will have to put in place legal and institutional arrangements necessary to implement such flexibilities. For example, Senegal could adopt legislation to operationalize the transition period available for pharmaceutical products until its graduation. Domestic law could also be adopted to expand the grounds on which a compulsory license can be granted, including public health and anti-competitive grounds. Domestic laws and regulations could also be adopted to institute streamlined and user-friendly administrative procedures for the grant of compulsory licenses. Senegal could also pursue further reforms within OAPI to introduce substantive patent examination as a requirement for the grant

of a patent, in order to thoroughly assess the merits of all patent applications, particularly for pharmaceutical and related products and processes.

4.4. Zambia

Zambia grants patents in all fields of technology and therefore does not use the transition periods that are available to LDCs. Patents can be obtained through direct applications in the Zambian IP office or through regional patent applications through the ARIPO office. While information on patent applications by technology sectors in Zambia is lacking, there is significant increase in patent applications filed through ARIPO and that the majority of patents in force in Zambia are granted through ARIPO. The pharmaceutical sector is the leading technology sector in terms of patents granted by ARIPO. Extrapolating this trend to Zambia suggests that the major impact of patenting activity in Zambia will be in the pharmaceutical sector. While Zambia adopts a strict approach towards the patentability of pharmaceutical products and excludes secondary patents, it has very limited examination capacity to conduct rigorous search and examination. Consequently, it is reliant on ARIPO, which applies a permissive approach towards secondary patents. Even though Zambia seeks to limit the grant of secondary patents, its ability to ensure the consistency of a decision by the ARIPO office, regarding a secondary patent with the Zambian law within a limited timeframe (6 months), is constrained by its limited examination capacity. Therefore, it will be critical for Zambia to expand the patent examination capacity in its national IP office, and strengthen the examination standards applied by ARIPO.


United
Nations