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ACCESS TO MEDECINES IN BURKINA FASO UNDER THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS AND THE ECONOMIC PARTNERSHIP AGREEMENT.

SUBMITTED IN PARTIAL FULFILMENT OF THE LLM IN INTERNATIONAL TRADE AND INVESTMENT LAW IN AFRICA (TILA)

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DECLARATION

I, **Bertille Charlotte N. T. OUÉDRAOGO**, declare that this mini dissertation is wholly my own work except for references specifically indicated in the text. This mini dissertation is hereby submitted for the award of Legum Magister (LL.M) in International Trade and Investment Law in Africa at the International Development Law Unit, Centre for Human Rights, Faculty of Law, University of Pretoria. It has not been previously submitted for the award of a degree at this or any other tertiary institution.

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Bertille Charlotte N. T. OUÉDRAOGO

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LIST OF ABBREVIATIONS

ACP –African, Caribbean, and Pacific countries

CBD –Convention on Biological Diversity

CAMEG –Centrale d'Achat des Médicaments Essentiels Génériques

DGPML –Direction Générale de la Pharmacie, du Médicament et des Laboratoires

GDP – Gross Domestic Product

EAC – East African Community

EDF –European Development Fund

EEC –European Economic Community

EU – European Union

ECOWAS –Economic Community of West African States

EPA – Economic Partnership Agreement

GATT–General Agreement on Tariffs and Trade

HIPC –Heavily Indebted Poor Country

IMF – International Monetary Fund

IP – Intellectual Property

IPRs – Intellectual Property Rights

LDCs – Least-Developed Countries

OAPI – Organisation Africaine de la Propriété Intellectuelle

OCT –Overseas Countries and Territories

OHADA – Organisation Africaine pour l'Harmonisation en Afrique du Droit des Affaires

PNDS –National Health Development Plan

PPPs – Public-private Partnerships

R&D – Research and Development

SADC –Southern African Development Community

TRIPS –Trade-Related Aspects of Intellectual Property Rights

USD – United States Dollar

WAEMU –West African Economic and Monetary Union

WAHO–West African Health Organisation

WHO –World Health Organization

WTO – World Trade Organization

GLOSSARY

Burkina Faso: Proper noun made up of two particles, each from a national language of the country under study. Mooré and Dioula. "Burkina" comes from Mooré, the language of the country's majority ethnic group (53% of the national population speaks it, and five million people speak it across Africa in countries such as Mali, Ghana and Côte d'Ivoire), the Mossi.[1] Burkina means "integrity". "Faso" is a Dioula word (the second most spoken national language in the country) composed of "fa", "my father" and "so", "home/nation", and literally means "my father's nation" or "fatherland".[2] Thus, Burkina Faso means "Homeland of men of integrity". The name was chosen under the presidency of Thomas Sankara on August 4, 1984.

Burkinabè: A word derived from the marriage of two expressions from two of Burkina Faso's national languages, Mooré and Fulfuldé, the country's third most widely spoken national language.[3] Burkina", meaning "integrity", and "Bè", a Fulfulde suffix meaning "from...", or "originating from". The word "Burkinabè", which designates the inhabitants of Burkina Faso, is therefore not a French word and does not normally obey the ordinary rules of adjective agreement applicable to the French language. The word burkinabè is therefore invariable and never takes a silent "e" or an extra "s", even when it designates a female person or a group of several people. Burkinabè means "from the land of men of integrity" or "man of integrity".

Decentralization: Decentralization is a system of political governance that consists in transferring part of the State's powers to legal entities governed by public law that are distinct from the State. This political system is widespread in Europe and French-speaking Africa.

Patent: Exclusive right conferred on an invention. It protects the creator or inventor for a period determined by law, generally twenty years.

[1]Burkina Faso Demolinguistic data BURKINA FASO (ulaval.ca) (accessed on 14 September 2023).
[2](n1).
[3](n1).

Pharmacopeia: These are traditional herbal remedies concocted by the local populations of a given region. This is why they are often referred to as traditional pharmacopoeia.

KEYWORDS

Burkina Faso - European Union - Intellectual property Rights - Patent - Access to medicines - Economic partnership agreement- TRIPS - Doha Declaration - Flexibilities- OAPI.

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ABSTRACT

Cooperation between the European Union and Burkina Faso began several decades ago. Trade relations between the two partners are significant, with the European Union representing Burkina Faso's third-largest economic partner. Negotiated under the aegis of ECOWAS, the Economic Partnership Agreement signed in 2014 between the West African states and the European Union will govern relations between the European Union and Burkina Faso once it comes into force. With this in mind, this study sets out to analyze the impact of this agreement in a key area: access to medicines. The study takes into account both the TRIPS agreement and the EPA, because according to the Cotonou Agreement, which precedes and justifies the EPA, the TRIPS agreement is the reference in terms of intellectual property rights. As a least-developed country and signatory to the TRIPS agreement, Burkina Faso has access to numerous flexibilities that may enable it to adopt health policies favorable to its situation. With regard to access to medicines, the TRIPS agreement states that patents protect inventors. There is a clear link between intellectual property and access to medicines. There are two opposing viewpoints on this subject. One is that there is a direct link between a weakened patent system and access to medicines, while the other is that patentability needs to be strengthened to encourage drug research. After an in-depth presentation of the main flexibilities of the TRIPS Agreement, this study will determine which one is suitable for Burkina Faso and which may be difficult to apply given the country's lack of resources. After studying the case of other least developed countries in Africa, an appropriate course of action will be proposed to the EPA to facilitate access to medicines in Burkina Faso.

Finally, the conclusion of this research will be to make proposals along the same lines that Burkina Faso could apply at national level, but also with the help of its collaborators such as the EU, under the aegis of the EPA.

CHAPTER ONE
GENERAL INTRODUCTION

1.1 Introduction of the research subject matter

Burkina Faso faces significant difficulties in accessing affordable medication due to the expensive nature of patented drugs and the limitations imposed by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

In the spirit of aligning itself with the benefits of regionalism and international integration,[4] Burkina Faso is included in regional groupings that are both geographical and based on common interests. This sub-Saharan country in the western part of Africa, with a population of twenty-two million and a gross domestic product (GDP) of 19.74 billion dollars,[5] is also a member of the Economic Community of West African States (ECOWAS).[6]

It is worth noting that the European Economic Community (EEC) initiated relations with African countries well before they achieved independence.[7] This was done through a collaborative strategy with the goal of achieving gains and rewards for both parties involved.[8] As stated in M Hunt's book "The World Transformed: 1945 to the Present," this interaction marked a significant milestone towards building a relationship between Europe and Africa that was mutually beneficial. Following such a conceptual vision of future relations between the parties, the European Treaty of Rome created the European Development Fund (EDF) in 1959 to financially support the cooperation of European countries with the African, Caribbean, and Pacific (ACP) countries[9] and the Overseas Countries and Territories (OCTs).[10] Through cooperative efforts, development has been at the forefront of the European Union and Burkina Faso's relationship. Burkina Faso has also collaborated with other States and groups, often under the umbrella of West Africa or ECOWAS. Similarly, the member States of the European Union often operate under the

[4] JDHavemanet *alInternational integration and growth: a survey and empirical investigation* (1998)
[5] Tableau de bord statistique de l'économie et des finances, Ministère de l'économie, des finances et du development du Burkina Faso, 2021.
[6] Lagos treaty, 1975.
[7] Treaty of Rome.
[8] M Hunt *The world transformed: 1945 to the present* (2017).
[9] Organization created by the Georgetown Agreement, 1975: Glossary:African, Caribbean and Pacific (ACP) - Statistics Explained (europa.eu) (accessed on 22 June 2023).
[10] Overseas Countries and Territories | EEAS (europa.eu) (accessed on 22/06/2023).

guidance of their supranational organization; in so doing, the Lisbon Agreement forms the legal basis for their action.[11] In the 1960s, the European Economic Community (EEC) signed two agreements in Yaoundé with African States, the first with Madagascar and the second with Mauritius. The agreements established a free trade agreement between the countries of the EEC and the African countries that signed them. This paved the way for the Lomé Conventions that followed.[12]

The Lomé Conventions aimed to regulate economic cooperation between a larger number of members, including the European Economic Community and the African, Caribbean, and Pacific countries. The main characteristic of the conventions was the asymmetrical relationship between the parties.[13] At the instigation of the United States of America and in the Banana case,[14] the Appellate Body of the World Trade Organisation (WTO) considered and ruled in 1996 that the Convention violated WTO rules, in particular the most-favored-nation treatment rule.[15] Consequently, in June 2000, a new agreement was signed in Cotonou, Benin, between the European Union and the ACP countries. The Economic Partnership Agreement (EPA), which came into force in 2003 and has since been revised three times,[16] is specifically presented on paper as a means of eradicating poverty in the ACP countries and enabling them to participate effectively in the global economy while achieving sustainable development.[17] Given its objective and its programme, the relevance of the EPA seems obvious: in 2000, sub-Saharan African countries accounted for 61.34% of trade in their GDP. By 2020, this had fallen to 45.41%.[18] Trade is a key factor in the development of African countries, and Burkina Faso is no exception. After a general EPA with all the ACP countries, the European Union embarked on the signing of EPAs more specifically geared towards sub-regions. In 2014, an EPA was signed between the EU on the one hand and the countries of West Africa on the other, to address economic exchanges between the two partners within the framework of a free trade area.[19] It appears that a

[11]Treaty of Lisbon.
[12]There were four Lomé Conventions signed respectively in 1975, 1979, 1985 and 1989.
[13]JFryer*The new Lomé convention: marriage on the rocks but no separation* (1980)
[14]Appellate Body Report, European Communities — Regime for the Importation, Sale and Distribution of Bananas, WT/DS27/AB/R, adopted 25 September 1997, DSR 1997:II, 591.
[15]General Agreement on Tariffs and Trade (GATT), article 1.
[16]2005, 2010 and 2017.
[17]The Cotonou Agreement, article 1.
[18]Reports by the World Integrated Trade Solution.
[19]Economic partnership agreement between the West African States, the Economic Community of West African States (ECOWAS) and the West African Economic and Monetary Union (UEMOA, of the one part, and the European Union and its member States, of the other part.

provisional application is not possible at this time while waiting for the agreement to be implemented, as it requires all ECOWAS countries to become signatories, and Nigeria has delayed signing it.[20]However, it is worth noting that the Cotonou Agreement and the EU-West Africa EPA constitute the legal framework for relations between Burkina Faso and the European Union. The EPAs contain a wide range of provisions covering many aspects of trade. One of these, of particular relevance to this study, is the protection of intellectual property rights.

According to the World Intellectual Property Organization, "intellectual property (IP) refers to creations of the mind, such as inventions, literary and artistic works, designs, and symbols, names and images used in commerce". Consequently, the protection of intellectual property rights refers to the legal and judicial frameworks put in place to ensure that the inventor's rights, *usus, fructus, and abusus* are recognized and protected against any misuse or appropriation by a third party. Intellectual property rights guarantee respect for a person's ownership of their original creation. There are various intellectual property rights. Patents are one of them. A patent is, in all fairness and simplicity, a right to exclude others.[21] It is an intellectual property right that gives its holder, under certain conditions, the exclusive right to use, design or sell an invention. Patents are a protective shield for inventors and creators. Companies file patents to protect the ownership of medicines. Investment impact assessment forecasts predicted that by 2023, the global pharmaceutical industry would be worth 1,000 billion dollars. [22] According to the World Health Organisation, more than 1.5 million teenagers and young adults aged between 10 and 24 - those considered to have their whole lives ahead of them and to be the strongest - died in 2021, at a rate of around 4,500 a day.[23] Life is fragile, and humans in particular are fragile beings. In 2021, the mortality rate in Burkina Faso was 8.96 per thousand inhabitants.[24] Since 2010, advanced malaria has been the leading cause of death in Burkina Faso. In 2015, 23.9% of deaths were caused by this infectious disease. Respiratory infections, malnutrition, HIV/AIDS, sexual transmitted diseases, tuberculosis, non-communicable diseases, and neglected tropical diseases are still among the leading causes of death.[25] It's no secret that having access to affordable medication is incredibly important, especially for

[20]EPA EU-West Africa, article 107.
[21] *Herman v. Youngstown Car Mfg. Co.*, 191 F. 579, 584–85, 112 CCA 185 (6th Cir. 1911).
[22]Report of the Indian Chambers of Commerce and Industry.
[23]Adolescent and young adult health (who.int) (accessed 22 June 2023).
[24]Burkina Faso - death rate 2011-2021 | Statista (accessed 22 June 2023).
[25]Organisation mondiale de la santé, profil sanitaire complet du Burkina Faso (2017).

the people of Burkina Faso. Their lives often depend on it. That is why the provisions set forth by the EPA regarding intellectual property rights are so crucial. The protection regime for rights like patents will have a direct impact on how accessible medicines are, which in turn can have a significant impact on life expectancy. It is worth noting that the EPA is at the forefront of the international trade wagon and is anchored within the World Trade Organization. As a member of the WTO, Burkina Faso is in a unique position to benefit from the EPA's provisions and the protections they provide. In 1995, the WTO proposed the Trade-related aspects of intellectual property rights agreement (TRIPS).[26] The TRIPS appears to be the EPA's reference point for intellectual property rights. Article 46 (1) of the Cotonou Economic Partnership Agreement states that "without prejudice to the positions of the Parties in multilateral negotiations, the Parties recognize the need to ensure an adequate and effective level of protection of intellectual, industrial and commercial property rights, and other rights covered by TRIPS including protection of geographical indications, in line with the international standards with a view to reducing distortions and impediments to bilateral trade." The second paragraph of the same article states that the agreement is subject to TRIPS: "They underline the importance, in this context, of adherence to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) to the WTO Agreement and the Convention on Biological Diversity (CBD)". More generally, the EPA between the EU and the West African states recognizes the need to protect intellectual property rights[27] while organizing, through a *rendez-vous* clause[28] a possibility and a commitment by the member States to "initiate discussions" on the issue of intellectual property protection. The TRIPS Agreement is therefore the cornerstone of intellectual property rights in Burkina Faso and governs access to medicines under the EPA, especially as the existing national intellectual property regime in Burkina Faso is that of the *Organisation Africaine de la Propriété Intellectuelle* (OAPI), which revised its provisions in 1999 to comply with TRIPS. The TRIPS itself builds on the Doha Declaration to give greater precision and clarity to its provisions, while leaving developing and least-developed countries greater flexibility to implement the agreement according to their needs and at an appropriate pace.[29] In 2020, the world was hit by an unprecedented pandemic, making the issue of access to medicines more urgent than ever.[30] At the height

[26]Trade Related Aspects on Intellectual Property Rights (TRIPS).
[27] [article 87, v.]
[28] [article 106, b.]
[29]Ministerial Conference Fourth Session Doha, 9-14 November 2001, Ministerial Declaration.
[30]MBurgan& HQ *WhoWhat is the coronavirus disease: COVID-19?* (2021).

of Covid 19, as companies fought to impose their vaccines, and the race for access was on, with its attendant costs, financing, and other health issues. In Burkina Faso, from 3 January 2020 to 15:20 CEST, 14 June 2023, 22,056 confirmed cases of COVID-19 and 396 deaths were notified to the WHO.[31] As of 18 March 2023, a total of 6,674,010 doses of vaccine had been administered. By 13 June 2023, 13,397,334,282 doses of vaccine had been administered worldwide. The ratio speaks for itself and shows the disadvantage suffered by the least developed countries in terms of access to treatment in what has been a global shock. There will never be a time when access to medicines will not be an issue.

The European Union is Burkina Faso's third-largest trading partner and one of the most important: it is the country's largest export market.[32]It is imperative that both parties come to a comprehensive understanding of the crucial issues at hand, such as the right to heal and the right to live. A proper assessment must be made, considering the legal framework of intellectual property protection that will be applied in any agreement reached. Only then can a fair and just agreement be formed.

1.2 Research problem

The EPA between the European Union and the West African States has not yet been implemented, but as soon as it is, the agreement will be at the heart of the regulation of trade between the parties and, consequently, trade between Europe and Burkina Faso. The mortality rate has exacerbated the precarious standard of living in Burkina Faso, making the country a breeding ground for poverty and dependence on foreign aid. In every country in the world, access to medicines is the key to improving living conditions, especially as the country faces various threats to public health. However, despite the importance of intellectual property rights in the protection of medicines and, at the same time, in access to them, the Cotonou agreement and the EPA are so brief on the subject that it is almost absent. Only one article in the Cotonou agreement refers to intellectual property rights, and all it prescribes is that reference be made to the TRIPS Agreement.[33] But if the TRIPS agreement is the reference, that is also where Burkina Faso should be looking for provisions on the protection of intellectual property rights.

[31]Burkina Faso: WHO Coronavirus Disease (COVID-19) Dashboard With Vaccination Data | WHO Coronavirus (COVID-19) Dashboard With Vaccination Data (accessed on 22 June 2023).
[32]Burkina Faso - Market Overview (trade.gov) (accessed on 22 June 2023).
[33]The Cotonou Agreement, article 46.

The TRIPS Agreement provides a legal framework for intellectual property rights, and its implementation through the EPA may have significant implications for access to medicines. Under some of its provisions, member States may have some flexibility to implement the agreement at their own pace or to take measures that allow exceptions or derogations. However, the EPA, which will govern relations between Burkina Faso and the EU, has left room for interpretation and further negotiations on the matter of IP rights, creating a potential loophole. This study therefore aims to provide a comprehensive analysis of the impact of TRIPS and the EPA on access to medicines in Burkina Faso. By examining the legal frameworks and international agreements relating to intellectual property rights and access to medicines, the research seeks to highlight the challenges and potential solutions to ensuring equitable access to medicines in Burkina Faso. There are many areas for improvement in the future EPA negotiations between the EU and West Africa. Intellectual property rules relating to access to medicines include, among others, patents on pharmaceutical products, data exclusivity, as well as TRIPS flexibilities, including compulsory licensing[34], Bolar provisions,[35] and parallel importation, among others.[36] A future EPA that considers the needs of Burkina Faso will enable it to benefit from the advantages and flexibilities of the TRIPS agreement in order to improve public health by facilitating access to medicines. For that reason, access to essential medicines is a major public health concern in Burkina Faso, one of the least developed countries in West Africa.[37]

Interim agreements have been signed with two West African countries pending the implementation of the EPA.[38] These are Ghana and Côte d'Ivoire. Even in the "stepping stone" agreements, there is a visible gap in the area of intellectual property rights.

Therefore, the research problem that this study aims to address is: In its quest for better access to medicines, should Burkina Faso, through the EPA, weaken its intellectual property rights regime, and therefore its patent regime, or should it strengthen it? What are the implications of this choice for innovation and the availability of medicines, and what is the relevance of the TRIPS agreement in this area?

[34]TRIPS agreement, art 31.
[35]TRIPS agreement, art 30.
[36]Doha declaration, art 6.5 (d).
[37]UN list of least developed countries | UNCTAD(accessed on 22 June 2023).
[38]EPA - West Africa | Access2Markets (europa.eu) (accessed on 22 June 2023).

1.3 Research questions

The broad research question which this study will seek to answer is: Under the aegis of the EPA, and relying on the flexibilities of the TRIPS agreement, is it a weakened patent system that Burkina Faso needs for better access to medicines, or rather a strong patent system?

However, in answering the core research question, this study will also address the following collateral questions-

i. What is the position of the TRIPS agreement regarding access to medicines for a least-developed country?

ii. What were the implications of TRIPS at the height of global health issues such AIDS and COVID-19 pandemic when Burkina Faso was fighting for access to medicines and vaccines?

iii. What is the right course of action to enable countries like Burkina Faso to benefit fully from flexibilities and other public health protection measures provided for under the TRIPS provisions of the EPA? For that matter, does Burkina Faso need the EPA in its fight for access to medicines, or is its current regime (that of the OAPI) more than sufficient?

iv. How can policymakers and stakeholders address these questions to ensure access to essential medicines for the country's population?

1.4 Thesis statement

This study will explore the implications for a State of TRIPS flexibilities and their potential inclusion in the EPA agreement. The challenges facing Burkina Faso in terms of access to essential medicines and the impact of TRIPS and EPA implementation on the country's public health sector will also be analyzed. When it comes to access to medicines, research and innovation are key factors. It will therefore be argued in the research that for Burkina Faso to derive maximum benefit from an intellectual property rights protection regime, this regime must encourage inventors by protecting their rights. A strengthened patent system will encourage the production of the medicines Burkina Faso needs, and some of the flexibilities offered by the TRIPS Agreement will help make these medicines affordable.

Through legal and policy analysis, this topic aims to contribute to a better understanding of the legal challenges and opportunities related to intellectual property rights and access to medicines in Burkina Faso and to provide recommendations for policy and practice in this area.

1.5 Justification of the study

Burkina Faso is an important economic partner of the European Union. This importance increases when trade is based on regional agreements. The well-being of the country is a matter of survival.[39] Diseases, epidemics, and pandemics generally begin in one geographical area before spreading elsewhere.[40] Health is a global issue. The EPAs' mandate is to ensure the sustainable development of ACP countries. There can be no development, let alone sustainable development, in a country where people are dying because they cannot afford to buy medicines. Many factors affect the supply of medicines and, although regulation of intellectual property rights is necessary, the downside is that essential health products become very expensive. In addition to market knowledge about the price and supply of medicines and forecasting demand, other factors need to be considered, including global coordination between governmental and non-governmental agencies, local production opportunities in low- and middle-income countries, the capacity and available budgets of the healthcare system and regulatory capacity. While factors such as local production, regulatory capacity and available healthcare system capacity are important, the use of "flexibilities" through exemptions and the granting of certain benefits in the TRIPS agreement play a key role in promoting the global and regional availability of essential medicines. This study argues that West African states in general, and Burkina Faso in particular, must ensure that future economic partnership negotiations include rules that will serve member States in their quest to resolve these issues, particularly those in the African bloc who have far less access to medicines.

The Agreement on Trade-Related Aspects of Intellectual Property Rights is a legal instrument that defines minimum standards for the protection and enforcement of intellectual property rights. It has a major impact on access to medicines, particularly in developing countries like Burkina Faso, where many people do not have access to essential

[39]P Englebert *Burkina Faso, Unsteady Statehood In West Africa* (1996).
[40]E Petersen *et al* infectious diseases: geographic guide (2017).

medical goods.[41] The EPA, signed between the EU and the ECOWAS, aims to promote regional economic integration and development. However, the EPA also contains provisions relating to intellectual property rights and access to medicines, which could have significant consequences for Burkina Faso and other developing countries in the region.

Burkina Faso's health situation is unique. Indeed, most of the diseases prevalent in the country require what some call "orphan drugs". This means that research into the development of treatments for these diseases is rare. Burkina Faso must therefore encourage inventors to take an interest in these diseases. A comparative study of the situation in Burkina Faso and other least-developed African countries shows that Burkina Faso should look to TRIPS flexibilities that encourage research. Burkina Faso should not adopt an IPR protection regime that discourages researchers and inventors. It would also be in the country's best interest to encourage local production. This study reveals the strengths and areas for improvement of Burkina Faso's current system for protecting intellectual property rights, before analyzing how the EPA can contribute to better access to medicines in this country. It is considerations such as these that State parties to the EPA must bear in mind when negotiating future intellectual property provisions.

This study will provide findings that will enable Burkina Faso to make the most of international agreements on intellectual property rights such as TRIPS. Recommendations will also be made so that, even at the national level, the country can take initiatives to improve access to medicines. On the basis of these same findings, proposals will be made to ensure that the EU, through the EPA, becomes more aware of the importance of intellectual property in view of the particular challenges facing African States.

1.6 Literature review

Although there is not an abundant literature on the specific case of Burkina Faso in terms of access to medicines under the influences of the EPA and TRIPS, many researchers have examined the relationship between TRIPS and access to medicines in developing and least-developed countries. By analogy, some of this research is also relevant to Burkina Faso.

[41] V Le Mao Circuit du médicament essentiel générique au Burkina Faso: problèmes de qualité et d'accessibilité, exemple en zone rurale dans le district sanitaire de Léo (2014).

Intellectual property rights (IPRs) have become an increasingly important factor in access to medicines worldwide.[42]

Researchers agree that in low- and middle-income countries such as Burkina Faso, limited access to medicines is a multidimensional problem. Grabowski HG,[43] et al in "The Role of Patents and Research and Development Incentives in Biopharmaceutical Innovation" go on to cite financial limitations, state dependence on external aid, and infrastructure challenges, among others.

In the same vein, Watal J[44] points out that when we talk about access to medicines, we are not just talking about their availability in the market, but also their affordability. His reasoning is as follows: it's not just a question of inventing drugs, but also of having the financial means to buy them.[45]

Soyeju and Wabwire then go further denouncing the fact that many countries seem to be linking intellectual property to lower drug prices. Thus, according to this trend, a weakened patent system will reduce companies' monopoly on research and lead to lower drug costs. According to Soyeju and Wabwire, such an approach is counter-productive in terms of access to medicines.[46]

In addition, other researchers, Pedro Roffe, Geoff Tansey, and David Vivas-Eugui,[47] in their book "Negotiating Health: Intellectual Property and Access to Medicines", examine the role of IPRs in access to medicines, particularly in developing countries. They argue that IPRs have been used, for example with the extension of patent rules for pharmaceuticals, to restrict access to essential medicines and that a more balanced approach to IPRs is needed to ensure access to medicines for all.[48]

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[42] Pedro Roffe *et al* 'Negotiating health: intellectual property and access to medicines' (2006).
[43] Grabowski HG *et al* 'The role of Patent and Research and Development Incitatives in Biopharmaceutical Innovation' (2015), *Health Affairs*.
[44] J Watal 'Access to Essential medicines in Developing countries: Does the WTO TRIPS Agreement Hinder it?' (2000) *Science, Technology and Innovation Discussion Paper No. 8, Center for International Development, Harvard University*, Cambridge, MA, USA.
[45] (n 44).
[46] O Soyeju and J Wabwire 'The WTO-TRIPS flexibilities on public health: a critical appraisal of the East African Community Regional Framework' (2018) *World Trade Review.*
[47] (n 42).
[48] (n 42).

Peter Drahos,[49] argues that intellectual property rights such as patents have created significant challenges for developing countries seeking to ensure access to essential medicines. They have become a tool in the hands of multinationals and cooperation to restrict access to knowledge in the field of health and related technologies. He suggests that the use of flexibilities such as compulsory licensing and parallel importation is necessary to meet these challenges. In the same vein, the African Union suggests that countries use TRIPS flexibilities to promote public health interests.[50]

However, another challenge is to equip the country with the research infrastructure and medical tools it needs to apply the IPR provisions in such a way as to improve access to medicine. The COVID-19 global pandemic has highlighted the difficulties of access to medicines in Burkina Faso, as well as the potential gaps in health protection in the context of intellectual property rights and the TRIPS agreement for least-developed and developing countries. The pandemic has highlighted the importance of ensuring access to medicines during public health emergencies and has increased scrutiny of the role of IPR in limiting access to essential medicines.

Nilay Köleoglu, Laura Agolli, Rriollza Agolli and Senol Celik, in their book "Socio-economic impacts and challenges of Covid-19",[51] have also examined the impact of COVID-19 on access to medicines in a study applicable to Burkina Faso. They argue that the pandemic has highlighted the need for flexible approaches to certain aspects of the trade, particularly in the context of public health emergencies, and that greater coordination is needed between governments and international organizations to ensure access to essential medicines in such emergencies.

Overall, the literature suggests that IPRs and TRIPS have significant implications for access to medicines in a country. The use of flexibilities is essential to meet the challenges posed by IPR and TRIPS, and policymakers should carefully consider the implications of EPAs on access to medicines in Burkina Faso, as depending on the course of action chosen,

[49] Drahos P & Mayne, R '*Global Intellectual Property Rights : Knowledge, access and Development'* Palgrave MacMillan London (2022).
[50] African Union. Roadmap on shared responsibility and global solidarity for AIDS, TB and malaria response in Africa (2012).
[51] Koleoglu, N *et al 'Socio-economic Impacts And Challenges of Covid*-19' (Rating Academy Publishing 2021). https://books.google.co.za/books?id=EoIYEAAAQBAJ&printsec=frontcover&hl=fr&source=gbs_ge_summary_r&cad=0#v=onepage&q&f=false (Accessed on 13 September 2023).

research into pharmaceutical drug production will either be incentivized or discouraged. This study aims to consider the two main currents of analysis of the impact of intellectual property rights on access to medicines: that which tends to defend a weakened patent system, and that which tends to defend a strong patent system. The objective is to prove that, contrary to popular belief, a country like Burkina Faso needs a strong system for protecting intellectual property rights. This will help bridge the current gap in research and innovation.

1.7 Research methodology

This research will use a desk-based study approach involving analysis of international treaties and agreements, national legislation, especially that of Burkina Faso, and existing literature about TRIPS provisions under the Economic Partnership Agreement and their implications for intellectual property rights and access to medicines in Burkina Faso.

The main treaties to be consulted in this study are the TRIPS Agreement, the Cotonou Agreement, the founding text of the EPA between West Africa and the European Union, the Vienna Convention on the Law of Treaties and the Bangui Agreement, which governs Burkina Faso's national intellectual property regime.

It will be followed by a critical analysis of the identified literature. The analysis will involve synthesizing the findings of the research, identifying gaps in knowledge, and highlighting key issues related to TRIPS provisions, intellectual property rights, and access to medicines. The analysis will also explore the potential implications of TRIPS provisions under the Economic Partnership Agreement for Burkina Faso.

This study will also analyze the text of other EPAs signed by the European Union with other regions of Africa and compare them with the provisions of the West African EPA in order to identify the trend in decisions concerning the protection of intellectual property rights.

Furthermore, an analysis of TRIPS provisions and their implementation in other countries could provide a useful reference point for understanding the issues and challenges facing Burkina Faso. This will involve examining the policies and practices of other countries in implementing TRIPS provisions and their impact on intellectual property rights and access to medicines. More specifically, the comparison will be extended in the sense that this

paper will observe the application of TRIPS flexibilities in the least-developed countries of the East African Community to compare the results with the case of Burkina Faso.
The study will search for literature published in English and French, and will include academic journals, books, reports and policy documents, in an approach that is at once descriptive, analytical, comparative and prescriptive, as the conclusion will be made with a summary of the findings and recommendations in line with the subject.

1.8 Limitations of the study

The very nature of the bilateral agreement at the heart of this study determines its scope. Indeed, as the EPA was signed between the European Union and ECOWAS, most of the analyses carried out will also concern the other West African States, before being limited to Burkina Faso. Nevertheless, this study will endeavor to isolate Burkina Faso in its conclusions.
With regard to the content of the research itself, it is important to stress that despite the importance of analyzing the implications of the provisions of the Economic Partnership Agreement (EPA) on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for intellectual property rights and access to medicines in Burkina Faso, this study has limitations due to the lack of up-to-date data and available research on the pharmaceutical industry, the healthcare system and access to medicines in the country under study.

Burkina Faso is a low-income country for which there are few specific studies. The country also has a very weak IT system, making data archiving difficult. As a result, data on the country's pharmaceutical industry, healthcare system and access to medicines is not readily available or reliable, and is often outdated, dating back several years. And even when they are available, most of these data are the result of research by international bodies rather than that of national institutions.

These limitations may have an impact on the generalisability of the study results and on the ability to formulate conclusive recommendations for policymakers and stakeholders in Burkina Faso. However, this dissertation aims to contribute to a better understanding of the legal challenges and opportunities related to intellectual property rights and access to medicines in Burkina Faso and to provide recommendations for policy and practice in this area based on available data and research.

1.9 Overview of chapters

This study aims to analyze the interaction between TRIPS and the EPA and the potential consequences of such a relationship on access to medicines in Burkina Faso. The study will explore the flexibilities offered by TRIPS, the challenges Burkina Faso faces in using them, and what it would take for the EPA to help it achieve greater access to medicines through TRIPS. This study will be divided into five chapters.

The first chapter is an introduction that provides an overview of the research topic, including its importance and the research questions to be addressed. The chapter also presents the methodology used in the study, while providing a detailed background to the EPA, the relevance of the TRIPS agreement to this EPA, its objectives and provisions. It also discusses the concept of access to medicines and its importance for least-developed countries in general.

Chapter Two will begin by justifying the joint reading of the EPA and TRIPS in the context of the present subject. To this end, the articles of the Vienna Convention on the Law of Treaties will be invoked. Next, the chapter will explain the raison d'être of flexibilities in international law, to better understand the essence of TRIPS and its flexibilities, and their role in access to medicines. Finally, it will detail the main flexibilities in the TRIPS agreement that Burkina Faso can potentially use through the EPA.

The third chapter is a case study of Burkina Faso. It gives an overview of the country's pharmaceutical industry, its health system and the availability of essential medicines. It then describes the national health policy in force and presents the various international agreements on intellectual property to which the country is a party. The current national intellectual property regime will be presented, along with the main gaps that the EPA will need to address.

Chapter four consists firstly of an analysis of other EPAs signed by the European Union in the African region, to identify the IP trend; the results will be compared with the West African EPA. Secondly, an analysis of the implementation of the TRIPS agreement in the other least developed countries of the EAC will be carried out to determine what the consequences of the TRIPS agreement might be in the context of the EPA between the European Union and Burkina Faso (under the aegis of ECOWAS), depending on the

approach chosen by the latter.[52] This part will focus on the extent to which some least-developed countries have utilized TRIPS flexibilities and the impact of these flexibilities on access to medicines.

The fifth chapter is the conclusion. It will provide a summary of the study's findings and an interpretation of the results. It will also examine the implications of the study for policy and practice and make recommendations to be applied both nationally and internationally (through the EPA) to improve access to medicines in Burkina Faso.

[52]O Soyeju & J Wabwire ' The WTO–TRIPS Flexibilities on Public Health: A Critical Appraisal of the East African Community Regional Framework'. (2018) *World Trade Review.*

CHAPTER TWO

UNDERSTANDING THE TRIPS FLEXIBILITIES AND JUSTIFICATION OF THEIR INTEGRATION INTO THE EPA FRAMEWORK

2.1 Introduction

The WTO covers and protects a wide range of sectors affecting the national and international interests of its member states.[53] Thus, the treaties signed under the aegis of the WTO are numerous. The Treaty on Trade-Related Aspects of Intellectual Property Rights (TRIPS) protects intellectual property rights. As stated by Patrias and Wendling, when we talk about medicines, we are obviously also talking about inventors.[54] Patents,[55] which are essential to protect inventions such as medicines, are also protected by TRIPS. The TRIPS agreement is special in that it provides for special arrangements[56] that take into account and vary according to whether a member state is developed, developing, or least developed. TRIPS recognizes that not all member states are at the same level of progress; they therefore need different paces to apply the agreement to the best of their abilities and interests.[57] These are known as TRIPS flexibilities.[58]

The question of access to medicines of a country signatory to the TRIPS like Burkina Faso[59] may be based on the treaty's flexibilities, but ultimately, as explained by Correa and Hilty,[60] it's up to the state to decide how to incorporate these flexibilities into its national legislation. This is where the EPA between West Africa and the European Union comes in, governing relations between Burkina Faso and the European Union, one of its main trading partners,[61] including in the field of health, and by extension medicines.

[53]V Chemutai and H Eschait, 'Mesuring World Trade Organization (WTO) Accession Commitments and their Economic Effect' (2017) Journal of International Commerce, Economics and Policy (JICEP), *World Scientific Publishing Co. Pte. Ltd.,* vol. 8 (02) at 1-27.
[54]K Patrias and D Wendling, 'Citing Medicines: The NLM Style Guide for Authors, Editors, and Publishers' (2007) *National Library of Medicines (US)* , chapter 7, Patent.
[55]TRIPS agreement 1994, art 27.
[56]TRIPS agreement 1994, art 1.1.
[57]WTO | intellectual property (TRIPS) - frequently-asked questions (accessed on 13 September 20023).
[58]G Velasquez, 'Access to medicines and intellectual Property: The Contribution of the World Health Organization' (2013) *South Centre* at 5.
[59]WTO | Burkina Faso - Member information (accessed on 13 September 2023).
[60]CM Correa and R M Hilty *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual property Law* (2022) *Springer* 2.
[61]The European Union and Burkina Faso | EEAS (europa.eu) (accessed on 13 September 2023).

This chapter will begin by explaining the philosophy of TRIPS in general terms, before analyzing the logic of flexibilities and their relevance in a treaty. Next, the cross-reading between EPAs and TRIPS in terms of access to medicines in Burkina Faso will be justified. The chapter then presents the main TRIPS flexibilities and their importance in facilitating a country's access to medicines.

2.2 General context justifying the existence of the TRIPS agreement and subsequent Declarations and amendments related to access to medicines

The TRIPS Agreement is a cornerstone of the framework of international treaties operating under the auspices of the World Trade Organisation (WTO). Conceived during the Uruguay Round negotiations in 1994, this agreement establishes a comprehensive set of rules and standards designed to safeguard and enforce intellectual property rights worldwide. Its scope extends to a wide range of areas of intellectual property, including patents, copyright,[62] trademarks,[63] trade secrets,[64] etc.

The TRIPS agreement has an essential social dimension that underpins its fundamental philosophy. This dimension has been brought to the forefront of international discourse, particularly in the context of access to medicines, especially for nations with limited economic resources.

In 2001, the WTO took a crucial decision on patents and public health, commonly known as the "Doha Declaration on the TRIPS Agreement and Public Health".[65] This landmark decision recognized the sovereign rights of WTO member states to take measures to safeguard public health and facilitate access to medicines, even if such measures required the temporary suspension of patent protection in specific circumstances.

In 2017, an important amendment [66] to the TRIPS agreement gained prominence, reinforcing its relevance in light of Sustainable Development Goal number 3,[67] which is access to healthcare, notably through the prevention of curable diseases. This amendment

[62]TRIPS agreement 1994, art 19.
[63]TRIPS agreement 1994, art 15.
[64]TRIPS agreement 1994, art 39.
[65] WTO | Ministerial conferences - Doha 4th Ministerial - TRIPS declaration (accessed on 13 September 2023).
[66]WTO | intellectual property (TRIPS) - TRIPS and public health (accessed on 23 September 2023).
[67]S Walker, 'The TRIPS Agreement, Sustainable Development and the Public Interest: Discussion Paper' (2021) *IUCN, Gland,* Switzerland and Cambridge, UK and CIEL at 4.

sought to address an urgent issue concerning access to essential medicines in developing and least-developed countries. Its fundamental objective was to ensure that these nations could obtain affordable life-saving medicines without being hindered by rigid intellectual property regulations.

The 2017 amendment codified and perpetuated the principles and flexibilities enshrined in the 2003 Decision[68] on the enforcement of paragraph 6 of the Doha Declaration directly into the TRIPS Agreement itself. This proactive measure has ensured that these principles and flexibilities will continue to exist, preserving access to essential medicines for those who need them.

This amendment represented a significant step forward in addressing the global issue of access to affordable medicines, and it was widely seen as a positive development in the ongoing effort to improve access to life-saving medicines for those who need them most, particularly in low-income and developing countries.

Furthermore, to underline the social objectives of the agreement, it is essential to recognize that the TRIPS provisions on patentability are intimately linked to the protection of human rights. Indeed, Articles 25 and 27 of the United Nations Declaration of Human Rights explicitly state that the inventor's right to benefit from intellectual property rights and the human right to a decent standard of living are important and mutually reinforcing rights promoted by the United Nations.

Intellectual property rights, including patents, can also be seen as economic rights that enable individuals and organizations to reap the rewards of their creative and innovative efforts. Saha and Bhattacharya even go so far as to say that it is a well-established fact that intellectual property plays a vital role in the modern economy[69]. Indeed, it is imperative to note that when we talk about access to medicines, we are talking about individuals, and patients certainly, but we're also talking about inventors and companies. On both sides of the spectrum, the economic argument is crucial. Individuals need the financial means to obtain medicines, and the people behind the creation of these medicines need to reap the financial rewards of their research and invention.[70] Consequently, safeguarding these

[68] WTO | intellectual property (TRIPS) - Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health (accessed on 13 September 2023).
[69] C N Saha and S Bhattacharya 'Intellectual property Rights: An Overview and Implications in Pharmaceutical Industry' (2011) *National Library of Medicine* 88-93.
[70] Saha and Bhattacharya (n 58).

economic rights linked to intellectual property can be considered crucial to the full enjoyment of human rights, as it can foster innovation, and economic growth, stimulate job creation, and propel societal progress. The TRIPS agreement strives to strike a delicate balance between the interests of innovators and creators by providing legal frameworks that protect their intellectual rights while promoting access to essential medicines, facilitating technology transfer, and advancing knowledge and innovation on a global scale.[71]

It was in consideration of all the above that the WTO established the TRIPS Agreement. Understanding that patent protection and human rights intersect in various ways and recognizing that this relationship can be complex and multifaceted explains the existence of the so-called "flexibilities" in the TRIPS Agreement.

2.3 Philosophy and raison d'être of flexibilities in international law

Treaties often offer a degree of flexibility to Member States, for a number of compelling reasons.[72] Firstly, these flexibilities recognize and take into account the diverse needs and circumstances of participating nations, recognizing that a one-size-fits-all approach is neither practical nor equitable. By allowing a degree of flexibility, treaties take account of the differences between Member States' legal systems, economic capacities, and stages of development. This first justification for the existence of flexibilities in a treaty is that defended by the TRIPS Agreement, which states in its preamble that it is aware of these differences: "Recognizing also the special needs of the 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"...[73]

Secondly, flexibility enhances the ability of a treaty to adapt to changing global conditions, ensuring its sustainability and relevance over time. This ability to adapt becomes particularly crucial when dealing with emerging challenges, such as public health crises or environmental problems, where circumstances can change rapidly. Finally, granting certain flexibilities to Member States may encourage greater participation in the Treaty

[71]TRIPS agreement 1994, art 7.
[72]J Kucik and E Reinhardt 'Does Flexibility Promote Cooperation? An Application to The Global Trade Regime' (2008) *Cambridge University Press* 480-481.
[73]TRIPS agreement 1994, preamble.

agreements. [74] States are more inclined to commit to agreements that respect their sovereignty and allow them to adapt treaty provisions to their particular contexts. In essence, treaty flexibility fosters inclusiveness, resilience and cooperation between diverse nations pursuing common goals.

However, while there are many advantages to including a degree of flexibility in treaties such as TRIPS, there are also inherent disadvantages. One important disadvantage is the risk of inconsistency and ambiguity in the implementation of these treaties. [75] Where Member States have discretion in interpreting and applying the provisions of a treaty, this can lead to diverse outcomes and interpretations, which can undermine the effectiveness of the treaty and the predictability of its implementation. Moreover, excessive flexibilities may allow Member States to exploit or misuse them, exploiting ambiguities in the text of the Treaty to further their own interests or to evade their obligations. Such exploitation can erode trust between the parties and hamper cooperative efforts.[76]

Furthermore, excessive flexibility can dilute the original objectives of the treaty, as concessions made to satisfy various interests could weaken its overall impact. It is therefore imperative to strike the right balance between flexibility and clarity in treaty agreements to ensure an effective response to global challenges while mitigating potential drawbacks.

2.4 Understanding in the EPA of the relevance of intellectual property rights protection for a better access to medicines

The Cotonou Agreement, which precedes and underpins the Economic Partnership Agreement (EPA) between the European Union and West African countries, aims to reduce distortions and obstacles to bilateral trade between the European Union and African, Caribbean, and Pacific (ACP) countries.[77] The protection of intellectual property rights is only briefly addressed in this convention. However, Article 46, paragraph 5, defines the scope of intellectual property and recognizes, among other things, the protection of data and against unfair competition. The protection of intellectual property rights is closely linked to the overall development objective of the ACP States.

[74]L R Helfer 'Flexibility in International Agreements' (2012) *Duke Law Scholarship Repository* 175.
[75]L R Helfer (n 66) 190.
[76]L R Helfer (n 66) 176.
[77]Cotonou Agreement 2000, art 1.

Unlike TRIPS, which recognizes that member states do not have the same level of development,[78] and therefore have the right to apply the treaty to different degrees and at different speeds, the Cotonou Agreement does not distinguish between least-developed countries, developing countries, and developed countries.

While the Economic Partnership Agreement (EPA) between West Africa and the European Union does not yet provide a comprehensive solution to the issue of intellectual property, it does explicitly recognize the vital importance of safeguarding intellectual property rights.[79] In the agreement, both parties expressly recognize the need to protect intellectual property and undertake to negotiate the specificities of intellectual property rights and innovation.[80] The intentions of the EPA between the EU and West Africa regarding intellectual property rights are elaborated in a general exceptions clause[81] and a *rendez-vous* clause.[82] They underline the parties shared commitment to creating an environment conducive to innovation, respecting intellectual property rights, and promoting technological progress in the region. As intellectual property plays an increasingly important role in trade and economic development, these provisions demonstrate the intention of the West African and European parties to engage in serious negotiations on this essential aspect of their partnership.

2.5 Justification for cross reading the EPA and the TRIPS agreement in the present study

The EPA's reference to TRIPS in relation to intellectual property rights is governed by the Vienna Convention on the Law of Treaties.[83] This Convention states that "when a treaty specifies that it is subject to or is not to be considered as incompatible with an earlier or later treaty, the provisions of that other treaty shall prevail".[84] In addition, it states that "when all the parties to the earlier treaty are also parties to the later treaty but the operation of the earlier treaty has not been suspended or terminated under Article 59, the earlier treaty applies only to the extent that its provisions are compatible with those of the later

[78]TRIPS Agreement 1994, preamble.
[79]Cotonou Agreement 2000, art. 46(1).
[80](n 69) art 46(6).
[81]Economic Partnership Agreement EU-West Africa 2014, art 87.
[82](n 69) art 106.
[83]Vienna Convention on the Law of Treaties (1969) (un.org) (accessed on 13 September 2023).
[84]Vienna Convention on the Law of Treaties (1969), art 30(2).

treaty".[85]Therefore, until the EPA resolves the issue of intellectual property rights through the *rendez-vous* clause, the TRIPS Agreement takes precedence over the issue, since all parties to the EPA are also parties to the TRIPS Agreement.

The flexibility shown by the Economic Partnership Agreement (EPA) in its approach to intellectual property rights underlines the latitude inherent in the TRIPS Agreement. The EPA's first demonstration of flexibility lies in its recognition of the power of the parties to define their specific course of action on intellectual property rights within the framework of a broader agreement.[86]This underlines the fact that, within the framework of the TRIPS Agreement and its minimum standards of protection, Member States enjoy substantial autonomy to adapt their legislation and policies to suit their specific circumstances and objectives.[87] In fact, some countries may even choose to go beyond the minimum requirements of the TRIPS Agreement by entering into what are commonly known as TRIPS-plus agreements.[88] The European Union, in particular, is renowned for its participation in such bilateral agreements.[89] For example, the 1999 Free Trade Area between the EU and South Africa[90] stipulates that South Africa must implement "the highest international standards" and exceed the TRIPS threshold for the protection of intellectual property rights. However, in its current form, the EPA is formulated in such a way as to give member states the option of framing the protection of intellectual property, reflecting their different approaches and priorities. The way forward will therefore depend on how the parties approach the issue of improving access to medicines through intellectual property rights.

In the area of access to medicines and innovation, the TRIPS agreement introduces the concept of patents as a central mechanism for protecting and granting rights.[91]

2.6 Historical background to patenting and rationale behind patentability

2.6.1 Historical background

[85] (n71), art 30(3).
[86](n 68).
[87](n 50) 2.
[88](n 50) 2.
[89]J F Morin and J Surbeck ' Mapping the New frontier of international IP Law: introducing a TRIPs-plus dataset' (2020) *World Trade Rev* 19 (1).
[90]MC Lee 'The European Union-South Africa Free Trade Agreement: In whose interest?' (2002) *Journal of Contemporary African Studies.*
[91]TRIPS agreement 1994, art 28.

A patent is a legal and exclusive right granted by a government to an inventor or creator of a new and useful invention.[92] This patent gives them exclusive permission to produce, use, sell, and license their creation for a specified period, usually 20 years from the date of filing.[93] Patents are a cornerstone of intellectual property law and provide powerful incentives for innovation, offering inventors protection and control over their intellectual creations.

The concept of the patent has a rich and varied history spanning several centuries and different cultures. The origins of patent protection go back to ancient civilizations. In ancient Greece,[94] for example, inventors and creators were sometimes granted exclusive rights over their innovations for a specific period. Similarly, in ancient China,[95] inventors could receive government recognition and rewards for their revolutionary inventions. In the Middle Ages, European monarchs and sovereigns began to grant exclusive privileges to individuals for various inventions and commercial activities.[96] These privileges were often granted in the form of royal charters or letters patents, hence the term "patent".[97] It should be noted that this historical limitation on the period of patent coverage in the Middle Ages echoes the current patent system, which generally offers protection for a period of twenty years.

The concept of patents continued to evolve and in 1624 England enacted its Statute of Monopolies, an important step in the progression of patent law.[98] This statute defined the types of inventions eligible for patent protection and introduced a 14 year term for such protection.[99]

When the United States was founded, the framers of the Constitution recognized the essential role of encouraging innovation and creativity. Article I, Section 8, Clause 8 of the

[92] Patents (wipo.int) (accessed on 13 September 2023).
[93] TRIPS agreement 1994, art 33.
[94] M Witty 'Athenaeus describes the most ancient intellectual property' (2017) *School of pure and applied sciences, Florida South Western State College*, Florida, USA.
[95] W Qian ' The Science and Invention in Chinese History' (2009) *University of Shanghai Press* 49.
[96] M Sabattini 'Filippo Brunelleschi, the Medici, the Silicon Valley and Intellectual Property' (2016) (17) Filippo Brunelleschi, the Medici, the Silicon Valley and Intellectual Property | LinkedIn (accessed on 13 September 2023).
[97] Royal grants in letters patent and charters from 1199 - The National Archives (accessed on 13 September 2023).
[98] C Dent 'Generally Inconvenient: The 1624 Statute of Monopolies as Political Compromise' (2009) *Melbourne University law Review* 442.
[99] England Statute of Monopolies 1624, section 6.

US Constitution, often referred to as the "Patent and Copyright Clause",[100] gives Congress the power to grant patents to inventors for a limited time to promote the progress of science and useful arts. In 1790, the first U.S. patent law was enacted, laying the foundation for the modern U.S. patent system. As technology and innovation gained global prominence, international agreements such as the Paris Convention for the Protection of Industrial Property (1883) and the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (1994) contributed significantly to the standardization of patent protection and enforcement across countries.

Today, patent systems are firmly established in most countries of the world, playing an essential role in promoting technological progress and economic development.

2.6.2 Justification for patentability and importance for access to medicines

There are several compelling reasons for the concept of patentability and the introduction of patent systems. Firstly, they provide powerful incentives for innovation[101] by offering inventors a legal monopoly on their creations for the duration of the patent's validity. This exclusivity is a powerful incentive for individuals and companies to invest in research, development, and creation. The prospect of potential profits from their inventions encourages innovation in a multitude of fields, propelling advances in technology, science, and art.

In addition, to obtain a patent, inventors must provide a detailed and complete description of their invention, which is then made public in the form of a patent document. This dissemination of knowledge[102] benefits society by spreading technical information and allowing others to learn from and be inspired by existing innovations, thereby accelerating progress.

Thirdly, a strong patent system can be a driver of economic growth,[103] stimulating innovation and entrepreneurship. Patents enable inventors and companies to obtain financing, penetrate markets, and create jobs. They also attract foreign investment and fuel competition, which can lead to the development of new industries and technologies.

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[100] US Constitution - Stanford Copyright and Fair Use Center (accessed on 13 September 2023).
[101] R Mazzoleni and RR Nelson 'The benefits and costs of strong patent protection: a contribution to the current debate' (1998) *Research Policy* 275-276.
[102] (n 88) 278.
[103] (n 88) 276.

Patents play an essential role in protecting inventors' intellectual property by preventing the unauthorized use, production, or sale of their inventions. This protection is an essential mechanism for inventors and companies to recoup their investments while protecting their innovations from unfair competition and piracy.

Patents also establish a legal framework for dealing with disputes concerning intellectual property rights. This framework serves to prevent disputes and provides inventors with a means of enforcing their exclusive rights in the event of patent infringement.

These patent systems also promote international cooperation and trade by providing a standardized approach to the protection of intellectual property rights across borders. This standardization encourages the exchange of knowledge, facilitates technology transfer, and promotes collaboration between nations.

However, it is essential to emphasize, as will be done throughout this study, that while patents confer exclusive rights on inventors, they are not absolute. Patent laws often contain provisions designed to strike a balance between the interests of inventors and the public interest.[104] These include measures to ensure that patented inventions remain affordable and accessible, particularly in critical sectors such as healthcare and essential technologies.

Article 27.1 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) sets out the criteria for patentability worldwide. According to this provision, for an invention to be eligible for patent protection, it must meet several essential criteria. Firstly, it must be new, i.e. it must not have been publicly disclosed anywhere in the world prior to the patent application. Secondly, the invention must involve an inventive step, which means that it must not be obvious to a person skilled in the relevant field. Thirdly, it must be capable of industrial application, meaning that it can be made or used in some form of industry.

In addition, Article 27 of the TRIPS Agreement prohibits the patenting of certain subject matter, such as inventions contrary to *ordre public* or morality and plant or animal varieties. These criteria strike a balance between encouraging innovation and ensuring that patents are granted for genuinely new and useful inventions while respecting ethical and public interest considerations.

[104](n 47) 307.

Patents cover a wide range of inventions, including new products, processes, machines, chemical compounds, and even specific types of plants. They are generally granted on a national or regional basis, requiring inventors to file a patent application in each country or region where they intend to protect their invention. When the patent expires, the invention falls into the public domain[105] and can be used by anyone, contributing to the advancement of technology and innovation.

The TRIPS agreement, which is part of the World Trade Organisation, often attracts attention because of its provisions, which are known to be aligned with the patent laws of developed countries.[106]According to Jiang this alignment establishes a minimum standard of intellectual property protection that member countries are required to implement,[107] often mirroring the more comprehensive patent laws that prevail in economically advanced countries. As a result, this global treaty has facilitated the harmonization and strengthening of patent laws around the world, sometimes posing challenges for developing and least-developed countries seeking to balance incentives for innovation with concerns about affordable access to essential goods, particularly in the areas of public health and technology transfer.

In the context of the Economic Partnership Agreement between West African countries and the European Union, as in the negotiations that led to the establishment of the TRIPS Agreement, the intellectual property rights provisions resulting from the *rendez-vous* clause would emerge from discussions between developed countries with strong intellectual property protection laws and developing or least developed countries with weaker or non-existent intellectual property protection laws.[108]

The TRIPS Agreement also allows member States to exclude certain subject matter from patentability, including diagnostic, therapeutic, and surgical methods.[109] In Burkina Faso, a member state of the African Intellectual Property Organisation (OAPI), the granting of patents follows OAPI guidelines.[110] This means that individuals or entities wishing to

[105] A Hossam and A El-Saghir 'Patents and Public Domain' (2013) *Third Module Of training of Trainers on the World Intellectual Property Organization (WIPO) Development Agenda* 2-3.
[106] JF Duffy 'Harmony and Diversity in Global Patent Law' (2002) 17 *Berkeley Tech LJ* 685-695.
[107] P Jiang 'Comments, Fighting the AIDS Epidemic: China's Option Under the WTO TRIPs Agreement (2002) 13 *ALB.LJ.SCI.&TECH* 223-229.
[108] (n 93).
[109] TRIPS Agreement 1994, art 27(2) & 27(3).
[110] PCT Applicant's Guide African Intellectual Property Organization - Valid as from 1 Feb 2023 (wipo.int) (accessed on 13 September 2023).

obtain patents in Burkina Faso must go through the OAPI patent application procedure. Under the OAPI Convention, pharmaceutical products are not excluded from patentability,[111] allowing individuals[112] or companies[113] to seek patent protection for their pharmaceutical inventions in OAPI member states, including Burkina Faso.

Although the text of the EPA between West African countries and the EU does not explicitly address access to medicines, the Cotonou Agreement refers to TRIPS as the framework for intellectual property rights, including patents, thus incorporating TRIPS flexibilities and provisions regarding access to medicines in future relations between the European Union and Burkina Faso under the aegis of the EPA.[114]

2.7 TRIPS flexibilities

Under TRIPS, Member States have flexibility to ensure access to medicines, with key provisions such as compulsory licensing, [115] parallel importation, [116] provisions for technology transfer[117] and capacity building, the Bolar provision,[118] transition periods,[119] the mailbox,[120] and data transfer.[121]

2.7.1 Compulsory licensing

Compulsory licensing is a legal mechanism provided for under the TRIPS agreement which allows a government or competent authority to authorize a third party (often a generic drug manufacturer) to produce, use, or sell a patented invention without the consent of the patent holder.[122] This is usually done in situations where public health interests, national emergencies, or other compelling reasons require the widespread availability of a patented product, such as pharmaceuticals, at an affordable price. Article 31 of the TRIPS agreement stipulates that compulsory licenses for patented inventions may be granted under specific conditions. These include the evaluation of applications on a

[111]Bangui Agreement 2015, Annex I, art 2.
[112]Bangui Agreement 2015, Annex I, art 9.
[113](n 99).
[114]Cotonou Agreement 2000, art 46.
[115]TRIPS Agreement 1994, art 31.
[116]TRIPS Agreement 1994, art 6.
[117]TRIPS Agreement 1994, art 62(2).
[118]TRIPS Agreement 1994, art 30.
[119]TRIPS Agreement 1994, art 66(1).
[120]TRIPS Agreement 1994, art(70).
[121]TRIPS Agreement 1994, art(7).
[122](n 102).

case-by-case basis and reasonable efforts to negotiate voluntary licenses with patent holders. Although the treaty does not enumerate the circumstances that may justify the granting of compulsory licenses, it has been recognized since the Doha Declaration that states have the right to use their discretionary power to determine the circumstances which, in their opinion, justify recourse to compulsory licenses, or situations of urgency.

The TRIPS Agreement emphasizes that compulsory licences must strike a balance between the interests of patent holders and those of the public. These licences must be non-exclusive and give rise to adequate remuneration for the patent holder. In addition, TRIPS allows countries to determine the scope and duration of such licences, provided they are consistent with their national laws and international obligations. [123] This provision recognizes the importance of safeguarding intellectual property rights while giving governments[124] the flexibility to ensure access to essential goods, such as medicines, in the event of an emergency or public health crisis.

This approach overcomes patent-related obstacles and promotes the availability of affordable medicines. A notable case of the WTO exercising this flexibility in the interests of member States and global public health occurred on 30 August 2003.[125]

The WTO decision of 30 August 2003 marks an important milestone in the field of intellectual property and trade policy at the global level. This decision concerns the waiver of countries' obligations under a specific provision of the WTO's agreement on intellectual property, the Agreement on Trade-Related Aspects of Intellectual Property Rights. More specifically, it concerns Article 31(f) of the TRIPS Agreement, which traditionally required the production of goods under compulsory license to serve primarily the domestic market.

By temporarily suspending the strict domestic market requirement, this waiver gave member States greater flexibility to produce and export patented medicines, particularly in response to public health emergencies such as pandemics. The WTO's objective was to ensure the wider manufacture and distribution of essential medicines, helping to resolve critical health crises and improving global access to life-saving treatments. This decision

[123](n 102).
[124] C May and SK Sell 'Intellectual Property Rights: A critical history' (2006) *Lynne Rienner Publishers, Boulder*.
[125]WTO | NEWS - Decision removes final patent obstacle to cheap drug imports - Press 350 (accessed on 13 September 2023).

underlined the WTO's commitment to finding a balance between intellectual property rights and public health priorities in cases of urgent need.

In July 2007, Rwanda was the first country to announce its intention to import a generic fixed-dose combination of different drugs from a foreign generic company, a significant step forward in its fight against HIV.[126]

Another notable case of member States exercising TRIPS flexibilities through allowing compulsory licensing occurred at the 12th Ministerial Conference in 2022 (MC12)[127]. During this Conference, a Ministerial Decision on the TRIPS Agreement was taken. This decision enabled WTO members to strengthen their ability to actively promote the diversification of COVID-19 vaccine production and to temporarily circumvent patent exclusivity through a specific waiver, which extends over the next five years. The decision was developed in direct response to the unique challenges posed by the pandemic and was strategically designed to facilitate the expansion of vaccine production capacity.[128]

2.7.2 Parallel importation

Parallel importation is another flexibility granted in the TRIPS agreement.[129] This is the practice of importing genuine products from one market to another without seeking authorization from the holder of the intellectual property rights.

This can happen when the same product is sold at different prices in different regions due to variations in demand, exchange rates, or local pricing strategies.

Let's take the example of a pharmaceutical company that manufactures a life-saving drug and holds the patent. In France, the company sells the drug at a high price because of the high research and development costs involved. However, in a low-income country like Burkina Faso, the same drug is sold at a much lower price to make it accessible to the local population. However, a third-party distributor in Burkina Faso may decide to buy the drug at a lower price in Burkina Faso, and then import it into France at the same time, where it is sold at a much higher price. This practice enables the distributor to offer the drug to French consumers at a lower price than in France, while still making a profit.

[126] JC2049_PolicyBrief_TRIPS_en_1.pdf (unaids.org) (accessed on 13 September 2023).
[127] directdoc.aspx (wto.org) (accessed on 13 September 2023).
[128] Weekly epidemiological update on COVID-19 - 10 August 2023 (who.int) (accessed on 13 September 2023).
[129] (n 103).

The TRIPS Agreement contains guidelines and provisions concerning this practice.[130] It recognizes that parallel imports can help to increase competition and benefit consumers. In addition, it recognizes the principle of exhaustion of intellectual property rights,[131] which means that once a patented product is introduced onto the market by the patent holder or with his consent, his exclusive rights are considered exhausted. This principle allows patented products to be imported and sold without infringing the patent holder's rights.

However, the TRIPS Agreement also allows Member States to set specific conditions and limits on parallel imports.[132] These conditions may be imposed to prevent certain commercial practices that may harm the legitimate interests of right holders, such as trademark counterfeiting or unfair competition. Member countries have the flexibility to adopt measures to regulate parallel imports while balancing the interests of right holders and promoting healthy competition.

In summary, regarding parallel imports, although the TRIPS Agreement recognizes the principle of exhaustion of intellectual property rights, member countries retain the power to impose limitations and conditions to regulate such imports. This regulatory framework aims to protect rights holders against unfair practices while promoting competition.

The value of parallel importation for least-developed countries such as Burkina Faso lies in its ability to allow these nations to import patented medicines from other countries where they are available at lower prices. This practice can help to reduce the high cost of medicines. At the WTO ministerial meeting in November 2001, ministers stated in the Doha Declaration on the TRIPS Agreement and Public Health that countries have the freedom to use parallel imports as they see fit.[133] The member states of the EPA between the West African states and the European Union thus have considerable leeway in deciding whether or not to authorize parallel imports under the agreement. They can make this decision without fear that such a provision will be challenged, as the TRIPS Agreement explicitly states that parallel imports cannot be challenged through the WTO dispute

[130] WTO | Intellectual property (TRIPS) - fact sheet - pharmaceuticals - 2 (accessed on 13 September 2023).
[131] (n103).
[132] (n103).
[133] Doha Declaration 2001, 5(d).

settlement mechanism.[134] This effectively gives countries the autonomy to decide whether or not to allow parallel imports.

2.7.3 Technology transfer and capacity building

The TRIPS Agreement actively encourages technology transfer and capacity-building initiatives to support the indigenous pharmaceutical industries of least-developed countries.[135]These initiatives are essential to strengthen these countries' pharmaceutical sectors and improve access to essential medicines. Article 62.2 of the TRIPS Agreement explicitly obliges developed countries to assist least-developed countries in achieving these objectives. Technology transfer, in particular, plays an essential role in enabling developed countries to acquire the capacity to produce essential medicines locally. This will reduce their dependence on expensive imported medicines and improve access to affordable treatments.

In line with these flexibilities, financial assistance from developed to least-developed countries can help the latter to set up research and development facilities, modernize manufacturing infrastructures, and train personnel in the various aspects of pharmaceutical production, quality control, and regulatory compliance. This aid would help to strengthen the capacity of low-income countries to achieve self-sufficiency in the production of affordable medicines, thereby promoting the long-term viability of healthcare.

Technology transfer would enable least-developed countries to acquire the knowledge and expertise they need to produce medicines locally, thereby reducing their dependence on imported pharmaceutical products.[136]

2.7.4 Price fixing

This study has already recognized that when it comes to access to medicines, as Watal said, accessibility and affordability are two totally different issues.[137] Medicines can be accessible, but in a country like Burkina Faso, it is still necessary to make them affordable for people with very limited purchasing power.

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[134](n103).
[135](n104).
[136] DB Audretsch and others 'Technology Transfer in a global economy' (2012) *Springer Science+Business Media,* New York 305-307.
[137]J Watal 'Access to Essential medicines in Developing countries: Does the WTO TRIPS Agreement Hinder it?'(2000) *Science, Technology and Innovation Discussion Paper No. 8, Center for International Development, Harvard University*, Cambridge, MA, USA 2.

TRIPS does not deal directly with the control or pricing of products protected by intellectual property. The Agreement focuses primarily on establishing minimum standards for the protection and enforcement of intellectual property rights.The pricing of these products is a matter of the national laws and regulations of each country.[138] Member States may adopt measures within their national legal frameworks to address concerns about pricing and access to medicines.

Some countries have implemented legislation or policies to regulate the prices of medicines, promote affordable access to medicines, or use mechanisms such as compulsory licensing to address public health needs.[139]The majority of EU nations regulate the maximum sale price of generic medications (price caps) and establish the maximum reimbursement rate, particularly using reference pricing systems[140]. Similarly, in Burkina Faso, since 2006, a joint order by the ministers of trade and health has allowed the price of essential generic medicines to be set, while leaving a 32% margin to pharmacists.[141]

In addition, the TRIPS Agreement refrains from prescribing a specific type of legislation, leaving countries with a certain degree of autonomy in the way they choose to implement its provisions. This decision reinforced the balance between global protection of intellectual property and considering the unique circumstances and stages of development of individual member states within the WTO framework. The Doha Declaration confirmed this interpretation of the TRIPS Agreement.

2.7.5 The transition period

The transition period gives developing countries a specific deadline to implement certain provisions of the agreement, giving them more time and leeway to bring their national legislation and intellectual property systems into line with TRIPS standards. [142] Recognizing countries' different levels of development, the transition period offers developing countries the space they need to build their capacity to effectively protect

[138](124) 5.
[139]India for instance has a price control system that can reduce medicines price by about 40 per from patent monopoly levels
Microsoft Word - Selvaraj Drug Paper 7.30.07.DOC (harvard.edu) (accessed on 14 September 2023).
[140]J Puig-Junoy 'Impact of European pharmaceutical price regulation on generic price competition: a review' (2010) *National Library of Medicine* 1.
[141] Burkina Faso : "L'augmentation des prix de produits pharmaceutiques est inopportune et inacceptable", selon le Ministre de la Santé - Bulletin Santé (bulletinsante.net) (accessed on 14 September 2023).
[142](n 106).

intellectual property rights. For instance, on 6 November 2015, the TRIPS Council extended the transition period for pharmaceuticals until 2033 for least-developed countries.[143]

However, in the case of *China - Intellectual Property Rights* before the World Trade Organisation, the panel decision highlighted a fundamental principle inherent in the TRIPS agreement.[144] It states that while the Agreement allows member States a certain degree of flexibility to adapt their intellectual property laws to their specific needs and level of development, this does not relieve them of their obligation to adhere fully to the fundamental provisions of the TRIPS Agreement.[145] In essence, this decision emphasizes that the TRIPS Agreement establishes specific minimum standards for the protection of intellectual property and that Member States are obliged to respect these standards.

During a transition period, developing and least-developed countries are not required to implement all the provisions of the TRIPS Agreement immediately, allowing them to meet their obligations progressively. This transitional flexibility can facilitate access to medicines for least-developed countries in several ways.

The transition period granted by the TRIPS Agreement allows least-developed countries to prioritize their pressing public health concerns and allocate resources to strengthen their healthcare systems.[146] This strategic focus on improving healthcare infrastructure and access to essential medicines enables these countries to better meet the healthcare needs of their populations.

It also offers the least-developed countries a valuable opportunity to develop their domestic pharmaceutical industry. Indeed, they can then invest in the capacity needed to research, develop, and produce generic medicines. This strategic move can lead to an increase in the

[143] Microsoft Word - 9483_D_01 (wto.org) (accessed on 14 September 2023).
[144] WTO | dispute settlement - the disputes - DS611: China – Enforcement of intellectual property rights (accessed on 14 September 2023).
[145] TRIPS Agreement 1994, art.66(1).
[146] The Doha Declaration provided that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all." http:// www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (accessed on 14 September 2023).

local manufacture of affordable medicines, thereby reducing their dependence on expensive imported products.[147]

In addition, the transition period gives countries time to implement measures to improve access to medicines.[148] This includes adopting policies such as compulsory licences, which allow generic versions of patented medicines to be produced and distributed at lower cost. These policies significantly improve the affordability and availability of essential medicines, which ultimately benefits those who need them.

In summary, the transition period provided for in the TRIPS agreement takes account of the difficulties encountered by developing and least-developed countries in implementing the provisions of the agreement. It gives them the flexibility and time they need to strengthen their health systems, develop their national pharmaceutical industries and adopt measures to improve access to medicines. These efforts can facilitate access to medicines by promoting affordability, availability and local production of essential medicines, ultimately benefiting their people.

2.7.6 The use of generic drugs

The TRIPS Agreement does not explicitly contain provisions on the approval of generic medicines.[149] However, member countries are authorized to adopt measures to streamline the approval process for generic medicines. In addition, TRIPS encourages countries to put in place efficient procedures for processing patent applications for pharmaceutical products.[150] These measures avoid unnecessary delays in the approval of generic medicines, which promotes competition in the pharmaceutical market.

The role of generic medicines in improving access to healthcare is paramount;[151] for example, generic medicines have increased access to life-saving medicines for people with

[147]UNAIDS technical brief, Implementation of TRIPS and access to medicines for HIV after January 2016: Strategies and options for least-developed countries, http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2258_techbrief_TRIPS-access-medicines-LDC_en.pdf (accessed on 14 September 2023).
[148]Kaiser Family Foundation/UNAIDS report, Financing the Response to AIDS in Low- and Middle-Income Countries: International Assistance from Donor Governments in 2011 http://www.kff.org/hivaids/upload/7347-08.pdf (accessed on 14 September 2023).
[149](n 124) 5.
[150]TRIPS Agreement 1994, art 27(1).
[151]H Gothe and others 'The impact of Generic Substitution on Health and Economic Outcomes: A systematic review' (2015) *National Library of Medicine* 21-33.

diseases such as HIV, particularly in low-income countries such as Burkina Faso.[152]The high cost of patented HIV medicines, particularly at the start of the epidemic, was a major barrier to access to treatment. Generic manufacturers, thanks to their ability to produce identical versions of these patented medicines after patent expiry or through legal mechanisms such as compulsory licences, have been able to offer these medicines at a fraction of the cost.[153] This has not only made antiretroviral therapy more affordable but also extended access to a wider population. Generic HIV medicines have made it possible to expand treatment programmes worldwide, saving countless lives and contributing to the ongoing fight against the HIV/AIDS pandemic.

2.7.8 The Bolar exception

The Bolar exception, also known as the "regulatory review", is a provision recognized by the TRIPS to allow generic drug manufacturers to engage in preparatory activities and research related to obtaining marketing approval for a generic version of a patented drug before the patent's expiration.[154]

The Bolar exception typically allows generic drug manufacturers to perform activities such as conducting research and development to prepare for the regulatory approval process; performing tests and trials necessary for obtaining marketing approval from regulatory agencies, and manufacturing and stockpiling generic versions of a patented drug in anticipation of market entry once the patent expires. These activities are generally exempt from patent infringement claims, provided they are conducted solely for the purpose of obtaining regulatory approval and launching the generic drug after the patent's expiration.[155]

The Bolar exception aims to facilitate the timely entry of generic medicines into the market once the original patent expires, which can lower drug prices, and improve access to affordable medications for patients.

In the *Canada-Pharmaceuticals Patent case*, a WTO dispute settlement panel ruled that the Bolar provision was not contrary to the TRIPS agreement. It was the Patent Act of Canada that was at issue. The panel upheld its Section 55.2(1), which reads: "It is not an

[152]JC2049_PolicyBrief_TRIPS_en_1.pdf (unaids.org) (accessed on 14 September 2023).
[153] See *Fact sheet on settlement agreements*. Cape Town, Treatment Action Campaign, 2003. http://www.tac.org.za/newsletter/2003/ns10_12_2003.htm (accessed on 14 Septembre 2023).
[154](n 105).
[155](n 47) 136.

infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product".

2.7.9 The mailbox

The mailbox applies to WTO members that do not yet offer patent protection for pharmaceuticals and agricultural chemicals.[156] Under this provision, these countries must set up a system for accepting and processing patent applications for these products. In addition, they are required to set up a system for granting "exclusive marketing rights" for these products once patent applications have been filed.

This provision is designed to provide a transitional mechanism enabling countries to progressively implement patent protection for pharmaceutical and agricultural chemical products, allowing them to adapt to TRIPS requirements over time.

2.8 Conclusion

The EPA is based on the TRIPS agreement, which is the cornerstone of patent protection treaties. As it stands, TRIPS flexibilities are not explicitly incorporated into the EPA, but the provisions of this bilateral agreement between the European Union and West Africa leave plenty of room for States Parties to implement related rules in the future, if they so wish. The flexibilities available to Burkina Faso as a WTO member state and as a least-developed country are manifold. However, each of them comes with conditions, and the effectiveness of their application may depend on a country's specific circumstances.

[156](n 107).

CHAPTER THREE

CASE STUDY ON THE GENERAL HEALTH SITUATION IN BURKINA FASO AND ASSESSMENT OF THE COUNTRY'S CURRENT INTELLECTUAL PROPERTY PROTECTION REGIME

3.1 Introduction

Having explained in the previous chapter to what extent TRIPS and other WTO decisions such as the Doha Declaration can help a country gain better access to medicines, it now makes sense to analyze the specific case of Burkina Faso. Indeed, it is essential to understand Burkina Faso's general situation to grasp the challenges it faces regarding access to medicines. There is a close relationship between the country's economic crisis, the resources available to the population, the health and infrastructure situation, and the level of access to medicines.

After presenting and analyzing Burkina Faso's national health situation, this chapter will review the various regional and international intellectual property agreements to which Burkina Faso is a party. Such an approach aims to establish the current legal regime for protecting intellectual property rights in Burkina Faso. Before determining what the EPA should correct or leave unchanged to improve access to medicines in Burkina Faso, it is helpful to determine what the EPA will find there.

3.2 Burkina Faso's general political, administrative and health context

3.2.1 Political and administrative context

Burkina Faso, designated as a Heavily Indebted Poor Country (HIPC)[157] by the International Monetary Fund (IMF),[158] is facing economic difficulties that are reflected in its gross domestic product (GDP) per capita, which stands at just USD 832 in 2022.[159] According to the World Bank, this economic context has laid the foundations for a significant poverty problem, with almost 40% of the population

[157] Heavily Indebted Poor Countries (HIPC) Initiative - Perspectives on the Current Framework and Options for Change (imf.org) (accessed on 14 September 2023).
[158] Debt Relief Under the Heavily Indebted Poor Countries Initiative (imf.org) (accessed on 14 September 2023).
[159] PIB par habitant ($ US courants) - Burkina Faso | Data (banquemondiale.org) (accessed on 14 September 2023).

living below the poverty line of 72,690 CFA francs (around 110 euros) per adult per year for 2021-2022.[160]

These economic difficulties seriously impacted on the country's health indicators, with several mortality rates remaining abnormally high. The crude death rate was 9 per 1,000 people, in 2021 indicating a considerable burden of disease and ill-health.[161] Unfortunately, infant (under one year) and child (under five years) mortality rates are also alarmingly high, at 52 and 83 deaths per 1,000 live births respectively the same year.[162] According to World Health Organization, Burkina Faso also had an alarming maternal mortality rate of 330 deaths per 100,000 live births.[163] This stark reality highlights the considerable difficulties expectant mothers face in accessing quality healthcare and obstetric services, and for other couches of the Burkinabè society in general to access medicines.[164]

Burkina Faso is a secular, democratic, unitary state in West Africa.[165] The country functions as a republic under the official name of "Faso". French is the official language.

Law 055-2004/AN of 21 December 2004 on the General Code of Territorial Authorities instituted a system of decentralization within the country, dividing it into administrative regions, communes, and villages.[166] This decentralization deserves to be highlighted because, in addition to territorial restructuring, it transfers specific powers from central government to local authorities. In this context, the Ministry of Health has played a central role by delegating some of its powers to these decentralized structures. This strategic approach is part of Burkina Faso's commitment to promoting local governance and enabling communities to play an active role in general shaping their health services and development.

[160] Burkina Faso Vue d'ensemble (banquemondiale.org) (accessed on 14 September 2023).
[161] Taux de mortalité, brut (pour 1 000 personnes) - Burkina Faso | Data (banquemondiale.org) (accessed on 14 September 2023).
[162] Taux de mortalité infantile, moins de 5 ans (pour 1 000) - Burkina Faso | Data (banquemondiale.org) (accessed on 14 September 2023).
[163] Profil sanitaire complet du Burkina 1.pdf (who.int) (accessed on 14 September 2023).
[164] Taux de mortalité infantile (pour 1 000 naissances vivantes) - Burkina Faso | Data (banquemondiale.org) (accessed on 14 September 2023).
[165] Burkina Faso Constitution 1991, art 31.
[166] Country and territory profiles - SNG-WOFI - BURKINA FASO - AFRICA (accessed on 14 September 2023).

3.2.2 The Local pharmaceutical industry in Burkina Faso

3.2.2.1 General context

Burkina Faso relies heavily on imports for most of its pharmaceutical and healthcare products. The country's healthcare system depends on imported products, given the limited scope of local production, which is mainly centered on traditional pharmacopeia.[167] The public and private sectors have set up relatively strong distribution networks to ensure the availability of these imported health products if the political authorities first make them available in the country. This is why bilateral agreements such as the EPA are important because where Burkina Faso produces almost no pharmaceutical products, the European Union is a very large producer and has more resources to boost a pharmaceutical industry focused on the type of products that a country prone to tropical diseases needs.[168] This study raises this point because the feasibility of establishing local production facilities for modern medicines has been a recurring topic of discussion in the sub-region.[169]

Several factors contribute to the challenges facing local pharmaceutical production in Burkina Faso. These include the high cost of energy and water, the scarcity of skilled personnel in pharmaceutical manufacturing, and sub-optimal environmental conditions marked by heat and dust. These unfavorable conditions require significant investment in infrastructure and ongoing operating costs, making the production of modern medicines, particularly generics and solutions, virtually non-existent. Although initially viable, the few production units set up in the 1990s, encountered a series of difficulties that led to their closure in the 2000s.[170]In 2022, Burkina Faso began the process of marketing its first domestically produced generic drugs, thanks to its only modern pharmaceutical manufacturing plant, Propharm.[171]

It should be noted that Burkina Faso also has a few production units dedicated to medicines derived from traditional pharmacopeia. Some of these products, such as those from Laboratoires Phytofla, have received support from the Ministry of Health, notably

[167]K Ouoba and others 'Phytopharmaceutical practices of traditional health practitioners in Burkina Faso: a cross-sectional stydy' (2023) *National Library of Medicine* 215.
[168]L Blanc 'The European Pharmaceutical Industry in Global Economy: What drives EU exports of pharmaceuticals overseas?' (2014) *College of Europe, Department of Economics* 13.
[169]A Ekeigwe 'Drug manufacturing and access to medicines: the West African story. A literature review of challenges and proposed remediation' (2019) *AAPS Open* 5, 3.
[170]World Bank Document (accessed on 14 September 2023).
[171]Le Burkina Faso se dote de sa première usine de production pharmaceutique (lepoint.fr) (accessed on 14 September 2023).

inclusion on the national list of essential medicines and distribution in public health establishments.[172] In addition, efforts are underway to cultivate Artemisia annua, a valuable source of anti-malarial active ingredients (artemisinin derivatives) in high demand on the international pharmaceutical market.[173] However, these efforts fall far short of the health needs of the country's growing population.[174]

Despite the government's intention to promote local pharmaceutical production, a comprehensive strategy in this area remains elusive. Regional initiatives within organizations such as WAMU and ECOWAS have not yet produced tangible results, and local producers of traditional medicines face difficulties in protecting their knowledge through mechanisms such as patenting. In addition, existing customs regulations do not offer favorable conditions for local production, whether of improved traditional medicines or contemporary pharmaceutical products. Tackling these complexities and fostering an environment conducive to the local manufacture of pharmaceuticals remains an ongoing challenge.

3.2.2.2 Implications of the general state of the local pharmaceutical industry in Burkina Faso

Local pharmaceutical production in Burkina Faso faces a number of daunting challenges, summarized in the table below:

- Institutional obstacles: Some local production units are encountering difficulties related to their institutional organization.

- Lack of incentives: There is a lack of tax benefits and incentives to encourage preference for locally manufactured products.

- Taxation of inputs: Production inputs such as raw materials, packaging items, and reagents are not exempt from import duties.

[172] Accueil - Les Laboratoires Phytofla (accessed on 14 September 2023).
[173] Création de La Maison de l'Artemisia nationale du Burkina Faso - La Maison de l'Artemisia - Cette plante peut sauver des millions de vie (maison-artemisia.org) (accessed on 14 September 2023).
[174] CM zu Biesen 'The rise to prominence of Artemisia Annua L: The transformation of a Chinese plant to a global pharmaceutical' (2010) *African Sociological Review* 24-46.

- Distribution difficulties: Local products often face distribution problems, particularly with wholesale distributors such as La Centrale d'achat des médicaments essentiels génériques et des consommables médicaux (CAMEG).

- Under-utilisation of research: The results of research into healthcare products are under-utilised, which limits the impact of innovation.

- Weak collaboration: Collaboration between pharmaceutical producers and researchers is often lacking, hampering product development and improvement, particularly in the pharmacopoeia sector, which is in dire need of the scientific input that modern research can provide.

Indicators relating to service provision in the health sector in Burkina Faso hardly present a more favorable picture than that of access to medicines. In 2019, data from the WHO Health Observatory revealed that coverage of essential health services was 43.19% for both men and women.[175] Meanwhile, statistics from the World Bank Group's databases in 2018 indicated that only 14.40% of the population had access to electricity.[176] In 2020, the WHO Regional Office for Africa showed an increase in access to health services to 44.40%.[177] However, in 2014, the percentage coverage of all social assistance programs was just 2.29%, according to the World Bank.[178] Furthermore, in 2018, the availability of the equipment needed to administer crucial medicines to mothers was estimated at 36%.[179]

Considering these statistics, the question now arises as to what national policy Burkina Faso has adopted to resolve the shortcomings of its healthcare sector, particularly in terms of access to medicines.

3.3 Burkina Faso's national health policy

[175] Burkina Faso (who.int) (accessed on 14 September 2023).
[176] Access to electricity (% of population) - Burkina Faso | Data (worldbank.org) (accessed on 14 September 2023).
[177] Burkina Faso | OMS | Bureau régional pour l'Afrique (who.int) (accessed on 14 September 2023).
[178] Burkina Faso Overview: Development news, research, data | World Bank (accessed on 14 September 2023).
[179] Burkina Faso | Data (worldbank.org) (accessed on 14 September 2023).

The actions undertaken by Burkina Faso in the field of health are in harmony with its operating model, which is often adapted to the specific needs of its population.

3.3.1 The Constitution

Burkina Faso's national health policy, with particular emphasis on pharmaceutical policy, is rooted in fundamental principles and guidelines, mainly set out in its Constitution. Article 18 of the Constitution emphasizes the fundamental right of every citizen to "health, maternity and childhood protection, assistance for the elderly or disabled and support for social cases". This constitutional commitment serves as the cornerstone for the development of health policies in the country.

With regard to the recognition of intellectual property by Burkina Faso's legislative system, Article 28 of the Constitution states that "The law guarantees intellectual property. Freedom of creation and artistic, scientific, and technical works are protected by law. The expression of cultural, intellectual, artistic, and scientific activity is free and is exercised in accordance with the texts in force".

Bearing in mind that, as the TRIPS Agreement emphasizes, intellectual property rights are private rights,[180] it is also important to note that Article 15 of the Constitution of Burkina Faso enshrines these rights in the following terms: "The right of ownership is guaranteed. It may not be exercised contrary to social utility in such a way as to undermine the security, freedom, existence, or property of others. This right may only be infringed in cases of public necessity established in accordance with the law. No one may be deprived of the enjoyment of his property except in the public interest and in return for fair compensation determined in accordance with the law. Such compensation must be paid prior to expropriation, except in cases of emergency or force majeure". These constitutional provisions support the conditions to be met for the application of certain TRIPS flexibilities, such as government use or compulsory licensing, which may require that an inventor's rights be disregarded in favor of the general public interest, while still guaranteeing respect for his right to compensation and to a negotiation phase prior to any government decision.[181]

[180]TRIPS Agreement 1994, preamble.
[181](n 102).

3.3.2 Law and other policies

Burkina Faso aligns its pharmaceutical policy with the strategic guidelines set out in the national health policy.[182] This policy places particular emphasis on the development of health infrastructures, access to essential medical equipment, and the supply of quality health products.

In Burkina Faso, the government and the private sector collaborate on the circulation and supply of medicines. The *Centrale d'achat des médicaments essentiels génériques et des consommables médicaux* (CAMEG) is a Burkinabè private company responsible for coordinating the supply of medicines on national territory. In 2017, an internal crisis shook the company, calling into question its very existence.[183] The reasons were irregularities in managing accounts and stocks, a shortage of pharmaceutical products, and a breakdown in supplier confidence. Such turmoil prompted the Burkinabè government to seek to transform the association into a state-owned company, but an agreement was finally reached that enabled this private-sector player to continue its mission of supplying medicines to Burkina Faso.

The state-owned body most relevant to our topic is the Direction Générale de la Pharmacie, du Médicament et des Laboratoires (DGPML).[184]
The DGPML plays a central role in the healthcare ecosystem, as it determines the selling prices of medicines and other essential pharmaceutical products. As a result, Burkina Faso exercises effective control over the pricing of pharmaceutical products on its territory, ensuring that these essential health resources remain accessible to its population.

In terms of its national policy on access to medicines and healthcare, Burkina Faso embarked on a significant reform of its hospital system in 1998, marking a turning point in its health development with the promulgation of law no. 034/98/AN on the hospital law, dated 18 May 1998. This legislative step marked the country's commitment to improving its health infrastructure and services.

[182] ccsbrief_bfa_en.pdf;jsessionid=D97C706CFF95E3B6FBC475E2E4A35314 (who.int) (accessed on 14 September 2023).
[183] Crise à la CAMEG : La fin d'une douloureuse série de onze mois - leFaso.net (accessed on 14 September 2023).
[184] La Direction générale de la pharmacie, du médicament et des laboratoires - Ministère de la Santé et de l'Hygiène Publique (sante.gov.bf) (accessed on 14 September 2023).

Following this initiative, the government of Burkina Faso took further steps to strengthen its health sector. In September 2000, the government introduced a National Health Policy (PSN), setting out a strategic framework for responding to the population's urgent health problems. In July 2001, the National Health Development Plan (PNDS) for 2001-2010 was adopted. This comprehensive plan underlined the government's determination to provide rapid and practical solutions to the nation's health problems, demonstrating its unwavering commitment to the well-being of its citizens.

Following the final evaluation of the PNDS 2001-2010 in October 2010, the Ministry of Health embarked on an ambitious project to draw up a new national health development plan for the 2011-2020. This proactive approach has highlighted the government's desire to continually improve the delivery and accessibility of healthcare.

As an illustration of the above arguments, Article 7 of the 1998 Hospital Act is particularly noteworthy, as it proclaims that "every patient has the right of access to the hospital of reference required by his or her state of health". This unequivocal statement illustrates the Burkinabè government's long-standing commitment to guaranteeing universal access to healthcare for its population. It is important to note that this commitment was formulated well before establishing the EPA and even outside the regulatory framework of the Trade-Related Aspects of Intellectual Property Rights (TRIPS). This article certainly echoes the constitution of Burkina Faso, which states that "The right to health is recognized. The State shall work to promote it".

Article 4 of the same law goes further, stating that "hospitals with a national vocation constitute the first level of reference for their high level of specialization" and that "hospitals with a regional vocation constitute the second level of reference". These provisions illustrate the Burkinabè government's determination to give priority to national health policies and legislation. Nevertheless, these efforts do not exclude the possibility of regional or international collaboration, underlining Burkina Faso's willingness to engage in cooperative health initiatives while preserving its commitment to national health priorities.

3.4 Burkina Faso's international health policy

Burkina Faso's commitment to promoting access to medicines is also reflected in the country's adherence to numerous treaties and its support for relevant declarations in this

area, as well as to many regional and international organizations concerned with public health issues.

To tackle the issue of access to medicines, Burkina Faso is a signatory to many regional agreements in this field. These pharmaceutical cooperation efforts extend mainly to sub-regional political blocs, with a focus on the West African Economic and Monetary Union (WAEMU), the Economic Community of West African States (ECOWAS), the *Organisation pour l'Harmonisation en Afrique du Droit des Affaires* (OHADA) *and the Organisation Africaine de la Propriété Intellectuelle* (OAPI). The country is also party to international agreements such as the TRIPS and EPA, which govern relations between Burkina Faso and various partners in protecting intellectual property rights.As a side note, it may also be worth mentioning that the country engages in bilateral cooperation in the pharmaceutical sector with various nations, including France,[185] Tunisia,[186] Algeria,[187] and Belgium, [188] among others. These collaborations contribute to various aspects of pharmaceutical development, quality control, and regulatory standards.

3.5.1 The Alma-Ata Declaration, the Ouagadougou Declaration on Public Health, and the Bamako Initiative

The Alma-Ata Declaration, which emerged from the International Conference on Primary Health Care held in Alma-Ata, Kazakhstan, in 1978, is a key public health document. It affirms that health is a fundamental right for all, and emphasizes universal access to health care and primary health care (PHC). The Declaration emphasizes community involvement, intersectoral collaboration, and consideration of the social determinants of health. It advocates affordable, accessible, and quality healthcare, encouraging preventive and promotional measures. Alma-Ata calls for global cooperation to achieve these goals, laying the foundations for universal health coverage and comprehensive health systems worldwide.

Burkina Faso supports the Alma-Ata Declaration, and therefore firmly adheres to the principle that the profound disparities in health between populations represent an intolerable challenge on multiple fronts, including the political, social, and economic

[185] Burkina Faso - Generic Pharmaceutical (trade.gov) (accessed on 14 September 2023).
[186] Tunisia | Universal Health Coverage Partnership (who.int) (accessed on 14 September 2023).
[187] Country Report: Algeria (pharmexec.com) (accessed on 14 September 2023).
[188] Belgium takes a key role in European initiative to boost African Vaccine Manufacturing - Enabel - Belgian Development Agency | (accessed on 14 September 2023).

dimensions.[189] These disparities, both on a global scale, where gaps between developed and developing countries persist, and within each country, are considered an issue of the utmost importance by Burkina Faso. The country's government strongly affirms that these inequalities know no borders and that they justify collective and international action.

The Alma-Ata Declaration underlines the imperative of tackling these disparities in a comprehensive manner, emphasizing the vital role of equitable access to healthcare as a fundamental human right and an indispensable pillar of societal well-being. By subscribing to this declaration, Burkina Faso aligned itself with the global commitment to correct these imbalances and aspired to create a future where health disparities become obsolete. Burkina Faso envisions a world in which everyone, regardless of geographic location or socio-economic status, enjoys the highest attainable standard of health and well-being.

Another example of Burkina Faso's commitment in this direction is its participation in the Bamako Initiative, launched in 1987 as an extension of the principles of the Alma-Ata Declaration.[190] In the same vein, this initiative promoted the implementation of strategic measures to improve the availability of essential medicines and other vital health services for sub-Saharan African countries. The concept, initially proposed by UNICEF Executive Director James P. Grant, was based on the idea of supplying medicines to countries at prices slightly above their cost. The profits generated by these sales were then reinvested in purchasing new medicines, establishing a self-sustaining mechanism to improve access to and delivery of healthcare in the region.

The Ouagadougou Declaration on Primary Health Care and Health Systems in Africa, adopted in 2008, on which Burkina Faso's internal health policy is aligned, also plays a central role in the country's health agenda.[191] The Declaration calls on governments, partners, and communities to redouble their efforts to improve health outcomes emphasizing community participation and empowerment as key elements in improving health.

With these general principles in mind, Burkina Faso's pharmaceutical policy is guided by a number of fundamental values and principles that reflect a commitment to providing

[189] decouagadougou_declaration_eng.pdf (who.int) (accessed on 14 September 2023).
[190] World Bank Document (accessed on 14 September 2023).
[191] (n 176).

quality health services, promoting local pharmaceutical production, and ensuring that the entire population has access to essential health products and services.

Once again, all these political actions on the international stage demonstrate Burkina Faso's unwavering commitment supporting global health equity and also to actively participating in initiatives that lead to tangible improvements in the accessibility and affordability of healthcare on its territory.

3.5.2 The Bangui Agreement

Burkina Faso is a party to the Bangui Agreement, a regional framework for intellectual property law signed in 1977, that sets up the *Organisation Africaine de la propriété Intellectuelle* (OAPI).[192] This agreement is important because it serves both as a regional convention applicable to all member countries and as national intellectual property legislation for Burkina Faso, and for each of the other seventeen member states. While the Bangui Agreement provides a regional basis, each member State has its own copyright and intellectual property legislation. Taken as a whole, the Bangui Agreement includes numerous annexes dealing with various aspects of intellectual property, such as patents. The OAPI system has a number of distinctive features that help to streamline intellectual property procedures in its member States, thereby promoting a unified approach to industrial property rights:

- Unified industrial property office: OAPI has a single industrial property office serving all seventeen member states, including Burkina Faso.

- Uniformed intellectual property legislation: The legal framework for intellectual property is coherent in all member States, as governed by the Bangui Agreement and its annexes.

- Centralized application procedures: OAPI centralizes the processing of applications for various industrial property titles, such as patents, utility models, trademarks, industrial designs, trade names, plant varieties, geographical indications, and layout designs of integrated circuits. Applications submitted to Burkina Faso or any other Member State are considered national applications in each Member State.

[192] Organisation africaine de la propriété intellectuelle — Wikipédia (wikipedia.org) (accessed on 14 September 2023).

- Cross-border protection: Intellectual property titles issued by the OAPI confer a set of rights that extend to all Member States, thus offering complete protection.

- Competent jurisdiction in the event of infringement of intellectual property: Legal recourse in the event of infringement of intellectual property falls within the jurisdiction of the courts of Burkina Faso and the respective courts of each member country.

- Exclusivity of the regional system: Within the framework of the OAPI, there are no parallel national systems for industrial property titles, which guarantees a harmonized regional approach.

These features of the OAPI system underline the organization's commitment to simplifying the management and protection of intellectual property rights in its member states, including Burkina Faso. The unified approach facilitates streamlined processes for creators, inventors, and businesses seeking to secure and defend their intellectual property across the region.

The Bangui Agreement harmonizes Burkina Faso's national intellectual property legislation with various international conventions, including the Paris Convention for the Protection of Industrial Property, the Convention of the International Union for the Protection of New Varieties of Plants (UPOV Convention) and the TRIPS Agreement.
In 1999, the seventeen member States of the African Intellectual Property Organisation undertook to revise their common regional framework for protecting intellectual property, known as the Bangui Agreement. These revisions were essential to align with the provisions of the TRIPS.[193] In 2023, a revised version of Annex I of the Bangui Agreement about patents entered into force with some major changes, pertaining to the notably substantive examination, opposition before grant, and divisional applications.[194]

3.5.3 ECOWAS

[193] Agreement of February 24, 1999, Revising the Bangui Agreement of March 2, 1977, on the Creation of an African Intellectual Property Organization*(Bangui (Central African Republic)) (wipo.int) (accessed on 14 September 2023).
[194] The key changes from the amendments to the Bangui Agreement (europa.eu) (accessed on 14 September 2023).

Since 2007, Burkina Faso has been actively involved in a process to harmonize pharmaceutical policies within ECOWAS with a pharmaceutical manufacturing plan.[195] This initiative, led by the West African Health Organisation (WAHO), serves as an institutional anchor for regional harmonization efforts.

Another positive development is the directive authorizing doctors and pharmacists from UEMOA countries to practice in all member states.[196] Finally, Burkina Faso's participation in the WHO's International Drug Monitoring Programme demonstrates its commitment to global pharmaceutical quality and safety standards.[197]

The rationale behind ECOWAS's efforts towards harmonization is that the Organization primary mission is to promote cooperation, integration, and coordination between the countries of West Africa.[198]Nine of the fifteen member countries of ECOWAS are also members of the African Intellectual Property Organisation.

3.5.4 WAEMU

The West African Economic and Monetary Union (WAEMU) was founded on 10 January 1994 in Dakar. Its objective is to build a harmonized and integrated economic zone in West Africa where the free movement of people, capital, goods, and services is guaranteed.[199] This initiative supports regional economic cooperation and reinforces the principles of a common economic union in the West African region.

WAEMU has eight member States: Benin, Burkina Faso, Côte d'Ivoire, Guinea-Bissau, Mali, Niger, Senegal and Togo. All these member States are also members of the OAPI.

The Organization operates within the framework of regional intellectual property agreements, particulary the Bangui Agreement, with the intellectual property registration system administered by OAPI.[200] WAEMU has developed a comprehensive intellectual property rights policy enable member States to use intellectual property rights to move from natural resource-based economies to knowledge and innovation-based economies. For instance, Guidelines have been established within its framework for the inspection of good distribution practices, good manufacturing practices, the approval of cosmetic

[195]ECOWAS_Regional_Pharmaceutical_Plan_0.pdf (unido.org) (accessed on 14 September 2023).
[196]ECOWAS_situtation_analysis_report.pdf (accessed on 14 September 2023).
[197]Programme for International Drug Monitoring (who.int) (accessed on 14 September 2023).
[198]The ECOWAS treaty 1975, art.3.
[199]The WAEMU treaty 2010, art.3.
[200]Microsoft Word - Programme_Forum_Atelier_ sous-rÃ©gional_Abidjan (wipo.int) (accessed on 14 September 2023).

products and nutritional supplements, and the regulation of information and advertising relating to medicinal products.[201]

3.5.5 OHADA

The Organization for the Harmonization of Business Law in Africa (OHADA) does not yet have a harmonized system for protecting intellectual property rights. For the time being, OHADA relies on the OAPI for intellectual property. This is because both organizations are made up of the same members, even though Mauritania, although a member of OAPI, is not a member of OHADA. Conversely, the Democratic Republic of Congo, a member of OHADA, is not a member of OAPI. The two organizations signed a cooperation agreement on May 9, 2016.[202]

Nevertheless, OHADA's emphasis on legal predictability and the rule of law is helping to create an environment conducive to investment in the healthcare and pharmaceutical sectors, thereby facilitating the availability and affordability of medicines for the populations of its member States.

3.5.5 TRIPS

Burkina Faso's commitment to international agreements on trade and intellectual property testifies to its commitment to global cooperation and protecting intellectual property rights. The country has been a member of the World Trade Organization (WTO) since June 3, 1995, and of the General Agreement on Tariffs and Trade (GATT) since May 3, 1963.

As evidenced by the 1999 amendment of the Bangui Agreement that governs Burkina Faso’s national framework on intellectual property rights, Burkina Faso, as a signatory to the Agreement on Trade-Related Aspects of Intellectual Property Rights, has adopted laws that are largely compliant with its provisions. This demonstrates the country's commitment to establishing a legal framework for the protection and enforcement of intellectual property rights in accordance with international agreements. It also proves its commitment to global intellectual property standards.

However, although its active participation in these international agreements reflects its commitment to promoting innovation, creativity, and the protection of intellectual property

[201] 1WAUEA2022001.pdf (accessed on 14 September 2023).
[202] OHADA.com - L'OHADA signe un Accord de coopération avec l'OAPI (accessed on 14 September 2023).

rights at both regional and global levels, being a least-developed country, Burkina Faso has a waiver to not apply all provisions of the TRIPS until 2033.[203] More specifically, under TRIPS, Burkina Faso has till 2033 to enforce or grant patents and data protection on pharmaceutical products, if it decides so.

3.5.6 The EPA

As an ECOWAS member State, Burkina Faso will be governed by the EPA signed between West Africa and the European Union, once it has entered into force. However, in accordance with the general principle of international law that "*pacta sunt servanda*",[204] the EPA will govern Burkina Faso's intellectual property rights only in its relations with the European Union or with the member states of the European Union.

As regards the protection of intellectual property rights and access to medicines, to date the only two explicit references to this issue in the EPA are in Article 87 as a general exception clause, which guarantees the right of the parties to protect intellectual property rights, and in Article 106, the *rendez-vous* clause, which underlines the commitment of the parties to enter into discussions on the protection of intellectual property rights and innovation within the framework of the EPA. For the time being, the question has not yet been fully resolved.

However, Article 46.1 of the Cotonou Agreement, which is the general agreement between the EU and the ACP countries, and which underpins each of the EPAs between the EU and the various African regions, such as the EPA with the countries of West Africa, states that "Without prejudice to the positions of the Parties in multilateral negotiations, the Parties recognize the need to ensure an adequate and effective level of protection of intellectual, industrial and commercial property rights, and other rights covered by TRIPS including protection of geographical indications, in line with the international standards with a view to reducing distortions and impediments to bilateral trade. This highlights the EPA's reliance on TRIPS provisions. The question that might then be asked is whether TRIPS is not an excuse for not taking new decisions in the field of intellectual property that would significantly upset the legislative systems of the States party to the EPA, especially as these legislative systems are at the opposite end of the spectrum. Some, notably those of

[203]Decision of the Council for TRIPs of 6 November 2015
Microsoft Word - 9483_D_01 (wto.org) (accessed on 14 September 2023).
[204]Vienna Convention on the law of treaties 1969, art.26.

the European bloc, are those of developed States, while others, notably those of the West African bloc, are those of either developing or least-developed States.

As OAPI currently governs patentability rules in Burkina Faso, the provisions of the African Intellectual Property Organization should be consulted to determine whether patentability in Burkina Faso is currently strong or weak. From there, this study can conclude and determine the right course of action for a better access to medicines.

3.6 The patentability regime in Burkina Faso and its implication in access to medicines

3.6.1 Conditions pertaining to filing a patent application in Burkina Faso

Under OAPI provisions, the right to file a patent application is held by different parties, who are, in the first instance, the inventor or his legal successor.[205] Where two or more persons independently create the same invention, the right to the patent belongs to the person with the earliest filing date or, in the case of a priority claim, the earliest claimed priority date.[206]If two or more persons jointly create an invention, they jointly share the right to the patent.[207] When employees make an invention as part of their employment contract involving innovative tasks related to their duties or as part of assigned studies and research, the patent right belongs to the employer.[208]

To be patentable, an invention must meet specific criteria: it must be new,[209] involve an inventive step,[210] and be applicable in the industrial sector.[211]

On the contrary, certain types of inventions are not eligible for patent protection under OAPI.[212] This applies in particular to those contrary to public order or moral values. In addition, methods relating to the medical treatment of humans or animals through surgery or therapy, and inventions relating to plant varieties or animal species are excluded from patentability.

[205]The Bangui Agreement 2015, art 9(1).
[206]The Bangui Agreement 2015, art 9(2).
[207]The Bangui Agreement 2015, art 10.
[208]The Bangui Agreement 2015, art 11.
[209]The Bangui Agreement 2015, art 3.
[210]The Bangui Agreement 2015, art 4.
[211]The Bangui Agreement 2015, art 5.
[212]The Bangui Agreement 2015, art 2.

Patent applications are not subject to substantive examination, which results in shorter registration periods, generally ranging from 9 to 12 months.
Under the OAPI's regime, patents are protected for a period of twenty (20) years from the date of filing, subject to payment of annual maintenance fees.[213]

Following the revision of the Bangui Agreement in 2022, an important change has been introduced to the patent management system. It concerns opposition. Article 20 says that after publication of the patent application, there is a three-month period during which any person may oppose the grant of a patent or certificate of addition. Opposition must be submitted in writing and the grounds for opposition must be clearly indicated to the Organization. An opposition may be lodged based on the inventive character of the thing in question (article 1), or of a number of other articles laying down the conditions for the grant of patents (articles 2, 3, 4, 5, 9 and 17); or it may be lodged based on an existing prior registration right held by the opponent. The applicant shall be served the notice of opposition having three months (with an extension of one month) to refute the opposition and defend the invention. Before ruling on the opposition, the Organization will set a hearing with both parties or their legal representatives. This innovation in the Bangui Agreement makes the patenting process very liberal and gives a great deal of power to the individual.

3.6.2 Burkina Faso's mirroring of the TRIPS agreement in relation to access to medicines

In several respects, the Bangui Agreement confirms some of the flexibilities authorized by the TRIPS Agreement. Article 6 recognizes that only the patent owner on an invention has the right to "manufacturing, importing, offering for sale, selling and using the product". However, the Bangui Agreement notes in its preamble that the TRIPS' provision guarantees compulsory licensing for member States "to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement". This explains why article 58 of the Bangui Agreement authorizes the granting of a non-voluntary license in the national interest. According to this article, and following a regime that indicates that it is what TRIPS qualifies as compulsory licensing,

[213]The Bangui Agreement 2015, art 8.

the administration of a State can decide to use a patented invention in the best interests of the nation. As in the case of TRIPS, the Bangui Agreement recommends an amicable agreement between the State and the patent owner, but if this is impossible, the State retains the right to decide on priority, leaving it to the competent judicial authorities to set the conditions for non-voluntary licensing in the event of a dispute.

On the other hand, Article 7 recognizes the legality of parallel import into the territories of OAPI member States. Indeed, it says that after the product is legally placed on the market in any country by patent owner or with his express consent, the rights conferred by the patent no longer apply to the sale or import of the same product in other member States.

3.6.3 Assessment of the TRIPS under EPA in Burkina Faso, and implication for access to medicines

The EPA's assessment reveals that Burkina Faso is not operating in a state of intellectual property rights lawlessness. Instead, it underscores the presence of a regulatory framework that needs to take advantage of the existing gaps and deficiencies within Burkina Faso's intellectual property regulations. Indeed, there is no shortage of shortcomings. For example, when the Bangui Agreement was amended in 1999, constraints were introduced that limited the ability of signatory states to use compulsory licenses, even in public health crisis.[214]

The latest amendment corrected this, but the mistake had already been made. The problems that Burkina Faso could face due to the inclusion of TRIPS flexibilities in the EPA are manifold. This situation became evident during the COVID-19 pandemic when, despite the provisions of the MC12 waiver, Burkina Faso faced significant difficulties in producing vaccines or ensuring full medical coverage for its population without external assistance, notably from the European Union.[215] The country's capacity to fully leverage TRIPS flexibilities remains constrained due to its lack of financial, logistical, and scientific resources. As recently as 2021, Burkina Faso entered into a partnership agreement with the Global Fund and external collaborators to subsidize medications for combating AIDS,

[214] I Mgbeoji 'TRIPS and TRIPS Plus Impact in Africa' (2007) *Oxford university Press* 268.

[215] European Union provides fresh funding to support COVID-19 vaccination in sub-Saharan Africa (unicef.org) (accessed on 14 September 2023).

tuberculosis, and malaria, with this partnership set to continue until 2023.[216] Consequently, TRIPS flexibilities appear irrelevant and unfeasible for a country like Burkina Faso, given the absence of necessary resources. In contrast, the European Union can offer such resources to its partners.

An appraisal of the health situation in Burkina Faso has revealed the areas in which the country needs to concentrate its efforts. These include boosting local production and encouraging invention. The critical dilemma now revolves around whether the EPA should work towards weakening or strengthening the patent system.

Given the majority trend observed in States that have already implemented TRIPS provisions for improved access to medicines, it seems that, according to the most widespread opinion, the EPA should introduce conditions favoring the weakening of intellectual property protections, which will lead to a reduction in the price of medicines and therefore make them more accessible.[217]Striking the right balance between intellectual property protection and ensuring affordable access to essential medications will be a key challenge for Burkina Faso and the EU under the EPA.[218] Nevertheless, the agreement offers cooperation and capacity-building opportunities, which could help Burkina Faso develop its pharmaceutical industry and improve its ability to provide essential medicines to its population. The EPA thus represents a multifaceted partnership that requires careful negotiation and implementation to ensure that both intellectual property rights and public health needs are adequately addressed.

To shed light on this question, examining several African countries' experiences will provide valuable insights and guidance.

3.7 Conclusion

Burkina Faso's health map presents a peculiar picture. The country is prone to tropical diseases that researchers and pharmaceutical companies often neglect in their research and production of new drugs. That's why this chapter has highlighted Burkina Faso's

[216]Le Burkina Faso et le Fonds mondial mettent en œuvre de nouvelles subventions pour accélérer la lutte contre le VIH, la tuberculose et le paludisme - Communiqués de presse - Le Fonds mondial de lutte contre le sida, la tuberculose et le paludisme (theglobalfund.org) (accessed on 14 September 2023).
[217]O Soyeju and J Wabwire 'The WTO-TRIPS flexibilities on public health: a critical appraisal of the East African Community Regional Framework' (2018) *World Trade Review* 145.
[218]M Boldrin and D K Levine'Does Intellectual Monopoly Help Innovation?'(2009)*Review of Law and Economics* 991 at 991.

great need to encourage research into the type of diseases that recur on its territory. The country's dire financial situation is another problem. Nevertheless, the EPA does not find Burkina Faso in a situation of lawlessness regarding protecting intellectual property rights. The country is party to a number of conventions, and its national intellectual property law is currently that of the OAPI, to which it is a signatory. The consequence of this state of affairs is that Burkina Faso's national law authorizes it to apply the TRIPS flexibilities and to avail itself of them. However, having noted the gap in the EPA, which does not explicitly mention TRIPS flexibilities, the question arises as to whether all flexibilities would, on an equal footing, be a good idea in Burkina Faso's particular context and whether the country's difficult financial and infrastructural conditions allow it to implement TRIPS flexibilities, even if they are authorized.

CHAPTER FOUR

COMPARATIVE ANALYSIS BETWEEN THE EU-WEST AFRICA EPA AND OTHERS EPAs IN THE AFRICAN REGION, ON THE ONE HAND, AND THE REGULATORY FRAMEWORK OF OTHER LEAST-DEVELOPED COUNTRIES IN THEIR APPLICATION OF THE TRIPS FLEXIBILITIES, ON THE OTHER

4.1 Introduction

Having analyzed the specific case of Burkina Faso, it is now time to compare it with other countries under similar conditions while facing an EPA with the European Union.

Intellectual property rights (IPRs) and access to medicines have been the subject of intense debate and concern in developed and developing countries.[219] The question of the relationship between the protection of intellectual property rights and access to medicines has thus been particularly raised within the States party to the various EPAs between the European Union and the ACP countries. Even though the comprehensive EPA between the EU and West African States has not yet entered into force, two stepping-stone agreements have been signed as transitional EPAs, with two West African states pending the entry into force of the main EPA: Ghana and Côte d'Ivoire.[220] This chapter will analyze these stepping -stone agreements in order to establish a trend that EPAs appear to be adopting in patenting and their relevance to access to medicines. To broaden the scope of the analysis, the EPA between the EU and the Southern African Development Community (SADC) and the one between the EU and Eastern and Southern African States will also be analyzed to establish whether or not there seems to be a common strategy, a standardized trend in the EPAs' treatment of the relationship between intellectual property rights and access to medicines. The second part of chapter 4 will be a case study of the EAC, an African regional organization that has introduced TRIPS flexibilities into its normative body. The aim is to determine the potential advantages and disadvantages of TRIPS flexibilities in future EPA negotiations on intellectual property could have on access to medicines in Burkina Faso.

[219](n 47).

[220]EU trade relations with West Africa (europa.eu) (accessed on 14 September 2023).

4.2 The EPA between the EU and SADC

The Southern African Development Community (SADC) comprises Botswana, Lesotho, Mozambique, Namibia, South Africa, and Eswatini. The EPA between SADC and the EU was signed on June 10, 2016. It entered into force provisionally on October 10, 2016, with Mozambique applying it provisionally from February 4, 2018.

Compared to the EPA between the EU and West Africa, the EPA between the EU and SADC is more detailed on the matter of intellectual property rights, but Article 16.1 also draws on the Cotonou Agreement and TRIPS, whose flexibilities it invokes, as is the case in the West African EPA. The same article goes further, specifying in the second paragraph that the parties undertake to provide adequate protection for intellectual property rights. Paragraph 6, as mentioned in the EU-West Africa EPA, establishes a *rendez-vous* clause in which member States agree to enter into future negotiations on intellectual property rights. However, no article deals with specific conditions of patentability or the use of specific TRIPS flexibilities. It merely guarantees patents at the level of the general exception clause, which also exists in this agreement, thus implicitly leaving it up to each member State to set its own patent rules, just like the EPA between the EU and West Africa.

4.3 EC-Côte d'Ivoire stepping stone Economic Partnership Agreement

Signed in 2009 as Decision 2009/156/EC, the stepping stone agreement between Côte d'Ivoire and the European Union entered into force on September 3, 2016. This agreement, which is also known as the interim agreement, stipulates that any future negotiations involving intellectual property rights between the European Community and Côte d'Ivoire must not require TRIPS+ obligations from West African WTO members, meaning that they must not go beyond the threshold of protection set by the WTO, and therefore TRIPS. Therefore, there is an explicit banning of any provision that, could be regarded as TRIPS+. Such a provision does not exist in the global West African EPA, thus preserving the possibility of setting rules beyond WTO standards for both parties, including Côte d'Ivoire, if this agreement comes into force and cancels the interim agreement. Nevertheless, the interim agreement's decision to prohibit a TRIPS+ may indicate that the same thing will be done later for the global West African EPA.

4.4 EC-Ghana stepping stone Economic Partnership Agreement

All parties including the United Kingdom signed this agreement on 28 July 2016 and has been provisionally applied since 15 December 2016. Article 44 states that the EPA between West Africa and the European Union protects intellectual property rights in relations between the parties. The stepping stone agreement thus encourages the parties to work towards the effective implementation of the global EPA. There is also a general exception clause in this convention, which states that nothing in the current provisions should compromise the adoption or reinforcement of rules protecting intellectual property.[221] However, there is no *rendez-vous* clause, unlike the EPA with West Africa.

Having identified what appear to be the general trends in the EPAs' approach to protecting intellectual property rights, and hence in applying TRIPS flexibilities, it is now important to establish the driving force behind the use of patents to improve a country's access to medicines. This study may then reveal whether the current state of the EPA between the European Union and West Africa puts Burkina Faso on the right track to improving its access to medicines.

4.5 Utilitarian theory to justify the right course of action for Burkina Faso's access to medicines under the EPA

4.5.1 A definitional approach to justify utilitarian theory

The utilitarian justification for patent protection is one of the key philosophical and economic rationales behind granting patents.[222] It is rooted in the broader framework of utilitarianism, a moral and ethical theory that asserts that the best action is the one that maximizes overall happiness or utility for the greatest number of people. Applied to the field of intellectual property, particularly patents, the utilitarian perspective argues that providing inventors and creators with exclusive rights to their inventions for a limited period can lead to several beneficial outcomes:

[221]Stepping stone agreement EU-Ghana 2016, art 68.
[222]EC Hettinger'Justifying Intellectual Property'(1989) 18 *Philosophy and Public Affairs* 36, 47.

- **Incentive for Innovation**: Patents create a financial incentive for individuals and companies to invest in research and development (R&D) efforts. Knowing that they can enjoy a temporary monopoly on their inventions, inventors are more likely to dedicate time and resources to create new and valuable products, technologies, and processes.

- **Knowledge Sharing**: The patent system encourages inventors to disclose the details of their inventions in a publicly accessible manner. This disclosure contributes to the overall body of knowledge and promotes further innovation by allowing others to build upon existing ideas.

- **Economic Growth**: By stimulating innovation and technological advancement, patents can drive economic growth and prosperity. New inventions can lead to the creation of new industries, products, and jobs, benefiting society as a whole.

- **Consumer Choice**: Patents can result in a wider array of products and technologies for consumers to choose from. Competition among inventors and companies can lead to improved products, lower prices, and increased consumer welfare.

- **Funding for R&D**: Patents can help inventors secure funding for their R&D activities. Knowing that they have exclusive rights to their inventions, inventors can attract investors and partners who are more willing to support innovation.

However, it's important to note that the utilitarian justification for patent protection is not without criticism. Critics argue that the current patent system may, at times, hinder innovation by creating patent thickets (complex webs of overlapping patents), fostering patent trolling (exploitative use of patents for litigation), and impeding access to essential medicines or technologies due to high prices.[223] As such, the balance between granting exclusive rights to inventors and ensuring the public's access to innovations remains a subject of ongoing debate and reform efforts in intellectual property law.

[223]E Marseille and JG Kahn 'Utilitarianism and the ethical foundations of cost-effectiveness analysis in resource allocation for global health' (2019) *Philos Ethics HumanitMed* 5.

Based on utilitarian theory, a case study of the East African Community, an East African regional organization, will enable us to conclude the case of least-developed and developing countries faced with the use of TRIPS flexibilities to facilitate access to medicines.[224] The consequences of their choice to incorporate TRIPS flexibilities into their treaty and national legislation will provide a basis for determining the ideal way forward for Burkina Faso.

4.5.2 A case study of the EAC

The East African Community (EAC) is a regional intergovernmental organization in East Africa that fosters economic, political, and social integration among its member States. Established in 1967, the EAC initially comprised three countries: Kenya, Tanzania, and Uganda. Over the years, it has expanded to include The Democratic Republic of Congo, Rwanda, Burundi, and South Sudan. The EAC's overarching goal is to promote cooperation and development in the region, emphasizing creating a common market, customs union, and shared infrastructure to facilitate trade, investment, and socio-economic growth.[225]The organization also works on various other areas, including health, education, and environmental sustainability, aiming to enhance East African citizens overall well-being and prosperity. The EAC plays a significant role in advancing regional integration efforts in East Africa, contributing to greater political stability and economic advancement in the region.

The East African Community's Common Market Protocol is a comprehensive framework that promotes the free movement of goods, services, labor, and capital within the member states and emphasizes cooperation in crucial areas such as public health and intellectual property.[226] This protocol marks the commitment of member states to implement TRIPS flexibilities in the field of health and access to medicines. The aim is to ensure member States adapt their national legislation to take advantage of the TRIPS agreement and its flexibilities.[227]

[224](n 204).
[225]Overview of EAC (accessed on 14 September 2023).
[226]The Protocol on the Establishment of the East African Community Common Market (the Common Market Protocol),art.5(3)k & 43.
[227]The Common Market Protocol, para. 10 of the preamble.

Six member States are least-developed countries like Burkina Faso: The Democratic republic of Congo, Rwanda, Burundi, Tanzania, Uganda, and South Sudan. Consequently, like Burkina Faso, they benefit from the transition period waiver in applying TRIPS. This means that they are not obliged to offer patents for pharmaceutical products until the expiry of the TRIPS grace period, i.e., 2033.

What could have opposed this waiver offered by the transition period is the mailbox since the mailbox is a provision that requires members who do not yet have a patent system covering pharmaceutical products and chemical inventions to apply the provisions of TRIPS.[228] The transition period offered by TRIPS, therefore, allows LDCs not to have the mailbox applied and thus appears to be an exception to this flexibility.[229]

For example, in the case of the EAC LDCs, Rwanda and Burundi have included the transition period in their national legislation, thus taking advantage of the mailbox, while Tanzania and Uganda have a national patent system for pharmaceuticals, thus refuting the leeway they had not to offer them until 2033.

One of the disadvantages of using the transitional period by States, and therefore of the non-application of the mailbox provision, is that it discourages research and innovation.[230] Indeed, in a legal system that guarantees the patenting and protection of inventions by granting inventors exclusive rights over their inventions for a limited period of time, patents provide a strong incentive for individuals and organizations to invest in research and development. This incentive arises from the promise of temporary monopolies, allowing inventors to recoup their investments and generate profits. In return, inventors must disclose their inventions in detail, contributing to the pool of publicly available knowledge. This disclosure helps society builds upon existing innovations and ensures transparency and accountability in the patent system. Consequently, the application of the transition period does not seem to be adapted to the Burkina Faso context. Indeed, as demonstrated in the section analyzing the problems facing Burkina Faso's health sector, innovation and local production must be encouraged if access to medicines is to be facilitated.

[228](n 107).

[229]Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001 WT/MIN (01)/DEC/220 November 2001 (01-5860) para. 7; Decision of the Council for TRIPS of 27 June 2002.

[230](n 204) 155.

The East African Community framework on intellectual property rights takes a strategic approach to utilize the flexibility of the patentability criteria to create room for public health considerations. Firstly, it suggests that States employ 'wide prior art definitions' when assessing novelty. This approach makes it more challenging to establish the novelty of an invention, thereby limiting the number of patents granted. Secondly, concerning the inventive step requirement, the Policy of the EAC mandates that inventions must be non-obvious to highly skilled individuals in the relevant field.[231] This higher threshold for inventiveness further narrows the scope of patentable inventions. Thirdly, in terms of industrial applicability, the framework demands that research tools specifically identify their use for patentability.[232] This specificity sets a stringent standard, making it harder for broad and non-specific patents to be granted. The overall objective is to make patentability more arduous, ensuring that patents are only granted to truly innovative and valuable inventions. This approach of the EAC seems to align with the broader goal of providing States with the necessary flexibility to safeguard public health and ensure access to essential medicines while addressing the intellectual property aspects of healthcare.

The Bolar exception, as stipulated under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, is a crucial provision that allows member countries some flexibility in utilizing intellectual property rights for research purposes. According to TRIPS, member States can establish exceptions to patent rights to facilitate scientific research, experimentation, and the development of new technologies. This provision recognizes the importance of fostering innovation and promoting the progress of science, as it permits researchers to conduct experiments and investigations without infringing on existing patents. The Bolar exception, as stipulated under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, is a crucial provision that allows member countries some flexibility in utilizing intellectual property rights for research purposes.
According to TRIPS, Member States can establish exceptions to patent rights to facilitate scientific research, experimentation, and the development of new technologies.[233] This provision recognizes the importance of fostering innovation and promoting the progress of science, as it permits researchers to conduct experiments and investigations without infringing on existing patents. The EAC allows this flexibility to improve patented

[231]The Policy, para. 3.2.
[232](n 217).
[233](n 47).

products.[234] This could reinforce and encourage targeted local production in a context where neglected tropical diseases prevail and require special drug production.

A flaw in the EAC's use of the research exception is that it only intends to improve the product in question, not to draw inspiration from it to invent a valuable new product. The policy specifies that "the predominant purpose of the commercial research must be the improvement of the patented substances, as opposed to mere reverse engineering and copying of the patented invention".[235]

However, there is a positive aspect to using this flexibility, since under it, the generic drug is marketed only after the patent has expired. In this way, the exception does not discourage research and innovation. The rights associated with obtaining a patent are fully available even when the Bolar provision applies.[236] The Bolar provision does not call into question the inventor's rights and is a solution suited to the context of a country seeking to stimulate local pharmaceutical production.

The EAC also authorizes the protection of test data, in terms that imply that member States consider that the original author of the database would necessarily be a foreign pharmaceutical company. [237] Such an apprehension contradicts the objectives of the research exception because if we apply flexibility that tends to promote local production, it is not very coherent to adopt measures that seem to be tailor-made for foreign producers.[238] If a legal system such as the EPA decides to include test data protection in favor of Burkina Faso, it will have to take into account Burkina Faso's specific need to encourage local production; test data will, therefore, have to be formulated in such a way as to protect national pharmaceutical companies first and foremost, and enable them to save money on research.

4.6 Conclusion

[234]The Policy,para.3.4.
[235](n 220).
[236](n 204) 158.
[237]The Policy,para.3.6.
[238](n 203) 159.

An examination of most of the other EPAs signed between the European Union and other African countries or regions reveals a general tendency not to address intellectual property rights protection. On the other hand, all the EPAs recognize the importance of this issue and have set a date in the indefinite future for negotiations on the protection of intellectual property rights. A closer look at the case of the East African Community highlights the advantages and disadvantages of TRIPS flexibilities for a least-developed country like Burkina Faso. It is clear that some of the flexibilities offered by the TRIPS agreement, such as the transition period, would slow down Burkina Faso's efforts to improve its population's access to medicines. Others, on the other hand, such as the Bolar exception, would fit in perfectly with this policy and could do so through the EPA.

CHAPTER FIVE
CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

In line with the Sustainable Development Goals, Burkina Faso is committed to putting itself on the right track by offering its population better living conditions and, therefore, better access to medicines. Burkina Faso is one of the world's poorest countries and faces many challenges. Thanks to international collaboration, this sub-Saharan African country can benefit from the support of partners with greater financial resources, capable of helping it in its quest for better health for its population. The EPA between the European Union and the West African States does not alter the intellectual property laws already in force in Burkina Faso.

After a general presentation of the context in which the EPA was signed and its various intersections with the TRIPS Agreement in the introductory chapter of this study, Chapter 2 set out and explained the rationale behind the TRIPS Agreement and the extent to which its provisions, flexibilities, amendments, and other declarations play a role in a country's access to medicines. The same chapter then defined the main options granted by TRIPS, which the EPA can include in its text, to enable a State to exploit it to its best advantage.

Chapter 3 was then devoted to a case study of Burkina Faso in the light of the previous findings. The third chapter highlighted Burkina Faso's financial and infrastructural difficulties and the need to invest in and encourage local production of the medicines it needs. In the same section of the study, the various international agreements to which Burkina Faso is a party in terms of intellectual property were discussed, as well as the current national regime in this field. Chapter 4 then built on the findings of Chapter 3 to compare the situation of the EPA governing Burkina Faso with other EPAs signed with other African States. This comparison revealed trends in treating intellectual property rights in these bilateral agreements with the European Union. Chapter 4 then concludes the case of the EAC, based on the TRIPS flexibilities best suited to Burkina Faso.

Chapter 4 concluded by revealing that a weakened patent system is not advantageous for a country like Burkina Faso because innovation needs to be encouraged. If the aim is to promote local production, a country's primary argument for facilitating access to medicines through a patent system with difficult conditions seems counter-productive. Indeed, how can local production be promoted when it is difficult for local inventors to obtain legal protection for their inventions through patents?

Chapter 5, which constitutes the overall conclusion of this study, will begin by summarizing the findings of the previous sections. It will then make proposals that Burkina Faso could apply at the national level to improve access to medicines. Finally, the chapter will propose measures to be taken by the EPA and the European Union to help the country in this mission.

5.2 Findings of the study

5.2.1 Burkina Faso's crucial need for better access to medicines

The first finding of this study confirms the relevance of the subject. Burkina Faso urgently needs to improve access to medicines to meet the country's prevailing health challenges.[239] With high rates of infectious diseases such as malaria, HIV/AIDS, and respiratory infections, combined with maternal and child health problems, access to essential medicines is vital to the population's well-being.[240] Inadequate infrastructure, limited healthcare resources, and economic constraints make access to medicines a major challenge for the government and people of Burkina Faso.[241] Ensuring better access to medicines is therefore not only a question of improving healthcare but also a fundamental step towards achieving the country's broader development goals.[242] Collaborative efforts, policy initiatives, and partnerships with international organizations are needed to overcome these obstacles and provide equitable access to essential treatments for all Burkinabè citizens.

[239](n 162).
[240](n 151).
[241](n 163).
[242](n 176).

5.2.2 In Burkina Faso's fight for better access to medicines, money is the sinews of war

Burkina Faso's difficulties in accessing medicines are mainly due to financial constraints.[243] The country faces budgetary constraints that prevent it from allocating sufficient healthcare resources, including purchasing essential medicines. Burkina Faso, classified as a low-income country, struggles to find the funds needed to maintain a solid healthcare infrastructure, support research and development, and ensure a regular supply of medicines. This financial obstacle affects the government's ability to invest in healthcare and weighs on the population, as many people struggle to afford the necessary medicines due to their limited economic means.[244] Tackling this financial aspect is essential to improving access to medicines and healthcare in general in Burkina Faso.

5.2.3 The existence in Burkina Faso of a system to protect intellectual property rights and patents

Burkina Faso has established a robust national system for protecting intellectual property rights and patents through its membership in the African Intellectual Property Organization (OAPI). As a member of OAPI, Burkina Faso benefits from a common intellectual property framework encompassing patent protection, copyright, and related rights in all 17 member states.[245] The OAPI system provides an effective platform for safeguarding intellectual property, including patents, by offering simplified procedures for registering and enforcing patents.[246] This regional approach strengthens Burkina Faso's ability to protect and enforce intellectual property rights, helping to create an environment conducive to innovation and creativity. Burkina Faso, therefore, already has a well-structured and harmonized national system that facilitates the protection of intellectual property rights within its borders.

5.2.4 The EPA's unfinished business in intellectual property rights

In its current form, the Economic Partnership Agreement (EPA) between the West African states and the European Union has not conclusively addressed the issue of intellectual

[243](n 146).
[244](n 147).
[245](n 179).
[246]The Bangui Agreement 2015, Annex I.

property rights protection. Instead, it offers member states, including Burkina Faso, a degree of flexibility to determine the extent to which they can shape intellectual property regulations in a way that best serves their interests, particularly in the context of improving access to medicines in the least developed countries. This flexibility allows individual countries to tailor their IP policies to prioritize public health concerns, affordability, and access to essential medicines, recognizing the unique challenges nations like Burkina Faso face. So, while the EPA sets out a framework for trade relations, it does not prescribe a one-size-fits-all approach to intellectual property, allowing Member States to make decisions that correspond to their specific needs and objectives regarding healthcare and access to medicines.

5.2.5 TRIPS flexibilities are put to the test in the specific context of access to medicines in Burkina Faso

Burkina Faso, like many other least-developed countries, faces specific challenges in its quest to ensure access to essential medicines for its population. While the flexibilities provided by the TRIPS Agreement offer valuable tools for addressing these challenges, not all of them are ideally suited to Burkina Faso's unique situation.[247] Factors such as limited financial resources, insufficient infrastructure, and a lack of local pharmaceutical production capacity can make using certain TRIPS flexibilities, such as compulsory licensing or transition period, complex and less effective. Consequently, Burkina Faso may need to carefully select and adapt the TRIPS flexibilities that best match its capacities and priorities to maximize their impact on improving access to medicines for its citizens.

5.2.6 The EPA is a way for the EU to help Burkina Faso gain better access to medicines.

In line with the TRIPS agreement, which emphasizes the importance of developed countries helping least-developed ones, the European Union strongly believes in extending its support to Burkina Faso to improve access to essential medicines.[248] The Economic Partnership Agreement between the European Union and the West African states provides a platform for channeling this aid. By taking advantage of the flexibilities in the TRIPS agreement, the European Union can play a pivotal role in helping Burkina Faso strengthen its capacity to guarantee affordable and accessible medicines for its population. Such

[247](n 204).
[248](n 104).

assistance could encompass technical expertise, financial resources, and collaborative efforts to strengthen Burkina Faso's pharmaceutical infrastructure, in line with the overall objective of promoting public health and equitable access to medicines in least-developed and developing countries.

5.2.7 The EPA can build on existing terrain

The Economic Partnership Agreement can perfectly integrate into Burkina Faso's existing intellectual property rights system. By strategically designing and incorporating rules within the EPA framework tailored to Burkina Faso's specific needs and circumstances, the Agreement can facilitate improved access to medicines. Such integration would require careful consideration of TRIPS flexibilities and provisions that align with public health objectives. The EPA can serve as an intermediary to align Burkina Faso's intellectual property regime with international standards while preserving its ability to adopt policies and measures prioritizing public health and affordable access to essential medicines for its citizens. By building on and enhancing the existing IP framework, the EPA can significantly contribute to the country's efforts to tackle healthcare disparities and promote the well-being of its population.

5.3 Summary of the implications of TRIPS flexibilities in Burkina Faso's special context of access to medicines

The main conclusion of this study on the implications of the TRIPS agreement, in the context of the EPA, for access to medicines is that the issue goes beyond the mere accessibility of medicines; it also profoundly concerns their affordability. [249] While ensuring that essential medicines are available and physically within reach is essential, it is equally imperative to consider the economic aspect. Many people and whole countries face difficulty accessing medicines due to the exorbitant prices imposed by intellectual property rights and patent protection. The cost of life-saving medicines can be prohibitive, making them financially inaccessible to countless people, particularly in developing countries. It is at the intersection of accessibility and affordability that the real struggle lies, as both are intrinsically linked and need to be addressed holistically to ensure that everyone, whatever their economic situation, can obtain and benefit from essential medicines.

[249](n 124).

With these considerations in mind, a country may opt for a first line of action that involves leveraging intellectual property rights to make medicines more affordable, often through measures to weaken patentability.[250] This approach becomes essential when the cost of patented medicines becomes a significant obstacle to public health, particularly in situations such as pandemics or the urgent need for life-saving treatments. Proponents of this approach argue that by exploring options such as compulsory licensing or allowing generic versions of patented medicines to be produced, countries can mitigate the monopoly pricing power of pharmaceutical companies, making essential medicines more accessible to their populations. This strategy is based on the conviction that the protection of public health and the well-being of citizens must take precedence over exclusive patent rights in exceptional circumstances.[251]

One key aspect of this study was to analyze the extent to which LDCs have utilized the flexibilities provided by TRIPS to protect public health and promote access to medicines. These flexibilities include compulsory licensing, a transition period, parallel importation, the Bolar exception, and government use provisions, which allow countries to overcome barriers posed by patent monopolies and ensure the availability of affordable generic medicines.

The utilization of TRIPS flexibilities by LDCs significantly impacts access to medicines. Promoting competition and reducing the cost of patented drugs enable governments to allocate resources for procuring a broader range of medicines. This can be particularly beneficial for marginalized communities and those affected by diseases only or predominantly present in Africa.

The potential consequences of the TRIPS agreement in the context of the EU-Burkina Faso EPA depend on the approach chosen by the latter. If Burkina Faso adopts a proactive stance in using TRIPS flexibilities, it can safeguard access to medicines for its population. On the other hand, as the EAC case study shows, not all flexibilities are to the advantage of a country like Burkina Faso.[252] Indeed, the specific context of its population and its needs must be considered before determining the best strategy for improving access to medicines.

[250](n 204).
[251](n 209).
[252](n 204).

As for the Bolar provision, even though this measure protects the inventor's rights and therefore does not discourage research, there are reasons why this flexibility would be challenging to apply in the case of Burkina Faso; these reasons are in line with those generally limiting local production of pharmaceutical products. Thus, Burkina Faso would face significant challenges in taking full advantage of the Bolar provision due to financial resources and infrastructure limitations. The Bolar provision, which allows generic manufacturers to research and prepare generic versions of patented medicines for the market before patent expiry, requires substantial research and development and state-of-the-art pharmaceutical production capacity. Unfortunately, Burkina Faso does not have the financial resources to support activities on this scale nor to set up the necessary infrastructure for large-scale pharmaceutical production. The country's limited budget for healthcare and pharmaceuticals and resource constraints would prominently hamper its ability to take advantage of the Bolar provision effectively.

Similarly, Burkina Faso could hardly effectively use compulsory licensing as a tool to improve access to essential medicines. Several factors contribute to the country's limited capacity in this respect. First, Burkina Faso lacks the domestic pharmaceutical production capacity needed to rapidly produce generic versions of patented medicines. Compulsory licenses generally require the existence of local pharmaceutical industries capable of manufacturing the necessary drugs, which is currently underdeveloped in Burkina Faso.

In addition, the country has resource constraints that would almost certainly hamper its ability to navigate the complex legal and administrative processes associated with compulsory licensing. This includes the costs of legal proceedings, negotiations with patent holders, and the potential legal and commercial implications of such actions.

On the other hand, one of the measures provided for in Burkina Faso's positive intellectual property law, the OAPI law, is better suited to the country's needs. This is parallel importation.

Parallel imports can bring several potential benefits to Burkina Faso's healthcare system and its population. Here are some of the reasons why this measure would greatly benefit the country's efforts to improve access to medicines:

- Access to affordable medicines: Indeed, Burkina Faso doesn't yet have a pharmaceutical market in the strict sense of the term, apart from small local

pharmacopeia drug production units and the only modern drug production unit, Propharm.[253] However, given that this study's main argument in favor of access to medicines in Burkina Faso is strengthening local drug production capacity, it would be wise to start considering legal measures to promote this solution. Parallel imports can introduce competition into the pharmaceutical market, driving down the price of patented medicines. This increased competition can make essential medicines more affordable for both the government and patients, tackling the problem of high drug prices, which can limit access to necessary treatments.

- Budgetary relief: Burkina Faso, like many low-income countries, faces budgetary constraints regarding healthcare expenditure. Parallel imports can help the government to allocate its health budget more effectively by reducing the cost of medicines, enabling it to provide a wider range of health services and treatments. This is because the heart of the parallel import mechanism lies in taking advantage of the leeway allowed by intellectual property law in a given country or region to legally acquire patented medicines and resell them at lower cost on another market. For example, if a company sells a drug called X for 10 Rands in country A but markets the same drug in country B for only 1 Rand, an individual may choose to import drug X from country B and sell it in country A for 3 Rands. Therefore, in this scenario, let's assume country A is Burkina Faso. Burkina Faso could then save 7 Rands on the purchase of drug X. The country and its people have everything to gain from such a measure.

- Increased availability of medicines: Parallel imports can also increase the availability of patented medicines in the country. This is particularly crucial for diseases that weigh heavily on Burkina Faso, such as malaria and HIV/AIDS. Greater availability can help meet the demand for these treatments, reduce disease prevalence, and improve public health outcomes.

- Encouraging competition: Parallel imports will encourage competition between pharmaceutical companies. When several suppliers offer the same drug, this can

[253] (n 158).

lead to negotiations for lower prices, better conditions, or technology transfer agreements. The result may be better access to a wider range of quality medicines.

- Improving public health: By making essential medicines more affordable and accessible, parallel imports can help improve public health outcomes. They can help reduce disease prevalence, lower mortality rates, and improve the general well-being of Burkina Faso's population.

- Allocation of resources: Savings from parallel imports can free up financial resources that can be reinvested in other key areas of the Burkinabe healthcare system, such as infrastructure improvements, training of healthcare staff, and the purchase of other essential medical supplies.

To remedy Burkina Faso's lack of pharmaceutical infrastructure, several strategies and actions can be envisaged, starting with a clear commitment from the political authorities at the national level. Secondly, the EPA can play a role in enabling Burkina Faso to benefit from the EU's advantages in promoting access to medicines for its population.

5.4 Proposed national solutions for access to medicines in Burkina Faso

5.4.1 Investment in local pharmaceutical production

Burkina Faso can invest in developing and strengthening its local pharmaceutical production capacity. This would involve providing incentives and support for pharmaceutical companies to set up or expand operations in the country. This will improve the availability of essential medicines and reduce dependence on imports.

5.4.2 Research and development (R&D) initiatives

Encouraging R&D in the pharmaceutical sector can lead to developing new medicines and healthcare solutions. This can be achieved through partnerships with universities, research institutes, and international organizations to promote innovation and knowledge sharing.

5.4.3 Capacity-building

Burkina Faso should invest in training and capacity-building programs for local pharmaceutical industry professionals. This would include training pharmacists, researchers, and technicians to improve their drug manufacturing, quality control, and pharmaceutical research skills and knowledge.

5.4.4 Infrastructure development

The idea here is to improve pharmaceutical manufacturing infrastructure, including constructing modern pharmaceutical production facilities, laboratories, and quality control centers. Ensuring compliance with Good Manufacturing Practices is essential to producing high-quality medicines.

5.4.5 Improving the regulatory framework

This proposal is for Burkina Faso to strengthen and streamline the regulatory framework for pharmaceutical products, ensuring that it meets international standards for safety, efficacy, and quality. This can boost investor confidence and facilitate drug registration and approval.

5.4.6 Public-Private partnerships

Burkina Faso should actively encourage partnerships between the government, the private sector, and international organizations, such as the European Union, to support the local pharmaceutical industry. Public-private collaborations can lead to much-needed joint investment, technology transfer, and knowledge sharing.

5.4.7 Access to financing

The crux of all the challenges facing Burkina Faso regarding access to medicines is the question of financial resources. Money is needed to implement all the solutions envisaged. The country needs to facilitate access to financing for pharmaceutical companies, especially small and medium-sized enterprises (SMEs) in the pharmaceutical production sector. Traditional pharmacopeia must not be forgotten. Financial incentives and subsidies can encourage local companies to develop and innovate.

5.4.8 Support for intellectual property

The idea is to implement policies that strike a balance between protecting intellectual property rights and ensuring affordable access to essential medicines. This can include using the flexibilities of international agreements such as TRIPS to facilitate access to generic medicines. This is where the agreement with the European Union comes in because if Burkina Faso does not have the means to apply the flexibilities provided by the TRIPS agreement, the European Union can do so and enable Burkina Faso to benefit from them. The EU can help Burkina Faso use TRIPS flexibilities to improve access to affordable medicines. This includes advocating compulsory licensing or supporting the production of generics for essential medicines. The European Union can, for example, use compulsory licenses to export medicines to Burkina Faso; this has been possible since the 2003 ministerial decision, which no longer limits production under compulsory license to the local market.

5.4.9 Regional collaboration

Burkina Faso can also collaborate with neighboring countries and regional organizations, such as the West African Economic and Monetary Union (WAEMU), to harmonize pharmaceutical regulations and promote intra-regional trade in pharmaceuticals. This idea is all the more pertinent given that the other countries in these regional organizations present the same health picture as Burkina Faso. They are all prone to tropical and/or neglected diseases and are all developing or least-developed countries. So, thanks to regional collaboration, the member states of these organizations can adopt an access-to-medicines policy based on common challenges and objectives. This is important because one of the challenges of collaboration between the European Union and West Africa is that the two blocs seem to have different interests and priorities. They do not have the same level of development, and their health maps are very different. In such a partnership, relations can hardly be collaborative. Rather, they will be relationships of help, assistance, support, and dependence.

5.4.10 Strengthening the healthcare system and taking account of the security context

At the same time as the above measures are put in place, Burkina Faso should also strengthen the entire healthcare system, including drug storage and distribution infrastructures, to ensure that pharmaceutical products reach the population. 80% of

Burkina Faso's population lives in rural areas, with roads that are often impassable and dusty. The vast majority of the population has no electricity either. Since 2015, the country has faced relentless terrorist attacks that further isolate people from vital systems such as hospitals, pharmacies, and other health facilities. Burkina Faso should implement secure solutions for supplying the population with medicines. For example, as with food supplies, caravans escorted by defense and security forces could, at regular intervals, travel to the most inaccessible areas and make medicines and healthcare available to vulnerable populations.

By implementing these strategies and fostering an environment conducive to the pharmaceutical industry, Burkina Faso can improve its pharmaceutical infrastructure, enhance access to essential medicines, and contribute to better healthcare outcomes for its citizens.

5.5. Proposals to be implemented at the international level within the framework of the EPA to improve access to medicines in Burkina Faso

The relevance of the EPA lies in the fact that the European Union (EU) can play an important role in helping Burkina Faso to finance the development of its infrastructure in the pharmaceutical sector through various mechanisms and partnerships. As stated in the TRIPS agreement, developed member states have an obligation to assist least-developed countries in this respect. The goal is always to lift least-developed countries out of poverty and increase their share in international trade.

5.5.1 Aid and subsidies

A first contribution that the European Union could make through the EPA would be development aid and subsidies. The EPA can stipulate that the EU should provide financial assistance to the West African bloc states and thus to Burkina Faso through development aid and subsidies. This funding can be used to build pharmaceutical manufacturing facilities, modernize laboratories, and improve quality control systems. These grants can also bridge the financial gaps that Burkina Faso faces in developing its pharmaceutical infrastructure.

5.5.2 Loans and preferential terms

The second proposal is like the first. The EPA can specify that the European Union, which has more financial resources than the West African states, can grant loans preferentially. The EU could then offer low-interest loans to Burkina Faso to invest in pharmaceutical infrastructure. The EPA can even specify that these loans should have favorable terms, extended repayment periods, and lower interest rates, making them more accessible for infrastructure projects in Burkina Faso.

5.5.3 Technical assistance and capacity building

Another area in which the EPA can intervene and set rules that would help Burkina Faso and the other least-developed countries party to the convention is technical assistance and capacity building. In addition to financial support, the EU can provide technical assistance and capacity-building programs. This may involve sending experts to Burkina Faso to help with infrastructure planning, the development of a regulatory framework, and best practices in pharmaceutical manufacturing. In this way, capacity building can improve Burkina Faso's ability to manage and maintain its pharmaceutical infrastructure effectively.

5.5.4 Public-Private partnerships

The solution that this study identifies for the European Union to assist Burkina Faso in its quest to improve access to medicines on its territory is also being proposed at the national level. It’s PPPs. The EPA can facilitate PPPs between European pharmaceutical companies and the Burkina Faso government or local pharmaceutical companies. These partnerships could involve technology transfer, investment, and knowledge sharing, enabling Burkina Faso to strengthen its pharmaceutical industry.

The EPA could also act as an incubator for collaboration between Burkina Faso and European research institutions and universities. The latter can promote innovation in Burkina Faso's pharmaceutical sector. The EU can support joint research projects, the exchange of knowledge, and the development of new medicines adapted to local health needs. This solution would circumvent the difficulties that make the Bolar exception virtually inapplicable in Burkina Faso as things stand.

5.5.5 Trade facilitation

More generally, trade facilitation between Burkina Faso and the EU can indirectly support infrastructure financing. By promoting trade in pharmaceutical products under the EPA, the EU can boost revenues from Burkina Faso's pharmaceutical industry, which can be reinvested in infrastructure development. Also, as mentioned above, the EPA can allow compulsory licensing and parallel imports. In this way, the EU can help Burkina Faso use TRIPS flexibilities to improve access to affordable medicines.

5.5.6 Monitoring and accountability

Following on from all these measures, the EPA between the European Union and West Africa can include a monitoring and accountability clause. By this, I mean that the EU can support the establishment of robust monitoring and evaluation systems to assess the impact of infrastructure investments, ensuring that funds sent to Burkina Faso are used efficiently and transparently.

By combining financial support, technical expertise, regulatory assistance, and collaborative efforts, the European Union can significantly contribute to improving access to medicines in Burkina Faso and, ultimately, to improving the health and well-being of its citizens.

5.6 Conclusion

This study established that Burkina Faso is very poorly equipped regarding infrastructure for producing medicines. What's more, the country itself is generally one of the poorest in the world, meaning that most of the population lives below the poverty line and suffers from multiple illnesses. Another factor to consider is the nature of the illnesses affecting the Burkinabè population. These are mainly tropical or neglected diseases such as malaria and respiratory illnesses. What all these diseases have in common is that they are widespread, if not exclusive, in poor Third World countries. As a result, very few pharmaceutical companies in developed countries are interested in developing drugs for these diseases. One of the best ways of encouraging pharmaceutical companies to focus on these tropical and/or neglected diseases is, to encourage them to start up. This is where patents come in. With a well-developed patent system that gives them protection and a guarantee of profitability for their inventions, there will be two major consequences for the people of Burkina Faso: On the one hand, at the national level, researchers will be

encouraged to work on developing medicines adapted to local needs. On the other hand, foreign companies will be encouraged to do the same; this second scenario is also good because even if the ideal would be to stimulate production, and therefore the local economy, the primary objective is the population's well-being and access to medicines.

Based on these findings, this study was able to analyze the provisions of the EPA and highlight the shortcomings to be corrected through the TRIPS Agreement. It appears that the EPA between West Africa and the European Union has not yet fully resolved the intellectual property rights protection issue. What it does do is commit the States Parties to effective protection of intellectual property rights, the ultimate objective of the bilateral agreement being to overcome poverty in West African States. The Agreement does not go any further nor specify the extent to which states must protect intellectual property. In this sense, it seems that, like the TRIPS agreement, the EPA leaves it up to its Member States to decide the direction they will give to their national legislation on intellectual property rights. For the time being, at least, given the *rendez-vous* clause, this position is not set in stone and may well evolve. Such an evolution could lead to the same result as the free trade agreement between South Africa and the European Union. This means that the EPA could still evolve to include provisions that would make it a TRIPS + agreement, i.e., one that sets out conditions for the parties in terms of intellectual property protection that go well beyond the minimum set by TRIPS.

If, at the end of the negotiations following the application of the *rendez-vous* clause, the parties to the EPA decide to make it a TRIPS + agreement for the West African States, and therefore for Burkina Faso, the consequence could be that obtaining a patent for an invention risk becoming complex, thus stifling the incentive to innovate. Innovation that Burkina Faso sorely needs to encourage research into the production of the medicines needed to treat the most widespread diseases in the country.

The study also revealed that not all TRIPS flexibilities would benefit access to medicines in Burkina Faso. Thus, after comparing the needs of Burkina Faso with the implications of including the mailbox in the national legislation of other least-developed countries such as Rwanda and Burundi, the conclusion is that the use of this waiver by a country like Burkina Faso, which needs to encourage research, would be counter-productive. No patent,

no incentive to invent or create. No incentive to create, and there are not enough medicines. Not enough medicines, no access to medicines for people with low incomes.

Thus, the main conclusion of this study is that the general trend seems to think that patenting must be weakened so that drug prices can be lowered. People can have easier access to them, which is detrimental to Burkina Faso's interests. Burkina Faso is plagued by diseases neglected by international multinationals in their research and development. It is, therefore, in Burkina Faso's good to encourage researchers to devote themselves to developing medicines for the diseases present on its territory. It is therefore necessary to offer a reinforced system of protection to patents and encourage inventors. This is the direction in which the EPA should be moving to encourage Burkina Faso's quest for better access to medicines.

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