CREATING MORE THAN A PROFITABLE REASON FOR PATENTS.
A PICTURE OF THE MEXICAN PATENT SYSTEM IN BIOMEDICINE

Palmira Granados Moreno

Degree of Doctor of Civil Law

Centre of Intellectual Property and Policy, Faculty of Law, McGill University

Montreal, Quebec, Canada

December, 2019

A thesis submitted to McGill University in partial fulfillment of the requirements of the degree of Civil Law (D.C.L.)

© Palmira Granados Moreno, 2019.

Library and Archives of Canada notice

Dedication

To my family, who has my “type-A” love and who supported me in more than one way every day throughout this journey. Special mention to my perfect Edgar, who has been my greatest inspiration, my loving mom and dad, who have always made me be better, my sister, who has been my life-long confidant, my one and only Mark who is my constant support, and my precious Luka, who gave me the final push.

Abstract

The patent system is frequently praised for its perceived ability to foster innovation, encouraging inventors and investors to devote their resources and efforts to the development of new products and ideas. However, in some contexts, the patent system may in fact hinder innovation and, in the field of biomedicine, contribute to the high prices of drugs, diagnostic tests, and treatments, thus impeding access to healthcare. Hence the question: "How can we tell when the patent system is benefiting or failing with respect to health-related innovation?" I focus on the specific case of Mexico, as an example of a developing country. Using the capability approach to devise a full definition of "utility/welfare," my findings lead me to conclude that the current patent system (including its legislation, policies, and practices) has failed to deliver on benefits to Mexico either in promoting local health-related innovation or in improving the health of its population. I argue that, while a law or a policy may be justified if it creates welfare to society, this welfare cannot be restricted to innovation for the sake of innovation or economic growth, particularly when the innovation in question is related to healthcare. Welfare denotes a state of doing well and health is a key element of human's – and therefore society's – well-being. In addition to looking at the impact of the patent system on research and development and access to healthcare at a national level, I undertake a limited case study on specific health-related research projects in Mexico to provide context for the theoretical analysis. The importance of my research lies in the geographic and social specificity of its approach, differentiating it from studies that are based on theoretical models alone and studies that focus on developed countries.

Resumé

Le système des brevets est souvent loué pour sa capacité perçue à favoriser l'innovation, car il encourage les inventeurs et les investisseurs à utiliser leurs ressources et leurs efforts afin de développer de nouveaux produits et idées. Cependant, dans certains contextes, le système de brevets pourrait en réalité entraver l'innovation, particulièrement dans le domaine biomédical, où il pourrait plutôt contribuer aux prix élevés des médicaments, des examens de diagnostic et des traitements, et par conséquent limiter l'accès aux soins de santé. La question suivante se pose donc: "Comment pouvons-nous déterminer si le système des brevets encourage ou nuit à l'innovation en santé?" Je concentre mon étude sur le cas spécifique du Mexique, à titre d'exemple de pays en développement. En employant une définition exhaustive des termes « utilité/bien-être » (« utility/welfare ») basée en l'approche des capabilité ("capability approach"), mes résultats mènent à la conclusion que le système actuel des brevets (incluant sa réglementation, ses politiques, et ses pratiques) a échoué à promouvoir l'innovation locale en santé ou à améliorer la santé des populations au Mexique. J'argumente que même si une loi ou politique pourrait être justifiée si elle génère un bien-être pour la société, ce bien-être ne doit pas se limiter à l'innovation dans le seul bût d'innover, ou bien encore à seule une croissance économique, particulièrement lorsque l'innovation est liée aux soins de santé. Le bien-être denote un état de bien-aller et la santé humaine (et donc sociale) en est un element determinant. En plus d'analyser l'effet du système des brevets sur la recherche et le développement, ainsi que sur l'accès aux soins de santé au niveau national, j'effectue une étude de cas portant sur des projets de recherche en santé au Mexique, afin de fournir le contexte à mon analyse théorique. L'importance de ma recherche découle notamment de sa spécificité

géographique et sociale, qui se distingue d'autres études effectuées, qui sont uniquement basées sur des modèles théoriques ou sur des pays développés.

Acknowledgements

First, I am forever thankful to my supervisor Prof. Richard Gold, who throughout this very long journey kept giving me his support and trust, who had the most insightful comments, discussions, and questions that made this thesis what it became, and who always inspired me (and still does) to keep working not only on my doctorate, but also on the subject. Second, I am thankful to Prof. Pierre Emmanuelle Moyse and Prof. Evan Fox-Decent for their opportune and valuable comments that contributed to a clearer and better presentation of ideas. Third, I am thankful to Prof. Yann Joly, Prof. Bartha Knoppers and my colleagues at the Centre of Genomics and Policy, who have contributed to the improvement of the researcher and writer I was and the one I am today. Fourth, I am thankful to Katie Saulnier, who edited this work from beginning to end making me sound more sophiscated and more "on point." Fifth, I am thankful to Emily Kirby, who dedicated her time to edit my very imperfect French abstract. I am also forever thankful to my friends Pepe, Luis, Andrei, Adriana, Amy, and Gaby and my family (including Jergas), who have stayed with me, cried with me, laughed with me, pushed me, put up with me, inspired me, supported me, and loved me.

Table of Contents

Introduction **11**
Background 11
Scope of my Research 12
Current Situation 14
Importance of my Research 17
Research Questions and Objectives 22
Hypotheses 23
Methods 24
Overview 26

Section 1 ..... **31**
Chapter 1. Theoretical Framework **31**
Introduction 31
1.1 Patent System and its Utilitarian Justification 35
1.2 Capability Approach 44
Conclusions 59

Section 2 ..... **62**

Chapters 2 and 3 Healthcare and Innovation in Mexico **62**
Introduction to Section 2 ..... **62**
Chapter 2 Access to healthcare **66**
2.1 Healthcare Services available in Mexico 66
2.2 Mexico's population and indigenous peoples 73
2.3 Impact of poverty and deficient healthcare on health 82
2.4 Final Remarks 85
Chapter 3 Research and development in medical genetics in Mexico **87**
3.2 Elements of the Innovative Environment Surrounding Medical Genetics in Mexico 91
3.3 Existing Innovation on Medical Genetics in Mexico and the Role of the Patent System 103
3.4 Final Remarks 114
Conclusions to Section 2 ..... **116**

Section 3 ..... **119**

Chapters 4 and 5: Case Study. **119**
Introduction to Section 3 ..... **119**
Chapter 4 P'urhépechas and their link with Tuberculosis **127**
4.1 Introduction 127
4.2 Access to Healthcare within P'urhépecha communities 129
4.3 Research and Development 145
4.4 Final Remarks 158
Chapter 5 Mazatecos, Mayas, and Nahuas and their link with Actinic Prurigo **162**
5.1 Introduction 162
5.2 Access to Healthcare within the Mazateca, Maya, and Nahua communities 165
5.2.3 Nahuas 172
5.3 Research and Development 182
5.4 Final Remarks 189
Conclusions to Section 3 ..... **191**

Section 4 195

Chapters 6, 7, 8 and 9. Justification of Patent System in Health-Related Innovation in Mexico 195

Introduction to Section 4 195

Chapter 6 Patent System, Health-Related Innovation, and Access to Healthcare .. 199

6.1 Benefits of the Patent System on Health-Related Innovation and Access to Healthcare as Discussed in the Literature 199

6.2 Concerns Regarding the Patent System on Health-Related Innovation and Access to Healthcare as Discussed in the Literature 205

Chapter 7 Impact of Patents on Health-Related Innovation and Healthcare in Mexico 234

7.1 Impact of Patents on Health-Related Innovation in Mexico 234

7.2 Impact of Patents on Access to Health-Related Innovation and Healthcare in Mexico 243

Chapter 8 Bases to Justify the Patent System in the context of Health-Related Innovation and Access to Healthcare in Mexico 252

8.1 Utilitarianism and the Patent System in Health-Related Innovation 254

8.2 Exceptionality of Health 267

8.3 Capability Approach and the Patent System in Medical Genetics 268

Chapter 9 Discussion: Health, Innovation, Patents, Mexico, and Suggested Solutions 272

9.1 The Utility/Welfare of Patents in Mexico 273

9.2 Implications of the Patent System on Health and Innovation in Mexico 274

9.3 Looking Ahead 281

Conclusions to Section 4 297

Conclusions 302

Importance of my Research 311

Moving Forward and Looking Ahead 314

Bibliography 317

Introduction

Background

The patent system is frequently praised and justified as a source of innovation. It is argued that the exclusive rights to commercialize and profit from patented inventions give patent holders the opportunity to recoup their investments and to make a profit out of their inventions.[1] This opportunity to recoup and profit becomes the economic incentive that encourages investors and inventors to devote their resources and efforts to innovation.

At least in the field of biomedicine, this assertion has been criticized. First, some authors raise concerns that the patent system may in fact hinder innovation in certain cases. Some of these concerns include the proliferation of patent thickets and the underuse of resources, information, and technologies, resulting in halted or delayed innovation. There is also a concern about an increase in costs and waste of resources due to excessive licensing fees and litigation.[2] Second, health is a determining factor in people's quality of life, and can mean the difference between life and death.[3] Therefore, the main concern

[1] *U.S. Constitution*, 4 March 1789 (Amended in 1992) [*U.S. Constitution*] art. 1 section 8; Committee on the Judiciary of the United States, *Report of the President's Commission on the Patent System* (United States of America: Senate, 1967); Nancy T Gallini, "The Economics of Patents: Lessons from Recent U.S. Patent Reform" (2002) 16:2 J Econ Perspect 131; Scott F Kieff, "Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science – A Response to Rai and Eisenberg" (2000) 43 Northwest Univ Law Rev 698; Kevin E Noonan, "Falsehoods, Distortions and Outright Lies in the Gene Patenting Debate", (15 June 2009), online: *Pat Docs* <http://www.patentdocs.org/2009/06/falsehoods-distortions-and-outright-lies-in-the-gene-patenting-debate.html>.

[2] Michael A Heller & Rebecca S Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" (1998) 280:5364 Science 698; Michael Heller, "The Tragedy of the Anticommons: Property in the Transition from Marx to Markets" (1998) 111:3 Harv Law Rev 622; Carl Shapiro, "Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting" in Adam B Jaffe, Josh Lerner & Scott Stern, eds., *Innovation Policy and the Economy* (United States of America: MIT Press, 2001) 119; E Richard Gold et al, "Are Patents Impeding Medical Care and Innovation?" (2010) 7:1 PLOS Med 1.

[3] Julie Clague, "Patent Injustice" in Severine Deneulin, Mathias Nebel & Nicholas Sagovsky, eds, *Transform Unjust Struct Capab Approach* (Netherlands: Springer Science & Business Media, 2006) 177; Ingrid Robeyns a), "The Capability Approach: a theoretical survey" (2005) 6:1 J Hum Dev 93.

raised specifically with respect to innovation in medicine[4] is that the patent system contributes to high prices of drugs, diagnostic tests, and treatments, thus impeding access to healthcare for many.[5]

Scope of my Research

The focus of this dissertation is on the impact that the current patent system (regulations, policies, and practices) has on health-related innovation in Mexico and on that country's most vulnerable populations' access to healthcare. In this thesis, I focus on the specific conditions under which health-related innovation unfolds in Mexico. These conditions include the incentives, sources of funding, partnerships, goals, and interests that members of the public (e.g. universities, academic research centres, and public hospitals) and private (pharmaceutical and biotechnology companies) sectors have in engaging in activities of research and development in the field, as well as in the resulting outcomes (e.g. medical products and services). I specifically look at these conditions in relation to the patent system to determine how the latter has influenced the former and the extent of any such influence. Likewise, I undertake a limited case study of the conditions under which specific health-related research projects involving human subjects took place in Mexico to provide context for the theoretical analysis. I compare my findings at both levels

[4] Throughout my thesis, I will use the terms "health-related innovation", "medical research" and "innovation in medicine" indistinctively.

[5] Julie Clague, *supra* note 3; Gold et al, *supra* note 2; Arti K Rai, "Proprietary Rights and Collective Action: The Case of Biotechnology Research with Low Commercial Value" in Jerome H Reichman & Keith Maskus, eds., *International Public Goods and Transfer of Technology Under the Globalized Intellectual Property Regime* (Cambridge: Cambridge University Press, 2005) 288; Stephen M Maurer, Arti Rai & Andrej Sali, "Finding Cures for Tropical Diseases: Is Open Source an Answer?" (2004) 1:3 PLoS Med e56; Aled Edwards, *Freeing Science — From Software to Medicine* (Montreal, Canada, 2017).

(national and individual) to the benefits and concerns discussed in the literature and to those claimed to have taken place in developed countries.

My analysis draws on a variety of sources and focuses on health-related innovation and access to healthcare in Mexico. The sources include statistical information publicly available in governmental and institutional websites, databases, and documents, as well as regulation and public governmental policies. I specifically focus on medical genetics as an example of an area of medical innovation for two reasons. First, medical genetics is a promising field in the areas of innovation in the pharmaceutical and biotechnology industries and one in respect to which Mexico has engaged in state-of-the-art projects (namely the Mexican Diversity Genome Project and the Indigenous Genoteca). Second, the research projects I present in the case study pertain to medical genetics. In addition to the Mexican patent system and the country's healthcare system, I examine the particular conditions of Mexico's most vulnerable sector of the population, including Indigenous Peoples, because close to half of Mexico's population lives under the poverty line and has very limited access to healthcare. This situation of inequality and low quality of life and welfare constitutes one of my main concerns and causes for criticism of the current patent system in respect of health-related innovation.

To provide greater context to my analysis, I conducted a limited case study involving two sets of medical genetics research projects performed in Mexico involving Mexican Indigenous Peoples relating to two different conditions. The first set of medical research projects focused on tuberculosis in the P'urhépecha community and the genetic-

based resistance that some of these patients exhibit to the fatal aspects of the disease. The second group focused on actinic prurigo suffered by members of the Mazateca, Maya, and Nahua communities, mainly as the result of a genetic predisposition to this disease. In addition to reviewing the scientific and medical findings of the research projects and the characteristics and socio-economic conditions of the communities involved, this qualitative analysis includes a limited number of interviews with public sector researchers in Mexico who work together conducting genetics research. This analysis is not designed to be representative of all public sector medical researchers in Mexico, let alone private sector researchers. Rather, I present this qualitative analysis to provide greater insight into the actual conduct and context of medical research in Mexico.

Current Situation

As I will show, Mexico's current patent regulations and policies are very similar to those that exist in higher-income countries: they provide similar exclusive rights, for similar terms, with similar users' rights and exceptions. These laws, regulations and policies are formally considered and promoted as essential to the country's scientific and technological development and innovation - and therefore, important for the country's socio-economic progress and social benefits - all of which results in societal welfare.[6] These expectations support the reasoning and utilitarian basis that, as long as the patent system (through the exclusive economic rights it grants innovators and companies)

[6] Ho Calvin Wai Loon, "Utilitarianism and Patents: Justification and Change" (2010) 2:3 Asian Bioeth Rev 202; Michael J Trebilcock, "An Introduction to Law and Economics." (1997) 23 Monash Univ Law Rev 123; Canadian Competition Bureau, *Enforcement Guidelines Intellectual Property* (Canadian Competition Bureau, 2016); Richard A Posner, "Utilitarianism, Economics, and Legal Theory" (1979) 8:1 J Leg Stud 103; Kieff, *supra* note 1.

promotes innovation, this innovation will create welfare in the form of direct improvements to society's well-being with the creation of innovative products and of economic growth for the industry, the region, and the country. Furthermore, given that these benefits are made available to everyone in the market, this welfare is offered to the greatest number of people.

However, while the patent system may be similar to that of higher-income countries, Mexico's pharmaceutical and biotechnology industries are not. Most local pharmaceutical and biotechnology companies focus on the manufacture of generics, biocomparables (biosimilar drugs in English), and similares,[7] while it is the same top ten foreign companies that lead most of the innovative activities and have close to 70% of the total market in Mexico. The public sector (academic institutions and public research centres) is focused on basic research without clear translation into commercial clinical applications. Mexico's public and private sectors are in the second lowest position among OECD countries with respect to their investments in science, technology, and innovation.

[7] Similares or similar medicines are those that may contain the same chemical active ingredient, dosage form, route of administration and identification therapeutic regimen as the innovator's and/or patent holder's, but they lack the certification of bioequivalence. A certification of bioequivalence is a pharmacokinetics analysis that determines whether two products are, for all purposes and intents, the same, causing similar effects in efficacy and safety. This certification is required to approve a generic medication. They differ from biosimilar (biocomparable) drugs in that the latter are equivalent to the biotechnological/biologic innovative clinical products and are required to have a bioequivalent certification, while similares are equivalent to a patented chemical drug and are not required to have a certificate of bioequivalence. They also differ from generics in that the latter are required to have the bioequivalence certification and are not offered to the public under a brand name, while the similares are not required to have that bioequivalence certification and are offered under a brand name. Claudia Burr et al, *Guía para el paciente participativo* (Mexico: LID Editorial Mexicana, 2011) at 77; A Mayoral-Zavala et al, "Actualización sobre los medicamentos biocomparables en la enfermedad inflamatoria intestinal: posición y recomendación en México" (2018) 83:4 Revista de Gastroenterología de México 414; *Ley General de Salud*, Diario Oficial de la Federacion, 7 February 1984 art. 376.

What I will argue in this thesis is that the Mexican patent system particularly benefits foreign companies as they own most of the patents in Mexico. Therefore, despite Mexico having a similar patent system to that of higher-income countries, the expectations typically associated with the patent system (namely advancement of local innovation, incentives to invest in innovation activities, patents for local innovators, and overall welfare for society and local economic growth) do not seem to have been met in Mexico, or at least not in the same way they have been met in developed countries.

Mexico's healthcare system is both public and private. The former is insufficient and the latter is often unaffordable. The federal and the state governments concurrently provide health services through Mexico's social security system administered by different agencies. Despite the involvement of both governmental sectors and these multiple agencies, in 2015, 23.1% of Mexico's population did not have access to public healthcare.[8] Private healthcare services are provided through doctors and specialists who have a private practice. The costs of doctors' appointments, hospitalization services, and clinical tests vary depending on the level of luxury of the premises, the reputation of the doctors, and the complexity of the medical condition. Patients either cover the medical expenses out of their own pockets or they obtain private health insurance.

[8] INEGI, "INEGI Cuadro Resumen. Indicadores Sociales", (24 January 2018), online: *INEGI* <http://www3.inegi.org.mx/sistemas/temas/default.aspx?s=est&c=19004>; INEGI, "Banco de indicadores", (30 June 2016), online: *Banco Indicadores Instituto Nacional de Estadistica y Geografia* <http://www.beta.inegi.org.mx/app/indicadores/>.

In 2017, there were 32 million people in Mexico without access to healthcare services.[9] These problems regarding access to healthcare are not the result of only the shortcomings or failures of one system, but of the combination of the shortcomings and failures of several relevant systems. As I will argue in the following chapters, the patent system contributes to these problems in two ways: the high prices of patented medical products and the unavailability of substitutes in the market. Considering the huge socio-economic gaps in Mexico's population, the aforementioned problems regarding access to healthcare put a large sector of Mexico's population's health at risk. In this sense, in the context of health-related innovation, the welfare that the patent system is expected to bring to society through innovative drugs, diagnostic tests, and therapies is only available to those who can afford them that, in Mexico's case, are likely not to be many. Limited access to these innovative products and services leads me to question whether this innovation should be considered to bring welfare at all. Innovation is only valuable if it has an actual societal impact. In healthcare-related innovation, this impact should only be deemed met if those who need the innovative drugs, diagnostic tests, and therapies can in fact have access to them.[10]

Importance of my Research

The importance of my research lies in its specifically located approach. This approach differs from studies that are based on academic presumptions and from studies

[9] Ruben Migueles, "Sin acceso a salud, 32.6 millones de trabajadores: Inegi", *El Universal* (15 November 2017), online: El Universal <http://www.eluniversal.com.mx/cartera/economia/sin-acceso-salud-326-millones-de-trabajadores-inegi>.
[10] Loon, *supra* note 6; Peter Mack, "Utilitarian Ethics in Healthcare" (2004) 12:3 Int J Comput Internet Manag 63; Julie Clague, *supra* note 3.

that focus on developed countries, whose characteristics and conditions are not found in Mexico.

Most existing studies and analyses regarding the impact of the patent system describe and discuss benefits, concerns, and proposed strategies from either a theoretical perspective or from a perspective based on circumstances and experiences of developed countries, particularly the United States. This is problematic and misleading for other countries, and especially for developing countries, in terms of what would in fact benefit or harm them.

As I have mentioned above and as I will further argue later, the patent system does not operate in isolation from other related systems, programs, policies, culture, and circumstances. Given this, the pace, extent, and focus of innovation are not only influenced by the patent system and the incentives and restrictions it provides to the public and the private sectors, but also by the science, technology, and innovation programs governments have in place, including the resources they devote to grants, awards, incentives, and tax and credits, as well as the resources the government invests directly in the creation and sustainability of public research centres, and the interactions that the patent system has with all these other programs, policies, and systems. A country's (or region's) infrastructure, human resources (trained inventors), and market (i.e. population's purchasing power) are other factors with which the patent system interacts and that will influence the final impact that the patent system will have on innovation.

Likewise, access to innovative medical products and services is impacted by the patent system, as it is one of the determining factors in the products' prices. However, this is not the only factor to consider while assessing the impact of the patent system on access to health-related innovation. The structure, regulation, resources, and ability of the healthcare system to provide services, as well as the population's socio-economic conditions will also influence the impact that the prices enabled by the patent system will have on people's access to healthcare. These circumstances tend to differ among countries.

Bearing all this in mind, a proper and thorough assessment of the impact of the patent system on health-related innovation should include the specific circumstances in which the patent system operates. My research aims to do that, focusing on the specific case of Mexico.

The case study contributes to this specificity by telling the stories of four very concrete vulnerable communities in specific circumstances (genetic uniqueness, participation in medical genetics projects, geographical isolation, very poor socio-economic conditions, and deficient access to healthcare) in relation to two diseases with a genetic component. The first story is of members of the P'urhépecha community, who, even though they were found to be vulnerable to developing tuberculosis, also showed a genetic resistance to the lethal effects of the disease.[11] This genetic resistance attracted the interest

[11] Francisco Loeza et al, "Distribution of class I and class III MHC antigens in the Tarasco Amerindians" (2002) 63 Hum Immunol 143; P Niño-Moreno et al, "P2X7 and NRAMP1/SLC11 A1 gene polymorphisms in Mexican mestizo patients with pulmonary tuberculosis" (2007) 148:3 Clin Exp Immunol 469; Malathesha Ganachari et al, "Joint effect of MCP-1 genotype GG and MMP-1 genotype 2G/2G increases the likelihood of developing pulmonary tuberculosis in BCG-vaccinated individuals" (2010) 5:1 PloS One.

of researchers from multiple disciplines in an attempt to understand a genetic resistance that could be useful in the development of drugs and genetic therapies that could better treat tuberculosis. The second story is of members of the Mazateca, Maya, and Nahua communities with a genetic predisposition to actinic prurigo, a non-lethal, but still life-changing, skin disease that has no available cure, despite existing research studies.[12] The purpose of the case study is to give a closer glimpse into the reality of the conditions that Mexico faces, particularly with those who are the most vulnerable.

The information gathered from these two levels of research (national and community) allows the discussion about the patent system's impact on medical research and development and on access to healthcare to assess whether the benefits and concerns that the supporters and critics of the patent system raise in the literature and in lobbying processes of the patent system do actually take place in Mexico. This information can be useful in identifying the conditions that could in fact favour the development of health-related innovation in Mexico and that could broaden that development's societal value, and therefore, be used to better inform decisions, amendments, policies or programs that could be proposed with respect to the patent system in health-related innovation in Mexico, as opposed to relying on studies and suggestions that were made using another context as a point of reference.

[12] G Vargas-Alarcón et al, "HLA-DR4 allele frequencies on Indian and Mestizo population from Mexico" (2000) 61:3 Hum Immunol 341; T Hojyo-Tomoka et al, "Actinic prurigo: an update" (1995) 34:6 Int J Dermatol 380.

Finally, as it has been seen in other fields and subjects, unrealistic and inaccurate benefits and concerns can cause inappropriate hype about the value and harm that a model, project or field can bring. It has been the case of stem cell research, biobanks, and personalized medicine to name some examples.[13] The patent system can be affected by a similar hype as well. Similar to the case of an unrealistic hype in stem cell research, biobanks, and personalized medicine, the consequences of overstating or overlooking the benefits or drawbacks of the patent system can include misinformed policy debates, misaligned and inefficient allocation of resources, and models and programs that do not bring about the expected welfare.[14] The specificity that I intend to bring to the debate on the impact of the patent system on health-related innovation in Mexico will aim to achieve two things. First, it will bring the discussion onto a platform based on actual conditions and not on the hype of the patent system. Second, it will increase the chances of finding the necessary balance in the way the patent system is regulated, promoted, enforced, and implemented in order to allow Mexico (and any given country) to truly benefit from a system that promotes medical innovation without negatively affecting access to healthcare.

[13] Kellia Chiu, Quinn Grundy & Lisa Bero, "'Spin' in published biomedical literature: A methodological systematic review" (2017) 15:9 PLOS Biol, online: <http://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.2002173>; Alessandro R Marcon, Mark Bieber & Timothy Caulfield, "Representing a 'revolution': how the popular press has portrayed personalized medicine" (2018) Genet Med Off J Am Coll Med Genet; Christiaan H Vinkers, Joeri K Tijdink & Willem M Otte, "Use of positive and negative words in scientific PubMed abstracts between 1974 and 2014: retrospective analysis" (2015) 351 BMJ h6467; Ubaka Ogbogu et al, "Newspaper coverage of biobanks" (2014) 2 PeerJ e500.

[14] Alan Petersen & Ivan Krisjansen, "Assembling 'the bioeconomy': Exploiting the power of the promissory life sciences" (2015) 51:1 J Sociol 28.

Research Questions and Objectives

Mexico's current patent system resembles that of developed countries such as the U.S., Canada or the E.U. in an attempt to promote benefits that are similar to those that such patent systems promise. In view of this, the main question that I address in my dissertation is "How can we tell when the patent system is benefiting or failing with respect to health-related innovation?" I focus this question on the specific case of Mexico, as an example of a developing country.

In order to answer this question, I also ask the following complementary questions: How have Mexico's current patent system (regulations, policies, and practices) and its promotion, implementation, and enforcement influenced the country's health-related innovation environment? How have they impacted its population's access to healthcare in general? Has this impact resembled that in developed countries? Has it been beneficial for the country's local health-related innovation and access to healthcare? In order to better answer this last question, and considering the importance of health for a person's well-being, I examine whether the benefits arising from innovative medical products and their availability in the market in general are enough to consider them beneficial for Mexico's society overall, especially if they simultaneously limit countervailing benefits in specific populations. Should the hardships suffered by Mexican Indigenous Peoples or impoverished populations in terms of access to healthcare justify a revision of what constitutes beneficial in this context, particularly since close to half of Mexico's population live under the poverty line? In this context, what constitutes "benefit" or "beneficial"? Finally, considering the previous questions, could other, more open, methods or models

help rebalance the patent system and thereby improve overall benefits extending to wider populations?

Hypotheses

My first hypothesis is that the answer to my question "How can we tell when the patent system is benefiting or failing with respect to health-related innovation?" has to be worked on and answered from a specific context. The arguments in favour of the current patent system in Mexico are usually made either solely on a theoretical basis, or by considering facts and conditions prevalent in developed countries. In those countries, industries are highly developed, resources are available for research. This is usually not the case in most developing countries: most of their industries are underdeveloped and they have more limited resources available for or devoted to research and development. This is the situation in Mexico. Mexico has its own particular conditions that differ in many respects with those in developed countries. Consequently, I will show that in Mexico, the patent system has had a different impact on innovation and in fact, it has failed to encourage local innovation.

My second hypothesis is that the current promotion, implementation, and enforcement practices of the patent system in Mexico can have a negative effect on access to healthcare, thereby putting many people's lives and well-being at risk.

My third hypothesis is that a better definition of what constitutes "benefit", "beneficial" or "welfare" would be helpful in evaluating and judging the impact of the

patent system and therefore determining how can we tell when the patent system is benefiting or failing with respect to health-related innovation.

My fourth hypothesis is that models of open collaboration (e.g. public-private partnerships, open science) can help make up for the shortcomings of the current patent regulations, policies, and practices. First, they can help balance, on the one hand, the investors' economic interests of obtaining patents and commercializing their inventions, and on the other, the users' (researchers, inventors, patients) need for a more efficient strategy of sharing and disseminating information, methods, and technology in order to democratize and truly promote innovation. Second, they are better suited to providing access to healthcare than the free market in which the patent system operates.

Methods

This dissertation uses two methods. For the qualitative part of the dissertation, I used a case study and literature review methodologies. The three reasons for using a case study methodology are as follows.[15] The first of these is the nature of the research questions I ask: *how* can we tell when the patent system is benefiting or failing with respect to health-related innovation, *how* does the patent system impact health-related research and development, *what* is the extent of that impact, *why* is this the case in Mexico, and *how* does it impact Mexico's vulnerable populations' (including specifically Indigenous

[15] The three requirements proposed by Robert Yin to choose a case study as methodology: a] "how" or "why" question being asked, b) contemporary set of events, and c] little or no control over the events under study. Robert K Yin, *Case Study Research: Design and Methods*, fourth ed (United States of America: SAGE, 2009] at 8–13; Irving Seidman, *Interviewing as Qualitative Research: A Guide for Researchers in Education and the Social Sciences*, third ed (United States of America: Teachers College Press, 2006].

Peoples) access to healthcare. Questions as to "how" and "why" of something are well-served through the case study approach.[16] The second reason is the nature of the phenomenon to be studied.[17] Contemporary events are best-examined using case studies because they allow the use of a variety of evidence, including documents, interviews, and observations.[18] Ongoing medical research projects involving Mexican Indigenous Peoples constitute a contemporary phenomenon with a real-life context and therefore, a case study could adequately address some of the concerns I will raise. The third reason is the fact that there is little control over the events' variables.[19] The parties in the research process and the beneficiaries of such research do not control or manipulate the variables; instead, they act as mere observers. My role in this case study was merely observational without exerting any control over any variable of the events: to report the role that the patent system plays in the biomedical research process and the access to healthcare in Mexico.

The subjects I interviewed were researchers who have participated in specific research projects associated with medical genetics. The majority of the researchers were selected based on the fact that they regularly collaborate in medical genetics research projects with Dr. Granados, who was my original contact. Two of the interviewees were selected because of their role in the technology transfer offices in the institution where they worked. The interviews concerned the researchers' personal research practices; information on the circumstances surrounding those practices, interests, and perspectives was highly useful. They were recorded in video, audio only, or written notes, depending on

[16] Yin, *supra* note 15 at 8, 9 & 13.
[17] *Ibid* at 8, 11 & 13.
[18] *Ibid* at 11.
[19] *Ibid* at 8 & 13.

the research subject's preference. Some of the interviewees chose not to be identified. All the interviews performed were subject to prior ethics approval from McGill University. The questions were drafted in terms according to the subject's background and asked in Spanish. I translated their answers into English.

The literature review for the analysis of the case studies included peer-reviewed articles, monographs, governmental information, and institutional reports and statistics, and focused on the selected Mexican Indigenous Peoples and the corresponding selected disease.

For the rest of my dissertation, I performed a scoping analysis of peer-reviewed articles, monographs, books and book chapters, legislation, governmental information, company websites, institutional reports and statistics, and documents issued by non-governmental organizations. The analysis for this part focused on the socio-economic conditions of Indigenous populations in Mexico and general population, the country's healthcare systems, its patent system, and its pharmaceutical and biotechnology industries in terms of actors, research patterns, and patenting practices. The analysis for the last part centred on discussions of the benefits and criticisms of the patent system in the area of medical innovation and access to healthcare.

Overview

This dissertation is composed of nine chapters. These nine chapters are organized in four sections. The first chapter provides the theoretical framework to lead the discussion

on the impact of the current patent system on Mexico's pharmaceutical and biotechnology innovation industries and on the access to healthcare of Indigenous Peoples in Mexico. It will present the capability approach to justice as the dissertation's framing theory. First, I describe the way in which utilitarianism is commonly used to justify the patent system based on the utility/welfare it is expected to create for society. I review the main criticisms with the way the concept of "utility/welfare" is used in the context of the patent system with respect to health-related innovation, and I introduce the capability approach as an option to reduce and even avoid those problems. I use the concepts of "capabilities" and "functionings" described in the capability approach to devise a concept of welfare that is mindful of the importance of global access to healthcare. In this sense, I argue that the assessment to determine whether the patent system brings about welfare as a way to justify its regulation and implementation in the context of medical innovation should entail ensuring (or at the minimum, not blocking) access to healthcare for everyone who needs it, regardless of socio-economic status, as opposed to solely focusing on ensuring that the patent system promotes innovation, scientific and technological advancement, industry development, and economic benefits. This chapter makes up the first section.

In the second section, I focus on the medical and medical genetics research and development and on the healthcare systems in Mexico. This section is composed of two chapters: two and three. In chapter two, I examine the conditions in which healthcare services are provided in Mexico: type of healthcare systems, actors and institutions involved, resources, coverage, policies concerning medications (patented or generic), challenges, and shortcomings. Then, I describe the socio-economic conditions in which the

country's population lives. In this chapter, I specifically describe the socio-economic conditions of the Indigenous Peoples as a sub-group of Mexico's most vulnerable populations. These conditions will provide a clear understanding of the means that different sectors Mexico's population commonly have available to access healthcare. In chapter three, I focus on the impact that the patent system has on medical genetics innovation in Mexico. I describe the patent regulations and policies specific to inventions concerning medical genetics, the status of the industry, the main actors, their activities and research foci, sources of funding, and the most common patenting practices in the field. The information contained in this chapter provides an overview of the interests, challenges, and needs that the different actors of the industry have in Mexico. This will help to determine the role that patents have played and could potentially play in the health-related innovation process.

The third section contains the case study and comprises two chapters: four and five. Each chapter focuses on one disease associated with Indigenous Peoples. Chapter four centres on the P'urhépechas and tuberculosis. Chapter five focuses on the Mayan, the Nahuas, and the Mazatecas and actinic prurigo. In each chapter, I describe the socio-economic conditions in which the Indigenous People associated with the selected medical research project live. I also identify the circumstances in which they regularly have access to healthcare. Then, I explain the specific disease on which the medical-genetics research projects that comprise my case study focus, describing its symptoms, prognosis, and available treatment. I finish my case study by giving details of the research projects examined by my case study, including information about the scientific elements and

results, involvement of the participants, benefit sharing practices, status of the project, conditions about inter and intra-institutional collaboration, and policies about patents. The case study explores the research process experienced by actual researchers in Mexico and the role that patents play in it. It also examines the impact that actual medical research projects and the current patent system have on a specific group's access to healthcare in Mexico. The specific details of these real stories will help to contextualize claims about the patent system's benefits and concerns on innovation and on access to healthcare. Furthermore, with respect to access to healthcare, they will help to understand the importance of ensuring people's "capabilities" and "functionalities" as elements of "welfare." Ultimately, they will help the reader to have a concrete image of those affected by the patent system. This will illustrate that when the patent system has an impact on access to healthcare, the welfare or benefits that it is expected to generate cannot be solely measured by an economic gain, but that they need to have an actual and tangible social impact and that the social impact on those who are the most vulnerable matters.

The aim of the fourth section is to establish whether it is justifiable/desirable to maintain the current patent system in Mexico to promote health-related innovation. In other words, it looks at whether the patent system benefits health-related innovation and healthcare in Mexico. It comprises four chapters: six, seven, eight, and nine. Chapter six includes a description of the benefits and concerns raised in the literature about the impact of the patent system on innovation and access to healthcare. In chapter seven, I use the information I obtained from the previous chapters to determine whether those benefits and concerns in fact occur in Mexico. I show that the specific circumstances surrounding the

health-related innovation and the healthcare system in Mexico influence the impact that the patent system has on the promotion of innovation and on access to healthcare. In chapter eight, I apply the concepts and justifications of utilitarianism and capability approach that I described in chapter one to the concerns and benefits of the patent system discussed in chapters six and seven. With this, I set the theoretical basis for the discussion in my last chapter regarding the elements that would justify the patent system in Mexico in health-related innovation. Taking into account these bases, findings, and arguments, in chapter nine, I propose a definition of "utility/welfare" and use it to examine whether the actual impact that the patent system has on medical innovation creates welfare to Mexico's society. I finish this chapter suggesting that Mexico would benefit from considering models of collaboration that tend to be more open than the current proprietary patent system to promote health-related innovation and access to innovative medical products and services. I argue that some of these models could provide a balance between the different interests and needs of the parties involved: investors, inventors from developed and developing countries, researchers, and all patients, but particularly, those patients who are poor or who belong to an Indigenous People.

Section 1

Chapter 1. Theoretical Framework

Introduction

The purpose of this first chapter is to provide, along with chapter eight, a theoretical framework to situate two aspects of the discussion. First, it will frame the discussion on the actual impact that the current regulation of the patent system has on promoting innovation in the area of health and on facilitating access to healthcare in Mexico. Second, it will provide the philosophical basis to determine whether this impact on both health-related innovation and access to healthcare can, in fact, justify the implementation and enforcement of Mexico's current patent system. The theoretical framework that I use borrows principles and concepts from Martha Nussbaum's and Amartya Sen's capability approach to justice in order to underpin my assessment and criticism of the current patent system.

One of the most common theories used to justify the intellectual property system, and particularly the patent system, is utilitarianism.[20] In accordance with a utilitarian perspective, the exclusive rights that the patent system grants to patent holders are commonly considered to be the economic incentives that investors and inventors need and want in order to devote their resources, efforts, and time to innovation. The resulting

[20] William Fisher, "Theories of Intellectual Property" in Stephen R Munzer, ed., *New Essays in the Legal and Political Theory of Property* (United States of America: Cambridge University Press, 2001) 168; Adam Moore & Ken Himma, *Intellectual Property*, winter 2014 eds., (Metaphysics Research Lab, Stanford University, 2014); Robert P Merges, *Justifying Intellectual Property* (United States of America: Harvard University Press, 2011); Michele Svatos, "Biotechnology and the Utilitarian Argument for Patents" (1996) 13:2 Soc Philos Policy 113 at 114.

innovative products and services are argued to contribute "utility/welfare" that leads to society's well-being. However, "utility/welfare" is currently predominantly defined in economic terms and, while having a patent system that encourages innovation that is potentially beneficial for society is positive, there have been a number of debates about this definition of utility/welfare.[21] The debates focus on whether the incentives granted effectively and efficiently promote innovation and on whether the mere existence of these innovative products and services in the market is enough to consider the patent system justified. These debates generate more controversy in the field of health-related innovation, as the combination of the patent system as a tool to encourage innovation and the free market as the means of distribution has resulted in several negative outcomes. These include neglected diseases, more lengthy innovation processes, proliferation of me-too-drugs[22] and beauty products, and highly-priced treatments, drugs, and diagnostics, which consequently lead to unequal access to healthcare.

I argue that justifications for the patent system should not solely focus on ensuring that the patent system promotes innovation, scientific and technological advancement, industry development, and economic benefits. Instead, for the patent system to be justified in health-related innovation, it should also aim to avoid contributing to unequal access to healthcare. This is particularly important when taking into account the most vulnerable population of a country and its access to healthcare. I use the capability approach to ground this argument.

---

[21] Fisher, *supra* note 20; Merges, *supra* note 20; Moore & Himma, *supra* note 20.

[22] This term is defined in the final chapter where the specific discussion about utilitarianism on the patent system in health-related innovation takes place.

The capability approach is a form of liberalism, sometimes framed as an alternative to classical utilitarianism[23] that provides theoretical constructs, such as "functionings" and "capabilities," to help evaluate the occurrence of well-being. I will use these constructs to frame the discussion on whether the benefits (i.e. scientific/medical innovation, economic incentives, economic growth, and innovative products and services) that the patent system generates can in fact be considered utility, and therefore advantageous. I will particularly use the capability approach's constructs of "functionings" and "capabilities" to explain and emphasize the importance of ensuring that the benefits resulting from innovation address the needs of everyone and can be accessed by everyone (e.g. access to healthcare), but particularly by Indigenous Peoples and other members of the most socio-economically disadvantaged sectors of the population.

The purpose of using the principles of the capability approach in my analysis is to provide a comprehensive framework that will help me to assess the appropriateness of the patent system in a specific field (health-related innovation) under concrete circumstances (specifically those of in Mexico, involving specifically Mexican Indigenous Peoples as representatives of the most vulnerable sector of the population). An analysis in these terms will help me justify my consideration of the specific needs and socio-economic, technological, scientific, and infrastructure conditions of a country to address and maybe decrease the possibility that innovation will result in neglected diseases or inefficient

[23] Amartya Sen, *Development as Freedom* (United States of America: Oxford University Press, 1999) at 54–63; Martha Nussbaum, *Creating Capabilities. The Human Development Approach* (United States of America: Harvard University Press, 2011) at 50–56 & 81–84.

innovation processes, and therefore untreated patients. Moreover, an analysis based on the capability approach can also provide the grounds to avoid neglecting and exacerbating the socio-economic inequalities of the poor sector of any population, including those of Indigenous Peoples. I am particularly interested in the inequality that the most vulnerable of the population suffer with respect to access to healthcare, because access to healthcare has a considerable impact on people's quality of life and life itself. In this sense, the capability approach can provide the grounds to argue for an equal distribution of medical innovation that could benefit Indigenous Peoples' access to healthcare.

I will begin this chapter with the principles and arguments (typically utilitarian) used to justify the patent system as a source of utility/welfare. After this, I will present some of the main criticisms raised against these justifications. This will provide the theoretical basis to understand the problems associated with the current regulation and justification of the patent system in Mexico that I will discuss in the following chapters. It will also provide the basis for constructing a theoretical framework based on the capability approach through which to analyze the current innovation process in medicine and medical genetics in Mexico in order to determine, in the following chapters, whether the patent system in fact creates the anticipated "utility/welfare".[24]

[24] I will explain this concept with respect to patents further on in this chapter and more thoroughly in the discussion of chapter nine.

1.1 Patent System and its Utilitarian Justification

Generally speaking,[25] utilitarianism has been used to justify the patent system because it provides a secular, rational, and even egalitarian way to compare gains and losses, and thereby to determine whether the gains of A outweigh the losses of B.[26] An act, law or policy is justified in utilitarian terms if it offers or enables the maximization of utility: the greatest good (welfare) for the greatest number.[27] With respect to the patent system, the justification in utilitarian terms is based on a balanced combination of rewards, dissemination, and access.[28]

---

[25] A more thorough and specific analysis of the involvement of utilitarianism in the justification of the patent system in health-related innovation is located in chapter eight, as important elements of the patent system in Mexico need to be explained in order for the analysis to be properly conducted.

[26] Will Kymlicka, *Contemporary Political Philosophy: An Introduction* (United States of America: Oxford University Press, 2002) at 36.

[27] According to utilitarianism, in its simplest and most traditional form, an act, law or policy is morally right when it produces the greatest happiness, pleasure or satisfaction for all members of society. This happiness, pleasure or satisfaction is considered morally right because it is deemed to lead to people's "welfare". People's welfare is what constitutes the "utility" that an act, law or policy should generate. Even though most economists consider this "welfare" or "utility" to be defined in economic terms, utilitarianism is broader than this reduction usually made by law and economics. In fact, the concept of "utility" and "welfare is difficult to define. Classical utilitarians define utility in terms of happiness and pleasure. For instance, for Jeremy Bentham and John Stuart Mill, an action or an activity creates welfare when it brings happiness or pleasure. For others, experiencing pleasure is an end in itself. This is known as welfare hedonism. George Edward Moore on the other hand, an ideal utilitarian, disagrees with the classical hedonistic view of defining utility as something that creates pleasure and asserts that not all pleasures are intrinsically good. According to the non-hedonistic/mental-state position of utilitarianism, there are things that are worth doing or having because of the experiences they bring rather than because they bring happiness or pleasure, which is why utilitarianism should be concerned with all kinds of experiences or mental states. Another position of utilitarianism focuses on preferences. In accordance with this position, an act, law or policy creates or increases people's utility when people's preferences are satisfied. Jeremy Bentham, *An Introduction to the Principles of Morals and Legislation* (London: Clarendon Press, 1781) at 14; John Stuart Mill, *Utilitarianism*, 7th ed (London: Longmans, Green, and Co, 1879) at 5–6; Kymlicka, *supra* note 26 at 13–14; George Edward Moore, *Principia Ethica* (Cambridge: Cambridge University Press, 1959) at 5–7.

[28] Merges, *supra* note 20 at 2; Richard A Posner, "Intellectual Property: The Law and Economics Approach" (2005) 19:2 J Econ Perspect 57 at 58; Fisher, *supra* note 20 at 168; Edwin C Hettinger, "Justifying Intellectual Property" (1989) 18:1 Philos Public Aff 31 at 47–48; Bita Amani & Rosemary J Coombe, "The Human Genome Diversity Project: The Politics of Patents at the Intersection of Race, Religion, and Research Ethics" (2005) 27:1 Law Policy 152 at 164.

The rewards that the patent system grants to patent holders consist of an exclusive right to commercially exploit their invention.[29] The promise of these exclusive rights provides an incentive to engage in innovative activities because inventors (or their investors) can recoup their investment, profit from their activities, and share their findings without the fear of free riders.[30] This justification is based on two assumptions: 1) that without these rewards the invention would not be created or would not be created or diffused as quickly or efficiently, and 2) that the invention benefits society. The gains, which are the existence and availability in the market of the invention, are weighed against the social losses, which are the sales of inventions above marginal costs (thereby sometimes making them unaffordable) and the extra costs (or outright inhibition) of introducing products or services that build on the invention.[31]

In the specific case of patents over health-related inventions, the justification of relying on the patent system to encourage innovation in the field is that it is the best-known mechanism for attracting the largest number of inventors, investors, research centres, and biotechnology and pharmaceutical companies to engage in research and development. This research and development is necessary to study and eliminate diseases and to help sufferers have access to the necessary treatment.[32] Those speaking on behalf of the pharmaceutical

[29] This series of rights is commonly perceived or considered as a "property" right. These property rights assign their holder control over the invention and the economic benefits associated with them. Merges, *supra* note 20 at 5.

[30] A free rider is someone who benefits from having access to resources, goods or services without paying for them. The problem is that this situation may result in an underprovision of those resources, goods or services. William J Baumol, *Welfare Economics and the Theory of the State*, 2nd ed. (United States of America: Harvard University Press, 1965).

[31] Svatos, *supra* note 20 at 114.

[32] Merges, *supra* note 20 at 278.

and biotechnology industries state that not only does the patent system ensure an efficient research and development process, but that it is absolutely necessary for these industries to survive.[33] They base this assertion on the very high costs involved in the research and development process and the risk of free riders.[34] Supporters of the patent system also assert that eliminating or weakening the patent system would reduce the supply of innovative medical products and services.[35]

Patent advocates also argue that under a law and economics analysis, the mere fact of having innovative treatments in the market creates utility/welfare in itself because anyone can have access to those treatments (maximization of utility/welfare). According to this analysis, this means that anyone who can have access to these treatments is better off. Furthermore, those who do not have access to them (e.g. because they cannot afford them) are not worse off, because without patents, the treatments that they cannot afford would not exist and their ailments would, in any event, go untreated. In other words, patent advocates contend that the patent system make the development and distribution of treatments efficient (Pareto efficient), and therefore beneficial without causing any harm.[36]

In addition to devising the model that best maximizes the incentives to encourage innovation, the principles of utility and efficiency upheld in utilitarianism and the law and economics approach have been used to set the basis for reconciling/balancing the exclusive

---

[33] Fisher, *supra* note 20 at 176.

[34] Merges, *supra* note 20 at 282; Posner, *supra* note 28 at 58; Louise Bernier, *Justice in Genetics: Intellectual Property and Human Rights from a Cosmopolitan Liberal Perspective* (United Kingdom: Edward Elgar Publishing, 2010) at 104–105.

[35] Merges, *supra* note 20 at 282.

[36] *Ibid*.

rights that the patent system grants with the need to ensure access to the resulting innovative knowledge/information[37] associated with the patented invention as an essential way to further innovation.[38] One example of this intended reconciliation or balance is the temporal limit of 20 years set for patents. Given that the patented invention will form part of the public domain at the time the patent expires, this expanded public domain will benefit society in general and constitute an important utility. Another example is the detailed disclosure/description of the invention that is required as part of the patent application. In this case, the alternative to secrecy provided by the rights that the patent system grants as well as the expansion of the prior art[39] are important forms of utility. A third example is the limits set on restrictions or conditions (also known as users' rights) that patent holders may impose on the public.[40] Access to the findings and the information associated with the innovative products and services enabled by the users' rights benefits society because it facilitates collaboration, the innovation process, and scientific and technological developments.[41] In health-related innovation, this could translate into faster or better diagnostic, preventive, and therapeutic products and services.[42]

---

[37] A more detailed description of the limitations that aim to achieve this balance between patent rights and ensuring access to the associated knowledge/information can be found in the chapter addressing the patent system and the discussion of the final chapter.

[38] Posner, *supra* note 28 at 57 & 68; Fisher, *supra* note 20 at 168; Hettinger, *supra* note 28 at 36; Bernier, *supra* note 34 at 104; Svatos, *supra* note 20 at 114.

[39] Prior art comprises all information that is disclosed or made publicly available that is associated with an invention. Examples include written documents, patent applications, oral presentations, and Internet posts. David Vaver, *Intellectual Property Law*, 2nd ed. (Canada: Irwin Law, 2011).

[40] More information about each of these examples will be provided in chapter four where I describe the current regulation of the patent system.

[41] The way in which the innovation process and the scientific and technological development are facilitated is more thoroughly described in the final chapter where I discussed open models of collaboration.

[42] Bernier, *supra* note 34 at 104–105.

Finally, the patent system is also justified in utilitarian terms because the scientific and technological developments that the patent system facilitates can also lead to economic growth. As I will describe more thoroughly in chapter eight, economic growth can attract more investment, generate more and better-remunerated jobs, foster competitiveness, and stimulate economic activities.[43] In summary, the utility/welfare that seems to justify the patent system can take the form of inventions, innovation, knowledge/know-how, industry development, and economic growth.[44]

However, as I will also discuss in more detail in chapters six, seven, and eight, the main criticism about the current patent system centres on whether it, in fact, generates the utility/welfare that it promises to create and to what extent this utility/welfare is maximized (i.e. whether it creates the greatest welfare for the highest number of people). The current patent system is justified because it is considered to be one of the most efficient ways to encourage innovation.[45] This innovation is believed to benefit society as a whole by increasing the number of products and services available in the market that could improve people's lives, and because of the economic, scientific, and technological growth it can bring to a country.[46] However, the main concerns regarding the current patent system with respect to health-related inventions focus on whether its current regulation and implementation give unbalanced importance to incentives for investors and associated economic gains, while neglecting other social needs.[47] These include the needs of

[43] *Ibid* at 106.
[44] Svatos, *supra* note 20.
[45] Fisher, *supra* note 20 at 169; Svatos, *supra* note 20 at 114.
[46] Fisher, *supra* note 20 at 172; Bernier, *supra* note 34 at 103; Svatos, *supra* note 20 at 114.
[47] Amani & Coombe, *supra* note 28 at 162.

researchers (mainly those focusing on basic research) who may encounter costly and lengthy transaction costs as a result of patents in crucial research areas, as well as the needs of patients, who require timely and affordable access to those inventions.

As I will describe and discuss in more detail in chapter six, some scholars are concerned that the patent system primarily encourages innovation that has the highest chances of bringing profitable economic gains to pharmaceutical and biotechnology companies, while neglecting research and development on diseases or conditions that are endemic in developing countries, because they are unlikely to have profitable markets.[48] There are also concerns that the rights granted to patent holders allow them to engage in anticompetitive strategies that would prevent other firms from entering the market, which could limit patients' options and affordability regarding access to healthcare.[49] Another concern is the impact of having too many patents and patent holders. In one direction, this could discourage researchers and investors from focusing on research and development areas that are cluttered with patents, thus leading to underutilization of resources. In the other direction, investors and inventors who do focus on an area that has a multitude of patents and patent holders, may end up duplicating efforts or wasting resources, either during licensing negotiations or inventing around the patented technology, thus diverting important resources from other research areas. In these two last cases, the fear is that innovation in potentially important areas is likely to be neglected.[50] I am aware that the

[48] Bernier, *supra* note 34 at 107; E Richard Gold, "The Reach of Patent Law and Institutional Competence" (2003) 1 Univ Ott Law Technol J 263; Svatos, *supra* note 20 at 122–124 & 129–130.

[49] Bernier, *supra* note 34 at 108; Svatos, *supra* note 20 at 117–120.

[50] Posner, *supra* note 28 at 61, 65 & 68; Fisher, *supra* note 20 at 175–176; Bernier, *supra* note 34 at 107–109; Svatos, *supra* note 20 at 117–120.

patent system would not be the main cause of or the solution to the aforementioned concerns (e.g. neglect of diseases that lack a profitable market could be addressed through better public funding, anticompetitive practices could be limited through better antitrust laws, and the underutilization of resources, abandonment of specific research areas, and duplication of efforts and waste of resources because of a proliferation of patents might not happen as frequently as predicted); however, the fact that the patent system could contribute to these concerns leads me to question the welfare that the patent system brings regarding promotion of innovation.

Finally, the most debated concern is that a patent system prioritizing the economic benefits to pharmaceutical and biotechnology companies is likely to neglect the extremely important social need of access to healthcare.[51] By following these economic terms, a patent system can allow companies to set prices so prohibitively high that some patients (many, as I will show in the following three chapters) will be unable to afford necessary medical products and services. In this case, I am also aware that, in accordance with a law and economics analysis, the patients who are unable to afford these innovative patented health-related products and services could not be said to be worse off with the patent system, because without it, the treatments they cannot afford would not exist anyways and their ailments would still go untreated. However, if the patent system has in fact promoted the creation of a treatment that is available to anyone who can afford it at the expense of other socio-economic considerations, then any patient would in fact be better off having access to that treatment, and any patient who lacks access to otherwise available healthcare

[51] Shobita Parthasarathy, "Whose Knowledge? What Values? The Comparative Politics of Patenting Life Forms in the United States and Europe" (2011) 44 Policy Sci 267.

services or products would be worse off going untreated.[52] In this case, the lack of actual access to the necessary medical products and services can deeply affect the lives of those patients who need them, influencing not only their quality of life, but also becoming the determining factor between life and death. If this lack of access is based on their socio-economic conditions and on whether the patients can afford the innovative medical product or service, the patent system that allows the prices of medical products and services to be set freely by patent holders (because they need their economic incentives to engage in innovation activities) is contributing to widening an already existing serious economic gap.[53]

In other words, the patent system, traditionally justified in utilitarian terms, focuses predominantly on economics, defining utility/welfare in economic terms and recognizing the validity and importance of satisfying the preferences that patent holders have of being able to recoup their investment and profit from their inventions. The validity and importance of these preferences are recognized on the assumption that this will increase the chances of patent holders reinvesting in research and development, and thereby ensuring innovation and the benefits that come with it for society. However, even if those assumptions are correct and the majority of the population can benefit by having the possibility of acquiring the resulting innovative products, there are still many who cannot afford them. In the specific case of patented health-related inventions, there are serious consequences for people who are unable to afford medical products and services, as these

[52] Jeremy Waldron, "Superseding Historic Injustice" (1992) 103:1 Ethics 4 at 11 & 13.
[53] Bernier, *supra* note 34 at 110–111.

people will have substandard healthcare, and consequently lives, in comparison to those who can in fact afford them. Having substandard healthcare affects people's lives because having poor health restricts people's freedom[54] to do what they want and to achieve what they aim for. Hampering that freedom affects "what it is about humans that deserves respect and concern."[55]

As I will show in subsequent chapters, Indigenous populations and people living under the poverty line in Mexico (which is close to half of the country's population) are very likely to be in the situation I just described. For this reason, in addition to assessing whether the patent system promotes R&D in health-related innovation in Mexico, the analysis of the role that the patent system plays in the (un)equal attainment of healthcare and freedom is another one of my main concerns and goals in my research.

The capability approach can provide a framework to broaden the definition of utility/welfare from one based merely on economic terms to one that includes social aspects of utility/welfare. This broader definition would justify the importance of promoting R&D that addresses all kinds of ailments (despite the profitability of their markets), avoid or minimize circumstances or situations that would delay or hinder R&D, and enable as much as possible equal access to healthcare (or at least reduce any action that could contribute to the opposite).

---

[54] Freedom in this context means the quality or state of being free, of having the power of self-determination attributed to the person's will in the absence of necessity, coercion or constraint in choice of action. *Merriam-Webster,* online s.v. "freedom".

[55] Kymlicka, *supra* note 26 at 44.

1.2 Capability Approach

1.2.1 Principles and Shortcomings

Developed by Amartya Sen and Martha Nussbaum, the capability approach is a normative framework that contributes to the evaluation and assessment of an individual's or a group's well-being. It is characterized by its interdisciplinarity and its focus on multiple aspects of what constitutes well-being. Some of the aspects of well-being that the capability approach examines and analyzes are inequality and poverty, as well as the physical, psychological, and social health of an individual or group.[56] It is considered a normative rather than explanatory theory because it does not intend to explain poverty, inequality or well-being, but rather to help to conceptualize, examine, and analyze them. The practical aspect of the capability approach, which aims to provide direct (or indirect) guidance to people's (and governments', institutions', and communities') actions and decisions, will be particularly useful to my topic as it will help analyze the utility/welfare that the patent system brings to innovation in Mexico and to Mexican Indigenous Peoples' access to healthcare throughout the following chapters.[57]

The capability approach is commonly used in two ways. First, it is used to evaluate people's quality of life, well-being, and human development. It starts by determining the information that is relevant to this evaluation. The determination of the relevant information is based on the statement that an individual's freedom or opportunities to achieve well-being will impact what they are able to do and to be, and thus the kind (or

[56] Ingrid Robeyns b), *The Capability Approach*, winter 2016 ed. (online: Metaphysics Research Lab, Stanford University, 2016); Robeyns a), *supra* note 3 at 93–94.
[57] Robeyns b), *supra* note 56.

quality) of life that they will effectively be able to have. As such, a capability approach analysis focuses on a person's capabilities and functionings, as defined below.[58] Second, the capability approach can be used to replace utilitarianism's traditional cost-benefit analysis, and to thereby evaluate and design governmental and non-governmental policies, as well as social institutions in poor countries and in affluent societies that aim to aid poor countries.[59]

The capability approach analysis focuses on two elements: a person's functionings and capabilities. Functionings refer to what capability theorists describe as a person's "beings" and "doings".[60] Examples of beings include being well-nourished or under-nourished, being educated or illiterate, being healthy, being in an adequate or inadequate house, and being part of a community or being isolated. Examples of doings are eating, studying, working, caring for a child (i.e. having a family), and traveling. Functionings can be good or bad. Considering a functioning good (and therefore desirable or valuable) or bad (and therefore undesirable) can be in some cases obvious, but in others, it may depend on the context. Capabilities refer to a person's real freedom or effective opportunity to achieve the functionings that he or she considers valuable. In other words, functionings refer to the achievements of doing or being, while capabilities are the real opportunities to reach those achievements.[61]

---

[58] Robeyns a), *supra* note 3 at 93–94.

[59] Robeyns b), *supra* note 56; Robeyns a), *supra* note 3 at 94.

[60] Martha Nussbaum & Amartya Sen, eds, *The Quality of Life* (United States of America: Oxford University Press, 1993) at 137; Robeyns b), *supra* note 56; Nussbaum, *supra* note 23 at 25; Amartya Sen, *Inequality Reexamined* (United States of America: Oxford University Press, 1992) at 40; Sen, *supra* note 23 at 74–76.

[61] Robeyns b), *supra* note 56; Robeyns a), *supra* note 3 at 93 & 95.

The reason for which a capability approach analysis has to include the assessment of a person's functionings is because functionings are constitutive of a person's being; every human being requires at least some functionings to exist. Identifying and understanding the set of opportunities available to a person (his or her capabilities) would help determine what that person would need in order to achieve their functionings.[62] People should have the "freedoms/opportunities to lead the kind of life they want to lead, to do what they want to do, and to be the person they want to be."[63] These two constructs greatly impact a person's quality of life, because when a person achieves what they want to be and do, they are able to feel they have a valuable life. Therefore, this is why, according to this approach, the evaluation of any policy or law should determine the effect that such a law or policy will have on a person's or a group's capabilities and functionalities.[64]

Focusing on people's functionings and capabilities makes it easier to understand the relevance of the means-ends distinction while determining the value of goods as well as the impact of laws, policies and institutions. For instance, having access to clean water, adequate sanitation, healthcare services (i.e. doctors, diagnostics, vaccines, drugs, treatments), basic knowledge on health matters, a nutritious and balanced diet, and a strong and caring community will provide individuals with the opportunity to be healthy.[65] Being healthy allows people to choose from almost any option of lifestyle available and to freely

[62] Sen, *supra* note 60 at 42; Robeyns b), *supra* note 56.
[63] Robeyns a), *supra* note 3 at 95.
[64] *Ibid*.
[65] Robeyns b), *supra* note 56; Robeyns a), *supra* note 3 at 96.

form their preferences. In this case, being healthy is both a means to an end (to choose the kind of life that one considers valuable, for instance to work, to travel, to interact with family or community members) and an end in itself (enjoying good health).[66]

With respect to this means-ends distinction, a capability approach analysis prioritizes assessing whether people actually achieve (or have the actual possibility to achieve) their ends over whether they attain the means to do so. Therefore, while it does not deny the importance of people having the necessary means, it does stress that means should be deemed instrumental towards reaching an end (e.g. increased well-being) and not be deemed ends in themselves, as they are not constitutive of people's well-being.[67] There are several advantages to this approach. One advantage is that it recognizes that, based on intrinsic skills, talents, and socio-economic conditions, people differ in their ability to turn their means into actual opportunities/freedoms (capabilities) or achievements (functionings). Another advantage is that the value of means is to be assigned insofar as they contribute to people's capabilities and functionings. In this sense, wealth or economic growth should only be valued as long as they translate into well-being. Finally, it also allows for the possibility that there may be different means by which we can foster and nurture people's capabilities and functionings. For example, social or cultural practices, social changes, social institutions or governmental policies can be as relevant as income or economic resources for enabling capabilities and functionings.[68]

---

[66] Robeyns a), *supra* note 3 at 95.
[67] *Ibid*; Robeyns b), *supra* note 56.
[68] Robeyns b), *supra* note 56; Robeyns a), *supra* note 3 at 99.

The different abilities that people have in order to turn the means available to them into capabilities or functionings are influenced by conversion factors.[69] Conversion factors are the characteristics and abilities that people possess that allow them to benefit from available resources; these factors influence how much a person can achieve with the goods or services available.[70] There are three types of conversion factors: personal, social, and environmental.[71] Personal conversion factors are internal to a person. Examples include physical conditions or disabilities, age, and intelligence, as well as physical and mental abilities. For example, people with learning disabilities will not be able to transform their education into a well-paid job to the same extent as people without those disabilities. Social conversion factors result from the society or community in which a person is immersed. Public policies, social norms, and social practices are examples. People who are not familiar with preventive medical measures because there have not been preventive public policies implemented in their community are not likely to seek vaccinations, diagnostic or genetic tests or even healthy habits when they are asymptomatic.[72] Environmental conversion factors refer to the physical and geographical environment and infrastructure available in the place where the person is located. Some examples are climate, pollution, closeness to water, mountains, roads, and means of transportation and communication.[73] People located in isolated rural areas (without adequate roads or means of communication)

[69] Sen calls these factors diversities and heterogeneities. Sen, *supra* note 23 at 69–72.

[70] Sen, *supra* note 60 at 92; Robeyns a), *supra* note 3 at 99.

[71] Sen's diversities and heterogeneities are personal (e.g. disability, illness, age, and gender), environmental (e.g. temperature, rainfall, flooding, and other climatic circumstances), variations in social climate (e.g. educational arrangements, prevalence or absence of crime and violence, and pollution), differencs in relational perspectives (e.g. established patterns of behaviour based on conventions and customs of the community), and income distribution within family. Sen, *supra* note 23 at 70–71.

[72] J Michael McGinnis, Pamela Williams-Russo & James R Knickman, "The Case for More Active Policy Attention to Health Promotion" (2002) 21:2 Health Aff (Millwood) 78.

[73] Robeyns b), *supra* note 56; Robeyns a), *supra* note 3 at 99.

will not be able to access the same innovative products and services available in the market of urban areas, and are therefore unlikely to attain and enjoy a better, more comfortable, or healthier life. Bearing the foregoing in mind, when assessing a person's well-being, it is not enough to determine whether people have certain goods and services (means) available; rather, it is necessary to understand the circumstances and conditions (conversion factors) surrounding those people's lives to discover their real opportunities to achieve well-being. The acknowledgement and consideration of these personal circumstances constitute part of the recognition and privileging of human diversity that the capability approach proposes.[74]

Furthering the acknowledgement of human diversity, the capability approach also recognizes that there is a plurality of functionings and capabilities. With respect to this plurality, Nussbaum pays special attention to what she calls basic capabilities: "the innate equipment of individuals that is necessary for developing the more advanced capabilities, and a ground for moral concern."[75] For Sen, a basic capability is "the ability to satisfy certain elementary and crucially important [necessary for survival] functionings up to certain levels."[76] Regardless of how basic capabilities are defined, the assessment of this specific type of capabilities is particularly useful in poor countries, as it is crucial for the analysis of poverty and socio-economic inequalities.[77] In this respect, the main focus of the debate revolves around which capabilities should qualify as basic and who should make this decision. Nussbaum on the one hand, proposes a list of "basic" or "central human"

[74] Robeyns a), *supra* note 3 at 97 & 99; Sen, *supra* note 60 at 81–87; Robeyns b), *supra* note 56; Martha C Nussbaum, *Women and Human Development: The Capabilities Approach* (United States of America: Cambridge University Press, 2000) at 41–50; Nussbaum, *supra* note 23 at 109–113.
[75] Nussbaum, *supra* note 74 at 84.
[76] Sen, *supra* note 60 at 45.
[77] Robeyns b), *supra* note 56; Robeyns a), *supra* note 3 at 101.

capabilities that should be included in every country's constitution. Despite asserting that her list remains open for review, it includes the following capabilities: life,[78] bodily health,[79] bodily integrity,[80] senses, imagination and thought,[81] emotions,[82] practical reason,[83] affiliation,[84] other species,[85] play,[86] and control over one's environment.[87] She argues that each of these capabilities maintains the dignity of a human being.[88] Sen, on the other hand, argues that the content of any list of basic capabilities should be publicly and democratically discussed and reasoned; even more, if human diversity (different social, cultural, and geographical conditions) is to be recognized.[89] This raises concerns of

[78] Life refers to being able to live to the end of a life of normal length. Nussbaum, *supra* note 23 at 33; Nussbaum, *supra* note 74 at 78–80; Amartya Sen, "Capabilities, Lists, and Public Reason: Continuing the Conversation" (2004) 10:3 Fem Econ 77 at 77–80.

[79] Bodily health means being able to have good health, to be adequately nourished, and to have adequate shelter. Nussbaum, *supra* note 23 at 33; Nussbaum, *supra* note 74 at 78–80; Sen, *supra* note 78 at 77–80.

[80] Bodily integrity is being able to move freely from one place to another. Nussbaum, *supra* note 23 at 33; Nussbaum, *supra* note 74 at 78–80; Sen, *supra* note 78 at 77–80.

[81] Senses, imagination, and thought refer to being able to use the senses, to imagine, think, and reason in a human and educated way. This includes being able to have freedom of expression and of religious beliefs. Nussbaum, *supra* note 23 at 33; Nussbaum, *supra* note 74 at 78–80; Sen, *supra* note 78 at 77–80.

[82] Emotions mean being able to have attachments to things and people. Nussbaum, *supra* note 23 at 33; Nussbaum, *supra* note 74 at 78–80; Sen, *supra* note 78 at 77–80.

[83] Practical reason includes being able to form a conception of the good to form critical reflection in planning one's life. Nussbaum, *supra* note 23 at 34; Nussbaum, *supra* note 74 at 78–80; Sen, *supra* note 78 at 77–80.

[84] Affiliation means being able to live with others and show concern for them engaging in social interactions and having self-respect and being treated with dignity. Nussbaum, *supra* note 23 at 34; Nussbaum, *supra* note 74 at 78–80; Sen, *supra* note 78 at 77–80.

[85] Other species refer to being able to live with concern for animals, plants, and nature. Nussbaum, *supra* note 23 at 34; Nussbaum, *supra* note 74 at 78–80; Sen, *supra* note 78 at 77–80.

[86] Play means to be able to laugh, play, and enjoy recreational activities. Nussbaum, *supra* note 23 at 34.

[87] Control over one's environment includes being able to have political rights, have freedom of expression and association as well as to being able to hold property. *Ibid*; Nussbaum, *supra* note 74 at 78–80; Sen, *supra* note 78 at 77–80.

[88] Nussbaum, *supra* note 74 at 70–77; Martha Nussbaum, "Capabilities as Fundamental Entitlements: Sen and Social Justice" (2003) 9:2–3 Fem Econ 33; Martha Nussbaum, *Frontiers of Justice: Disability, Nationality, Species Membership* (Cambridge: Harvard University Press, 2006) at 78–81; Robeyns b), *supra* note 56; Robeyns a), *supra* note 3 at 103–104.

[89] Amartya Sen, "Human Rights and Capabilities" (2005) 6:2 J Hum Dev 151 at 158; Robeyns b), *supra* note 56; Robeyns a), *supra* note 3 at 106; Sen, *supra* note 23 at 76–81.

legitimacy for Nussbaum's list.[90] Sen, however, does not provide any clear details on how to design and implement a process that would result in a public, democratic, and reasoned list of basic capabilities.[91]

An analysis based on the capability approach focuses more on whether people actually achieve their ends than whether they attain the means. The ends in this case are either people's capabilities or their functionings.[92] Out of these two, and based on the acknowledgement that people are diverse (e.g. different contexts, conversion factors and objectives), the focus of the capability approach analysis usually[93] centres more on capabilities rather than on functionings. The reason for this focus is that it acknowledges that, based on what different people may consider their most valuable options, they may have different ideas of what constitutes a good life. It also emphasizes the importance of allowing everyone to make their own choices, but ensuring that, underlying those choices, everyone has the same real opportunities and options from which to choose.

Finally, it is important to mention certain shortcomings commonly associated with the capability approach not being a full theory of justice, an egalitarian theory or a theory of social or distributive justice. First, as Robeyns mentions, it does not explain the basis that would justify its principles besides mentioning human dignity as a reason to ensure the achievement of Nussbaum's basic capabilities or the things or elements people reasonably

[90] Robeyns a), *supra* note 3 at 106.
[91] *Ibid*.
[92] Robeyns b), *supra* note 56.
[93] I say "usually" because capability theorists have not reached a consensus on whether the capability approach should focus more on capabilities than on functionings. *Ibid*.

value in their lives. Second, even though most capability theorists[94] lean towards prioritizing capabilities, there is no consensus on whether the theory should focus on people's functionings or capabilities as a way to assess injustices.[95] Third, the capability approach does not provide clear metrics to evaluate justice or distributive terms (e.g. there is the question about whether it will encourage plain equality,[96] sufficiency,[97] prioritarianism[98] or a combination of the sorts to ensure justice).[99] Fourth, despite Nussbaum's arguments on governments having the obligation to ensure everyone's rights to basic capabilities, the capability approach lacks a consensus view on responsibility (i.e. who will specifically be responsible).[100]

[94] Nussbaum, *supra* note 74; Amartya Sen, "Capability and Well-Being" in Martha Nussbaum & Amartya Sen, eds., *Qual Life* (Oxford University Press, 1993) 30; Rutger Claassen, "Capability Paternalism" (2014) 30:1 Econ Amp Philos 57; Robeyns b), *supra* note 56.

[95] Claassen, *supra* note 94.

[96] Equality is defined as "the quality or state of being equal." The theory that upholds equality is egalitarianism. Egalitarianism prioritizes equality for all people, especially with respect to social, political, and economic affairs. *Merriam-Webster,* online *s.v.* "equality"; *Merriam-Webster,* online *s.v.* "Egalitarianism".

[97] The doctrine of sufficiency "holds that it is morally valuable that as many as possible of all who shall ever live should enjoy conditions of life that place them above the threshold that marks the minimum required for a decent (good enough) quality of life." Richard Arneson, *Egalitarianism*, summer 2013 ed. (online: Metaphysics Research Lab, Stanford University, 2013).

[98] Prioritarianism is a view within ethics and political philosophy that holds that "benefits to those who are worse off have a greater moral weight or value than benefits to those who are better off." Ingmar Persson, *Prioritarianism* (online: Blackwell Publishing Ltd, 2013).

[99] Elizabeth Anderson, "Justifying the Capabilities Approach to Justice" in Harry Brighouse & Ingrid Robeyns, eds., *Measuring Justice: Primary Goods and Capabilities* (United States of America: Cambridge University Press, 2010) 81 at 81; Robeyns b), *supra* note 56.

[100] Robeyns b), *supra* note 56; Onora O'Neill, *Towards Justice and Virtue: A Constructive Account of Practical Reasoning* (United States of America: Cambridge University Press, 1996) at 122–135.

1.2.2 Relevance of the Capability Approach for Indigenous Peoples, the Patent System, and the Following Chapters

The patent system is frequently justified because it is deemed to provide the necessary economic incentives for investors and inventors to engage in research and development and create innovative products and services that are made available in the free market for anyone to benefit from them. The creation of these innovative products and services, their availability in the market, and the improvement to people's lives that these products are supposed to bring constitute the desired "utility/welfare" that the patent system can bring for society. In the healthcare field, this "utility/welfare" is the advancement in medical research and development, the quantity of treatments, drugs, and diagnostics available in the market, and the number of diseases or conditions that these treatments, drugs and diagnostics address. The efficiency or maximization of "utility/welfare" in this case lies in the fact that this medical advancement and the resulting innovative medical products and services are made available in the market for all members of society to access. The patent system in the healthcare field is then considered useful because all those who can access innovative medical products and services will increase their chances of having their health improved, and those who cannot afford them will not have their health made worse than it was when those innovative products did not exist. Furthermore, the advancement of the research and development will also bring about economic, scientific and technological growth, which is also expected to improve most people's lives.

This reasoning follows the assumption that economic growth, scientific and technological advancement, market profits, and availability of innovative products and services related to healthcare services, bring welfare to society. This can, however, lead to assigning too much weight to the economic incentives that investors (e.g. pharmaceutical and biotechnology companies or funding agencies) claim they need to maintain an increasing pace of innovation while neglecting the social need of ensuring proper access to healthcare services.

Health, access to healthcare and, hence, the health industry, possess a special link to life itself, and therefore they are inherent to being human and to the dignity with which every human being is supposed to be treated, which is why they constitute an internationally recognized human right.[101] Being healthy influences the extent to which people can take advantage or benefit from opportunities available to them. According to the *Constitution of the World Health Organization,* the "enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition."[102] The capability approach and its concepts of capabilities and functionings, conversion factors, and mean/ends help justify recognizing the importance of health and access to healthcare in the life and welfare of any human being. In view of this, the utility/welfare associated

[101] Office of the High Commissioner of Human Rights United Nations, "What are Human Rights?", (2017), online: <http://www.ohchr.org/EN/Issues/Pages/WhatareHumanRights.aspx>; *Constitution of the World Health Organization*, World Health Organization, 22 July 1946 (Last amended September 15, 2005) [*Constitution of the World Health Organization*]; *Universal Declaration of Human Rights*, General Assembly of the United Nations Organization, 10 December 1948, GA Res 217 III UN CAOR 3d Sess Supp No 13 UN Doc A810 1948 [*Universal Declaration of Human Rights*]; *International Covenant on Economic, Social and Cultural Rights*, United Nations General Assembly, 1976 [*International Covenant on Economic, Social and Cultural Rights*].

[102] *Constitution of the World Health Organization*, *supra* note 101.

with ensuring proper access to healthcare should have priority over the one created by economic growth or unspecified medical advancements in any utility/welfare assessment.[103] The economic growth and medical advancements should be pursued as means to achieve people's health, rather than as ends unto themselves. Hence, the assessment of the welfare that the patent system in health-related innovation is intended or expected to create in order to be justified should centre on whether the patent system in this area creates actual access to healthcare. The capability approach can provide the theoretical principles on which to found this statement.

The way in which the capability approach can help to evaluate a law or a policy is by determining the impact that such a law or policy may have on people's capabilities and functionings. For instance, the capability approach could help determine the impact that a particular law or policy could have on people's access to healthcare or education. It would help evaluate whether such a law or policy enables, limits or jeopardizes people's capabilities to be healthy or educated by determining if access to the necessary healthcare or education services is affected as a consequence of the enforcement of said law or policy.[104] It looks at whether people's capabilities are actually ensured. Furthermore, the focus on people's capabilities and functionings that the capability approach proposes explains the importance of health as an enabling factor for people's welfare and quality of life, despite there not being a consensus about Nussbaum's list of basic capabilities or some of the approach's shortcomings (whether capabilities should be prioritized over

[103] Nicola Lucchi, *The Impact of Science and Technology on the Rights of the Individual* (Switzerland: Springer International Publishing, 2016); Bernier, *supra* note 34; E Richard Gold, "Patents and human rights: a heterodox analysis" (2013) 41:1 J Law Med Ethics J Am Soc Law Med Ethics 185.

[104] Robeyns a), *supra* note 3 at 96.

functionalities or the metrics that should be used to evaluate justice) not being solved.[105] It also helps to understand the importance of differentiating between means and ends. In this sense, economic growth, industry development, technological and scientific advancement, and innovation are important and desirable in a society. However, if all these do not translate in actual benefits and improvement in people's quality of life, they cannot truly be deemed to generate welfare. Development and welfare should be evaluated in terms of the way in which they impact people's lives, their freedoms, their capabilities and functionings, and the way they are empowered. In this sense, the capability approach can be helpful in justifying the patent system in utilitarian terms by broadening the definition of utility/welfare from a narrow law and economics approach (merely based on economic terms) to include various social aspects of utility/welfare (i.e. incorporating actual benefits to people's quality of life, such as freedom and empowerment to live the life they want and choose).

The capability approach can also be useful to explain why the law and economics maximization of utility/welfare as upheld in economic terms (i.e. everyone could "potentially" have access to any innovative medical product and service) cannot be enough to justify the patent system with respect to health-related innovation, as in reality, it is only the people that can afford the innovative medical products and services who can in fact have access to proper healthcare. This is because in this scenario, there are many people who, even if they do not die, still suffer from diseases that go untreated, either because they are unable to afford the necessary innovative medical products and services or because

[105] Sen, *supra* note 23 at 82–83.

their diseases lack a treatment. Untreated diseases lead to a poorer quality of life and less freedom to live the kind of life a person may value. In terms of capabilities and functionings, ensuring equal access to proper healthcare would enable everyone to reach the life they want to live and flourish as human beings.[106]

Finally, the capability approach can also be useful for recognizing the vulnerability of certain groups, such as the Indigenous populations discussed in this dissertation, and for understanding the importance of protecting and empowering these groups against poverty and any other contributing factors (i.e. conversion factors). It can help to understand how contributing factors, such as the geographical marginalization in which the majority of Indigenous Peoples live in Mexico impacts their ability to access basic medical services, or the poverty in which they live prevents them from benefiting from medical or technological advancements available to others. Cost-benefit analyses based on people's capabilities and functionings would help to generate frameworks that are more sensitive to the reality of the different sectors of a population. These analyses could allow scholars, policy makers, and legislators to recognize the different conditions surrounding the different groups, understand their specific needs, and consequently to design, adapt, implement, and enforce patent laws, policies, and practices to the particularities of the different sectors, and specifically of health-related innovation.

It is important, however, that I clarify that throughout the following chapters I will not argue for the patent system to be completely subjugated to the right to health and access

[106] Julie Clague, *supra* note 3 at 178.

to healthcare. Instead, I will use the capability approach to develop a definition of "utility/welfare" with which the patent system should be assessed in order to determine its benefit or value for society in general, and for Mexico in specific. With this definition, I will argue that the patent system and the right to health and to access to healthcare should coexist and "promote an optimal amount of patent protection to stimulate and put into practice socially useful innovation."[107] This approach will be the basis for proposing in my last chapter the use of models of collaboration that are more open and participatory than the traditional proprietary ones. Bearing this in mind will be relevant in the context of my dissertation because Mexico, like any other country, needs to have a productive and favourable pace innovation. However, for this to occur, we need to be mindful of the conditions endemic to Mexico, namely its infrastructure, legal system, economic and human resources, and practices on the one hand, and the socio-economic conditions of its population on the other.

The capability approach will be useful while I try to determine the impact of the patent system on Mexico's healthcare system (i.e. its utility/welfare), and specifically, on the Mexican Indigenous Peoples' (and potentially other vulnerable groups) access to healthcare. The emphasis given to people's actual capabilities and functionings, as well as the consideration of the conversion factors and human diversity will help me determine whether the members of this vulnerable group have their freedoms, opportunities, and lives actually enriched with the existence and implementation of the current patent system for innovation in medical genetics. By examining the actual access to healthcare of Indigenous

[107] Gold, *supra* note 103 at 187.

Peoples in Mexico, and therefore their well-being, I expect to be able to assess whether they can achieve genuine and tangible welfare through the patent system.

Conclusions

The adoption of the utilitarian theory to justify the rightness of the patent system is usually based solely on its economic value and the economic growth that innovation and the development of the industry bring. However, utilitarianism is broader than and should not be reduced to economics. Furthermore, the relevance attributed to economic values may end up harming human/social welfare. This has certainly been the main concern in health-related innovation, as patents have been known to contribute to the high prices in patented treatments, drugs, and diagnostics making them, in some cases, inaccessible. Likewise, the patent system has been deemed successful and favourable in research fields and products with profitable markets (usually addressing the needs of those who can afford them) as well as in developed countries with already strong innovation settings. However, in both cases, there are concerns about equality. The concern of equality should be addressed because the impact of having a patent system justified as a source of economic value or innovation advancement without ensuring proper access distribution in health, as it is the case in Mexico, is too harmful to ignore.

The capability approach devises and develops the concepts of capabilities and functionings as a way to assess welfare. It takes into account human diversity and discusses the role that conversion factors play in people's attainment of their capabilities and functionings. As such, it opens the discussion about the different preferences that people

have, but among those preferences, it highlights the relevance of those considered "basic capabilities' and of the mean-ends distinction. Likewise, it recognizes the importance of economically valuable concepts, but it also emphasizes the importance of other concepts such as human rights, access to healthcare, equality, and physical abilities as part of an individual's or group's welfare.[108] Attention to human diversity, the different specific conditions in which people live, and of all the elements that make up the concept of welfare, would help to assess welfare created by the patent system in health-related innovation accurately and comprehensively. This assessment would therefore look at welfare that benefits not only majorities or success cases with the required pre-existing conditions, but also at welfare that benefits people in vulnerable conditions or even unique circumstances. This all-encompassing way of looking at welfare could then increase the chances of achieving actual equality.

Overall, different from what a reduced economic utilitarian justification of the patent system does, incorporating the capability approach into the definition of utility/welfare could contribute to a fuller and more true version of utilitarianism and justify and help to promote a fair distribution of benefits: innovative medical products and services (distributive justice).[109] As I state in this chapter and as I will further argue in chapters eight and nine, the definition of "utility/welfare" then should be determined assessing to what extent people have the opportunity to actually achieve their functionings and capabilities and to improve their quality of life in view of their specific circumstances. Recognizing in

[108] Robeyns b), *supra* note 56.
[109] Sen, *supra* note 23 at 62 & 66; Fisher, *supra* note 20 at 184–185.

these terms the nature and justification of the utility of the patent system as a tool for achieving human/social welfare (and not merely economic interests) as well as its limited (although important) role in innovation systems, will provide a framework according to which the patent system can be adapted to the local needs[110] of Mexico, particularly with respect to the health-related industry. This would force us to consider not only economic growth, but also actual human/social welfare as the adequate justification for and parameter of the patent system in this field. I intend to use this theoretical basis to justify the need to uphold some of the economic incentives granted by the patent system, but to also balance them with the need to promote and ensure patient welfare. I also intend to use it to justify focusing on the extent to which Mexico's pharmaceutical and biotechnology industries have benefited from the current patent system. Most importantly though, I intend to use the capability approach to justify focusing on the degree to which Indigenous Peoples in Mexico can obtain welfare from the patent system in association with health-related inventions. Finally, I will use it to justify the implementation of models of collaboration as a way to improve the innovation process in Mexico and, foremost, to ameliorate Indigenous People's access to the necessary healthcare products and services, regardless of their socio-economic conditions.

[110] Gold, *supra* note 103 at 194.

Section 2

Chapters 2 and 3 Healthcare and Innovation in Mexico

Introduction to Section 2

As I mentioned in the introduction of my dissertation, debates regarding whether patents promote research and development (R&D) or whether they hinder innovation usually take place in a theoretical context, typically focusing on analyzing theories and principles that have been developed within the area of intellectual property, without any real confirmation in practical conditions. Likewise, some contend that harmonizing patent systems among developing and underdeveloped countries with those adopted, implemented, and promoted in developed countries will not only make the patenting process more efficient and cost-effective for companies and citizens of developed countries, but will greatly benefit all countries and societies in the current and inevitable global marketplace.[111] However, the specific conditions that each country (scientific, economic, social, etc.) and that each industry (preexisting infrastructure needed, complexity and how much the progress builds on past innovation, market, focus, etc.) has can greatly influence the impact that patent system has on innovation and on its benefits for society.[112] In the two chapters of this section, I focus specifically on Mexico's specific conditions and on Mexico's health-related industry and system: has Mexico's patent

[111] Keith E Maskus, *Patents and Technology Transfer Through Trade and the Role of Regional Trade Agreements*, SSRN Scholarly Paper ID 2745455 (Rochester, NY: Social Science Research Network, 2016); Robert R Willis, "International Patent Law: Should United States and Foreign Patent Law Be Uniform - An Analysis of the Benefits, Problems, and Barriers" (2009) 10:2 N C J Law Technol 283.

[112] Kenneth C Shadlen et al, eds., *Intellectual Property, Pharmaceuticals and Public Health* (United Kingdom: Edward Elgar Publishing, 2011).

system had an impact on R&D in the area of health-related innovation and the access to health-related innovative products and services?

The scientific, technological, legal, economic, institutional, and social conditions specific to Mexico discussed in the two chapters of this section provide the context that will allow me to determine in chapter seven the actual impact that the patent system has on Mexico's R&D in the health-related industry and on its population's access to healthcare. Likewise, using this context to determine the impact that the patent system has will help to conclude in my last chapter (i.e. chapter nine) whether the current patent system in Mexico brings about the type of utility/welfare that should justify it as discussed in chapters one and eight (i.e. a definition of utility that includes various social aspects of human welfare, such as quality of life in terms of people's functionalities and capabilities, which in this case, it would lead to proper access to healthcare).

The reason for which I include scientific, technological, legal, institutional, and social conditions of Mexico's health-related industry and system is because systems do not function in isolation; they interact with and affect each other. The patent system interacts with, influences, and is affected by other systems such as political, economic, and healthcare. In health-related innovation, the patent system can affect not only innovation, but it can also modify access to healthcare. Furthermore, issues in access to healthcare do not only stem from the patent system and the innovation it promotes or hinders; they also spring from the healthcare system. Considering this, the healthcare system in Mexico is of particular importance. Answering the questions raised here (has Mexico's patent system

affected the activity of R&D in the area of health-related innovation and the access to health-related innovative products and services?) requires, in addition to the specific elements of the current patent system and health-related innovation in Mexico, that I consider the particularities of Mexico's healthcare system. This will lead to a more accurate and thorough assessment of the impact of the patent system on the activity of R&D in the area of health-related innovation and on access to health-related innovative products and services in Mexico.

With the foregoing in mind, I organize this section in two chapters. In the first chapter, I focus on the conditions of access to healthcare in Mexico. I first describe the healthcare system in Mexico. Second, I discuss the conditions in which the majority of the most vulnerable population in Mexico, including Indigenous Peoples, lives. I discuss their socio-economic situation, the infrastructure available to them, and their access to healthcare. In the second chapter, I focus on the activities of R&D in health-related innovation in Mexico. I include some details about one of the areas of health-related innovation (medical genetics) in Mexico: ongoing projects, the parties involved in those projects, their sources of funding, and relevant regulation that aims to promote innovation. I focus my analysis on medical genetics for two reasons: first, medical genetics is a promising field in the areas of innovation in the pharmaceutical and biotechnology industries and Mexico has engaged in state-of-the-art projects and second, the case study that I present in the following chapter pertains to medical genetics. This second chapter also includes a description and analysis of Mexico's patent system focusing specifically on health-related innovation and medical genetics. The information contained in these

chapters is obtained from governmental sources (legislation, documents, websites, databases) and literary sources.

Chapter 2 Access to healthcare

2.1 Healthcare Services available in Mexico

Mexico's healthcare system is founded in its federal constitution. The constitution states that everyone has the right to have his/her health protected and that the State has the responsibility to provide the necessary healthcare services.[113] The regulation and implementation of these healthcare services, policies, and social security benefits is described in article 123 fr. XI of the Mexican Constitution and in the relevant secondary legislation.[114]

Healthcare services are provided in Mexico either through the public or the private healthcare system.[115] The public healthcare expenditure between 2000 and 2013 has been between 4.4% of the country's GDP to 6.1%.[116] In 2017, Mexico's expenditure was estimated in 5.4% of its GDP.[117] The federal or state (provincial) governments concurrently provide public healthcare services. For this purpose, and in accordance with the relevant secondary legislation, the agencies that provide public healthcare services are the ISSSTE-

[113] *Constitucion Politica de los Estados Unidos Mexicanos*, Diario Oficial de la Federacion, 5 February 1917 (Amended on January 27, 2016) [*Constitucion*] at art. 4; Francisco Sales Heredia, ed., *Situación del sector farmacéutico en México*, 1st ed. (Mexico: Centro de Estudios Sociales y de Opinión Pública, 2010) at 21.

[114] Examples of this secondary legislation are: *LGS*, *supra* note 7; *Ley Federal de los Trabajadores al Servicio del Estado*, Diario Oficial de la Federacion, 28 December 1963 [*Ley Fed Trab Estado*]; *Ley del Instituto de Seguridad y Servicios Sociales de Trabajadores del Estado*, Diario Oficial de la Federacion, 31 March 2007 [*Ley del ISSSTE*]; *Ley del Instituto de Seguridad Social para las Fuerzas Armadas*, Diario Oficial de la Federacion, 7 July 2003 [*Ley del ISS Fuerzas Armadas*]; *Ley del Seguro Social*, Diario Oficial de la Federacion, 21 December 1995 [*Ley del Seguro Social*].

[115] Béatrice Séguin et al, "Genomics, public health and developing countries: the case of the Mexican National Institute of Genomic Medicine (INMEGEN)" (2008) 9 Suppl 1 Nat Rev Genet S5 at 6.

[116] OECD b), "Health Expenditure and Financing", (2016) online: *OECD Stat* <http://stats.oecd.org/index.aspx?DataSetCode=HEALTH_STAT>; OECD c), "Health expenditure and financing", (2017), online: *OECD Stat* <https://stats.oecd.org/Index.aspx?DataSetCode=SHA>.

[117] Canada on the othe hand, spent during that year 10.4% of its GDP. OECD c), *supra* note 116.

Institute for Social Security and Services for State Workers,[118] the IMSS- Mexican Institute of Social Security,[119] PEMEX,[120] the ISSFAM- Institute of Social Security for the Armed Forces,[121] the SSA- Ministry of Health,[122] the SPS- Popular Health Insurance,[123] and each state's own social security agency for provincial governmental employees.[124]

The ISSSTE, IMSS, PEMEX, SEDENA, and SEMAR have their own hospitals, clinics, and medical staff. These hospitals and clinics only admit patients who work for the State (ISSSTE), Petroleos Mexicanos (PEMEX), the military and the navy (ISSFAM) or for companies that are affiliated to the IMSS and that are duly registered in the program (i.e. that are registered and that are up-to-date in the payment of their fees).[125] These institutions provide medical, surgical, and hospital services, physical and mental rehabilitation, maternity and preventive medicine, and medication. The SPS provides

[118] The ISSSTE (Instituto de Seguridad y Servicios Sociales de Trabajadores del Estado), founded in 1959, is a federal governmental institute that administers and provides healthcare and social services exclusively in the benefit of federal government workers. Octavio Gomez Dantés et al, "The health system of Mexico" (2011) 53:2 Salud Publica Mex 220 at 224.

[119] The IMSS (Instituto Mexicano del Seguro Social) is an institution created by the government in 1943 to provide social security and healthcare to those people who are not government employees, but that are registered by their employers before the institute as insurees. *Ibid*.

[120] PEMEX (Petroleos Mexicanos) is the only Mexican oil company. It is state owned. Its employees are the only ones that are entitled to the social security services provided by PEMEX.

[121] ISSFAM (Instituto de Seguridad Social de las Fuerzas Armadas) is the Mexican governmental institution that provides social security services to active members of the army and those who are retired.

[122] The SSA (Secretaria de Salud) is the governmental branch responsible, among a number of health-related issues, of providing public healthcare services to patients who have no social security affiliation. It operates concurrently with the SPS described below.

[123] The SPS is an insurance created by the federal government in 2004 to cover the population that is not covered by the social security services ISSSTE, IMSS, PEMEX, SEDENA or SEMAR. In December of 2018 however, the current President of Mexico announced that, given the SPS failure to properly cover Mexico's uninsured population, his administration will replace the SPS for a federal public universal healthcare program (Instituto Nacional para la Salud y el Bienestar- National Institute of Health and Well-Being) that will be implemented gradually. "AMLO announces new health system; Seguro Popular to be replaced", *Mexico News Daily* (14 December 2018), online: Mexico News Daily <https://mexiconewsdaily.com/news/amlo-announces-new-integrated-health-system/>.

[124] PEMEX, SEDENA, SEMAR, and the provincial governmental agencies cover their own employees. Gomez Dantés et al, *supra* note 118 at 224.

[125] Burr et al, *supra* note 7; Claudia Burr et al., *Ruta para Recibir Atencion Medica en el IMSS e ISSSTE* (Centro de Contraloria Social y Estudios de Construccion Democratica, 2013).

coverage for certain packages of services that include medical attention and medication. These packages cover self-employed, informally employed, and unemployed people.[126] In addition, the Ministry of Health and its equivalent in the states (SESA- State Healthcare Services) have some hospitals and clinics of their own for populations that lack social security.[127]

Despite the constitutional and legislative provisions, the public policies implemented, and the number of institutions and agencies providing healthcare services within the public sector, there are serious deficiencies in Mexico's healthcare system. For instance, Mexico's healthcare expenditure, despite an increase seen throughout the last years, is still low in comparison to other OECD countries. For instance, whereas Mexico spent 6.1% of its GDP in healthcare in 2013, Canada spent 10.1%, Germany 10.9%, Netherlands 10.9%, and the United States 16.34%. In 2017, Mexico spent 5.4%, Canada 10.4%, Germany 11.3%, Netherlands 10.1%, and the United States 17.2%. Out of all the OECD countries, only Estonia and Turkey spent less than Mexico.[128] Furthermore, there is a considerable percentage of the population that does not have access to healthcare services.[129] In 2008, close to 45% of the population had access to healthcare coverage within social security services,[130] 25% to SPS, and 29% had no access to any healthcare services. In 2010, 31.8% of the Mexican population did not have access to healthcare services. In 2015, it was 23.1%[131] and in 2016, 15% (i.e. 19.1 millions) did not have access

[126]Secretaria de Salud, "Seguro Popular", online: Seguro Popular Secretaria de Salud <http://www.seguro-popular.gob.mx/>.
[127] Gomez Dantés et al, *supra* note 118 at 225.
[128] OECD b), *supra* note 116; OECD c), *supra* note 116.
[129] Sales Heredia, *supra* note 113 at 21.
[130]Social Security Services include those covered by the ISSSTE, the IMSS, PEMEX or ISSFAM.
[131]Presidencia de la Republica, *Plan Nacional de Desarrollo 2013-2018* (2012) at 44; INEGI, "Mexico en

to healthcare services This population resides mainly in the states of Oaxaca, Michoacan, Puebla, Veracruz, Estado de Mexico and Chiapas.[132]

As I more thoroughly described in the following two subsections, the foregoing situation can be particularly serious in certain populations, such as rural and Indigenous populations, for two reasons. First, their communities are usually located in areas with a high level of geographical isolation: either up on the mountains or in areas where there are no viable roads or means of public transportation. These conditions make most general and specialized hospitals and clinics inaccessible. Second, even if some of those general hospitals and clinics are within a reasonable distance, the members of these communities may not have access to them. Since it is very unlikely that they work for the State, PEMEX, SEDENA, SEMAR, or even for a company registered in the IMSS program, it is unlikely that they have social security. As a result, the hospitals and clinics accessible to them are only those administered by the SSA (federal Ministry of Health), the SPS (Seguro Popular), and the SESA (ministries of health of the states), which are very limited in rural areas.

Private healthcare services are provided through doctors and specialists who have a private practice either in their private offices, clinics, or private hospitals. The costs of

Cifras", (2015 2008), online: *Inst Nac Estad Geogr* <http://www.beta.inegi.org.mx/app/areasgeograficas/>; INEGI, *Censo de Poblacion y Vivienda 2010.* (Instituto Nacional de Estadistica y Geografia, 2011); INEGI, "Base de Datos del INEGI", online: *Inst Nac Estad Geogr* <http://www.inegi.org.mx/lib/olap/consulta/general_ver4/MDXQueryDatos.asp?proy=cpv10_pt>>; INEGI, *supra* note 8.

[132] CONEVAL, *Estudio de Diagnostico del Derecho a la Salud 2018* (Mexico: Consejo Nacional de Evaluacion de la Politica de Desarrollo Social, 2018); Alejandro Suarez, "Sin acceso a servicios de salud, 19.1 millones de personas", *El Sol de Mex* (8 April 2019), online: El Sol de Mexico <https://www.elsoldemexico.com.mx/mexico/sociedad/sin-acceso-a-servicios-de-salud-19.1-millones-de-personas-3292147.html>.

doctor appointments, hospitalization services, and clinical tests vary depending on the level of luxury of the premises, the reputation of the doctors, and the complexity of the medical condition. The costs of prescribed medication vary depending on the illness and on whether the medication is patented. Patients either cover the medical expenses from their own pockets or they obtain private health insurances. However, most of these services are prohibitive for the people living under the poverty line because their low incomes prevent them from being able to pay from their own pockets or to from being able to obtain private health insurances.

Healthcare services are provided in either hospitals (17.6%) or in clinics (82.4%). Out of the total healthcare units (hospitals and clinics) in Mexico, 86.8% are public and 17.2% are private. 27.3% of the total number of hospitals is public.[133] Even though close to half of those public hospitals admit patients without social security, they are not proportionally distributed. This results in some states and communities with fewer healthcare units available to patients without social security affiliation than in others. The size, equipment, and medical staff of any of these healthcare units also change depending on the state or the community.[134]

Regarding expenditures on pharmaceuticals, Mexico has three types of medication available in the market: innovative (usually patented), generic, [135] and similar

[133] Secretaria de Salud, *Programa Nacional de Salud 2007-2012*. (Mexico: Secretaria de Salud, 2007) at 54.
[134] *Ibid* at 55–58; Secretaria de Gobernacion, *Plan Sectorial de Salud 2013-2018* (Mexico: Secretaria de Gobernacion, 2013).
[135] Nitin Shukla & Tanushree Sangal, "Generic Drug Industry in India: The Counterfeit Spin" (2009) 14:3 J Intellect Prop Rights 236 at 236; Suzanne Dunne et al, "A review of the differences and similarities between generic drugs and their originator counterparts, including economic benefits associated with usage of generic medicines, using Ireland as a case study" (2013) 14 BMC Pharmacol Toxicol 1.

(medicamentos similares, hereinafter "similares").[136] In the public sector, out of the budget devoted to pharmaceuticals expenditure, the government spends 56% on patented medicines produced by multinational companies and 29% on generics, while 15% of expenditures are not identified. This expenditure buys, in terms of units, 10% of patented drugs, 73% generics, and 17% not identified.[137]

The supply of medication in the hospitals and clinics of the public sector is mostly generic. This occurs mainly because the public sector is obligated by law to obtain generic medication when available. The hospitals and clinics' capacity to supply patients with the medication prescribed varies according to the institution and the region in which such institution is located. For instance, in 2006, only some SPS clinics in big cities reported having supplied around 90% of the medications that were prescribed.[138] In that same year, some provincial hospitals were only able to supply 44% of the medications that were

[136] Similares or similar medicines are those that may contain the same chemical active ingredient, dosage form, route of administration and identification therapeutic regimen as the innovator's and/or patent holder's, but they lack the certification of bioequivalence. A certification of bioequivalence is a pharmacokinetics analysis that determines whether two products are, for all purposes and intents, the same, causing similar effects in efficacy and safety. This certification is required to approve a generic medication. They differ from biosimilar (biocomparable) drugs in that the latter are equivalent to the biotechnological/biologic innovative clinical products and are required to have a bioequivalent certification, while similares are equivalent to a patented chemical drug and are not required to have an certificate of bioequivalence. They also differ from generics in that the latter are required to have the bioequivalence certification and are not offered to the public under a brand name, while the similares are not required to have that bioequivalence certification and are offered under a brand name. Burr et al, *supra* note 7 at 77; Mayoral-Zavala et al, *supra* note 7.

[137] Alenka Guzman, "The Challenges of Constructing Pharmaceutical Capabilities and Promoting Access to Medicines in Mexico under TRIPS" in Kenneth C Shadlen et al., eds., *Intellectual Property, Pharmaceuticals and Public Health* (United Kingdom: Edward Elgar Publishing, 2011) 110 at 116; Octavio Gomez-Dantes et al., *WHO | A new entity for the negotiation of public procurement prices for patented medicines in Mexico* (Bulletin of the World Health Organization, 2012); Sales Heredia, *supra* note 113; Rolf Alter & Janos Bertok, eds., *Estudios de la OCDE sobre Gobernanza Pública Estudio sobre la Contratación Pública del Instituto de la Seguridad y Servicios Sociales de los Trabajadores del Estado en Mexico* (Paris: OCDE, 2013) at 261.

[138] Francisco Garrido-Latorre, Héctor Hernández-Llamas & Octavio Gómez-Dantés, "Surtimiento de recetas a los afiliados al Seguro Popular de Salud de México" (2008) 50:4 Salud Pública México S429 at 429–430.

prescribed.[139] These numbers were similar in 2010. However, these numbers decrease considerably in hospitals and clinics located in isolated regions.[140] In 2011, it was reported that only 13.3% of specialized clinics and hospitals of the SSA and SESA in urban areas had a complete inventory of the list of medications considered essential available in their pharmacies.[141] Similar problems were encountered in many SPS clinics in 2017.[142] In cases where the prescribed medication is not available, patients have two options. They can either not follow the prescribed treatment, or they can go to an external (private) pharmacy and buy their medication out of pocket.[143] This leads to the conclusion that a large number of patients who attend these clinics cannot be ensured access to the prescribed medication/treatment, and therefore to proper healthcare. Furthermore, it is important to mention that in the public setting, most patients bear the costs of their prescribed medication based on their socio-economic level. The public healthcare system only covers medication for patients of the SPS, and this coverage is limited to specific diseases. The supply of medication in the private sector is usually of patented medication and it is paid by the patients or their insurance companies.

The conditions of the healthcare system mentioned above can be very detrimental for the population living under the poverty line. People living under the poverty line are found all around the country, including urban areas. However, rural and Indigenous

[139] *Ibid*.
[140] Gomez Dantés et al, *supra* note 118 at 228.
[141] David Contreras-Loya et al, "Abasto y surtimiento de medicamentos en unidades especializadas en la atención de enfermedades crónicas en México en 2012" (2013) 55:6 Salud Pública México 618.
[142] Antonio Chemor Ruiz, Anette Elena Ochmann Ratsch & Gloria Araceli Alamilla Martinez, "Mexico's Seguro Popular: Achievements and Challenges" (2018) 4:3 J Health Syst Reform 194.
[143] Contreras-Loya et al, *supra* note 141.

populations are the main sectors of the population afflicted by these conditions of the healthcare system for the reasons explained below.

2.2 Mexico's population and Indigenous Peoples

2.2.1 Nation-wide socio-economic inequality

Mexico is a country with great economic disparity. Mexico's economy ranked, in 2017, 15th in the world, according to its Gross Domestic Product (GDP)[144] and 77th with respect to its Human Development Index (HDI: 0.762).[145] However, in this last decade, Mexico was also ranked as the second most unequal nation of the OECD.[146] The ratio between the richest 10% of the population and the poorest 10% was in 2010 25:1.[147] The top 30% of income earners account for 55% of the country's income. The disparity was so serious that between 2010 and 2014, the HDI of the Federal District (0.830) was similar to the one of the Czech Republic (0.861), the one of Chiapas (0.667) to Syria's (0.658) or Cape Verde's (0.636), the one of Benito Juarez, a political subdivision of Mexico City, to

[144] Wolfram Alpha, "Mexico: Wolfram|Alpha", online: <www.wolframalpha.com/>; World Bank, "Poverty headcount ratio at national poverty lines (% of population) | Data", (2016), online: <https://data.worldbank.org/indicator/SI.POV.NAHC?end=2016&locations=MX&start=2008&view=chart>; According to the Central Intelligence Agency's fact book, the raking number is 11th. CIA, "The World Factbook", online: *Central Intelligence Agency* <https://www.cia.gov/library/publications/the-world-factbook/fields/2012.html>.

[145] The HDI combines indicators of health (life expectancy), education and income. United Nations Development Programme, "Human Development Index (HDI) | Human Development Reports", online: *United Nations Development Programme* <http://hdr.undp.org/en/content/human-development-index-hdi>; United Nations Development Programme, "Human Development Reports: Human Development Indicators: Mexico", online: <http://hdr.undp.org/en/countries/profiles/MEX>; United Nations Development Programme, *Human Development Report 2016* (United Nations Development Programme, 2016).

[146] OECD, *In It Together: Why Less Inequality Benefits All - en - OECD* (Paris: OECD Publishing, 2015); OECD, "Compare your income - Perception of income inequality in OECD countries", (21 May 2015), online: *Organ Econ Coop Dev* <http://www.compareyourincome.org>.

[147] Presidencia de la Republica, *supra* note 131 at 44.

that of Italy (0.872), and the one of Metlatonoc (Guerrero), was similar to that of Malawi (0.414).[148]

This inequality results in close to half (43.6%) of the total population (approximately 53 million) living below the national poverty line in 2016.[149] Out of those living in poverty, 37.7% live in conditions of moderate poverty (living on no more than USD $177 a month in cities and USD $113 in rural areas) and 10.4% in conditions of extreme poverty (people who suffer at least three of the six forms of social deprivation,[150] and survive with USD $85 in cities and USD $60 in rural areas).[151]

---

[148] Luis Felipe Lopez Calva & Rodolfo De la Torre Garcia, *Informe sobre Desarrollo Humano México 2006-2007* (Mexico: Programa de las Naciones Unidas para el Desarrollo, 2007) at 3 & 22; United Nations Development Programme, *supra* note 145; United Nations Development Programme, "Human Development Reports: Human Development Indicators: Syria", online: <http://hdr.undp.org/en/countries/profiles/SYR>; United Nations Development Programme, "Human Development Reports: Human Development Indicators: Italy", online: <http://hdr.undp.org/en/countries/profiles/ITA>; United Nations Development Programme, "Human Development Reports: Human Development Indicators: Malawi", online: <http://hdr.undp.org/en/countries/profiles/MWI>; United Nations Development Programme, "Human Development Reports: Human Development Indicators: Cape Verde", online: <http://hdr.undp.org/en/countries/profiles/CPV>; United Nations Development Programme, "Human Development Reports: Human Development Indicators: Czech Republic", online: <http://hdr.undp.org/en/countries/profiles/CZE>; United Nations Development Programme, *Indice de Desarrollo Humano en Mexico: Cambios Metodologicos e Informacion para las Entidades Federativas* (United Nations Development Programme, 2012).

[149] World Bank, *supra* note 144; CIA, *supra* note 144; Christopher Wilson, "Mexico's Latest Poverty Stats", (12 August 2013), online: *Wilson Centre* <https://www.wilsoncenter.org/article/mexicos-latest-poverty-stats> at 1–3; INEGI, *supra* note 131.

[150] In order to determine and measure poverty, CONEVAL (Mexico's National Council for the Evaluation of Social Development Policy) considers current per capita income, level of education, access to healthcare services, access to social security, quality and size of one's home, access to basic services in the dwelling, and access to food. These factors help to determine whether someone has sufficient income and otherwise resources to fulfill their basic needs. The lack of each of these factors is considered a form of social deprivation. CONEVAL defines poverty as: "people with an income below the wellbeing threshold and with one or more social deprivations." Wilson Centre, *supra* note 149 at 1–2.

[151] Wilson Centre, *supra* note 149 at p. 1-3 and Banco de Informacion INEGI, Instituto Nacional de Estadistica y Geografia online: <http://www3.inegi.org.mx/sistemas/biinegi/?e=31&m=0&ind=1005000040> (INEGI), and Plan Nacional de Desarrollo 2013-2018 at p. 44.

Poverty and economic disparity can be observed in both urban and rural populations. However, the rural population (22% of Mexico's total population[152]) is particularly afflicted by these conditions, as 65% of that population lives below the poverty line.[153]

The conditions of moderate and extreme poverty in which the 43.6% of the population lives translate to deficiencies in their health and their access to healthcare. Their health is likely to be deficient due to the conditions of poor nutrition, and infrastructure (e.g. housing conditions, basic urban services, roads, etc.) in which they live.

The housing conditions for the people living in poverty include peripheral squatter settlements, houses made of used or discarded materials, and irregular or nonexistent basic urban services (water, electricity, sewerage). This deficiency in basic urban services is also caused by the fact that many of the people living under the poverty line are geographically isolated. The isolation is more noticeable in rural areas. Tabasco, Chiapas, Guerrero, and Oaxaca (the last three are states with a high Indigenous component) are the states with the least access to drinkable water. Between 38% and 27% of the homes in those states lack access to drinkable tap water.[154] In Guerrero and Oaxaca, close to 30% of the homes have no drainage.[155] Houses in Metlatonoc (Guerrero) give an example of these conditions. For

[152] "Rural Population" World Bank online: <http://data.worldbank.org/indicator/SP.RUR.TOTL.ZS/countries> (accessed June 5, 2015)
[153] Presidencia de la Republica, *supra* note 131 at 44.
[154] Secretaria de Salud, *supra* note 133 at 39; INEGI, "Servicios y Bienes en las Viviendas. Porcentaje de Viviendas Particulares Habitadas con Disponibilidad de Agua por Entidad Federativa 1990-2010.", online: *Inst Nac Estad Geogr* <http://www3.inegi.org.mx/sistemas/sisept/default.aspx?t=mviv09&s=est&c=22242>.
[155] INEGI, *supra* note 154.

every 100 houses in Metlatonoc, only 13 have bathrooms, 32 have tap water, one has sewerage, and 33 electricity.[156] This deficient access to infrastructure and poor housing conditions leads to deplorable sanitary and hygienic conditions, which consequently leads to poor health.[157] In fact, in Mexico, 1% of deaths are associated to these deplorable sanitary and hygienic conditions.[158]

Low incomes may affect people's health in two ways. A low income prevents people from having the means to afford a nutritious diet. Malnutrition weakens people's immune systems; consequently, they get sick more often or the symptoms and effects of the disease are more severe. A low income may also prevent people from having the means to go to the doctor and be diagnosed in a timely manner or to afford to complete the treatment.[159] In terms of the capability approach, low income is the type of conversion factor that would affect people's capabilities and functionings (e.g. being well-nourished and healthy), which ultimately, impact their quality of life.

Additionally, people living under the poverty line have deficient access to healthcare because of insufficient social security coverage and/or geographical isolation. In 2010, 31.8% of the Mexican population was unaffiliated with a social security program that included healthcare services.[160] In 2016, this number was close to 15% (19 million

[156] Luis Felipe Lopez Calva & Rodolfo De la Torre Garcia, *Informe sobre Desarrollo Humano México 2004* (Mexico: Programa de las Naciones Unidas para el Desarrollo, 2005) at 56.
[157] David Leon & Gill Walt, *Poverty, Inequality and Health. An International Perspective* (New York: Oxford University Press, 2001) at 10.
[158] Secretaria de Salud, *supra* note 133 at 41.
[159] Leon & Walt, *supra* note 157 at 10.
[160] Presidencia de la Republica, *supra* note 131 at 44.

people).[161] This means that this 15% could only have access to healthcare services either in hospitals or clinics administered by the SSA, SESA or SPS or in private hospitals or clinics. The levels of poverty in which this sector of the population lives exclude the possibility of using private hospitals or clinics and/or affording most medication and treatments.

Geographical isolation usually results in a reduced number of general and specialized hospitals and clinics in the area. Geographical isolation may also translate into deficient or nonexistent roads and systems of public transportation. These conditions make clinics and hospitals that are not within walking distance inaccessible. This isolation and the lack of social security reduce even more the number of hospitals and clinics that these vulnerable populations can access, as the number of SSA, SESA or SPS available would be smaller.[162]

2.2.2 Indigenous Peoples

Mexico has the highest concentration of Indigenous Peoples in Latin America, followed by Peru, Guatemala, Bolivia, and Ecuador.[163] In 2017, the total population in Mexico was of 129 millions people, out of which 7% are Indigenous Peoples (i.e. over

[161] CONEVAL, *supra* note 132 at 18; Suarez, *supra* note 132.
[162] Burr et al, *supra* note 7 at 61–63.
[163] Jose Luis Torres et al., "Salud de la Población Indígena en México" in Felicia Marie Knaul & Gustavo Nigenda, eds., *Caleidosc Salud Investig Las Políticas Las Políticas Acción* (Mexico: Case Salud & Fundacion Mexicana para la Salud, 2003) 41 at 42; IWGIA a), "Indigenous Peoples in Mexico", online: *International Work Group for Indigenous Affairs* <http://www.iwgia.org/regions/latin-america/mexico>; IWGIA b), "Indigenous peoples in Latin America - a general overview", online: *International Work Group for Indigenous Affairs* <http://www.iwgia.org/regions/latin-america/indigenous-peoples-in-latin-america>.

9,000,000).[164] There are 68 Indigenous Peoples in Mexico located in its majority (around 85%) in the southern states: Yucatán, Oaxaca, Quintana Roo, Chiapas, Campeche, Guerrero, Hidalgo, Puebla, Querétaro, State of Mexico, San Luis Potosí, and Veracruz.[165]

Despite the governmental obligation in the Mexican Constitution to promote and provide equality and protection to Indigenous Peoples,[166] as well as the several programs and policies[167] for achieving this, the Indigenous Peoples' socio-economic conditions in general are deplorable. In 2016, approximately, 71% of the Indigenous Peoples in Mexico live below the poverty line and close to 34.8% of them live in extreme poverty.[168] Only

[164] Wolfram Alpha, *supra* note 144; CIA, *supra* note 144; World Bank, "Mexico | Data : World Bank", (2019), online: <https://data.worldbank.org/country/mexico>; Gabriela Cordourier Real & Rodolfo De la Torre Garcia, eds., *Informe sobre Desarrollo Humano de los Pueblos Indigenas en Mexico* (Mexico: Programa de las Naciones Unidas para el Desarrollo, 2010); IWGIA a), *supra* note 165; INEGI, *supra* note 131.

[165] Federico Navarrete Linares, *Los Pueblos Indígenas de Mexico* (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2008) at 23; Alfonso Flores Reyes, Ildefonso Garcia Lara & Nora Hernandez Valdes, *Atlas de Infrastructura y Patrimonio Cultural de Mexico 2010* (Mexico: Consejo Nacional para la Cultura y las Artes, 2010) at 21; CONEVAL, *Informe de Evaluacion de la Politica de Desarrollo Social 2018* (Mexico: Consejo Nacional de Evaluacion de la Politica de Desarrollo Social, 2018) at 145.

[166] *Constitucion*, *supra* note 113 art. 2.

[167] Some of these programs and policies include the National Development Plan, the Program for the Development of Indigenous Peoples, the creation of the National Commission for the Development of Indigenous Peoples, the General Coordination of Intercultural and Bilingual Education, the National Institute of Indigenous Languages, the National Institute of Anthropology and History, and the National School of Anthropology and History, as well as policies individually developed and implemented by the Ministry of Education, the Ministry of Health, the Ministry of Social Development, the Ministry of Health, the Ministry of Environment and Natural Resources, the Ministry of Agriculture Livestock, Rural Development, Fishing and Food Supply, and the Ministry of Agrarian Reform. Presidencia de la Republica, *Plan Nacional de Desarrollo 2007-2012* (Presidencia de la Republica, 2006) at 201; Comisión Nacional para el Desarrollo de los Pueblos Indígenas, *Programa para el Desarrollo de los Pueblos Indígenas 2009-2012*. (Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2010).

[168] Hector Molina, "En pobreza, 71% de los indígenas en México", *El Economista* (9 August 2018), online: El Economista <https://www.eleconomista.com.mx/politica/En-pobreza-71-de-los-indigenas-en-Mexico-20180809-0145.html>; CONEVAL, *supra* note 167 at 144; Blanca Valadez, "En pobreza extrema, 39% de indígenas en México", (9 August 2010), online: *Medios En Mexico* <http://mediosenmexico.blogspot.com/2010/08/en-pobreza-extrema-39-de-indigenas-en.html>; Maria del Rosario Cardenas Elizalde et al, *La Pobreza en la Poblacion Indigena de Mexico* (Mexico: Consejo Nacional de la Evaluacion de la Politica de Desarrollo Social, 2014) at 42.

3.1% of the Indigenous Population is considered to be economically stable (i.e. neither poor nor vulnerable).[169]

Table 1.3 National Human Development Index and other components determined by their Indigenous condition, 2008

Group	HDI	Healthcare	Income
Non-Indigenous	0.7628	0.7572	0.6982
Indigenous	0.6761	0.7442	0.5791

Source: Prepared by the Office of Research Human Development of the PNUD-Mexico with information from the Module of Social Conditions of the ENIGH (2008)[170]

In terms of income, around 71.3% of the members of the Indigenous communities do not make more than USD $5 a day.[171] This low income forces them to exclusively rely on public healthcare, which, as I describe below, are very deficient. It also prevents them from meeting their basic needs regarding food and housing. For instance, in 2008, child malnutrition was 38% in Indigenous communities and 12.5% in non-Indigenous ones.[172] In 2016, 31% of the Indigenous population could not afford the necessary adequate food.[173] This malnutrition is visible in the weight and height of Indigenous children: 44% of them measure less and 58% weigh less than what is expected and considered healthy.[174] Regarding their housing conditions, in 2005, 29.5% of Indigenous homes lacked piped water, 44.4% lacked drainage, 9.9% lacked electricity, and 38% had dirt floors.[175] In 2016, 20.8% of the country's Indigenous population lived in these conditions (19.9% of

[169] Cordourier Real & De la Torre Garcia, *supra* note 164 at 49; INEGI, *supra* note 131.
[170] Cordourier Real & De la Torre Garcia, *supra* note 164 at 39.
[171] CONEVAL, *supra* note 165 at 149; Molina, *supra* note 168; Presidencia de la Republica, *supra* note 167.
[172] Cordourier Real & De la Torre Garcia, *supra* note 164 at 16.
[173] CONEVAL, *supra* note 165 at 36.
[174] Cordourier Real & De la Torre Garcia, *supra* note 164 at 112.
[175] Navarrete Linares, *supra* note 165 at 99; Cordourier Real & De la Torre Garcia, *supra* note 164 at 56; Secretaria de Salud, *supra* note 133 at 40.

Indigenous homes lacked piped water, 13.6% had dirt floors, and 24.6% lacked drainage).[176] Malnutrition combined with poor living conditions weakens their immune systems and makes them more vulnerable to infectious diseases, which affects their health short and long-term.[177] Like in the correlation of low income and access to healthcare mentioned above, conditions of extreme poverty are examples of conversion factors and therefore, affect people's capabilities and functionings of being well-nourished and having proper hygiene, which ultimately decimates their health and therefore, their quality of life.

In terms of infrastructure, close to 96% of Indigenous Peoples in Mexico live in rural areas with various levels of isolation that are characterized by insufficient roads, deficient public transportation, and poor housing conditions.[178] 35.9% of them live in highly and very highly marginalized areas of the country.[179] The municipality of Batopilas in Chihuahua, whose population is mainly Indigenous, has a lower HDI than Niger, which is the country with the lowest HDI in the world.[180] These levels of isolation constitute an example of environmental conversion factors that affect the Indigenous Peoples' ability to turn the healthcare infrastructure available to them into the possibility of accessing healthcare services and therefore, being healthy.

Access to healthcare is affected by differences in socio-economic conditions, such as income (lack of resources to attend to a doctor and follow up the treatment),

[176] CONEVAL, *supra* note 165 at 82 & 148.
[177] Claudio F Lanata, "Children's Health in Developing Countries: Issues of Coping, Child Neglect, and Marginalization" in David Leon & Gill Walt, ed.s, *Poverty, Inequality and Health. An International Perspective* (United States of America: Oxford University Press, USA, 2001) 137 at 150–151.
[178] Cordourier Real & De la Torre Garcia, *supra* note 164 at 56.
[179] INEGI, *supra* note 131; INEGI, *supra* note 131.
[180] Cordourier Real & De la Torre Garcia, *supra* note 164 at 15.

malnutrition, location (isolated regions), infrastructure (inadequate, inaccessible or lack of clinics and doctors, staff who speak their language) and levels of marginalization, all of which are conversion factors in terms of the capability approach that affect people's health, well-being, and quality of life (i.e. their capabilities and functionings).[181] The different conditions (i.e. conversion factors) between Indigenous and non-Indigenous peoples create different capabilities and functionings in each group. For instance, life expectancy is 72 years for Indigenous men and 77.3 for non-Indigenous men.[182] In 2010, the Indigenous infant mortality rate (children younger than 1 year old) was 228/10,000 as opposed to the non-Indigenous infant mortality rate of 140/10,000.[183] Particularly in Batopilas, the infant mortality rate reached 1,188 per 10,000 born children.[184] This number, along with the number related to life expectancy, showed that in 2003, the conditions in the municipalities with a high concentration of Indigenous population corresponded to the national numbers in 1980.[185]

Another factor that affects Indigenous People's health and access to healthcare is their affiliation to social security. In 2016, 77.6% of the Indigenous population was not affiliated to a social security institution and therefore, was not entitled to the healthcare

[181] According to the Consejo Nacional de Población (CONAPO – National Council of Population), the marginalization index is determined considering: level of illiteracy within a population, percentage of people living in houses without toilet, drinkable water, electricity, tap water, and drainage, percentage of people living in houses with dirt floors, percentage of people living in over populated houses, people whose income are not more than the equivalent to 2 minimum wages, and whether the community has less than 2500 inhabitants. Torres et al, *supra* note 163 at 45; United Nations Development Programme, *supra* note 145..

[182] World Bank, *supra* note 164; "North America :: Mexico — The World Factbook - Central Intelligence Agency", (2018), online: <https://www.cia.gov/library/publications/the-world-factbook/geos/mx.html>.

[183] Cordourier Real & De la Torre Garcia, *supra* note 164 at 55–56.

[184] *Ibid* at 47.

[185] Torres et al, *supra* note 163 at 50.

services provided by the governmental social security institutes (ISSSTE, IMSS, PEMEX, SEDENA, and SEMAR).[186] Hence, their only "options" left for this 15.1% to gain access to healthcare were: a) private healthcare, which, in most cases, is unaffordable or b) SSA, SESA or SPS hospitals, which are few and usually located far away from the Indigenous communities. It is also important to mention that the little healthcare infrastructure actually made available to Indigenous communities is deficient. For instance, whereas in some municipalities with high concentrations of Indigenous Peoples, there were 5 doctors and 1 bed per 1,000 inhabitants, in others, there would be just 1 medical student and a nurse, and neither of them with access to medication or tests.[187] The result is a situation where, even if the official governmental statistics state that only 15.1 of the Indigenous population lacks access to healthcare, in reality, it is that 77.6% who does not have social security, who does not have access to healthcare.[188]

2.3 Impact of poverty and deficient healthcare on health

Poverty can lead directly to insufficient or inadequate healthcare, and therefore to poor health. It could do so because a patient with a low income is unlikely to devote the few available resources to getting a timely diagnosis, taking preventive measures, or to

[186] Comisión Nacional para el Desarrollo de los Pueblos Indígenas, *supra* note 167 at 25; CONEVAL, supra note 165 at 146; Secretaria de Salud, supra note 133 at 40; INEGI*,supra* note 131*;* CONAPRED, "Discriminación en contra de la población indígena en México", (2012), online: *Consejo Nacional Para la Prevencion contra la Discriminacion* <http://www.conapred.org.mx/index.php?contenido=noticias&id=798&id_opcion=273&op=448>.

[187] In contrast, in municipalities with low concentration of Indigenous population there were 12 doctors per 1,000 inhabitants and 9 hospital beds per 1,000 inhabitants. Torres et al, *supra* note 165 at 46 & 49.

[188] Comision Nacional para el Desarrollo de los Pueblos Indigenas, *Programa Especial de los Pueblos Indigenas 2014-2018* (Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2014) at 75; CONEVAL, *supra* note 165 at 146; Molina, *supra* note 168.

follow up and complete treatment.[189] This could be true with regard to a complicated and life threatening disease as well as a preventable and treatable one.

Malnutrition itself could also lead to poor health by weakening the immune system and affecting the physical development of the malnourished person. When the expectant mother is malnourished, the baby's development may also be affected during prenatal stages.[190] L ikewise, poor health could give rise to malnutrition, because some of the effects of being sick include low appetite and inadequate metabolism of nutrients absorption. Moreover, poor health causes psychological and emotional distress, which contributes to insufficient malnutrition. Since malnutrition affects cognitive skills and brain development, it also leads to poor school performance.[191]

Finally, poor health could also lead to a low income by preventing patients from showing up to work on regular basis and from fulfilling their job responsibilities, making it hard thus to maintain a good job. Circularly, this low income then exacerbates the individual's level of poverty, which demonstrates how suffering from one deficiency tends to lead to other deficiencies.[192]

---

[189] Leon & Walt, *supra* note 157 at 3 & 10; Christopher Murray, Julio Frenk & Emmanuela E Gakidou, "Measuring Health Inequality: Challenges and New Directions" in David Leon & Gill Walt, eds., *Poverty, Inequality and Health. An International Perspective* (New York: Oxford University Press, 2001) 194 at 201 & 213–215.

[190] Eric Jensen, *Teaching with Poverty in Mind* (United States of America: ASCD, 2009) at 38–43; Olaf Müller & Michael Krawinkel, "Malnutrition and health in developing countries" (2005) 173:3 CMAJ Can Med Assoc J 279; Secretaria de Salud, *supra* note 133 at 35.

[191] Lanata, *supra* note 177; Kimberly G Noble et al, "Family income, parental education and brain structure in children and adolescents" (2015) 18:5 Nat Neurosci 773.

[192] "Health Poverty Action", online: *Health Poverty Action* <https://www.healthpovertyaction.org/>.

The effect that this harmful cycle has on people's health, quality of life, and life expectancy is particularly alarming. In Mexico, treatable infectious diseases are the cause of 13% of deaths in areas of low or no marginalization and of 21% of deaths in areas of high and very high marginalization.[193] For instance, tuberculosis is still a disease associated with poverty and social inequality.[194] Likewise, despite an important decrease in their mortality rate, diarrhea and acute respiratory diseases (e.g. pulmonary tuberculosis and asthma) are still a considerable cause of death in infants under 5 years old.[195] The rural (20% of the total population),[196] marginalized, and Indigenous populations (7% of the total population) are the main sector of the population suffering from the above-mentioned conditions.

The situation I just described illustrates that not only do the Indigenous Peoples in Mexico suffer from frequent cultural, social, and racial discrimination from society, but that they are also victims of systemic and structural forms of discrimination from the government. These forms of discrimination greatly limit them in the exercise of their rights and their access to opportunities to grow and achieve their own well-being that are in theory, available to everyone.[197]

[193] Secretaria de Salud, *supra* note 133 at 35.
[194] CONEVAL, *supra* note 132 at 150.
[195] *Ibid* at 109; Secretaria de Salud, *supra* note 133 at 35 & 37.
[196] World Bank, "Rural population (% of total population) | Data", online: *World Bank Data* <http://data.worldbank.org/indicator/SP.RUR.TOTL.ZS>.
[197] CONAPRED, *supra* note 186.

2.4 Final Remarks

Close to half of Mexico's population live under the poverty line. Indigenous Peoples (7% of the total population) and rural communities (20% of the total population) are particularly affected, as 75% of the Indigenous Peoples and 65% of the rural population live in these conditions.

People living under the poverty line are likely to suffer from poor health: malnutrition, unsanitary conditions, and very limited and deficient access to healthcare. However, it is important to keep in mind that these conditions affect not only the people directly suffering from poor health, but their children as well, given that the standard of care they will provide depends on the parents' health and resources. Therefore, poverty affects not only the lifestyles of those generations suffering directly, but the lifestyles of future generations as well, given that those new generations will lack the resources and tools to break the cycle.

The poverty in which a great part of Mexico's population lives and the country's deficient public healthcare system have an indisputable effect on access to healthcare and health. However, there are other factors (i.e. conversion factors) that contribute to this situation. Access to the necessary medical products and services (including innovative medical genetics products) is one of these factors. Access requires both that the medical product or service is available (i.e. that the product exists) and that the patients in need can in fact have access to them (i.e. that they or the public healthcare system can afford them). Therefore, the pace of innovation in the medical field (including medical genetics) and the

prices of medical products and services can greatly affect access. The patent system is considered to be one of the main mechanisms for promoting innovation. It is also an important contributing factor in the price of products, which if it is too high, it can aggravate even more the current negative conversion factors that vulnerable populations suffer from, and therefore lessen their ability to have a good quality of life.

In the following chapter, I present the circumstances surrounding the innovation activity in Mexico in the biotechnology and pharmaceutical industries. I describe the current regulation and policies of the patent system in Mexico focusing on medical genetics. I will use this information in determining, in the last chapters, whether the patent system positively impacts innovation in biomedicine in Mexico and whether this impact creates the utility/welfare in the utilitarian/capability approach terms (i.e. proper access to healthcare) that would justify its regulation and implementation.

Chapter 3 Research and development in medical genetics in Mexico

3.1 Basic Concepts of Medical Genetics[198]

Medical genetics is defined as the branch or specialty of medicine that studies the causes, diagnosis, history, development, management, and treatment of hereditary diseases and/or disorders associated with the patient's genes. Genetic diseases are caused by problems in the genome resulting from or influenced by a mutation or from an inherited condition. There are also diseases (for instance infectious diseases) in which susceptibility or resistance is influenced by genetic factors. The understanding of the foregoing allows healthcare providers to not only diagnose a disorder or a disease, but also to determine how best to manage it. As such, progress in this field can lead to the development of more accurate diagnostic tests that allows clinicians to identify a disease, possibly even prior to the onset of its symptoms. These tests could also help to determine a predisposition to certain diseases such as cancer or osteoporosis and suggest preventive measures. Drugs and therapies can also be specially tailored to the genetic make-up of each patient and enable them to treat the problem, if this is genetic, instead of merely treating the symptoms. There is also the possibility of developing gene therapies that are able to switch off or replace faulty genes.[199] Areas associated with medical genetics include biochemical genetics, clinical genetics, cytogenetics, molecular genetics, immunology, diagnostics, gene therapy, and personalized/predictive medicine.[200]

---

[198] For purposes of this dissertation, any mention to the area of "medical genetics" as an innovative industry shall be interpreted as referring to the biotechnological and pharmaceutical industries, unless otherwise specifically provided.

[199] Julie Clague, *supra* note 3 at 180.

[200] Thomas D Gelehrter, Francis S Collins & David Ginsburg, *Principles of Medical Genetics* (United States of America: Williams & Wilkins, 1998) at 2; Charles J Epstein, "Medical Genetics in the Genomic Medicine of the 21st Century" (2006) 79:3 Am J Hum Genet at 434; World Health Organization, *Genomics and World Health. Report of the Advisory Committee on Health Research* (World Health Organization, 2002).

In general terms, the main objective of activities of research and development (R&D) is to create new knowledge and technological and scientific innovation.[201] Innovation can be considered an economic and social phenomenon comprised of discrete units with the potential of having an economic and social impact.[202] It can also be regarded as a process that combines scientific and technological knowledge with managerial, financial, and commercial skills with the purpose of creating and disseminating new or significantly improved products, processes or services that would solve a problem or meet a need.[203] It can occur in different areas and stages, such as basic research, applied research and/or experimental development.[204]

In medical genetics specifically, R&D activities can lead to the creation of knowledge and innovation related to human genetics,[205] genomics,[206] molecular

[201] Vittorio Chiesa, "Strategies for Global R&D" (1996) 39:5 Res-Technol Manag 19.

[202] JA Schumpeter, *The Theory of Economic Development* (New York: Oxford University Press, 1961); J Adam Holbrook, "Are Intellectual Property Rights Quonta of Innovation?" in David Castle, ed., *The Role of Intellectual Property Rights in Biotechnology Innovation* (United Kingdom: Edward Elgar, 2009) 24 at 25.

[203] Jose Luis Solleiro Rebolledo & Alejandra Herrera Mendoza, "Conceptos Basicos" in Jose Luis Solleiro Rebolledo & Rosario Castanon, eds., *Gestion Tecnologica: Conceptos y Practicas* (Mexico: Plaza y Valdes, S.A. de C.V., 2008) at 16–17; Holbrook, *supra* note 218 at 25.

[204] Innovation in basic research generates theoretical or experimental knowledge that is the "foundation of phenomena and observable facts, without any particular application or use in view. Innovation in applied research brings about knowledge that has "specific practical aim or objective." Innovation in experimental development creates knowledge that could lead to the production of new materials, products or devices or to the improvement of the existing ones. OECD, *Frascati Manual: Proposed Standard Practice for Surveys on Research and Experimental Development* (OCDE, 2002) at 30.

[205] Human genetics focuses on the study of genetic inheritance as it occurs in human beings as a species. *Medical Free Dictionary,* online *s.v.* "human genetics".

[206] Genomics is defined as the study of genes and their functions. World Health Organization, "WHO definitions of genetics and genomics", online: *WHO* <http://www.who.int/genomics/geneticsVSgenomics/en/>.

genetics,[207] genetic diseases and disorders, pharmacogenetics,[208] etc. Some R&D activities can lead to sequencing a gene and mapping a complete genome, which can help to determine whether a disease is linked to a hereditary trait or genetic landmark by studying and comparing several families afflicted by the disease and pinpointing the location of a disease-causing gene.[209] Potential neighboring markers that tend to be inherited along with the disease can also be identified.[210] This knowledge enables a deeper understanding of genetic diseases, medical conditions that are influenced by genetic factors, and gene-specific drug response, which leads to the creation, manufacture, and distribution of genetic tests,[211] and gene therapy,[212] and personalized medicine (e.g. drugs and therapies).[213]

---

[207] Molecular genetics studies the structure, function, expression and regulation of genes at a molecular level. Ken Waters, "Molecular Genetics" in Edward N Zalta, ed., *Stanford Encyclopedia of Philosophy*, fall 2013 ed (online: Metaphysics Research Lab, Stanford University, 2013).

[208] Pharmacogenetics studies the response that a particular drug is likely to have in relation to specific genes. This opens the possibility to provide patients with a predicted drug metabolism phenotype profile resulting in personalized treatments that could prescribe the most adequate doses and prevent adverse drug reactions. Stuart A Scott, "Personalizing medicine with clinical pharmacogenetics" (2011) 13:12 Genet Med 987 at 990.

[209] Sequencing a gene shows the order of four letters of each of the bases. Mapping a genome helps to locate genes within the chromosomes, to learn the order in which they are located (genetic linkage map), and to determine the number of DNA base pairs between landmarks (physical map). Both types of mapping, genetic linkage and physical, help to find and identify new and known genes and would also allow sequencing a genome by providing information as to which specific pieces of DNA belong in the genome and where are they located. Edward Willet, *Genetics Demystified* (United States of America: McGraw Hill, 2006) at 61–63.

[210] *Ibid*.

[211] Genetic tests are defined as tools that "allow physicians and clinicians to detect in patients the existence or the likelihood of developing a chromosome or gene abnormality or mutation, and therefore of developing genetic diseases or disorders. Genetic tests can also help to detect the existence, effect, and function of biomarkers responsible for the processing of drugs or treatments, thereby contributing to the development of personalized medicine." Palmira Granados Moreno & Yann Joly, "Intellectual Property and Innovation in Translational Medicine" in Martin Wehling, ed., *Principles of Translational Science in Medicine 2nd ed.* (Boston: Academic Press, 2015) 281 at 289.

[212] Gene therapy is "an experimental technique that uses genes to treat or prevent diseases. In the future, this technique may allow doctors to treat a disorder by inserting a gene into a patient's cell instead of using drugs or surgery. [This would be possible by] replacing a mutated gene that causes the disease with a healthy copy of that gene, inactivating the mutated gene that is functioning improperly, and introducing a new gene into the body to help fight the disease." "What is Gene Therapy?" Genetics Home Reference online: <http://ghr.nlm.nih.gov/handbook/therapy/genetherapy> (accessed June 20, 2015).

[213] Personalized medicine is a medical model that "has the potential to assist clinicians in making diagnostic or therapeutic decisions specific to a particular individual's genetic profile by predicting whether a newly prescribed drug will likely be effective and/or safe in the treatment of a disease." Models of personalized medicine have three parts. The first consists in using a genetic test to detect whether the patient has the

Either as a phenomenon or as a process, innovation requires a particular environment in order to occur. This environment needs to allow and encourage the creation, flow, transfer, and dissemination of knowledge and of discrete units of innovation.[214] Legal, economic, and political frameworks and policies can be useful in the creation of this environment. For instance, legislation and governmental policies that grant and enforce intellectual property rights can be used to develop this environment. Institutional policies and programs that devote public funding to innovation, as well as the development and promotion of offices devoted to technology transfer are other ways to create the above-mentioned environment.[215] Tax policies (e.g. tax breaks and tax credits can also encourage a productive innovation environment.[216]

specific genes responsible for the production of the biomarkers (e.g. enzymes) that regulate the processing of drugs. The second is predicting the likely effect of a drug, dosage, therapy or treatment taking into account the results obtained from the test. The last element consists in making a decision to prescribe a specific drug, dosage or treatment based on the prediction made with the genetic test. Therefore, detecting any change or abnormality in the patient's genetic information plays an essential role in predicting the most effective treatment or course of action. Granados Moreno & Joly, *supra* note 211 at 290.

[214] Holbrook, *supra* note 202 at 24–25.

[215] E Richard Gold et al, *Toward a New Era of Intellectual Property: From Confrontation to Negotiation - A Report by the International Expert Group on Biotechnology, Innovation and Intellectual Property*, SSRN Scholarly Paper ID 1260099 (Rochester, NY: Social Science Research Network, 2008); David Castle, ed., *The Role of Intellectual Property Rights in Biotechnology Innovation* (United Kingdom: Edward Elgar Publishing, 2009).

[216] Svatos, *supra* note 20 at 131–132.

3.2 Elements of the Innovative Environment Surrounding Medical Genetics in Mexico

3.2.1 Legislation

Mexico has intellectual property legislation that, in alignment with the main international intellectual property treaties,[217] grants copyright, patents, plant breeders' (also known as plant variety) rights, trade secrets, and trademarks. The main forms of intellectual property used to promote innovation in the area of medical genetics are patents and trade secrets.[218] Given the focus of my dissertation on patents, I only address the former.

According to Mexican patent law (art. 23 of the Industrial Property Law, "LPI"), patents grant their holders a 20-year[219] set of exclusive rights to make, use, sell, and import the invention they protect. The recently reached Trans-Pacific Partnership and USMCA Free Trade Agreement provide an adjustment to this 20-year patent term of protection for unreasonable delays (i.e. more than 5 years) caused by the patent office during the patent granting process to compensate the patent holder for those delays. However, these agreements have not yet been translated into legislation, the terms of this adjustment are

[217] Some of these treaties are the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), the North America Free Trade Agreement (NAFTA), the Patent Cooperation Treaty (PCT), the Union for the Protection of New Varieties of Plants Convention (UPOV), the Paris Convention for the Protection of Industrial Property, the Berne Convention for the Protection of Literary and Artistic Works, and the WIPO Copyright Treaty. Mexico is also a participating country to the Trans-Pacific Partnership Agreement.

[218] Tania Bubela, Garret A FitzGerald & E Richard Gold, "Recalibrating Intellectual Property Rights to Enhance Translational Research Collaborations" (2012) 4:122 Sci Transl Med 1; Yann Joly, Angus Livingston & Edward S Dove, *Moving beyond commercialization: Strategies to maximize the economic and social impact of genomics research*, Policy Brief 5 (Canada: GPS-Genome Canada, 2012).

[219] This 20-year period starts on the date on which the patent application is filed. *Ley de la Propiedad Industrial*, Diario Oficial de la Federacion, 27 June 1991 (Amended on June 1, 2016) [*Ley de la Propiedad Industrial*] art. 23.

still unclear.[220] Inventions[221] can be patented provided that they are new,[222] they result from an inventive activity,[223] they have an industrial application,[224] and they fall within what constitutes patentable subject matter at the date on which the patent application is filed.[225] In accordance with the USMCA, even after being granted, patents could be cancelled, revoked or nullified if the invention does not fullfill these requirements.[226]

The rights granted by a patent are to make, use, sell, and import the patented invention. The scope of rights is delimited by the description of the invention and the claims included in the patent application. The description should include the best-known method to reproduce the invention and all the information relative to the invention's industrial application in a clear and thorough manner so as to allow a person skilled in the art to fully

[220] *USMCA Free Trade Agreement*, October 2018 [*USMCA Free Trade Agreement*] art. 20. F 9; Mauricio Jalife Daher, "TPP: amenaza para el mercado de genéricos", (2 April 2016), online: <https://elmundodelabogado.com/revista/posiciones/item/tpp-amenaza-para-el-mercado-de-genericos>.

[221] Invention is defined as any human creation (e.g. art, process, machine, manufacture, composition of matter) that transforms matter or energy that already exists in nature for the benefit of men so they can satisfy their needs. *Ley de la Propiedad Industrial*, *supra* note 219 art. 15.

[222] An invention is new if it has not been described, disclosed or predicted in the national or international prior art by the day on which the patent application is filed or within the twelve months prior to that filing date. Prior art in medical research includes written documents (e.g. scientific/technical articles, books, newspaper's or magazine's commentaries, and teaching materials), patent applications, oral presentations, conferences, and Internet posts available to the public. *Ibid* arts. 17 & 18; Granados Moreno & Joly, *supra* note 211 at 283.

[223] An invention results from an inventive activity and is non-obvious if the inventor required some creativity while producing the invention and an unimaginative person skilled in the art does not see the invention as the next obvious thing to happen in the technical or scientific field. In this context, a person skilled in the art refers to a fictional researcher, physician or clinician with ordinary scientific expertise and access to publicly available information associated with the invention. *Ley de la Propiedad Industrial*, *supra* note 219 art. 16; Granados Moreno & Joly, *supra* note 211 at 283.

[224] An invention is considered to have an industrial application Mexico if it has a practical utility or it can be produced or used for the purposes described in the patent application. For instance, a drug is patentable as a product and its active ingredient as a composition of matter provided that they treat or are predicted to be able to treat a specific disease in a new and non-obvious way. This association to a specific disease or disorder constitutes the industrial application. *Ley de la Propiedad Industrial*, *supra* note 219 art. 16; Granados Moreno & Joly, *supra* note 211 at 283.

[225] *Ley de la Propiedad Industrial*, *supra* note 219 arts. 16-18.

[226] *USMCA Free Trade Agreement*, *supra* note 220 art. 20. F 3.

understand the invention and to be able to reproduce it, if necessary or wanted.[227] This requirement is intended to promote innovation by increasing the state of the art available to anyone. Likewise, the claims should be clear and concise, so as to define the extent of the protection granted by the patent.[228]

The regular process to grant a patent takes approximately 3 years[229] and it costs USD$ 700, minimum.[230] These costs increase, however, throughout the 20 years of protection, as there are maintenance fees, the possibility of needing to obtain patents in other countries, as well as the costs required to enforce the patents in litigation. For instance, the costs to obtain and maintain a simple patent in the US is around $10,000 and to litigate a contested patent in the US fluctuates between 3 and 6 million at least per side, most of which is incurred during discovery.[231] This shows the actual burden that obtaining a patent may create and explains the reason why certain inventors may decide not to pursue one.

---

[227] In patent applications where gene sequences are involved, it is necessary to include a list of the relevant nucleotide or amino acid sequences. Moreover, in case the invention refers or includes biological material that cannot be described, a deposit of such biological material in an institution appointed by the IMPI is required. *Reglamento a la Ley de la Propiedad Industrial*, Diario Oficial de la Federacion, 23 November 1994 (Amended on December 16, 2016) [*Reglamento a la Ley de la Propiedad Industrial*] art. 46.

[228] *Ley de la Propiedad Industrial*, *supra* note 219 arts. 45 & 47.

[229] For a more detailed description of the process to file a patent see: *Ibid* arts. 38-61.

[230] IMPI, "Servicios que ofrece el Tarifas: Invenciones, Modelos de Utilidad, Diseños Industriales y Esquemas de trazado de Circuitos Integrados", online: *Instituto Mexicano de la Propiedad Industrial* <http://www.gob.mx/impi/acciones-y-programas/servicios-que-ofrece-el-impi-tarifas-invenciones-modelos-de-utilidad-disenos-industriales-y-esquemas-de-trazado-de-circuitos-integrados>.

[231] Yann Joly, "Open Source Approaches in Biotechnology: Utopia Revisited" (2006) 59:2 Maine Law Rev 386 at 391; Jim Kerstetter, "How much is that patent lawsuit going to cost you?", (5 April 2012), online: *CNET* <https://www.cnet.com/news/how-much-is-that-patent-lawsuit-going-to-cost-you/>; WIPO, *IP Litigation Costs* (World Intellectual Property Organization, 2010) at 3.

There are four types of patents associated with medical genetics. The first type includes patents on products. Examples of patentable products include drugs and diagnostic tests. The second type refers to patents on processes or methods. Methods that identify genetic alterations or abnormalities or methods to extract or manipulate genes are two examples of patentable methods. The third type of patents covers compositions of matter. Inventions that are patentable as compositions of matter are those that combine different types of genetic material or those that include genes identified as determinant in the development of diseases or in the regulation of bodily functions. The final type of patents protects improvements on any of the above-mentioned inventions.[232]

In Mexican patent law (arts. 16 and 19 LPI), there are four categories of innovations relevant to medical genetics that are excluded from patent protection for being considered outside the patentable subject matter. The four categories are: 1) "essentially biological processes for the production, reproduction, and propagation of plants and animals,"[233] 2) "higher life forms,"[234] 3) "biological and genetic material as found in nature and discoveries that merely reveal something that exists in nature, regardless of whether they are known," and 4) "diagnostic, surgical and therapeutic methods used in human beings or

[232] Robert Cook-Deegan, "Gene Patents" in Mary Crowley, ed., *From Birth to Death and Bench to Clinic: The Hastings Center Bioethics Briefing Book for Journalists, Policymakers, and Campaign* (Garrison, New York: The Hastings Center, 2008) 69; Vaver, *supra* note 39; David B Resnik, *Owning the Genome: A Moral Analysis of DNA Patenting* (United States of America: State University of New York Press, 2004); Granados Moreno & Joly, *supra* note 211.

[233] Plants Breeders' Rights (another form of intellectual property) usually protect this type of processes. This exclusion prevents multiple intellectual property rights on the same advance or invention.

[234] This exception however, does not exist in all jurisdictions. Whereas Canada considers higher (multicellular) forms live organisms, such as the oncomouse (a genetically modified mouse created in Harvard University to carry an activated gene that significantly increases the mouse's susceptibility to cancer used in cancer research) unpatentable, in the United States, non-naturally ocurring, non-human multicellular living organisms, including animals such as the oncomouse, are patentable.

animals."[235] Innovations involving isolated genes, gene sequences, and biomarkers have been said to fall within the biological and genetic material as found in nature in some jurisdictions, such as the US.[236] The higher life forms and the biological and genetic material as found in nature exclusions are explained by the lack of human inventiveness or ingenuity in materials and discoveries that already exist in nature. The reason for this unpatentability is that merely identifying, locating, and correlating gene sequences and biomarkers to a disease, disorder or reaction is not considered a discovery, regardless of the complexity and hard work involved in identifying, locating, and finding that correlation.[237]

The diagnostic methods excluded from patentability are only those practiced on the human body. Diagnostic tests performed on body tissues or fluids after they have been removed from the human body, provided that those tissues or fluids are not returned to the human body, are still patentable. The purpose of this exception is to prevent having patent rights interfering with saving a human or animal life. Methods involving the excision of tissue, organ or tumour samples from the body are considered forms of surgery, and therefore unpatentable. This exception does not, however, extend to purely cosmetic treatments or to drugs and products for treating human or animal illnesses.[238] These

[235] For purposes of this exception, a therapeutic or medical method cures, prevents, or ameliorates an ailment or pathological condition or treats a physical abnormality or deformity.
[236] *Association for Molecular Pathology v Myriad*, 569 U.S. 576 (2013).
[237] Koichi Sumikura, "Intellectual property rights policy for gene-related inventions - toward optimum balance between public and private ownership" in David Castle, ed., The *Role of Intellectual Property Rights in Biotechnology Innovation* (United Kingdom: Edward Elgar, 2009) 73; Subhashini Chandrasekharan & Robert Cook-Deegan, "Gene patents and personalized medicine - what lies ahead?" (2009) 1 Genome Med 92; Granados Moreno & Joly, *supra* note 211.
[238] *Ley de la Propiedad Industrial*, *supra* note 219 arts. 17 & 18; Granados Moreno & Joly, *supra* note 211 at 283.

categories and the reasons that support their exclusion will be useful in my last chapter when I discuss the expected purpose of the patent system and its actual impact in Mexico and on access to healthcare.

Patent rights may be assigned[239] or licensed[240] to third parties. The transfer or license of patents allows patent holders to profit from and commercially exploit their patented inventions. These assignments and licenses allow parties other than the original inventor (i.e. inventors, researchers or manufacturers who are not the patent owners) to use the patented invention.

Under Mexican patent law, users are allowed to use patented inventions without needing to obtain the patent holder's authorization in certain situations (art. 22 LPI). These situations are known as users' rights. There are three users' rights relevant to medical genetics. The first allows users (e.g. researchers) to use a patented invention for experiments, research, and teaching in a non-commercial private or academic setting.[241] The second allows generic manufacturers to use the patented invention before the patent of the original drug expires in their application to obtain the regulatory approval for their

[239] Assignments transfer ownership on the patented invention (and all the rights granted by the patent) to a third party. They may be partial or total and must be in writing and registered before the IMPI. *Ley de la Propiedad Industrial*, *supra* note 219 art. 62.

[240] Licenses grant a third party consent or permission to use, make, sell or import the patented invention. They may be sole, exclusive or non-exclusive. Exclusive licenses need to be in writing, whereas others may be oral. Licenses may be gratuitous or for a royalty. They must be registered before the IMPI. *Ibid* art. 63.

[241] *Ibid* art. 22.

generic drug.[242] The third users' right allows developed countries to export and less developed countries to import patented drugs.[243]

In addition to the users' rights, the patent system also provides three cases when a compulsory license might be granted (art. 77 LPI). The three cases are: 1) when patent holders have not exploited their inventions in or outside the country for 3 years after they have been granted or for 4 years after they have been applied for without any reasonable justification, 2) when patent holders are considered to be abusing their patents,[244] or 3) when the government needs to address a national emergency or extreme urgency (e.g. public health crisis).[245]

[242] The purpose of this user's right or exception is to avoid extending the monopoly that a patent grants beyond the stated term of 20 years. With this user's right, the generic manufacturer can start marketing the generic version of the patented drug right after the patent expires. Anthony Tridico, Jeffrey Jacobstein & Leythem Wall, "Facilitating generic drug manufacturing: Bolar exemptions worldwide", *WIPO Mag* (2014), online: <http://www.wipo.int/wipo_magazine/en/2014/03/article_0004.html>.

[243] *Doha 4th Ministerial - Ministerial declaration*, WTO, 14 November 2001 [*Doha 4th Ministerial - Ministerial declaration*]; *Doha: Declaration on the TRIPs Agreement and Public Health*, WTO, 14 November 2001 [*Doha: Declaration on the TRIPs Agreement and Public Health*]; WHO, "The Doha Declaration on the TRIPs Agreement and Public Health", online: <http://www.who.int/medicines/areas/policy/doha_declaration/en/>; "WTO | intellectual property (TRIPS) - TRIPS and public health: Compulsory licensing of pharmaceuticals and TRIPS", online: <https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm>; *Agreement on Trade-Related Aspects of Intellectual Property*, WTO, 1 January 1995 [*Agreement on Trade-Related Aspects of Intellectual Property*].

[244] Patent holders are considered to abuse their patents in the following cases: if they do not meet the local demand for a patented product, if they refuse to grant a license without providing a reasonable explanation or if the terms of the license they offer are abusive. In these cases, the government could grant a non-exclusive compulsory license to use the patented invention without the need to obtain the patent holder's authorization. This compulsory license would have the scope and duration necessary to serve the purpose for which it was authorized (e.g. health national emergency). The patent holder would receive a reasonable fee set by the government. Vaver, *supra* note 39; Lori B Andrews, "Genes and patent policy: rethinking intellectual property rights" (2002) 3:10 Nat Rev Genet 803; *Agreement on Trade-Related Aspects of Intellectual Property*, *supra* note 243.

[245] Granados Moreno & Joly, *supra* note 211; *Ley de la Propiedad Industrial*, *supra* note 219 arts. 70-77.

The purpose of users' rights and of the compulsory licenses scheme in general is to balance the interests of patent holders and users, to limit the extent of control granted to the patent holders, and to promote innovation. In the area of medicine, users' rights are also intended to promote and facilitate access to healthcare.

In the area of medical genetics, genes (gene sequences)[246], cDNA,[247] and biomarkers[248] (e.g. genes, proteins, metabolites, enzymes, etc.) can be used in the development of genetic tests, new and repositioned drugs, gene therapy, and personalized medicine.[249] As such, they can be patented as an essential part in a process or as

[246] A gene is a segment of DNA or RNA that contains genetic information. The genetic information contained in the gene includes the specific order in which the nucleotides contained in the DNA create amino acids, which are used in the body to build proteins. A mutation is a change in the sequence of a person's nucleotides. A mutation of this kind can be as small as an alteration of a single nucleotide. This small mutation can result in the production of an entirely different amino acid and thereby alter the production of proteins. Another mutation can consist in the deletion, rearrangement or duplication of nucleotides, genes, and proteins. Whereas some mutations are harmless, others can significantly increase the risks of developing life-threatening diseases. Genetic tests can detect this type of mutations and gene therapy and personalized medicine can be prescribed to treat or repair them. *Association for Molecular Pathology v. Myriad*, *supra* note 236; Granados Moreno & Joly, *supra* note 211.

[247] Complementary DNA (cDNA) is DNA that complements or matches mRNA. cDNA is synthesized by copying a mRNA chain using the enzyme reverse transcriptase. cDNA contains only the exons because mRNA does not have introns. cDNA is used to express a particular protein in a cell that does not normally express such a protein. John Bradley, David Johnson & Barbara Poher, *Medical Genetics* (United States of America: Blackwell Publishing Ltd, 2006); *Association for Molecular Pathology v. Myriad*, *supra* note 252; *(n.d.)*.

[248] A biomarker is a "characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention." There are four types of biomarkers. A prognostic biomarker provides information on the likely course of a disease in untreated individuals. A predictive biomarker determines the patients who are most likely to respond to a given therapy. A diagnostic biomarker indicates the existence of a disease. A drug-related biomarker helps to predict the efficacy of a drug in a particular patient or the way in which patient's body will likely process the drug. Genes, proteins, metabolites, and enzymes are some examples of the most common biomarkers. Kyle Strimbu & Jorge A Tavel, "What are Biomarkers?" (2010) 5:6 Curr Opin HIV AIDS 463; Martin Wehling, "Translational medicine: science or wishful thinking?" (2008) 6 J Transl Med 31; Garret A Fitzgerald, "Opinion: anticipating change in drug development: the emerging era of translational medicine and therapeutics" (2005) 4:10 Nat Rev Drug Discov 815; A S Kesselheim & N Shiu, "The evolving role of biomarker patents in personalized medicine" (2014) 95:2 Clin Pharmacol Ther 127; Granados Moreno & Joly, *supra* note 211; Martin Wehling, "Introduction and Definitions" in Martin Wehling, ed., *Principles of Translational Science in Medicine. From Bench to Bedside*, 1st ed (United States of America: Cambridge University Press, 2010).

[249] Personalized medicine takes into account the patient's genetic profile in order to inform and influence the medical decisions associated with the prevention, diagnosis, and treatment of a disease. AWS,

compositions of matter with the purpose of being used in a specific genetic test, drug, or therapy.

Patentability of inventions involving genes, gene sequences, and biomarkers varies depending on the jurisdiction and on whether the gene, gene sequence or biomarker is used as it is found in nature or whether it is used in its isolated form. In almost every jurisdiction, including Mexico, genes, gene sequences, and biomarkers as existing within the human body are not patentable.[250] Patentability of those same genes, once removed and isolated, can, however, be patented in most jurisdictions, with the notable exceptions of the US and Australia. This patentability is explained by the process of isolation of the gene.[251] cDNA is considered patentable because (other than in Australia) it is deemed synthetic DNA created in the laboratory as a result of human ingenuity. Its main difference from the DNA existing in nature is that whereas the natural human DNA has exons and introns, the cDNA includes only the exons and excludes the introns.[252]

Personalized Medicine and Genomic Research (AWS); "Personalized Medicine", (7 October 2015), online: *National Institutes of Health* <https://www.nih.gov/about-nih/what-we-do/nih-turning-discovery-into-health/personalized-medicine>; "Personalized Medicine: How the Human Genome Era Will Usher in a Health Care Revolution", (17 March 2012), online: *National Human Genome Research Institute* <https://www.genome.gov/13514107/Personalized-Medicine-How-the-Human-Genome-Era-Will-Usher-in-a-Health-Care-Revolution>.

[250] Sumikura, *supra* note 237; Chandrasekharan & Cook-Deegan, *supra* note 237; Granados Moreno & Joly, *supra* note 211.

[251] During the process of isolation, the natural bonds of that segment break from the rest of the genome in the human body. As a result, the chemical qualities, characteristics, and structure of an isolated gene or gene sequence are different from those of a gene in the human body. This difference is deemed sufficient to make isolated genes different from how they are found in nature. Consequently, this isolated gene is considered to have been "created" by a human-invented process of isolation and is therefore patentable, provided that they meet the other requirements (e.g. new, non-obvious, and utility or industrial application). The US denies patentability to isolated genes and gene sequences. According to the US Supreme Court, isolated gene sequences should be considered discoveries because they maintain the same molecules as the genes found in the human body, and the differences found at the ends of the segments of the isolated genes are merely ancillary to the isolation. Granados Moreno & Joly, *supra* note 211; *Association for Molecular Pathology v. Myriad*, *supra* note 236.

[252] *Association for Molecular Pathology v. Myriad*, *supra* note 236; European Patent Office, *Guidelines for Examination in the European Patent Office* (European Patent Office, 2016).

Genetic tests can be patented as processes or as products. A genetic test can be patented as a process if it describes a new and non-obvious method for detecting a genetic abnormality or mutation associated with a genetic disease or disorder or if it detects a biomarker to determine the reaction to a drug or treatment. In this case, for the genetic test to be patented in Mexico as a method or a process, the diagnosis needs to be performed outside of the body (e.g. gene tests performed in vitro). A genetic test can be patentable as a product if it is embodied as a kit. The instruments or equipment used in these tests can also be patentable as products.[253]

Personalized therapies are patentable as processes or as products. A patent could be granted to protect the process that integrates the genetic screening detecting a specific gene or biomarker, determines the likelihood of developing a reaction, and prescribes a specific treatment. A patent could also be granted to protect the kit that allows for this analysis.[254]

In Mexico, as in most other jurisdictions, the extent and terms of the patent protection granted aims to provide economic incentives to national inventors and investors to advance the national science and technology. This is done by allowing them to recoup their investment and to make a living off their work through the exercise of the 20-year exclusive rights to profit from their inventions. The protection granted is also intended to

[253] Granados Moreno & Joly, *supra* note 211; *Ley de la Propiedad Industrial*, *supra* note 219; European Patent Office, *supra* note 252.
[254] Kesselheim & Shiu, *supra* note 248; Granados Moreno & Joly, *supra* note 211.

attract inventors and investors from technologically and scientifically advanced countries to invest and settle innovation hubs and subsidiaries in Mexico and thereby advance national science and technology. This is done by providing them with a protection that is similar to the one that they would find in their home countries. Regardless of whether the innovation results from foreign or national inventors/investors, the patent system is expected to benefit the country's population by making pioneering products and services available, advancing the state of the art, and growing the country's economy by creating qualified jobs and facilitating the trade of those innovative products and services as well as of the knowledge involved.[255]

3.2.2 Policies regarding patents and innovation

In Mexico, patents and intellectual property in general are considered a key element in the country's scientific and technological development and innovation, which is seen as an important source of sustainable socio-economic progress and social benefits.[256] This perspective is adopted in the legislation, by governmental agencies, and in a number of policies within the regulatory framework. For instance, the objective of the Mexican Industrial Property Law is to promote inventive activities and technical improvements that have an industrial application within the country's productive sectors.[257] The Mexican Institute of Industrial Property (IMPI) aims to ensure the legal protection necessary to allow inventors and investors to profit from their creative and inventive activity, and thereby

[255] Granados Moreno & Joly, *supra* note 211.
[256] Presidencia de la Republica, *supra* note 131 at 128.
[257] *Ley de la Propiedad Industrial*, *supra* note 219 art. 2.

promote private investment, job creation, national economic development, and competitiveness throughout the country.[258]

This perspective is also found in policies and strategies contained in every National Plan of Development (governmental strategic plan for each presidential period). The 2012-2018 plan[259], for example, states that, bearing in mind that the basis of the country's socio-economic sustainable progress is scientific and technological development, the government will contribute to increase the current investment on scientific research and technological development and promote the private sector's further involvement. It also promises to contribute to a better formation and financial support of scientists and researchers through increased funding for graduate studies (mainly through the CONACYT) and for the SNI program. This Plan also mentions that the government will encourage a stronger collaboration among public and private research centers and universities, resulting in knowledge and technology transfer not only through collaboration agreements, but also through the use of intellectual property.[260] Furthermore, the National Program of Health expressly promotes a partnership between medicine researchers and practicing doctors on technological and scientific innovation.[261]

[258] IMPI, "Conoce el IMPI | ¿Qué es el IMPI?", online: *Instituto Mexicano de la Propiedad Industrial* <http://www.gob.mx/impi/acciones-y-programas/conoce-el-impi-que-es-el-impi>.

[259] The latest plan (2019-2024) considers the advancement of science and technology important to the country's development and society's welfare. It mentions the federal government's commitment to grant scholarships and funds to students and academics through the programs implemented by the CONACYT. However, it does not give any further details as to the exact policies or programs to achieve this. For this reason, I do not mention this plan in the main text. Presidencia de la Republica, *Plan Nacional de Desarrollo 2019-2024* (2019).

[260] Presidencia de la Republica, *supra* note 131 at 128–129.

[261] Secretaria de Salud, *supra* note 133 at 125–127.

The CONACYT and the SNI are the two main programs/agencies that the government has to implement the policies related to the funds assigned to innovation and patents mentioned above. The SNI awards the different levels of "national researcher" based on the researcher's contributions. Patents are a specifically listed example of one of these contributions. The CONACYT designs and proposes national public policies regarding science and technology. It supports, funds, and encourages the development of basic and applied scientific research and oversees the training of researchers in all the fields of science and technology. Having patents on their names as inventors or patent holders increases a researcher's/student's chances of obtaining funds and scholarships from CONACYT. This agency also provides legal counsel, templates of successful commercialization and licensing schemes to transfer technology, and financial support for the start-up of technology transfer offices.[262]

3.3 Existing Innovation on Medical Genetics in Mexico and the Role of the Patent System

Public research centres play an essential role in research activities in the area of medical genetics and health in Mexico. There are close to 1200 full-time health-related researchers affiliated to public research institutes. Most of them (70%) belong to the SNI program.[263] The researchers of these centres produce a high number of annual publications. The research centres are affiliated with the National Institutes of Health (INSalud), the

[262] CONACYT-Red OTT, "Red OTT - Nosotros", (3 July 2013), online: *CONACYT-Red OTT* <http://www.redott.com.mx/swb/ROTT/Nosotros>.
[263] Secretaria de Salud, *supra* note 133 at 60.

Ministry of Health (SSA) or the IMSS.[264] The CONACYT and the SSA are the two main bodies that administer and fund them.[265] Examples of these centres are the National Institute of Cardiology, the Pediatrics Institute, the National Institute of Neurology and Neurosurgery, the National Institute of Respiratory Diseases, the National Institute of Oncology, the INCMNSZ, the INMEGEN, the Hospital Gea Gonzalez, and the Biomedical Research Centre, among others.[266] Public universities and institutions of higher education, such as the National University Autonomous of Mexico (UNAM), the Institute of Biomedical Research, the Centre for Research and Advanced Studies (CINVESTAV), the National Polytechnic Institute (IPN), the National School of Anthropology (ENAH), and several state universities produce important research in medical genetics as well.[267] Since further and complementary funding is still needed, partnerships between research centres and the industry are encouraged.[268]

Two research centres stand out for the national relevance that two of their projects have in medical genetics. One of these research centres is the National Institute of Genomic Medicine (INMEGEN). The INMEGEN was created in 2000 with the objective of creating solutions to Mexico's particular health challenges. In order to achieve this, it focuses its research on the link between genomic variations in the Mexican population, disease susceptibility, and the different ways in which patients respond to drugs.[269] Its main project

---

[264] *Ibid*.
[265] Daniel Malkin et al, *OECD Reviews of Innovation Policy: Mexico* (France: OCDE, 2009) at 132.
[266] *Ibid*.
[267] Autonomous University of Nuevo Leon, Autonomous University of San Luis Potosi, Metropolitan Autonomous University, and University of Guadalajara are some of these state universities. Francisco G Bolivar Zapata et al., *Recomendaciones para el Desarrollo y Consolidacion de la Biotecnologia en Mexico* (Mexico: CONACYT - Academia Mexicana de Ciencias, 2003) at 45–55.
[268] Secretaria de Salud, *supra* note 133 at 127–128; Presidencia de la Republica, *supra* note 131 at 44.
[269] Séguin et al, *supra* note 115 at 5.

so far has been the Mexican Genome Diversity Project (MGDP). The MGDP aims to determine the most common genetic variations in the mestizo population and to compare the variations in the different regions. In this comparison, the MGDP focuses on the variations that have a medical application.[270] The other centre is the National Autonomous University of Mexico (UNAM). The UNAM is responsible for Indigenous Library (Genoteca Indigena).[271] The aim of the Genoteca is to allow researchers to evaluate the several genetic components associated with the susceptibility or resistance to certain diseases common among the Mexican population, including Indigenous and mestizo populations. With this information, the project is intended to develop preventive measures and medical treatments personalized to Mexico's population.[272] The utility/welfare created

---

[270] The project collected blood samples from 300 non-related self identified as Mestizo donators from the states of Sonora, Zacatecas, Guanajuato, Veracruz, Yucatan, and Guerrero (all located in different regions from the north, centre, and south of Mexico) and 30 members of the Zapoteca community in Oaxaca. Later on, blood samples have been collected from Campeche, Tamaulipas, and Durango as well. Irma Silva-Zolezzi et al, a) "Analysis of Genomic Diversity in Mexican Mestizo Populations to Develop Genomic Medicine in Mexico" (2009) 106:21 PNAS 8611; Irma Silva-Zolezzi et al, b) *Mapa del Genoma de Poblaciones Mexicanas*, 2d ed. (Mexico: Instituto Nacional de Medicina Genomica, 2010); INMEGEN, "Estados Participantes at Mapa del Genoma de Poblaciones Mexicanas", online: *INMEGEN* <http://genomamexicanos.inmegen.gob.mx/jornadasestados.htm>.

[271] The Library, maintained in the Department of Biology of the Faculty of Chemistry of the UNAM, and directed by Dr. Marta Menjivar, researcher and professor of the Department of Biology of the Faculty of Chemistry of the UNAM, currently includes the DNA of 13 Indigenous peoples on which their ancestry has been evaluated and polymorphisms associated with diabetes and obesity have been tried to determine. Some of the Indigenous peoples whose samples have been collected are Mazahuas, Tenek, Chontales, Coras, and Mayas. Specifically from the Mayan area, over 1,000 individuals have participated. This number has increased to 2,000 in other areas. In return, analysis of their glucose, cholesterol, and triglycerides levels, their blood type, their blood pressure, their anthropomorphic measurements, and their diagnostic and referral in case they are found to be sick. For the coming year, the project plans to work in the Huichol, Tepehuano, and Mexicanero communities. Facultad de Química - UNAM, "Recibe la FQ donativo de Fundación Coca Cola para conformar la Genoteca Indígena", (2 September 2012), online: *Facultad de Química - UNAM* <https://quimica.unam.mx/recibe-la-fq-donativo-de-fundacion-coca-cola-para-conformar-la-genoteca-indigena/>; "Genoteca indígena recopila ADN de mexicanos", *El Universal* (31 December 2013), online: El Universal <http://archivo.eluniversal.com.mx/ciencia/2013/genoteca-indigena-adn-mexicanos-82420.html>.

[272] A third project that results interesting in the area of medical genetics is the Candela Project, an international consortium created, in 2010, to analyze the diversity and evolution of the population in Mexico and of other countries of Latin America (e.g. Colombia, Peru, Chile, and Brazil). The project is funded and supported by the Leverhulme Trust, the Biotechnology and Biological Science Research Council (UK), the University College London, the UNAM, the INCMNSZ, the ENAH, and the CONACYT. It focuses on the variety of the physical, social background, self-perception, and genetic characteristics of the population of Latin America. Its first stage has consisted of the collection of blood

by these public research centres is promising in terms of health-related products and services they may lead to, but since the research done is yet to be translated into tangible clinical products, this utility/welfare is still undetermined.

In addition to the public research centres, there are private companies that devote their activities of R&D to the areas of pharmaceuticals and biotechnology and human health. Out of the close to 200 pharmaceutical companies in Mexico in 2011, 46 were multinationals. These foreign companies had 68% of the total market. Out of the top ten companies of pharmaceutical R&D in Mexico, nine are foreign multinational and one (Laboratorio Senosiain)[273] is Mexican.[274] In fact, 14 out of the 15 main pharmaceutical companies in the world have set up laboratories in Mexico and most of the production of pharmaceuticals in the country is done for those foreign multinationals (e.g. Merck, Boehringer Ingelheim, Schering Plough, Bayer, Astrazeneca, Pfizer, Glaxosmithkline, Baxter, Eli Lilly, and Novartis). As a result, these multinationals generate very prominent employment and product markets.[275] This obviously brings about the economic utility that economists uphold and even some knowledge transfer from these foreign companies to their Mexican employees.

---

samples, physical characteristics (shape of the skull and body measurements and proportions, shape of the face, eye colour, skin tone, and colour and type of hair), metabolic data (glucose, triglycerides, uric acid, creatinine, and cholesterol) and social background from human subjects from Latin America. The information collected will be used to determine the percentage of Indigenous, European, and African ancestry of selected populations, explore the complex relationship between social and biological factors in ethnic identity and race, as well as to provide information related to other questions relevant to anthropological, biological, and medical research in the following stages of the project. Proyecto Candela, "Proyecto Candela México - About", online: <https://www.facebook.com/pg/CandelaMx/about/>; University College London, "Candela - Consortium for the Analysis of the Diversity and Evolution of Latin America", (29 February 2016), online: *Univ Coll Lond* <http://www.ucl.ac.uk/candela>.

[273] "Senosiain Laboratorios", (2013), online: *Senosiain Lab* <http://www.senosiain.com.mx/index.php?id=4>.

[274] Guzman, *supra* note 137 at 115.

[275] Giselle Perez Zazueta, *Industria Farmaceutica* (ProMexico, 2013) at 13–17.

With a few exceptions, most of Mexico's pharmaceutical and biotechnological companies focus on the development and improvement of biological products and generics, [276] as opposed to R&D of new innovative products. [277] The Instituto Bioclon, [278] Probiomed,[279] Genzyme,[280] Sanfer,[281] and Armstrong Laboratorios[282] are some examples of companies devoted to biological and generic products, as well as to the manufacture of other companies' active ingredients.[283] These companies focus mainly on the manufacture and commercialization of biocomparable products[284] related to antivenoms, diabetes, rare

[276] There are two types of pharmaceutical products: chemical and biological (also known as biotechnological). Chemical products are created based on chemically created active ingredients. Biotechnological products are created using living organisms and techniques of molecular biology with recombinant proteins as their active ingredients. Both, chemical and biological are patentable provided that they are innovative, new, non-obvious, with an industrial application (or utility), and within the patentable subject matter. Once the patent expires, given that they become part of the public domain, they can be manufactured and commercialized by third parties (different from the patent holder) without the need of any license. The chemical products manufactured by those third parties are known as generics. The biological or biotechnological products manufactured by those third parties are biocomparable. Christian Lopez Silva, "México retoma un liderazgo regulatorio sobre medicamentos biotecnológicos y biocomparables" (2012) 148:1 Gac Médica México 83 at 84–88.

[277] Pierre Moise & Elizabeth Docteur, *Pharmaceutical Pricing and Reimbursement Policies in Mexico* (2007) at 34–35.

[278] Bioclon focuses on antivenoms. "Instituto Bioclon", (2015), online: *Instuto Bioclon* <https://www.silanes.com.mx/instituto-bioclon.html>.

[279] Probiomed was founded over 40 years ago. It focuses on the production of recombinant proteins used in the areas of Endocrinology, Cardiology, Neurology, Psychiatry, Otorhinolaryngology, Gynecology, Traumatology, Nephrology, Oncology, and Hematology. "Probiomed", (2015), online: *Probiomed* <http://www.probiomed.com.mx/>.

[280] Genzyme is a company that belongs to Sanofi. It focuses on rare diseases and it also manufactures products for renal diseases, osteoarthritis, and immunologic diseases. "Sanofi - Genzyme Mexico", (27 February 2014), online: *Sanofi - Genzyme Mexico* <http://www.sanofi.com.mx/l/mx/sp/layout.jsp?scat=FE714E51-3701-4B40-8EC3-7868B3487A48>.

[281] Sanfer is a company that belongs to the Invektra Group. It focuses on the manufacture of other companies' active ingredients and products. Sanfer, "Products and Operations Sanfer", (2019), online: *Sanfer* <http://www.sanfer.com.mx/compania/operaciones>.

[282] Armstrong Laboratorios devotes to the manufacture of pharmaceutical products of Italian, Swiss, German, and American companies. Armstrong Laboratorios, "Products Armstrong Laboratorios", (2019), online: *Laboratorios Armstrong* <https://www.laboratoriosarmstrong.mx/armstrong/armstrong.html>.

[283] Lourival D Possani, "The past, present, and future of biotechnology in Mexico" (2003) 21:5 Nat Biotechnol 582 at 582.

[284] A biocomparable biotechnological product is a non-innovative product that is biologically equivalent in terms of safety, quality, and efficacy to the registered innovative biotechnological product with which it is compared. The equivalence that a biocomparable product has to prove is in accordance with the relevant regulation. Christian Lopez Silva, *supra* note 276 at 88; "Medicamentos Biotecnologicos

diseases, and cardio-vascular, renal, and immunologic diseases. Despite this focus, there still are few Mexican companies that focus on innovative pharmaceutical R&D: Liomont, the above-mentioned Laboratorio Senosiain, and Laboratorios Silanes.[285] Liomont's products range from antivirals, medication for respiratory diseases, painkillers, urinary and gastric conditions, heart and high blood pressure diseases, bone conditions, bacterial infections, antihistamines, erectile dysfunction, to obesity. The company has applied for and been granted close to 30 patents.[286] Laboratorio Senosiain has close to 200 patents on antibiotics, antifungals, antihistamines, anti-inflammatories, antidepressants, painkillers, and medication dealing with obesity, hypertension, rheumatology, gastric conditions, and anxiety.[287] Laboratorios Silanes focuses on products that treat pain, diabetes, cardiovascular diseases, anti-venoms, and even some diagnostic tests. The company holds close to 70 patents.[288] The utility/welfare generated in this case would be with respect to the availability of the products in the market: affordable generics on the one hand, and some innovative products on the other.

Notwithstanding the existence of these research centres, the intellectual property legislation intending to promote innovation (in the same terms as in developing countries), and the formal inclusion of policies, objectives, and strategies in the National Plan of Development and other governmental documents, Mexico's investment in science and

Biocomparables. Definiciones", (24 October 2014), online: *Medicamentos Biotecnológicos Biocomparables* <https://biotecbiocomparables.wordpress.com/acerca-de/>.

[285] Perez Zazueta, *supra* note 275.

[286] Liomont, "Products Liomont", (2019), online: *Liomont* <http://liomont.com.mx/portfolio/respiratorios/>; "Búsqueda Patentes-- SIGA", online: *IMPI Database* <http://siga.impi.gob.mx/content/common/busquedaSimple.jsf>.

[287] Senosiain Laboratorios, "Products Senosiain Laboratorios", (2019), online: *Laboratorios Senosiain* <http://www.senosiain.mx/index.php?id=12&start=0>; note 302.

[288] "Silanes", (2019), online: *Silanes* <https://www.silanes.com.mx/>; note 286.

technology is below the minimum suggested, the pace of innovation is slow, and the proper use of intellectual property is insufficient.[289] Whereas according to the OECD, countries should invest at least 1% of their GDP in R&D, Mexico has invested 0.48% in 2012, 0.49% in 2013, 0.53% in 2014, 0.52% in 2015 and 0.48% in 2016[290] (approximately 60% from the public sector and 40% from the private sector[291]).[292] This makes Mexico the second lowest OECD country in investment in science, technology, and innovation.[293] This low reinvestment into their R&D limits the scientific and technological infrastructure that the companies and research centres can afford and their capacity to hire and retain qualified researchers and lab staff.[294] The utility/welfare in terms of innovation is less obvious than the economic utility mentioned above regarding the employment and product markets brought about by the foreign pharmaceutical companies.

Regarding the pace of innovation, the current regulation and policies have not brought about the results expected. In the public sector, despite the specialization and current relevance of the above-mentioned research centres and their projects, research activities on medical genetics in Mexico are still mainly focused on basic research without having yet reached its translation into any marketable product. For instance, the MGDP

[289] Séguin et al, *supra* note 115.
[290] OECD, "Research and development (R&D) - Gross domestic spending on R&D - OECD Data", (2018), online: *OECD Data* <http://data.oecd.org/rd/gross-domestic-spending-on-r-d.htm>.
[291] While Mexican companies devote between 8% and 10% of their revenue to R&D, U.S. companies reinvest 17-20% of their revenues back into R&D. Felipe Gazcon, "México es el que menos invierte en investigación y desarrollo: OCDE", (23 November 2012), online: *Dinero En Imagen* <http://www.dineroenimagen.com/2012-11-23/11447>; Guzman, *supra* note 137 at 129–133; Stuart O Schweitzer, *Pharmaceutical Economics and Policy* (New York: Oxford University Press, USA, 2007).
[292] Diana Saavedra, "Estiman lejano 1% del PIB a Ciencia", *Reforma* (20 November 2013), online: Reforma <http://www.reforma.com/ciencia/articulo/722/1442233/?Titulo=estiman-lejano--1-del-pib-a-ciencia>.
[293] Malkin et al, *supra* note 265 at 11.
[294] Moise & Docteur, *supra* note 277 at 45.

started in June 2005 and ended its first phase in May 2009. This first phase resulted in a database with the genotypes and SNPs of the sampled Mexican mestizo population and a number of associated publications. The subsequent phases are still ongoing focusing on a number of research fields including the genomics associated with rare diseases, cancer, heart, liver, metabolic, infectious, autoimmune, psychiatric, and neurodegenerative diseases, as well as proteomics, nutrigenomics, population studies, and ethical, legal, and social issues. These future phases are expected to bring about inventions in genomic medicine, pharmacogenetics, and personalized medicine (e.g. diagnostic tests, personally tailored treatments, gene therapies, and preventive measures) that would render less expensive and improve the quality of healthcare services.[295] The Genoteca Indigena, initiated in 2008, is expected to conclude its data collection in 2019.[296] Similar to the MDGP, there have not been any products of medical translation.

In the private sector, innovation has not progressed as it has in other first world countries with similar intellectual property regulation. Most of the private companies devoted to medical genetics in Mexico focus their R&D on the manufacture and commercialization of biocomparables without showing any real presence in the manufacture of innovative biotechnological products. R&D in the chemical pharmaceutical industry in Mexico focuses on generics and similares, without getting too involved in

[295] Irma Silva-Zolezzi et al, b) *supra* note 270; Béatrice Séguin et al, *supra* note 115; INMEGEN, *supra* note 270; INMEGEN, "Líneas de Investigación - Instituto Nacional de Medicina Genómica", (16 August 2017), online: *Instituto Nacional de Medicina Genómica* <http://www.inmegen.gob.mx/es/investigacion/lineas-de-investigacion/>.

[296] El Universal, *supra* note 271.

innovative pharmaceutical products. Therefore, as I indicated above, the utility/welfare created by these research centres in terms of innovation is yet to be determined.

Finally, with respect to the use of intellectual property and patent activity, the current regulation (policies and legislation) has not resulted in substantial or clear benefits for either Mexican inventors/investors or the Mexican population. Instead, it has benefited, in terms of numbers of patents and the associated profits, countries such as France, Germany, Japan, Switzerland, United Kingdom, and the United States, residents of which collectively own between 93% and 97% of the patents in Mexico.[297] For instance, regardless of the high numbers of patent applications filed by Mexicans, the numbers of patents actually granted are much lower. Out of the 453 patent applications filed by Mexicans in 1998, only 141 were granted. In 2012, out of the 1,292 patent applications filed by Mexicans, only 281 were granted.[298] This is not the case for patent applications filed by foreigners. In 2012, out of the 6,609 patent applications filed by the United States, 5,924 were granted. Germany has a similar case. Out of the 1,293 patent applications filed by Germans in 2012, 1027 were granted. In that same year, Japan obtained 792 patents out of the 992 it applied for.[299] The aforesaid conditions were maintained in 2013 and 2014. Out of the 15,444 applications filed in 2013 and 16,135 in 2014 before the IMPI, 1,292 and 1,244 respectively were of Mexicans and 14,152 and 14,891 were of foreigners. Out of the 10,343 and 9,819 patents granted in 2013 and 2014, 302 and 305 were of Mexicans and

[297] Miguel Angel Margain b), *IMPI en Cifras 2015* (Mexico: IMPI, 2015); Miguel Angel Margain a), *IMPI en Cifras 2013* (Mexico: IMPI, 2013); Miguel Angel Margain c), *IMPI en Cifras 2017* (Mexico: IMPI, 2018).
[298] Margain b), *supra* note 297; Margain a), *supra* note 297; Malkin et al, *supra* note 265 at 104.
[299] Margain a), *supra* note 297.

10,041 and 9,514 were owned by foreigners.[300] In 2015, the ratio between patent applications filed by national or companies/centres/researchers remain very similar: out of 18,071 patent applications received by the IMPI, over 92% were filed by foreign companies.[301] In 2017, there were 17,184 patent applications filed in total, out of which only 1,334 were filed by Mexican companies/centres/researchers. In this same year, out of the 8,510 patents granted, only 407 were granted to Mexican companies/centres/researchers. US companies and inventors filed 8,370 applications, and 3,950 were granted to them.[302] The main Mexican patent holders are the National Autonomous University of Mexico (UNAM), the Technological Institute of Post Secondary Studies of Monterrey, the CINVESTAV of the National Polytechnic Institute, the Meritorious Autonomous University of Puebla, and the Autonomous University of Nuevo Leon. There are seven other universities and only one company in the list: MABE. The US has more than 130 companies in its list of main patent holders in Mexico.[303]

It is also worth noting that much of the patenting by Mexicans is done in collaboration with foreign co-inventors.[304] Out of the total number of patents granted, only 7.6% of patents granted by the IMPI are owned by Mexicans.[305] Another observation that is worth mentioning is that the number of patent applications submitted by all the above-mentioned countries has been considerably decreasing since 2013, reaching the lowest

[300] WIPO, "WIPO Intellectual Property Statistics Data Center", (2014 2013), online: *World Intellect Prop Organ* <https://www3.wipo.int/ipstats/index.htm?tab=patent>; WIPO, *WIPO Report on Patents* (online: World Intellectual Property Organization, 2014) at 24, 26, 48 & 52.
[301] Dayna Mere, "Destacan Inventores Mexicanos", *Reforma* (3 May 2016), online: Reforma <http://www.negociosreforma.com/aplicaciones/articulo/default.aspx?id=834230&v=impresion=1>.
[302] Margain c), *supra* note 297 at 6 & 9.
[303] *Ibid* at 13–18.
[304] Malkin et al, *supra* note 265 at 106.
[305] Presidencia de la Republica, *supra* note 131 at 59.

number since 2005.[306] Even though the foregoing statistics refer to patent applications and patents granted in general without any distinction based on the specific field, similar conditions occur in the area of medical genetics. The UNAM is the Mexican organism that obtains the most patents in medical genetics and yet, its number is still low.[307]

In the area of pharmaceuticals, 98.4% of the patents granted were held by foreign companies/inventors and 1.6 to nationals between 1980 and 2006, with almost half of them being granted to the United States. The companies with the highest number of patents were Pfizer, Pharmacia, GlaxoSmithKline, Eli Lilly, Merck, Johnson, Abbot, and Bayer. [308] The difference in numbers of patent applications submitted and of patents obtained by Mexico in comparison to other countries observed in the IMPI's database is also seen in other jurisdictions. The United States, Germany, Japan, Korea, and China were the countries with the highest number of patent applications worldwide in 2013 and 2017 (82%).[309] Switzerland, United Kingdom, the United States, Russia, Israel, India, and the Netherlands were the countries that had the most patent applications published in pharmaceuticals and medical technology in 2010-2012.[310] Mexico has one of the lowest numbers of patent applications filed per capita at the European Patent Office, the United States Patents and Trademarks Office, and the Japanese Patent Office.[311]

---

[306] Margain a), *supra* note 297; Margain c), *supra* note 297 at 9.
[307] Manual search using the keywords "UNAM" & "Universidad Nacional Autonoma de Mexico" note 302; Interview of Jose Luis Solleiro Rebolledo (June 26, 2012), UNAM [*Solleiro's interview*].
[308] Guzman, *supra* note 137 at 137.
[309] WIPO, *supra* note 316; WIPO, *supra* note 316 at 15; WIPO, *Who Filed the Most PCT patent applications in 2017?* (online: World Intellectual Property Organization, 2018).
[310] WIPO, *supra* note 300; WIPO, *supra* note 300 at 32–34.
[311] Malkin et al, *supra* note 265 at 103.

Finally, I could not find any significant case in which a patent had been used to impede any activity research or development. The most common cases of litigation involving patents in the area of medical genetics have aimed to extend the terms of patent protection of certain drugs.[312]

3.4 Final Remarks

The environment established in Mexico for innovation in the area of medical genetics includes legislation and policies that seem to provide a similar level of protection and encouragement to those of countries with high levels of innovation. However, the pace of innovation in medical genetics in Mexico is not comparable to that in those same countries. Despite the relevance of many of the projects led by Mexico's research centres (particularly the MDGP and the Genoteca), most of the public research centres seem to continue to focus their R&D on basic research and the publication of academic texts, as opposed to translational and clinical products. This situation makes the utility/welfare brought about by these research centres and their projects in terms of innovation still to be determined. The private sector focuses on the manufacture and commercialization of generic and similares drugs and biocomparable products. The availability of these products in the market could be deemed the utility/welfare generated.

Mexican research centres do not seem to have an active role in filing and obtaining patents. According to the statistics published by the IMPI and the World Intellectual

[312] "Disputan farmacéuticas ampliación de patentes – Mexico", *Bitácora Farmaceutica* (22 September 2009), online: Bitacora Farmaceutica <https://bitacorafarmaceutica.wordpress.com/2009/09/22/disputan-farmaceuticas-ampliacion-de-patentes-mexico/>.

Property Organization (WIPO), Mexico has a noticeably low rate of filing and obtaining patents. Patents do not seem to play an important role funding R&D either, as much of the funding for innovative research projects is provided by the public sector. Therefore, the patent system does not seem to have played a significant role in the promotion of innovation in medical genetics in Mexico. It is also important to mention that the existence of patents in the area of medical genetics does not seem to have a hindering effect on innovation in Mexico either.

Conclusions to Section 2

The Mexican population is characterized by a very noticeable socio-economic gap that results in half of the population living under the poverty line, while having 15 Mexicans in the list of the richest people of 2017.[313] Indigenous Peoples and rural populations are the most affected by this gap, as 75% of the Indigenous population and 65% of the rural population live under said poverty line.

The conditions of poverty lead to malnutrition and inadequate healthcare, which jointly result in poor health. People living below the poverty line lack the means to afford healthy and sufficient food and the infrastructure and education to maintain hygienic habits, which by itself weakens the people's immune system. Additionally, they lack the resources to afford the necessary diagnostic tests, drugs, and therapies to timely and effectively treat their ailments, when they are not covered by the public healthcare system. This undesirable situation of poverty is perpetuated throughout generations, as poor health leads to poor education and insufficient income, thus restarting the cycle and conditions of poverty not only for the current generation, but for future generations as well. This is why if we are to justify the patent system in the health-related industry based on the utility/welfare it brings (access to health-related products and services) conversion factors such as poverty need to be kept in mind.

The patent system is said to promote innovation and bring a number of benefits to countries' economies and societies. These benefits (i.e. utility/welfare) include the

[313] Forbes, "The World's Billionaires List", (2017), online: *Forbes* <https://www.forbes.com/billionaires/list/#version:static_country:Mexico>.

invention and manufacture of and access to innovative medical products. Mexico has implemented mainly the same patent regulations and policies as the most innovative and advanced countries and regions of the world in medical genetics, with the intention of promoting the creation and manufacture of innovative medical products of its own. However, innovation in Mexico has not progressed as expected. Regardless of current national and foreign as well as public and private R&D, innovative medical products have not been invented at the necessary pace. Filing and obtaining patents does not seem to be a regular practice in Mexico, except for foreign or transnational companies. Interestingly, I did not find any of the hindering effects in national innovation raised by many of the detractors of patent system either.

However, patents do seem to hamper access to innovative medical products. Most of the patented medication, tests, and therapies can be so expensive that they become unattainable for a great part of the population. In the public healthcare system, while most tests, drugs, and therapies are not fully covered and patients have to cover a portion of their cost depending on their socio-economic level, those that are patented are not covered at all by the public healthcare system because of their high price. In the private healthcare system, patients either pay out of their pockets for the tests, drugs, and therapies and wait for their private insurance to reimburse them or they cover the entire cost on their own. This makes it prohibitive for vulnerable populations to access patented innovative products and services.

In the two chapters that comprise the following section, I present a case study that illustrates a) the specific conditions in which determined Indigenous communities who participate in medical research projects access healthcare services and b) the circumstances in which those research projects took place. Unlike my analysis in these two chapters, which was at the national level, the analysis I do in my case study focuses at a lower and more specific level.

Taking into account the findings and conclusions reached in these chapters and in the following two chapters with respect to the circumstances and conditions of medical research and vulnerable populations such as the Indigenous Peoples in Mexico (conversion factors and actual capabilities and functionings), in my fourth and last section, I will further the analysis of the potential effect that the patent system may have on innovation in the area of medical genetics in Mexico, but more importantly, on the access to healthcare in vulnerable populations. With this in mind, I will discuss the importance of ensuring universal access to innovative medical products in order to properly justify the patent system in terms of the utility/welfare it actually brings. This discussion will hopefully lead scholars and policy makers to question and modify the terms in which the patent system is regulated and implemented in countries like Mexico with respect to innovation in the area of medical genetics.

Section 3

Chapters 4 and 5: Case Study.

Introduction to Section 3

In the previous section, I described the circumstances and conditions of Mexico's innovation ecosystem, focusing particularly on medical genetics as a specific area of health-related innovation relevant to the pharmaceutical and biotechnology industries. I showed that despite Mexico having a similar patent system to the one adopted in developed countries/regions like the US or Europe, it does not have a comparable pace of innovation or reaction to the patent system to the ones in those countries/regions. Hence, there are circumstances and conditions surrounding cases of research and development in medical genetics in Mexico distinct from the patent regulations that influence the outcomes of the innovation system.

Since systems do not function in isolation, I looked into the healthcare system in Mexico, including the parties involved, its deficiencies, and the kind of access its most vulnerable population has available. I described a large number of interacting factors that affect overall access to healthcare and well-being of Mexico's most vulnerable population. This provided the necessary context needed to assess the actual impact that the patent system can have on this specific area.

The two chapters of that section provided a national perspective. The chapters of this section will provide a more focalized approach, with the intention of helping to visualize and understand the way in which the circumstances, conditions, and interacting

factors mentioned in the previous section fail to generate basic capabilities and overall well-being discussed in chapter one on specific cases of Indigenous Peoples as an example of a vulnerable population. To accomplish this, I provide a case study. Throughout this case study, I ask the following questions: what are the healthcare services available to the specific communities?; what are the socio-economic conditions in which these communities live?; how can their socio-economic conditions affect their access to healthcare?; how does the patent system affect a specific and concrete research project in Mexico?; what role does the patent system play in the innovation process in that specific project?; and what is the impact of the research project and of the patent system on the access to healthcare by the participants of that project? The answers to these questions will allow me to concretely illustrate how the interacting factors discussed so far (i.e. conversion factors) can affect the attainment of basic capabilities and functionings in the case of specific communities.

The circumstances and conditions addressed in this case study are those of two medical genetics research projects performed in Mexico involving Mexican Indigenous Peoples. The reasons for choosing these research projects are that Indigenous Peoples in Mexico are representative of the most vulnerable population in the country, and because the genetic isolation that many of them maintain can be of great interest in medical genetics.

Each research project makes up one part of the case study. The first part (chapter four) focuses on the genetic-based resistance that some members of the P'urhépecha community have shown to tuberculosis. The second part (chapter five) centres on the

genetic-based predisposition to actinic prurigo that has been observed in some members of the Mazateca, Maya, and Nahua communities.

Each of the research projects addresses the circumstances and conditions surrounding two aspects. The first is the research and development associated with the medical genetics research projects that explore the genetic component of the disease in relation to the Indigenous community. The second is the healthcare services to which that Indigenous community has access.

With respect to research and innovation, I describe the specific incentives the researchers had for participating in the research projects, their funding conditions, the terms of their collaboration, and their approach to patents (i.e. obtaining patents for their own innovations and/or ensuring that they are not infringing any third parties' patents prior to initializing a research project). I also give a brief account of the patents related to the two selected diseases that were granted before the Instituto Mexicano de la Propiedad Industrial (IMPI). The purpose of this information is to determine the role that patents have played in the specific research projects, in the researchers' personal incentives, and in the projects' funding. This will verify: a) whether the patent system promoted or positively influenced in any way the innovation process in the projects investigated in this case study or b) whether the patent system hindered innovation through control and restrictions imposed by patent holders on their patented inventions and research tools. These findings will help enrich the discussion in section four by providing a concrete example.

Regarding the circumstances and conditions surrounding the Indigenous Peoples' access to healthcare, I describe the impact that the specific disease, the treatment prescribed, and the medical research projects have had on the lives of those in Indigenous communities (i.e. customary lifestyles, social structure, economic situation, and healthcare). I include information on the Indigenous communities' socio-economic conditions, geographic isolation, and available infrastructure to the extent to which these circumstances influence the Indigenous communities' limited access to healthcare. Additionally, I describe the conditions of benefit-sharing agreed on for each of the research projects that make up this case study so as to determine whether this benefit sharing could improve the communities' access to healthcare and counteract their standard deficient healthcare services.

The distinctive element between the two research projects in the case study is related to the disease on which they focus. The first part of the case study (chapter four) focuses on tuberculosis. The rate of current and new cases of tuberculosis has decreased throughout the years.[314] However, tuberculosis still afflicts people from around the world with consequences as serious as death, particularly in patients with compromised immune systems.[315] This translates to a demand for new and improved treatment, drugs, therapies, and tests, which attracts the interest of researchers and companies.

[314] World Health Organization a), *Global tuberculosis report 2016* (Switzerland: World Health Organization, 2016) at 1 – 4 & 76 – 79; World Health Organization b), *Tuberculosis. Fact Sheet* (online: World Health Organization, 2017); World Health Organization c), *Global Tuberculosis Report 2013* (France: World Health Organization, 2013) at 184; World Health Organization d), *Tuberculosis. Fact Sheet* (online: World Health Organization, 2012).
[315] World Health Organization a), *supra* note 314 at 4 & 86; World Health Organization b); World Health Organization c) at ix.

An important finding of the medical genetics research projects involving the P'urhépechas and tuberculosis is that some P'urhépechas have been shown to carry a gene that creates resistance to some of the most serious and fatal symptoms of the disease. Understanding this resistance could result in groundbreaking drugs and therapies that could benefit the world's population, which could increase the pharmaceutical companies' and public health research centres' interest in tuberculosis and in the P'urhépechas' genetic information. Unfortunately, given that the lives of these P'urhépechas do not seem to be at risk, this same resistance can lead to policies that neglect to provide an appropriate treatment for their tuberculosis.

In the second part of the case study (chapter five), I focus on actinic prurigo. Actinic prurigo is a skin disease that affects mainly members of Indigenous populations, and even among them, it is not very common. Its symptoms affect the patients' lifestyle without actually risking their lives.[316] As a result, pharmaceutical companies have not shown an interest in investing in finding a better treatment.

The medical genetics research projects involving actinic prurigo and the Mazatecos, Nahuas, and Mayas communities suggest that some members of these communities carry a gene that has been shown to predispose them to developing the disease. Despite the vulnerability that this genetic predisposition creates for the carriers of this gene, the non-life threatening effects of the disease, its low morbidity, and the low

[316] Iris Estrada-G et al, "Evidence that thalidomide modifies the immune response of patients suffering from actinic prurigo" (2004) 43:12 Int J Dermatol 893; Irene Man, "Actinic Prurigo" in James Ferguson & Jeffrey S Dover, eds., *Photodermatology* (United Kingdom: Manson Publishing, 2006).

socio-economic conditions of the population afflicted by it, maintain a low demand and a practically nonexistent market for drugs, treatment, therapies, and tests for actinic prurigo. Likewise, public healthcare authorities have not included the treatment against actinic prurigo in the public healthcare system.

The incentives that researchers, companies, and research centres have for devoting their efforts and resources to a specific disease, population or project may differ depending on the predicted social and medical impact or expected commercial market that the research outcome (e.g. findings, drugs, therapies, and diagnostic tests) may have. The economic incentives that the patent system provides are particularly based on the market expectations. The differences between the two research projects concerning the specific disease and whether the population shows a genetic predisposition or a resistance to the disease may influence the aforesaid predictions and expectations. Likewise, the prognosis of the disease (i.e. whether the disease is fatal or whether it can evolve into an epidemic) may also affect such predictions and expectations, as well as the urgency of providing access to the innovative medical products and services. Therefore, examining two research projects with the aforementioned differences could be helpful in determining the effect that the patent system may have on medical genetics-related research and development and access to healthcare in Mexico.

Finally, for this part of my dissertation, I interviewed eight researchers in addition to Dr. Julio Granados. Five of these researchers worked with Dr. Granados in parts of the projects included in the research projects that make up this case study as well as in other

projects outside the case study. The other two interviewees were involved in the technology transfer offices of their place of employment (public research centres). They all have different backgrounds: doctors, healthcare providers, immunologists, anthropologists, chemists, employees of liaison offices, and research directors. They also belong to different institutions (public hospitals, public universities, public research institutes). In these institutions, they comply with different policies and practices in terms of research, collaboration, ethics, funding, and commercialization. In addition to the projects mentioned in this part, they lead and participate in other research projects with other researchers and other institutions and companies with their own policies and practices. Therefore, in the interviews, these researchers shared their personal practices, policies, and experiences that applied not only to the projects that comprised this case study, but also to other unrelated research and development activities and practices in which they have personally participated. Despite the usefulness of this information, there are important limitations to my research. The main limitation is that, given the size of the research teams, the number of interviews was inherently limiting. Thus, my results reflect the opinions, practices, and circumstances of a very small group of researchers who, although they belong to different institutions, have different backgrounds, and engage in their own projects with other institutions, belong to the same circle. Given this limitation, the results of this case study should not be assumed to be representative or a generalization of the entire genetics community in Mexico.

It is also important to mention that Dr. Julio Granados is my father. This personal link however, does not create a conflict of interest, as my analysis in this part of my

dissertation focuses on the factual aspects of their research activities without intending to evaluate the correctness of such activities. Contrary to having a negative impact on my research, this link provided me with faster and more efficient access to those projects, activities, and researchers.

Chapter 4 P'urhépechas and their link with Tuberculosis

4.1 Introduction

There have been many studies identifying the genes associated with tuberculosis and attempting to determine the genetic component in the pathology of the disease.[317] Some of those studies have focused on the Indigenous population of Mexico for two reasons. First, there is a special course of the disease observed in some of those communities, some of which are genetically isolated. Second, there is a high probability of extending these findings to the mestizo[318] population, which is 60% of the Mexican population.[319]

This part of the case study focuses on three genetic research projects that study a genetic bond between tuberculosis and the P'urhépechas and Mexican mestizos. They suggest the existence of genetic factors that provide some level of protection against the most serious and fatal symptoms of tuberculosis. Despite the medical and scientific relevance of this suggested genetic association and the medical interest that it has engendered, none of these projects has, so far, resulted in clinical products.

In this chapter, I discuss: 1) the P'urhépechas' access to healthcare and 2) activities of research and development involving the genetic link of tuberculosis with the P'urhépechas and Mexican mestizos. I begin by describing brief details about the

[317] Erwin Schurr, "The contribution of host genetics to tuberculosis pathogenesis" (2011) 86:1 Kekkaku 17; E Schurr, "Is susceptibility to tuberculosis acquired or inherited?" (2007) 261:2 J Intern Med 106; Attapon Cheepsattayakorn & Ruangrong Cheepsattayakorn, "Human genetic influence on susceptibility of tuberculosis: from infection to disease" (2009) 92:1 J Med Assoc Thail Chotmaihet Thangphaet 136.
[318] Mestizo is "a person of mixed blood, specifically a person of mixed European and American Indian ancestry." *Merriam-Webster,* online *s.v.* "mestizo".
[319] Torres et al, *supra* note 163 at 42; Wolfram Alpha, *supra* note 144; note 182.

P'urhépecha people. I also address the socio-economic and general healthcare conditions in which the P'urhépecha communities live. This part aims to provide a context for the usual lifestyles of this community and their essential needs. I additionally show the level of poverty in which the P'urhépechas live, focusing particularly on their appalling access to healthcare. I also include information about tuberculosis: its symptomatology, types, common treatments, prognosis, and epidemiology. This part gives an insight into the disease and its most common treatment, discussing it in association with the P'urhépechas' socio-economic and healthcare conditions. This discussion will include the associated problems – economic and social- if the disease is not adequately treated, regardless of the apparent genetic resistance or protection against the fatal symptoms of the disease. It will corroborate the P'urhépechas' status as a vulnerable population, therefore justifying my later argument about the need for a more just distribution of healthcare that ensures their ability to access the healthcare they need (capability) and their possibility of being healthy and having a decent quality of life (functioning) as a way to quantify the welfare resulting from the patent system in the medical field.

I then briefly describe the medical genetics research projects associated with this part of the case study, including details about their findings, funding conditions, perspectives and practices related to patents, benefit sharing policies, and impact on the associated research activities and communities. I also mention any plans of further innovation that the interviewed researchers who participated in the medical genetics research projects may foresee. This section provides insight into concrete medical genetics research activities involving Indigenous Peoples in this country, their human genetic

information, and the role that patents have played in these activities. These findings will allow me to assess any utility/welfare the patent system has brought about in economic, technological, scientific, and social terms.

The three research projects of this chapter include the collaboration of Dr. Julio Granados (Instituto Nacional Ciencias Medicas y de la Nutricion Salvador Zubiran-INCMNSZ) as one of the co-authors. His co-authorship and participation in these projects required collaborative work with his colleagues from the Faculties of Chemistry and Medicine of the Universidad Nacional Autonoma de Mexico (UNAM), the Escuela Nacional de Antropologia e Historia (ENAH), and the Instituto Nacional de Medicina Genomica (INMEGEN) for the access to the P'urhépecha and mestizo communities, collection of samples, anthropological interpretations, and statistical analysis.

4.2 Access to Healthcare within P'urhépecha communities

4.2.1 P'urhépechas

The P'urhépechas (called Tarascos by outsiders) are a Mexican Indigenous People who inhabit the area around Lake Pátzcuaro, in the north central part of the state of Michoacán. Today, this area comprises 43 localities within 21 municipalities. The P'urhépecha economic activities include agriculture, harvesting, fishing, hunting, trade, cattle farming, traditional craftwork, and tourism.[320]

[320] Enrique Vela, "Culturas Prehispanicas de Mexico", *Arquelogia Mex* 53 at 62.

P'urhépecha Region[321]

There are approximately 141,000 p'urhés[322] most of which (around 113,000) live in the P'urhépecha region.[323] There has been an increasing migration phenomenon with approximately 25-35% of the p'urhé population moving to the United States.[324] In 1970, there were 60,411 P'urhépecha speakers, in 2000 that number increased to 121,409 and in 2015 to 141,177.[325]

In terms of infrastructure, some P'urhépecha communities are connected to each other and to the rest of the region by highways and roads. There is also public transportation (buses, taxis, and 170 km of railways) and some clinics and schools, out of which some of

[321] SIL, "Familia tarasca", online: *SIL Mex* <http://www.mexico.sil.org/es/lengua_cultura/tarasca>.
[322] A p'urhé is how each member of the P'urhépecha community is called. Comisión Nacional para el Desarrollo de los Pueblos Indígenas, *Monografía de los Purépechas or P'urhépechas*, 1st ed. (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2009); INEGI, *supra* note 131.
[323] Patricia Fernandez Ham et al., *Informe Sobre Desarrollo Humano de los Pueblos Indígenas de Mexico*, 1st ed. (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2006) at 136; Jarco Amezcua Luna & Gerardo Sanchez Diaz, *Pueblos Indigenas en el siglo XXI: P'urhépechas*, 1st ed. (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2015) at 47.
[324] Comisión Nacional para el Desarrollo de los Pueblos Indígenas, *Acciones de Gobierno para el Desarrollo Integral de los Pueblos Indígenas. Informe 2009* (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2009) at 84.
[325] *Ibid* at 64; INEGI, *supra* note 131.

them are Indigenous primary schools. In the 1970s, the government introduced a complete network of distribution of drinkable water and sewer systems in some localities and a partial one in others.

However, according to the National Counsel of Population, the P'urhépecha region is considered to be among the poorest regions in Michoacán in general terms, with high and very high levels of marginalization.[326] For instance, the P'urhépechas who have access to drinkable water have been forced to ration their access and consumption. The Human Development Index (HDI)[327] of the state of Michoacan was 0.700 in 2012.[328] However, the HDI is not the same in the P'urhépecha communities. In 2008, the HDI in Indigenous communities in Michoacan was .6565, whereas in non-Indigenous communities it was .7298.[329] The percentage of the P'urhépecha population without any right to social security benefits, including retirement, healthcare services, and pension in 2012 was 71.6%.[330]

With respect to healthcare services and infrastructure, the P'urhépechas have only one hospital in Cheran and some public clinics or rural medical units in medium and small

[326] Comisión Nacional para el Desarrollo de los Pueblos Indígenas, *supra* note 324; Amezcua Luna & Sanchez Diaz, *supra* note 323 at 65 & 158.
[327] According to the United Nations Development Program, the HDI measures three basic dimensions of human development: a] a long healthy life (health/life expectancy], b) access to knowledge (education/years of schooling), and c] a decent standard of living (income]. United Nations Development Programme, *supra* note 145.
[328] Fernandez Ham et al, *supra* note 323 at 173; Rodolfo De la Torre Garcia & Cristina Rodriguez Garcia, *Índice de Desarrollo Humano para las entidades federativas, México 2015. Avance continuo, diferencias persistentes* (Mexico: Programa de las Nacionaes Unidas para el Desarrollo and Oficina de Investigacion en Desarrollo Humano, 2015).
[329] Cordourier Real & De la Torre Garcia, *supra* note 164 at 41.
[330] Fernandez Ham et al, *supra* note 323 at 291; Consejo Nacional de Evaluacion de la Politica de Desarrollo Social, *Pobreza 2010. Informacion a Nivel Estatal: Michoacan 2010-2012* (CONEVAL).

sized communities.[331] These clinics or medical units are affiliated with the DIF,[332] the IMSS,[333] the ISSSTE,[334] the SSA,[335] SEDENA,[336] the SEMAR,[337] and the municipality.[338] There are also some private clinics.

Similar to what I discussed in chapter two, the conditions of poverty, isolation, and lack of social security in which the P'urhépechas live are deemed part of the relevant conversion factors. As such they have an effect in which P'urhépechas have access to healthcare (and any innovative medical product and service resulting from the patent system). For this reason, they should be taken into account when determining if vulnerable populations achieve being healthy and having a good quality of life and when assessing the benefits (utility/welfare) that the patent system creates in health.

4.2.2 Tuberculosis and the P'urhépecha communities

Tuberculosis (Tubercle Bacillus, TB) is a highly contagious disease caused by the Mycobacterium Tuberculosis bacteria.[339] It particularly infects the lungs, but it also affects

---

[331] Amezcua Luna & Sanchez Diaz, *supra* note 340 at 98–100; Biblioteca Digital de la Medicina Tradicional Mexicana, "La Medicina Tradicional de los Pueblos Indigenas de Mexico", (2009), online: *Biblioteca Digital de la Medicina Tradicional Mexicana* <http://www.medicinatradicionalmexicana.unam.mx/pueblos.php?v=p&t=purepecha&l=2>.

[332] DIF stands for Sistema Nacional para el Desarrollo Integral de la Familia - National System for the Integral Development.

[333] IMSS stands for Instituto Mexicano del Seguro Social - Mexican Institute of Social Security.

[334] ISSSTE stands for Instituto del Seguridad y Servicios Sociales de los Trabajadores del Estado - Institute of Social Security and Service for the State's Workers.

[335] SSA stands for Secretaria de Salud – Ministry of Health.

[336] SEDENA stands for Secretaría de la Defensa Nacional - Ministry of National Defense.

[337] SEMAR stands for Secretaría de Marina - Mexican Navy.

[338] Amezcua Luna & Sanchez Diaz, *supra* note 340 at 98–100; Secretaria de Salud de Michoacan, "Catalogo de Unidades Medicas. Secretaria de Salud de Michoacan", online: *Secretaria de Salud de Michoacan* <http://salud.michoacan.gob.mx/index.php/clue>.

[339] During the time of Hippocrates, tuberculosis was known as phthisis. During the XVII century, tuberculosis was referred to as consumption given the characteristic loss of weight. B R Bloom & C J Murray, "Tuberculosis: commentary on a reemergent killer" (1992) 257:5073 Science 1055 at 1056; Secretaría de

the kidneys, intestines, genitals, spine, and brain. The main symptoms are cough, fever, loss of weight, general weakness, and in some cases, death. Tuberculosis is airborne, and is transmitted via coughing, laughing, sneezing, singing, and even talking to someone with active tuberculosis. Given that the bacteria can stay in the air for hours, a person could become infected by simply inhaling those bacteria hours later. Some of the factors that contribute to the likelihood of contagion are: the number of organisms expelled, the concentration of organisms, the length of exposure time to contaminated air, and the immune status of the exposed individual.

There are two types of tuberculosis infection: active and inactive (latent). In the former, the tuberculosis germs are growing in the person's body and they may be spreading. The disease is contagious (an untreated person with active tuberculosis infects 10 to 15 people a year on average) and it may present some of the aforesaid symptoms. The opposite occurs in inactive tuberculosis. The tuberculosis germs are alive in the person's body, but they are not growing nor spreading. The disease is not contagious and it is asymptomatic. Inactive tuberculosis can become active at any time, if not treated. The populations most susceptible to contracting and being more negatively affected by tuberculosis include very young people (babies and children), individuals with compromised immune systems (people with HIV or AIDS, or people who have had another serious disease, such as diabetes, and organ transplant recipients), malnourished people, people who have been infected with tuberculosis and have failed to have proper treatment, people who smoke tobacco, and people in close contact with people infected with tuberculosis (prison,

Salud, "Tuberculosis", online: *Secretaria de Salud* <https://www.gob.mx/salud/acciones-y-programas/tuberculosis>.

shelters).[340] Another cause for susceptibility for some people may include genetic predisposition and environmental factors.[341]

The treatment for regular cases of tuberculosis involves taking a combination of antibiotics for a significant treatment period lasting between six and nine months.[342] There are several classes of antibiotics ranging from first to fifth generation antibiotics. The antibiotics from the first generation are no longer patented so their generic versions are usually covered by social security and, in the cases when they are not, the cost for the whole treatment is around USD $800.[343] Examples of these antibiotics include rifampicin, ethambutol, and isoniazid.[344] However, in most cases, antibiotics from the first generation encounter an 80% chance of resistance. The antibiotics from the second generation encounter a resistance of 40%. Some of these are still patented, and their prices are higher than those of the first generation of antibiotics. The most efficient class of antibiotics are those of the third, fourth, and fifth generations. Examples of this type of antibiotic include bedaquiline and linezolid. These antibiotics are still patented and difficult to obtain, and their costs can reach USD $700 a month. They are not covered by social security.[345]

---

[340] BREATH The Lung Association, "Tuberculosis | the lung association", (6 September 2015), online: *BREATH Lung Association* <https://www.lung.ca/lung-health/lung-disease/tuberculosis>; Meghan A Baker et al., "The impact of diabetes on tuberculosis treatment outcomes: a systematic review" (2011) 9 BMC Med 81.

[341] Niño-Moreno et al., *supra* note 11.

[342] Centers for Disease Control and Prevention. Tuberculosis. Treatment. CDC online: http://www.cdc.gov/tb/topic/treatment/

[343] Liliana Alcantara, "Surge Tuberculosis Farmacorresistente", *El Universal* (24 January 2011), online: El Universal <http://www.eluniversal.com.mx/nacion/183207.html>; Secretaría de Salud, *supra* note 361; E Lopez Segundo, *Tuberculosis Pulmonar* (Mexico).

[344] Centers for Disease Control and Prevention, "CDC | TB | Treatment", online: Centers for Disease Control and Prevention <http://www.cdc.gov/tb/topic/treatment/>.

[345] Mayo Clinic, "Tuberculosis Treatment", online: *Mayo Clinic* <http://www.mayoclinic.org/diseases-conditions/tuberculosis/diagnosis-treatment/treatment/txc-20188961>; MSF México/América Central, "Los nuevos medicamentos para la TB sólo llegan al 2% de las personas que lo necesitan.", (3 December 2015), online: *MSF México/América Central* <http://www.msf.mx/article/los-nuevos-medicamentos-

Inappropriate treatment - failure to complete the treatment in the doses and throughout the time prescribed or use of poor quality medicines or of antibiotics with high resistance - could transform the bacteria into an antibiotic-resistant form. The main problem with drug-resistant tuberculosis (MDR-TB) is not only that it renders the drug treatment futile, but that it could also result in a more serious and potentially fatal case of tuberculosis. The treatment in these cases is second-line drugs,[346] including fifth generation antibiotics and extensive chemotherapy for up to 2 years. This treatment is more expensive, less available (particularly in developing countries), and has more adverse effects than the first-line drugs commonly used. The costs for MDR-TB treatment can range from USD $2,000 to USD $250,000 for the whole treatment per patient depending on the type and level of resistance.[347]

In addition to antibiotics, there is the Bacille Calmette-Guerin (BCG) vaccine that has a protection timeframe of approximately 15 years and a success rate of 80% at the best, particularly against brain tuberculosis.[348] In Mexico, the BCG vaccine is provided at birth

para-la-tb-solo-llegan-al-2-de-las-personas-que-lo-necesitan>.

[346] A second-line drug is "a drug that is not the usual or preferred choice. *Merriam-Webster,* online *s.v.* "Second-line drug".

[347] World Health Organization, World Trade Organization & World Intellectual Property Organization, *Antimicrobial resistance – a global epidemic* (online: World Trade Organization, 2016); MSF México/América Central, *supra* note 367; Lopez Segundo, *supra* note 365.

[348] CDC, "TB | Fact Sheets - BCG Vaccine", online: *CDC* <https://www.cdc.gov/tb/publications/factsheets/prevention/bcg.htm>; World Health Organization, "BCG vaccine", online: *WHO* <http://www.who.int/biologicals/areas/vaccines/bcg/en/>.

as part of the National Vaccination Program.[349] The vaccine is free if it is applied in a public clinic or hospital.[350]

Tuberculosis diagnosis requires a physical examination, a PPD (purified protein derivative) skin test, a sputum sampling, and chest radiographies. The last two are essential because there are patients, such as elderly patients and patients with compromised immune systems, who are asymptomatic. For the extrapulmonary types of tuberculosis (spine, kidney, brain), a correct diagnosis requires DNA probes, PCR (polymerase chain reaction) amplification, lumbar puncture, and CT (computed tomography) scanning or MRI (magnetic resonance imaging).[351]

In 1996, Mexico adopted the World Health Organization's Directly Observed Therapy Strategy (DOTS)[352] to control tuberculosis. Most of the institutions involved in DOTS in Mexico are located in Mexico City.[353] In addition to DOTS, the Mexican

[349] Secretaria de Salud, "Vacunas que integran el Esquema Nacional de Vacunación", online: *Secretaria de Salud* <http://www.gob.mx/salud/articulos/vacunas-que-integran-el-esquema-nacional-de-vacunacion>.

[350] Procuraduria Federal del Consumidor, *Boletin electronico: Brujula de Compra de PROFECO. Vacunas para Todos* (Mexico: Procuraduria Federal del Consumidor, 2016).

[351] Thomas Herchline, "Tuberculosis Clinical Presentation", online: *EMedicine Medscape* <http://emedicine.medscape.com/article/230802-clinical#showall>.

[352] Directly Observed Therapy (DOTS) is a tuberculosis control strategy implemented by the World Health Organization implemented in 1995. Its components include: 1] Political commitment to establish a centralized and prioritized system of tuberculosis monitoring, recording, and treatment with increased and sustained financing, 2) Case detection through quality-assured bacteriology, 3] Standardized treatment regimen with supervision and patient support, 4) Effective drug supply and management system, and 5] monitoring and evaluation system and impact measurement. World Health Organization, "The five elements of DOTS", online: *WHO* <http://www.who.int/tb/dots/whatisdots/en/>.

[353] The institutions involved in DOTS in Mexico include: the IMSS (Instituto Mexicano del Seguro Social-Mexican Institute of Social Security), the ISSSTE (Instituto del Seguridad y Servicios Sociales de los Trabajadores del Estado-Institute of Social Security and Service for the State's Workers), PEMEX (Petróleos Mexicanos-Mexican Oil), SEDENA (Secretaría de la Defensa Nacional-Ministry of National Defense), SEMAR (Secretaría de Marina-Mexican Navy), INER, Centro Médico Siglo XXI (Medical Centre XXI century), General Hospital "La Raza," INP (Instituto Nacional de Pediatría-National Institute of Pediatrics), UNAM, IPN (Instituto Politécnico Nacional-National Polytechnic Institute), and the Mexican Association of Infectious Diseases and Clinical Microbiology.

government implemented DOTS PLUS to prevent and treat the MDR-tuberculosis in 2000.[354] Additionally, a national program to fight tuberculosis was implemented in 2001 to extend these strategies in order to make the diagnosis, treatment, and prevention equally accessible to everyone in the country, regardless of their location or socio-economic conditions.[355] Today, attention and action is still devoted to tuberculosis through its inclusion as a priority in the 2013-2018 National Plan of Health.[356] With regard to treatment, access to first-line drugs and to the BCG vaccine is included in the vaccination schedule and administered free through the institutions, hospitals, and clinics of the public healthcare system, either through social security institutions or the public healthcare centres and hospitals funded by the Ministry of Health. Access to second-line drugs is generally available only through the private healthcare system, particularly because of their limited supply and high prices.[357]

The poor socio-economic conditions in which the P'urhépechas live make many of them vulnerable to tuberculosis and to its complications. First, most of them are malnourished. Since malnourished people usually have weak immune systems, the P'urhépecha population is therefore at an increased risk of contracting and spreading tuberculosis and of easily progressing from latent to active tuberculosis. Second, infected patients with poor socio-economic conditions usually lack the economic resources and medical understanding, time and opportunity, and the infrastructure to get diagnosed, start

[354] Secretaria de Salud, *Programa de Accion: Tuberculosis* (Mexico: Secretaria de Salud, 2001) at 13.
[355] *Ibid* at 23.
[356] Secretaria de Salud, *Programa Sectorial de Salud 2013-2018* (Mexico: Secretaria de Salud, 2013).
[357] Interview of Julio Granados Arriola, (June 19, July 31, Aug 2, and Aug 5,2012) INCMNSZ [*Granados' Interview*].

and properly finish treatment, and have access to the most effective drugs. Most P'urhépechas have very low incomes. The amount of economic resources they can devote to healthcare is therefore very low or even non-existent. The costs of anti-tuberculosis treatment vary depending on the drug used, the type of tuberculosis, and on whether the patient or the drug is covered by social security benefits. In cases in which the patients have social security, if the drugs prescribed are first or second generation (without a patent), they will be included in the public healthcare system and they will either get the treatment for free or for a very small amount of money. However, there are high numbers of Indigenous Peoples who lack social security. In these cases and in those where the anti-tuberculosis drugs prescribed are third, fourth or fifth generation (patented medication not included in the public healthcare system), completion of the treatment becomes unattainable. This is also the case in drug-resistant tuberculosis, as the required medication is not covered by the public healthcare system.[358]

Not knowing or understanding that a patient could be asymptomatic and still need treatment could make it difficult to achieve timely detection, prevention, control, and treatment of tuberculosis cases. It could also facilitate contagion and the development of drug-resistant forms of tuberculosis.

Finally, insufficient or inadequate healthcare infrastructure (inaccessible hospitals, clinics, and healthcare centres) is a determining factor in the P'urhépechas' deficient access

[358] Gema Yolanda Guzmán-Montes, Renata Heras Ovalles & Rafael Laniado-Laborín, "Indirect patient expenses for antituberculosis treatment in Tijuana, Mexico: is treatment really free?" (2009) 3:10 J Infect Dev Ctries 778 at 778.

to and completion of anti-tuberculosis treatment. The P'urhépecha region comprises 21 municipalities.[359] Only the Cheran P'urhépecha municipality has a hospital.[360] There are three of municipalities - Erongaricuaro, Tangancicuaro, and Tinguindin- that have no clinics or health units and seven - Charapan, Nahuatzen, Parangaricutiro, Tingambato, Trintzuntzan, Tangamandapio, Ziracuaretiro, and Jacona - have between one and nine clinics.[361] Most of these units and clinics belong to a social security institution (IMSS, ISSSTE, SEMAR, etc.). Given that most P'urhépechas in the region are employed in agricultural activities in the community's lands, self-employed in harvesting, fishing, hunting, and cattle farming, or working in informal commerce, construction sites or household services, they do not have any social security affiliations, and consequently cannot access healthcare services in most of those units. Individuals in communities that have no clinics or healthcare units have to travel long hours to see a doctor, be diagnosed, obtain and fill in a prescription, and to go back to follow up.

There are several problems with this situation. First, given the infrastructure in many of those communities, the roads and/or the public transportation available are either less than ideal or completely non-existent. Second, the long journey in which the P'urhépechas would have to engage in order to go to the nearest clinic often leads them to miss work, which obviously affects their income. Third, when transportation is possible, the costs can make it unaffordable for the P'urhépechas to go to one of those clinics.[362]

[359] Biblioteca Digital de la Medicina Tradicional Mexicana, *supra* note 331.
[360] Amezcua Luna & Sanchez Diaz, *supra* note 340 at 98–100; Secretaria de Salud, *Directorio de Unidades Medicas de la Secretaria de Salud* (Mexico: Secretaria de Salud).
[361] Secretaria de Salud de Michoacan, *supra* note 338.
[362] Guzmán-Montes, Ovalles & Laniado-Laborín, *supra* note 358 at 780.

Fourth, given the infrastructure and equipment required for some of the diagnostic tests, none of these diagnostic methods are available in the small basic clinics or rural medical units located in or close to many of the P'urhépechas' communities. Fifth, most of the P'urhépecha population (71.6%) lacks social security benefits, including healthcare services.[363] This is particularly serious because most of the clinics and healthcare units in the P'urhépecha communities belong to an institution of social security.

All the foregoing conditions are likely to discourage P'urhépechas not only from seeking medical attention, but also from completing the necessary treatment against tuberculosis. As noted above, late diagnosis and/or an incomplete or weak treatment would increase the chances of having simple cases of tuberculosis evolving into drug-resistant tuberculosis and infecting others. Therefore, the availability and quality of healthcare infrastructure and services in the vicinity of the P'urhépecha communities need improving. It is also essential that the availability and affordability of efficient medication (second-line drugs) be ensured. The availability and affordability of healthcare infrastructure, services, and medication depend greatly on the efficiency of socio-economic policies and programs that tackle poverty. However, as I will further argue in my last chapters, patents can also have a determinant effect on the availability and affordability of certain services (e.g. diagnostic tools) and medication, as they can allow and even encourage an increase in the price of those healthcare services and medication. The prices of the antibiotics of third, fourth, and fifth generations, all of which are patented, go as high as USD$700 a month for an effective treatment against a regular case of tuberculosis and USD$2000 for

[363] Fernandez Ham et al, *supra* note 323 at 291.

a case of drug-resistant tuberculosis.[364] These prices make those medications unequivocally unattainable for the P'urhépechas.

The socio-economic and geographic conditions in which the P'urhépechas live that I just describe constitute what in the capability approach is known as conversion factors. These should be taken into account because, as I previously discussed, they can greatly influence people's capabilities and functionings. In this case, poverty, isolation, and poor nutrition (conversion factors) make it very difficult for most P'urhépechas to have access to healthcare services (capabilities and functionings), even if these are available in many parts of the country. Patents contribute to the high prices of the most innovative and most effective treatments of tuberculosis. Therefore, even if we claim that the patent system has contributed to the creation of those drugs, even if those drugs are available in the market, if those prices make those drugs unaffordable for many (and in this case, for the majority of the P'urhépechas), then it is not reasonable to assert the P'urhépechas benefit from the patent system or that the patent system brings about the utility of promoting access to healthcare.

4.2.3 National and Global Impact of Tuberculosis

Tuberculosis morbidity and mortality rates have decreased in many regions due to the scientific improvements and advancements in the drugs used in its treatment, the vaccines used in its prevention, and the creation of global and regional policies to control and

[364] World Health Organization, World Trade Organization & World Intellectual Property Organization, *supra* note 347; MSF México/América Central, *supra* note 345.

eradicate tuberculosis. In fact, TB incidence is decreasing about 2% per year.[365] Nationally, the number of tuberculosis deaths has decreased from 7,300 in 1990 to 2,000 in 2017 (excluding HIV). The number of prevalent cases also decreased in the same period from 110,000 in 1990 to 28,000 in 2017 (including HIV). The number of new cases decreased from 52,000 in 1990 to 23,500 in 2017 (including HIV).[366] 49 million people were successfully treated for tuberculosis between 2000 and 2015.[367]

However, tuberculosis continues to be a global health problem, particularly because of poverty, weakened immune systems, and drug resistance.[368] In 2012 alone, there were 8.6 million reported new cases of tuberculosis (320,000 (13%) co-infected with HIV) and 1.3 million tuberculosis deaths (74,000 children) in the world (the second leading cause of death by infectious diseases in the world, only after HIV).[369] In the same year, one-third of the world's population was estimated to be infected with the tuberculosis bacteria without developing symptoms (i.e. without becoming active).[370] In 2011, 310,000 cases (20% of existing tuberculosis cases and 3.7% of new cases) were considered drug-resistant tuberculosis.[371] This number increased to 450,000 in 2012.[372] Out of the drug-resistant tuberculosis cases, 170,000 died in 2012.[373] Without treatment, up to two-thirds of the

[365] WHO, *Tuberculosis (TB)* (online: World Health Organization, 2018).
[366] World Health Organization, *supra* note 330 at 184; WHO, *Tuberculosis Profile: Mexico* (online: World Health Organization, 2017); PAHO, "Situacion de Control de la Tuberculosis en las Americas" (online: Organizacion Panamericana de la Salud, 2018).
[367] World Health Organization b).
[368] World Health Organization a), at 2, 36–42, 102.
[369] World Health Organization c), at ix.
[370] World Health Organization d).
[371] *Ibid.;* World Health Organization c) at 2.
[372] World Health Organization c) at 6.
[373] *Ibid* at 18.

tuberculosis patients will die.[374] In 2017, TB is still one of the top ten causes of death in the world, as 10 million people had TB (1 million children became ill) and 1.6 million died from it (95% of them from low and middle-income countries). TB is still the leading cause of death for people infected with HIV. In that same year, 558,000 people developed MDR-TB.[375] In 2017, Mexico also had an increase in the number of new and relapsed cases of TB (22,757) and of TB-related deaths (2,000 deaths excluding HIV).[376]

Given that HIV weakens patients' immune systems, the proliferation of this disease has had an important impact on the evolution of tuberculosis. At least one-third of the 34 million people infected with HIV are also infected with tuberculosis. In 2012, out of the 1.3 million tuberculosis deaths, 940,000 people were HIV-negative and 320,000 were HIV-positive.[377] In that year, close to 25% of deaths of people with HIV were due to tuberculosis.[378] In 2017, .3 million people died of HIV-associated TB.[379] In 2016, Mexico accounted for 12% of all cases of tuberculosis patients with a documented HIV tested result, just after Brazil and Peru.[380] The weakening effect that diabetes has on the human immune system has also contributed to the outbreak of new cases of tuberculosis and the complications of existing cases.[381]

[374] World Health Organization d).
[375] World Health Organization b).
[376] World Health Organization a), at 187 & 196.
[377] World Health Organization c), at 6.
[378] *Ibid* at 71.
[379] WHO, *supra* note 365.
[380] World Health Organization c) at 71; PAHO, *supra* note 366.
[381] Baker et al, *supra* note 340 at 1 & 12.

As in the case of the P'urhépechas, extreme poverty around the world has also increased the number of new cases of tuberculosis by making it more difficult to diagnose new cases in a timely manner, and by facilitating its spread through the lack of proper diagnostic tests and/or treatment. Furthermore, given the practices of some patients of stopping treatment and reselling those drugs to obtain money for other needs, extreme poverty has also led to more cases of drug-resistant tuberculosis.[382] The risk of death from tuberculosis in Mexico is 1.8 times higher in women and 2.3 times in men in regions with high incidences of Indigenous populations because of their conditions of extreme poverty.[383]

The negative effects of having undiagnosed or untreated tuberculosis patients in the P'urhépecha communities could extend to the rest of the Indigenous Peoples in Mexico and the country's rural, and poor populations and increase the number of national cases of tuberculosis and drug-resistant tuberculosis, as these patients could directly interact with healthy people under similar circumstances of extreme poverty.[384] This would raise the healthcare and economic resources that the government would be required to invest to confront and control the epidemic. Additionally, if the cases of tuberculosis in the P'urhépecha communities remain unknown by the healthcare authorities, the official numbers of national tuberculosis morbidity and mortality will likely be inaccurate. This

[382] WHO, *supra* note 365.
[383] Secretaria de Salud, *supra* note 133 at 40.
[384] J C Nájera-Ortiz et al, "Demographic, health services and socio-economic factors associated with pulmonary tuberculosis mortality in Los Altos Region of Chiapas, Mexico" (2008) 37:4 Int J Epidemiol 786; Lanata, *supra* note 177.

will lead to the government understating the necessary medical actions and supplies, thereby failing to eradicate the disease.

4.3 Research and Development

4.3.1 Research Projects

There are several aspects of tuberculosis that are the focus of current research projects. For instance, ongoing research and development aims to better understand the pathology of tuberculosis and to thereby diagnose it in a more accurate and faster way, to improve treatment, and to prevent its dissemination in a more efficient and effective fashion. New first and second-line drugs and vaccines are being developed and are entering the innovation pipeline as well.[385] The BCG vaccine is still being studied, particularly because its effectiveness has been inconsistent. Interactions and expressions of the Mycobacterium Tuberculosis with other genetic and environmental factors are also the subject of ongoing research.[386] In this regard, there have been a number of studies that have attempted to determine the genetic component in the pathology of tuberculosis. [387] Genes associated with tuberculosis have been identified. Some of the studies have focused on the Indigenous population in Mexico because of a special course of the disease observed in some of those communities, the genetic isolation in which some of those Indigenous Peoples live, and the probability of being able to extend these findings to the mestizo population, which is 60% of the Mexican population.[388]

---

[385] World Health Organization, *supra* note 314 at 1–3 & 122–130.
[386] *Ibid* at 125.
[387] See for instance: Schurr, *supra* note 317; Schurr, *supra* note 317; Cheepsattayakorn & Cheepsattayakorn, *supra* note 317.
[388] Torres et al, *supra* note 163 at 42.

This part of the case study comprises three genetic research projects that involve tuberculosis, the P'urhépechas, and/or Mexican mestizos. The research projects suggest that there are genetic factors that impact the prognosis of the disease, either providing some level of protection against the most serious and fatal symptoms of tuberculosis or making them more susceptible to developing complications when they have been vaccinated precisely against tuberculosis.

4.3.2 Specific Scientific Findings

The first research project is entitled "Distribution of Class I and Class II MHC Antigens in the Tarasco Amerindians."[389] It had been observed that P'urhépechas often have particular locus of the HLA-A and HLA-B antigens[390] that are either absent or found infrequently in other Amerindian groups. This project found that the HLA-B27 is one of these rare conditions. The findings of this project suggest that genetic factors, such as the HLA-A and HLA-B, could play an important role in the prognosis of tuberculosis, particularly with respect to an observed protection against the most serious and fatal symptoms of the disease. This hypothesis is based on two facts that have been observed: 1) the frequency of the HLA-B27 antigen in the P'urhépechas and 2) the finding that despite the high incidence of tuberculosis in P'urhépechas, the infection seems to not be a major health threat, particularly because those tuberculosis patients do not develop serious and

[389] Loeza et al, *supra* note 11.
[390] HLA antigenes (Human Leukocyte Antigenes) are a family of glycoproteins encoded by genes within the major histocompatibility complex on the surface of nucleated cells (including circulating and tissue cells). They are partially responsible for the rejection of transplanted organs or tissues when donor and recipient HLA antigenes do not match. Bradley, Johnson & Poher, *supra* note 247 at 129.

fatal cases of tuberculosis.[391] This finding has been the origin of ongoing research to determine the factors that seem to provide a form of protection and prevent the development of tuberculosis' more serious symptoms. For this study, blood samples were obtained from 120 Tarascos (Purépechas) individuals who belong to 33 families from Tarecuato (Tangamandapio, Michoacán). Records of settlements in this town date back to the ninth century BC, and population genetic analysis has confirmed a high proportion of Amerindian genes.[392]

The second and third research projects expand on this foundation by investigating the Mexican mestizo populations comparing their findings with the first study. The second study, "P2X7 and NRAMP1/SLC11 A1 Gene Polymorphism in Mexican Mestizo Patients With Pulmonary Tuberculosis" suggests that some of Mexico's mestizos who carry the NRAMP1/SLC11 A1 and P2X7 gene polymorphisms show a genetic resistance to tuberculosis, as opposed to the situation that occurs in similar carriers in other populations.[393] A number of studies on African and Asian populations have linked the NRAMP1/SLC11 A1 gene polymorphism to an apparent susceptibility to tuberculosis and the P2X7 gene polymorphism to a protective role against it.[394] The study in question found that, in the Mexican mestizo population, the NRAMP1/SLC11 A1 gene polymorphism is

[391] Loeza et al, *supra* note 11.
[392] *Ibid* at 144 & 147.
[393] Niño-Moreno et al, *supra* note 11.
[394] Judy Huang et al, "Analyses of the NRAMP1 and IFN- γ R1 Genes in Women with Mycobacterium avium-intracellulare Pulmonary Disease" (1998) 157:2 Am J Respir Crit Care Med 377; W Liu et al, "VDR and NRAMP1 gene polymorphisms in susceptibility to pulmonary tuberculosis among the Chinese Han population: a case-control study" (2004) 8:4 Int J Tuberc Lung Dis Off J Int Union Tuberc Lung Dis 428; H T Li et al, "SLC11A1 (formerly NRAMP1) gene polymorphisms and tuberculosis susceptibility: a meta-analysis" (2006) 10:1 Int J Tuberc Lung Dis Off J Int Union Tuberc Lung Dis 3; cited by Niño-Moreno et al, *supra* note 11.

not associated with susceptibility to tuberculosis, but rather, that the protein encoded by the NRAMP1/SLC11 A1 gene seems to have a role in the control of growth of the bacteria and the progression of the disease. The findings therefore suggest that the NRAMP1/SLC11 A1 gene has a protective role against tuberculosis in Mexican mestizos. On the other hand, with respect to the P2X7 gene, the findings of the study suggest that, while in the Gambian population this gene has been observed to have a protective effect against tuberculosis, this association has not been found in the Mexican population. This suggests that the precise mechanisms that lead to resistance against tuberculosis are not yet fully understood and further research is therefore necessary, particularly because it seems that other genetic and environmental backgrounds have a determining effect on gene expression.[395] For this study, blood samples were obtained from 94 patients (48 males and 46 female) from the south-east region of Mexico with pulmonary tuberculosis, as diagnosed by clinical and laboratory data. One hundred healthy contacts were studied as controls.

The third research project, "Joint Effect of MCP-1 Genotype GG and MMP-1 Genotype 2G/2G Increases the Likelihood of Developing Pulmonary Tuberculosis in BCG-Vaccinated Individuals," found that Mexican carriers of MCP-1 genotype GG and MMP-1 genotype 2G/2G who have been BCG-vaccinated were highly prone to having latent tuberculosis that progresses into active tuberculosis. The BCG vaccine seems to increase the amount of the MCP-1. This increase destabilizes the granuloma formation, which, along with the collagenase activity of MMP-1, causes intense inflammation and damages

[395] Niño-Moreno et al, *supra* note 11.

adjacent tissue, thus facilitating the spread of the disease.[396] For this project, Mexicans (193) and Peruvians (701) patients with active tuberculosis with at least three months of evolution were studied. Healthy tuberculin-positive people were also studied as a control. Subjects from both countries were selected because of their similar ethnic backgrounds, but with different environmental conditions. All study subjects were BCG-vaccinated at birth. None of them had preconditions to develop active tuberculosis (such as malnutrition, lung diseases, HIV positive status) or a history of previous tuberculosis infection or received previous treatment for tuberculosis.

4.3.3 Non-Scientific Details and the Involvement of Patents

Each of the three research projects includes a number of authors and collaborators, among whom is Dr. Julio Granados (Granados) -from the INCMNSZ-, whom I interviewed for this dissertation. Granados' participation in the research projects I presented required collaborations with colleagues from the Faculties of Chemistry and Medicine of the UNAM, the ENAH, and the INMEGEN. These collaborations were for the purposes of collecting samples, obtaining the various angles of interpretation and analysis of information, and the associated anthropological work.

The researchers interviewed from Granados' team asserted that they had two incentives to get involved in the projects mentioned. The first incentive was scientific curiosity: they found the research topic interesting and they felt that the knowledge generated would benefit and advance their own research. The second incentive was a

[396] Ganachari et al, *supra* note 11.

genuine interest in the Indigenous community's well-being and in helping to improve their lives in any way possible.[397] None of them considered obtaining and economically exploiting patents as an incentive to get involved in any of the research projects comprised in this part of the case study. Their immediate goal was usually not to translate their research into clinical applications, but merely to generate knowledge that results in academic publications, further research projects, collaborations, and to become National Researchers.[398] None of the interviewed researchers showed interest in obtaining a patent nor reported having applied for one in any of the research projects included in this part of the case study.

Since none of the projects has thus far resulted in any commercial product or process, there has not been any intellectual property resulting from any of the research

[397] For instance, an anthropologist from the UNAM and the members of the Candela Project are not interested in the association of the studied genes with the pathology of tuberculosis or actinic prurigo, but in the association of such genes with the evolution of the Latin American populations. The Indigenous Library and the INMEGEN's MDGP are projects that do not specifically focus on tuberculosis and actinic prurigo, but on the knowledge generated which would greatly enrich their databases, their practical application, and the fulfillment of their own goals. Granados Arriola, *supra* note 379; Interview of Marta Menjivar Iraheta, (June 25, 2012) UNAM [*Menjivar's Interview*]; Interview of Victor Acuña Alonzo, (June 19, 2012) ENAH-Laboratorio de Genetica Molecular [*Acuña's Interview*]; Interview of Monica Guadalupe Ballesteros Romano, (June 20, 2012) ENAH- Laboratorio de Fisiologia, Bioquimica y Genetica [*Ballesteros' Interview*]; Interview of INMEGEN Researcher, (June 21, 2012) [*INMEGEN Researcher's Interview*]; Interview of INCMNSZ Nutrition Specialist, (June 20, 2012) [*INCMNSZ Nutrition Specialist's Interview*].

[398] In Mexico, the system created by the government to provide researchers with incentives to do research is the National System of Researchers (Sistema Nacional de Investigadores-SNI). The SNI was created in 1984 to recognize full-time Mexican researchers' work in creating relevant scientific and technological knowledge. The recognition consists of awarding researchers the title of "National Researcher" with one of three levels. This award takes into account the quality and prestige of the researcher's scientific contributions and his/her contribution in forming the new generation of scholars and professionals in accordance with the evaluation made by his/her peers. The scientific contribution may be in articles, books, book chapters, patents, technological development, innovations, and technology transfers. The contribution to the formation of new scholars and professionals may be considered to take place by supervising undergraduate and graduate and postgraduate theses, teaching in undergraduate, graduate, and postgraduate levels, and creating research groups. The award includes a monthly economic prize. Sistema Nacional de Investigadores. Consejo Nacional de Ciencia y Tecnologia, "Sistema Nacional de Investigadores", online: *CONACYT* <https://www.conacyt.gob.mx/index.php/el-conacyt/sistema-nacional-de-investigadores>; *Reglamento del Sistema Nacional de Investigadores*, Diario Oficial de la Federacion, 21 March 2008 [*Reglamento del Sistema Nacional de Investigadores*].

projects except for copyrights over the publications. Benefit sharing, however, took place in one of the following different ways. There were some collectors/researchers who chose to provide basic, simple healthcare and medical services. This was particularly beneficial for the different communities involved because many of those Indigenous Peoples live in isolation, and the nearest clinic or healthcare centre is far away from those communities. Benefit sharing included as well the provision of some of the medications that the members of the community needed for their simple non-life threatening diseases, such as common cold, headache, etc. Particularly regarding tuberculosis, the researchers gave the tuberculosis patients from the community the medication needed for the complete treatment. This medication however, consisted of antibiotics of the first and second generation, which are the ones included in the public healthcare system. No antibiotics from the third, fourth or fifth generation were provided, as they were not accessible to the researchers, given their high prices. Also, as part of their idea of benefit sharing, when the participant required a more specialized treatment, the collectors/researchers transported the participant to the nearest clinic or healthcare centre.[399] In addition to those basic medical services, most collectors/researchers provided a copy of the results of the analyses done, including glucose, triglycerides, and cholesterol levels, blood type, blood pressure, and their percentage of their Indigenous ancestry.[400] In addition to the practices described above, the interviewed researchers brought commercial activities to the community during their stay. For instance, they stayed in the community and paid for housing. They bought their food from local stores and small "restaurants" (fondas). They also hired members of

[399] Granados Arriola, *supra* note 379; Acuña Alonzo, *supra* note 419; Ballesteros Romano, *supra* note 419; UNAM, *UNAM's Anthropologist's Interview* (June 21, 2012).
[400] Granados Arriola, *supra* note 357; Acuña Alonzo, *supra* note 397; Ballesteros Romano, *supra* note 397; UNAM, *supra* note 399.

the community to do a variety of temporary jobs while staying there during the research project.[401] There are other cases where, given that the project required them to take pictures of the subjects as part of the necessary documentation, they agreed to be the photographers in the community's social events as a way to give something back to the them for their participation in the research project.[402]

Some of the interviewed researchers stated that the reason for providing simple healthcare services, as opposed to more serious ones, is to avoid a situation in which the members of the community could feel that they were being taken advantage of. By providing simple healthcare services and other unrelated benefits, the researchers try to ensure that the communities' participation is free and autonomous and based on their genuine desire to volunteer and participate and not a way to obtain much-needed healthcare. They also stated that they provide instant benefits in return for the communities' participation 1) to avoid repeating the feeling of betrayal and abandonment that some Indigenous communities have had with respect to past experiences and 2) to build a reputation for themselves and their projects of being trustworthy and honest, thereby gaining the communities' trust for their current and future projects.[403]

Despite the good intentions, reasonable justifications, and positive impact, the practices of benefit sharing followed in the research projects of this case study do not fill in the deficiencies of proper access to healthcare from which many of these communities

[401] INCMNSZ, *supra* note 397.
[402] UNAM, *supra* note 399.
[403] Acuña Alonzo, *supra* note 397; UNAM, *supra* note 399.

suffer. The benefit sharing related to healthcare that the participating P'urhépechas obtained was the provision of simple healthcare services without addressing any of the serious medical conditions from which they suffer. Particularly with respect to the cases of tuberculosis, these were treated with medication of first and second generation, which have demonstrated high chances of resistance and failure, because those are the only ones available in the public healthcare system and to the interviewed researchers. In other words, the benefits shared with the participating communities have not materially changed their current socio-economic conditions or the healthcare services available, which is, in some cases, deplorable.

The collaborations contributed by Granados and his colleagues to the three research projects were publicly funded. The funds were obtained from CONACYT grants and UNAM's resources. There were no private funds and no partnerships with the national or international private industries.[404]

In terms of patent observance, none of researchers interviewed said to have the habit of performing, prior to engaging in a research project, a state of the art background check to ensure that there was no risk of infringing a third party's patent in the course of the project. They all said they were aware, though, of the risks that this practice entailed, despite the fact that they had never been contacted by a patent holder. As such, they openly chose not to verify the patent landscape associated with the state of the art of their research projects. This is noteworthy given the 166 patents associated with tuberculosis and the

[404] Granados Arriola, *supra* note 357; Menjivar Iraheta, *supra* note 397; UNAM, *supra* note 399; Acuña Alonzo, *supra* note 397; Ballesteros Romano, *supra* note 397.

genes and antigens studied in the research projects granted by the IMPI that I mention below. A possible explanation for this in the case of the interviewed researchers working directly with the Indigenous communities is that none of the projects in which they had been involved had resulted in a ready-to-commercialize clinical product.

Regardless of the individual practices and viewpoints that the interviewed researchers have, from an institutional perspective, the INMEGEN and the UNAM, two of the institutions involved in the research projects, have a different approach to patents. An officer from the INMEGEN stated that even though researchers in the academic and public spheres seem to lack interest in obtaining patents, those in the private/corporate sector might have a different perspective.[405] The one affiliated to the UNAM stated that, as part of his mandate, he regularly encouraged and supported the researchers with whom he had been in contact to obtain patents.[406] Therefore, according to these technology transfer officers, their offices are trying to change the individual perspectives of their researchers and implement practices where patents play a more active role in the future research projects they host and support.[407] The INMEGEN's Business Development Office is in the process of incorporating into its research committee system a state–of-the-art clearing background check as one of the requirements to approve a research project. This office is also negotiating with the IMPI to set up a local office in the INMEGEN to promote the use, application, and exploitation of intellectual property in the centre's research projects. It also plans to organize seminars regarding intellectual property matters for the INMEGEN's

[405] Interview of INMEGEN Business Development, (June 21, 2012) [*INMEGEN's Business Development Office*].
[406] Solleiro Rebolledo, *supra* note 307.
[407] INMEGEN, *supra* note 405; Solleiro Rebolledo, *supra* note 307.

researchers.[408] The UNAM has two agencies. The first is the Liaison Office of the Department of Innovation and Development that serves the whole university as a facilitator and advisor in technology transfer, business start up, and other technological counselling.[409] The second is the Centre of Applied Sciences and Technological Development. It provides researchers with advice in technology transfer, the training of a new generation of scholars and professionals, and commercial exploitation in the areas of Physics, Mathematics, and Engineering (including as well Micro and Macro Nanotechnology, Information Technology, Scientific Equipment, and Science and Technology).[410] These offices are expected to intervene in cases where there are potentially commercial patentable products in order to apply for such a patent and to require a patent infringement clearing process.

Finally, foreign inventors/companies seem to be more drawn to obtaining patents in the field of medical genetics and tuberculosis than national inventors/companies. In a search[411] I made at the IMPI's patents database looking for patents granted between 1995 and 2019,[412] I found 78 issued patents related to tuberculosis, 20 related to the P2X7 gene, 25 patents associated with the MCP-1 gene, and 43 related to the HLA antigene. These patents were granted on inventions that cover: methods and processes, compositions of

[408] INMEGEN, *supra* note 405.
[409]UNAM, "Coordinación de Innovación y Desarrollo - UNAM", online: UNAM <http://www.innovacion.unam.mx/>.
[410] UNAM, "Coordinación de la Investigación Científica - UNAM", online: UNAM <http://www.cic-ctic.unam.mx/cic/subsistema/institutos_centros/institutos_centros_general.cfm?vSiglasDep=CCADT>.
[411] The search was made using the search engine of the IMPI's patents database. The keywords used included: "tuberculosis," "P2X7," "MCP-1," and "HLA" alone and in combination with each other. The search was conducted during the first six days of May 2014 and verified for updates on the first six days of December 2015 and the last days of May 2019. I only included patents granted between 1995 and end of 2018.
[412]Mexican Institute of Industrial Property Database online: IMPI <http://siga.impi.gob.mx/> (accessed May 20, 2019).

matter, and products associated with preventing, diagnosing, and treating tuberculosis.[413] The patents on methods and processes refer to inventions that comprise techniques to create certain compounds or to prepare certain substances, antibodies, and proteins necessary in processes of induction of expression of genes that are used in genetic diagnostic tests and drugs (antibiotics like bedaquiline) related to tuberculosis. The patents on compositions of matter cover substances, enzymes, proteins, molecules, and antigenes, either isolated from the body or artificially created, as well as their derivatives, utilized in diagnostic, immunologic, and therapeutic methods. The patents on products encompass drugs (antibiotics like bedaquiline) and genetic and non-genetic diagnostic kits, as well as the kits' individual components.

Out of the 166 patents found, the majority was still valid in December 2018. Out of those 166 patents retrieved, only 9 are held by Mexican research institutions such as the UNAM, the Autonomous University of Nuevo Leon, the INNCMSZ, and the IMSS. The rest of the patents were held by foreign research centres, with those located in the United States, Germany, and Japan being the ones holding the most patents in the subject.

4.3.4 Future Research

In recent times, research on tuberculosis has also focused on determining the impact that other factors, such as the environment, poverty, and deficient healthcare, can have on the course of the disease.[414] This has led to research on the development of the disease in

[413]The patents related to the HLA antigene also refer to inventions preventing, diagnosing, and treating other diseases such as cancer and pruritic conditions, among others.
[414] See for instance: Arturo Torres-Dosal et al, "Indoor air pollution in a Mexican indigenous community:

other populations as a way of comparison.[415] Additionally, further genetic research on tuberculosis has resulted in research projects looking at the relation of other genes associated with tuberculosis.[416] Granados has more recently participated in research projects within the latter topic.[417]

Their incentives continue to be scientific curiosity and a genuine intention to improve the lives of those in the communities they visit. None of the interviewed researchers plans on filing a patent. Their funds keep originating from governmental and institutional grants. It is also worth mentioning that all these updated and future research projects in which Granados and his group of collaborators are involved keep focusing on the basic research of tuberculosis and its genetic component, and have not yet participated in the translation of their findings into clinical applications.

Research in this area, however, is only starting. Diagnostic tests, personalized therapies, and gene therapy could greatly benefit from the basic research resulting from the

---

evaluation of risk reduction program using biomarkers of exposure and effect" (2008) 390:2–3 Sci Total Environ 362; Nájera-Ortiz et al, *supra* note 406; Mariana Garcia Croda et al, "Tuberculosis control in a highly endemic Indigenous community in Brazil" (2012) 106:4 Trans R Soc Trop Med Hyg 223.

[415] See for instance: J C Nájera-Ortiz et al, "The Poor Survival among Pulmonary Tuberculosis Patients in Chiapas, Mexico: The Case of Los Altos Region" (2012) Tuberc Res Treat 1; Richard S Garfein et al, "Latent Tuberculosis Infection in a Migrant Agricultural Community in Baja California, Mexico" (2011) 13:5 J Immigr Minor Health 940.

[416] See for example: Areli Martinez-Gamboa et al, "Molecular analysis of Mycobacterium tuberculosis strains with an intact pks15/1 gene in a rural community of Mexico" (2008) 39:8 Arch Med Res 809; Martha Sosa-Macías & Adrián Llerena, "Cytochrome P450 genetic polymorphisms of Mexican Indigenous populations" (2013) 28:4 Drug Metabol Drug Interact 193; Marlo Möller & Eileen G Hoal, "Current findings, challenges and novel approaches in human genetic susceptibility to tuberculosis" (2010) 90:2 Tuberc Edinb Scotl 71; María Elena Soto et al, "Comparison distribution of HLA-B alleles in mexican patients with takayasu arteritis and tuberculosis" (2007) 68:5 Hum Immunol 449.

[417] Diana Torres-García et al, "Variants in toll-like receptor 9 gene influence susceptibility to tuberculosis in a Mexican population" (2013) 11 J Transl Med 220 at.

research projects of this part of the case study, particularly given the suggested genetic resistance to the fatal effects of tuberculosis that the P'urhépechas have shown.

4.4 Final Remarks

In the present day, despite advancements in medical products (vaccines, drugs, therapies) and governmental policies (DOTS and DOTS PLUS), tuberculosis continues to be a global and national health threat. On the one hand, immunologically weakening diseases such as HIV and diabetes have increased the number of cases of tuberculosis. On the other hand, the number of cases of drug-resistant tuberculosis has also grown.

The combination of these health threats along with the scientific advancement in medical genetics has brought about a high, ongoing interest in tuberculosis-related research to better understand the disease and to develop better means to prevent, control, and eradicate the disease. Identifying the genetic factors that come into play in its outbreak and its prognosis can lead to developing new treatments, drugs, therapies, and tests that can help in this process. However, the creation of these new treatments, drugs, therapies, and tests will very likely benefit those who can access them, but not necessarily all those who need them.

The research projects presented in this first part of the case study are examples of that ongoing scientific interest. They were aimed at identifying genetic factors involved in the particular prognosis of tuberculosis in the P'urhépecha population and some Mexican mestizos. Particularly, the suggested resistance to the most severe effects of tuberculosis

found in the P'urhépecha population could be useful in developing more efficient drugs and therapies. The predisposition to evolve from latent tuberculosis to active tuberculosis found in some sectors of the vaccinated Mexican mestizo population could shed essential light on the development of personalized medicine associated with tuberculosis.

The P'urhépecha communities, existing in conditions of extreme poverty, are an example of a sector of the population that do not and will likely not benefit from the current innovative and more effective and specialized medical products. Many members of the P'urhépecha communities suffer from extreme poverty, malnourishment, and weakened immune systems, all of which make them vulnerable to contracting diseases and developing complications. The extreme poverty they experience also creates inequality in the distribution of healthcare services, which translates into insufficient adequately equipped clinics and hospitals within accessible distances. It also increases the likelihood of not being able to afford the necessary preventive measures, timely diagnosis, effective medication (or any ground-breaking drug, gene therapy or personalized treatment), and of not even completing the required treatment. Despite the finding in Nino-Moreno, et. al.'s and Loeza's studies[418] about the genetic resistance to the fatal aspects of the tuberculosis observed in some of Mexico's mestizo and P'urhépecha populations, the inadequate healthcare treatment perpetuates the current differences and gaps in health, income and quality of life between P'urhépechas and the rest of the population. These conditions lead to the P'urhépechas being in disadvantage in the pursuit of what the capability approach defines as capabilities and functionings, which in this case would be having access to

[418] Niño-Moreno et al, *supra* note 11; Loeza et al, *supra* note 11.

healthcare, being healthy, and having a good quality of life. In other words, the P'urhépechas do not seem to benefit from the medical R&D done in tuberculosis in the short nor long term.

The role that the patent system played in the encouragement of innovation in these projects differed from what was predicted by those supporting the patent system and by those against it. Patents were not a factor considered by the researchers associated with the projects in terms of their incentives to engage in their research, their anticipated goals, commercialization of their findings, or funding. The three projects were encouraged by scientific curiosity and genuine interest in the well-being of the participants, were publicly funded, and were developed in public research centres with no links to the private industry. In other words, patents were not the source, driving force, or reason for promoting innovation in this part of the case study. Furthermore, based on the patents granted by the IMPI, patents did not seem to have an impact on the national industry in the field of tuberculosis either. Considering the number of patents obtained before the IMPI in association with tuberculosis and its genetic component, the patent system seems to attract more foreign companies than national ones. Patent infringement was not a concern for these researchers during the research process. Therefore, patents were not a deterrent or obstacle in their R&D activities either.

The role that patents played in access to healthcare was more in accordance with the predictions made by those against the patent system. The P'urhépechas' deplorable conditions with regard to access to healthcare are caused by several factors. Governmental

policies within the public healthcare system and those related to socio-economic development are among those factors. The existing patents on tuberculosis drugs and therapies are another factor. The costs of the most efficient treatment for regular tuberculosis and of all treatment for drug-resistant tuberculosis increase with the existence of patents associated with the medicines. This is likely to occur as well with any future innovative medical product (including, for instance, personalized drugs that could eventually result from the research described in this part of the case study). The increase in costs decreases the chances of the treatment being covered by social security and of the P'urhépechas being able to afford it by themselves. The patent system in medical-related innovation is expected to bring about improvements in people's health. The P'urhépechas already encounter many difficulties having access to healthcare and therefore being healthy and having a good quality of life. Given that the patent system contributes to increasing those difficulties by being an important factor in the high unattainable prices of the most effective drugs, it seems unreasonable to assert that it meets its expectations, at least with respect to the P'urhépechas.

Chapter 5 Mazatecos, Mayas, and Nahuas and their link with Actinic Prurigo

5.1 Introduction

Actinic prurigo is an autoimmune skin disease whose main symptoms are lesions that appear predominantly in the face, chest, neck, and extremities as an allergic reaction to exposure to sunlight.[419] A number of medical genetics research projects have focused on its suggested link to the HLA-DR4 gene, prevalent in Amerindian populations, particularly in Mazatecos, Mayas, and Nahuas.[420]

This chapter and second part of my case study describes two genetic research projects that focus on actinic prurigo in the Mazateca, Maya, and Nahua communities and Mexican mestizos. The two studies showed that a high percentage of actinic prurigo patients are carriers of the HLA-DR4 and HLA-A28 genes. The number of actinic prurigo patients and carriers of these genes is higher in Mazatecos, Mayas, and Nahuas than in Mestizos.

Notwithstanding ongoing medical research, there is no cure for actinic prurigo; instead, there are only means to mitigate some of its symptoms. The reason may be that despite not being one of the formally recognized neglected tropical diseases,[421] actinic

[419] María-Teresa Hojyo-Tomoka et al, "Further evidence of the role of HLA-DR4 in the genetic susceptibility to actinic prurigo" (1997) 36:6 J Am Acad Dermatol 935.

[420] S Zuloaga-Salcedo et al, "Class I and class II major histocompatibility complex genes in Mexican patients with actinic prurigo" (2007) 156:5 Br J Dermatol 1074.

[421] Neglected tropical diseases are a group of infectious (parasitic, viral or bacterial) diseases that cause substantial illness in a large number of the global population (approximately 1 billion people), usually endemic in low income populations in developing regions. They usually inflict severe health burdens on vulnerable populations. National Human Genome Research Institute. CDC, "Neglected Tropical Diseases", (19 April 2017), online: *Center of Disease Control and Prevention CDC* <https://www.cdc.gov/globalhealth/ntd/>; NHGRI, "FAQ About Neglected Diseases", (14 May 2012),

prurigo can be similarly overlooked by drug developers (e.g. pharmaceutical and biotechnology companies, research centers, and even funders) or drug access authorities (e.g. government officials and public healthcare programs).[422] This could be due to the fact that actinic prurigo is not lethal or infectious, the afflicted population is usually of low socio-economic classes in Mexico, Guatemala, Colombia, Bolivia, Peru, and Honduras[423] (as opposed to from developed countries), its prevalence is low (1.5-3.5% of Mexico's general population[424]), and, as a consequence, there is no sizeable, profitable market.[425] Furthermore, even if there were medical advances related to actinic prurigo in the future, it is doubtful that the Mazatecos, Mayas, and Nahuas would have access to them, given the likely high costs of the treatment, the Indigenous Peoples' socio-economic conditions, and the deficient public healthcare system.

A significant concern is that the Mazatecos, Mayas, and Nahuas, as I mentioned in chapter two is true of most Indigenous populations, are primarily devoted to agricultural activities, making it essential that they are able to work outside. Thus, suffering from actinic prurigo directly affects, and in grave cases, prevents, the afflicted Indigenous Peoples' involvement in those activities. This aspect is particularly important to keep in mind because even though actinic prurigo will not result in the death of those who suffer from it, it will greatly affect those people's capabilities and functionings of living the kind of life they choose.

---

online: *National Human Genome Research Institute NHGRI* <https://www.genome.gov/27531964/FAQ-About-Neglected-Diseases>; WHO, "Neglected Tropical Diseases", online: *World Health Organisation WHO* <http://www.who.int/neglected_diseases/diseases/en/>.

[422] NHGRI, *supra* note 421.

[423] Hojyo-Tomoka et al, *supra* note 419.

[424] Man, *supra* note 316 at 51.

[425] Maurer, Rai & Sali, *supra* note 5; NHGRI, *supra* note 421.

Similar to the previous chapter, in this chapter I discuss: access to healthcare and research and development. I first describe details about the Mazateca, Maya, and Nahua communities, including their socio-economic and general healthcare conditions, their usual lifestyles, and their essential needs. This provides the necessary context to understand their vulnerability in terms of healthcare, which in terms of the capability approach, is their conversion factors. I also include information about the actinic prurigo's symptomatology, common treatments, prognosis, and epidemiology. This information allows me to assess the impact of the disease on the Mazatecas', Mayas', and Nahuas' socio-economic conditions, health, and lives in view of the currently available treatment and of the absence of all treatment. It also allows me to argue that even a non-lethal disease such as actinic prurigo can cause havoc in people's lives, which, in terms of the capability approach, will make up their capabilities and functionings.

I then explain the scientific research projects associated with this second part of the case study, including their findings, funding conditions, perspectives and practices related to patents, benefit sharing policies, and impact on the communities. I also describe future research projects in the field. In this chapter, I further the conclusions reached in the previous chapter regarding concrete medical research activities in Mexico involving Indigenous Peoples, their human genetic information, and patents. The difference is that, unlike the previous chapter in which I dealt with a disease that threatened people's lives, in this chapter, I discuss a disease whose lack of treatment threatens people's chosen lifestyles and it highlights the importance of enabling the achievement of those choices.

Similar to the previous chapter, the two research projects of this part of the case study include the collaboration of Granados (INCMNSZ) as one of the co-authors of the publications resulting from the medical genetics projects. Likewise, his participation required the collaboration of his colleagues from the Faculties of Chemistry and Medicine of the UNAM, the ENAH, and the INMEGEN for the access to the Mazateca, Maya, and Nahua communities, collection of samples, anthropological interpretations, and statistical analysis.

5.2 Access to Healthcare within the Mazateca, Maya, and Nahua communities

5.2.1 Mazatecos

The Mazatecos (also called Ha Shuta Enima[426]) are located in the region known as the Cuenca del Papaloapan in the Sierra Madre Oriental (one of Mexico's main mountain ranges) in the states of Oaxaca, Veracruz, and Puebla. The population is of approximately 300,000[427] people inhabiting a territory divided in three regions: high, mid, and low, depending on their location with respect to the mountain range.[428]

[426] Xicohténcatl Luna Ruiz, *Mazatecos. Pueblos Indígenas del México Contemporáneo* (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2007); Indígenas, "Etnografía del pueblo mazateco de Oaxaca - Ha shuta Enima", (20 October 2017), online: *INPI Instituto Nacional de Los Pueblos Indigenas* <http://www.gob.mx/inpi/articulos/etnografia-del-pueblo-mazateco-de-oaxaca-ha-shuta-enima>.

[427] INEGI, "Diferentes lenguas indígenas", (2015), online: *Instituto Nacional de Estadistica y Geografia* <http://cuentame.inegi.org.mx/hipertexto/todas_lenguas.htm>.

[428] Luna Ruiz, *supra* note 426 at 24 & 30; Indígenas, *supra* note 426.

Mazateca Region[429]

76% of the Mazateca population works in the agricultural sector.[430] Any disruption in their agricultural activities, including suffering from actinic prurigo, would have a negative effect on economic lifestyles.

With respect to the infrastructure in the region, most Mazateca homes do not have drinkable tap water (only 15% do), only 10.7% have drainage, and the majority have dirt floors.[431] This makes hygiene habits difficult to implement, particularly when it comes to skin care.

There are two main highways that connect some of the Mazateca communities with Mexico City, Veracruz, and Tehuacán. However, most connecting municipal roads are hardly usable during the rainy season, as they are made up of dirt.

[429] SIL, "Familia popoloca", online: *SIL Mex* <http://www.mexico.sil.org/es/lengua_cultura/popoloca>.
[430] Luna Ruiz, *supra* note 426 at 55; Indígenas, *supra* note 426.
[431] Luna Ruiz, *supra* note 426 at 43 & 55.

With respect to healthcare services and infrastructure, only one of the nine municipalities that comprise the Mazateca region has a hospital, and that facility is only a rural hospital. The remaining eight municipalities have two or three rural medical units administered by the IMSS. Neither the ISSSTE nor the SSA has any healthcare units in the region.[432] Despite the existence of the IMSS and SSA healthcare centres, more than 80% of the population in the Mazateca region is not covered by any type of social security, and therefore any healthcare service has to be paid by the patients themselves.[433] Moreover, 19.2% of Mazatecos do not speak Spanish[434] and the personnel of those healthcare services do not speak Mazateco. The combination of these two factors makes it difficult for many Mazatecos to be treated in those healthcare centres, even in cases of emergencies.[435]

5.2.2 Mayas

The Mayas are located in Mexico in the states of Campeche (9.2%), Quintana Roo (20.6%), and Yucatán (69.5%) (together known as the Yucatan Peninsula).[436] They also

---

[432] INEGI, *Perfil Socio-demografico de la Poblacion que Habla Lengua Indigena.* (Mexico: Instituto Nacional de Estadistica y Geografia, 2009) at 81; IMSS, "Directorio de las Instituciones del Instituto Mexicano del Seguro Social", online: *Instituto Mexicano del Seguro Social* <http://www.imss.gob.mx/directorio>; ISSSTE, *Directorio de Unidades Medicas. ISSSTE* (Mexico: Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado, 2013) at 180–193; Secretaria de Salud de Oaxaca, "Directorio de Hospitales Oaxaca", online: *Secretaria de Salud de Oaxaca* <http://www.salud.oaxaca.gob.mx/directorio-de-hospitales/>.

[433] Luna Ruiz, *supra* note 426 at 44.

[434] INEGI, *supra* note 432 at 80.

[435] For instance, in October 2013, a Mazateca woman was not admitted in the healthcare centre of the city of Oaxaca and gave birth in the lawn of the clinic. Pedro Matias, "Irma, la indígena mazateca que parió en el patio de un hospital", *Proceso* (4 October 2013), online: Proceso <http://www.proceso.com.mx/354510/irma-la-indigena-mazateca-que-pario-en-el-patio-de-un-hospital>; "Mujer da a luz en el pasto de una clínica en Oaxaca", *Excelsior* (4 October 2013), online: *Excélsior* <http://www.*excelsior*.com.mx/nacional/2013/10/04/921864>.

[436] Yucatán is the state with the highest number of people speaking an Indigenous language in the country and this language is Mayan. Mario Humberto Ruz, *Mayas. Pueblos Indígenas del México Contemporáneo. Primera Parte* (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2006) at 17; INEGI, *supra* note 458 at 42; CDI, "Mayas - Etnografía", (2018), online: *Atlas Los Pueblos Indígenas México INPI* <http://atlas.cdi.gob.mx/?page_id=894>.

extend to Belize, Guatemala, and Honduras.[437] The Mayas are the second largest group of Indigenous People in Mexico after the Nahuas.[438] Today, there are more than 1.5 million Mayas.[439]

Mayan Region[440]

In terms of infrastructure, urban cities with a strong Maya component, such as Mérida, Cancún, Chetumal, Campeche, Quintana Roo, and Cozumel, are properly developed. They have airports and 10,000 km of highways.[441] Rural cities, on the other hand, are not. In the rural communities of Campeche, Yucatan, and Quintana Roo, close to 40% of the population lacks drainage, tap water, and electricity, and some of those still lack the use of toilets and latrines.[442] 3.9% of the population that speaks Mayan does not speak Spanish.[443]

---

[437] Ruz, *supra* note 436 at 5–6; CDI, "Mayas - Etnografía", (2018), online: *Atlas Los Pueblos Indígenas México INPI* <http://atlas.cdi.gob.mx/?page_id=894>; Cultura Maya, "Ubicación Geográfica de la Cultura Maya", (2018), online: <https://culturalmaya.com/geografia/>.
[438] Ruz, *supra* note 436 at 22.
[439] CDI, "Mayas – Estadísticas", (2018), online: *Atlas Los Pueblos Indígenas México INPI* <http://atlas.cdi.gob.mx/?page_id=951>.
[440] SIL, "Familia maya", online: *SIL Mex* <http://www.mexico.sil.org/es/lengua_cultura/maya>.
[441] CDI, *Mayas de la Península de Yucatán* (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2009).
[442] Ruz, *supra* note 436 at 53; INEGI, *supra* note 432 at 44.
[443] INEGI, *supra* note 432 at 42.

In economic terms, close to 50% of the Mayan population earns the equivalent of between CDN $135 and $270 a month.[444] Similar to the Mazatecas, the above-mentioned deficiencies in infrastructure in the Mayan communities limit their economic (work-related) options and confirm their condition as vulnerable populations. Their main economic activity is agriculture. The Mayas are located in one of the richest territories of the country in terms of biodiversity. The richness of these territories, particularly that of the Yucatán Peninsula, has greatly favoured agricultural activities. Agricultural activities are of particular relevance to the Mayas, as they are to most Indigenous Peoples, because, they are an important source of income.[445] For instance, their agricultural activities take place in *ejidos*, which are communal lands shared by the members of the community.[446]

The Mayas are also usually employed in construction, gardening, maquiladoras, and domestic cleaning.[447] They also work in animal farming, construction of their homes, furniture and other craftwork, hunting activities for survival (food production), and commerce. Most of the aforesaid economic activities take place outdoors and during the day.

[444] Ruz, *supra* note 436 at 67.
[445] CDI, *supra* note 436.
[446] This system of property was flourished during the Aztec empire. In 1991, the ejidos were abolished as a constitutional right with the execution of the NAFTA Agreement and since then, they have practically disappeared from the entire country except for some communities such as the Mayan in the Península of Yucatán.
[447] Mario Humberto Ruz, *Mayas. Pueblos Indígenas del México Contemporáneo. Segunda Parte* (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2006) at 8.

Failing to adequately treat actinic prurigo prevents those who suffer from it from engaging in most of the aforementioned economic activities. In other words, despite actinic prurigo not being a fatal disease, its prevalence can have a great negative impact on patients' lifestyles (i.e. capabilities and functionings).

The Mayas have deficient access to healthcare for several reasons. First, there is a problem of the availability of healthcare centres in the Maya territory. In Yucatan, out of the nine Mayan municipalities, only Merida and Valladolid have adequate healthcare centres (hospitals, specialty units, clinics, etc.) in terms of number, quality, and specialization. The SSA, ISSSTE, and IMSS administer these healthcare centres. Six of the remaining Mayan municipalities have between one and five centres each, with the majority being rural medical units administered by the IMSS. The remaining municipality (Temozon) does not have any clinics or healthcare centres.[448] The only Mayan municipality in Campeche has one rural medical unit administered by the IMSS, one medical unit administered by the ISSSTE, and one community hospital administered by the SSA.[449] In Quintana Roo, out of the four Mayan municipalities, only one (Benito Juarez) has a reasonable number (over fifteen) of hospitals and clinics administered by the ISSSTE, the IMSS, and the SSA. Out of the remaining three, one has two medical units (IMSS and SSA), another one has one hospital (SSA), and the last one has none.[450] In conclusion, even though there are few healthcare centres available to Mayan communities that belong to the

[448] INEGI, supra note 432 at 43; IMSS, *supra* note 432; ISSSTE, supra note 432 at 303‑311; Secretaria de Salud de Yucatan, "Directorio de Unidades médicas de Yucatán", online: *Secr Salud Yucatan* <http://salud.yucatan.gob.mx/unidades-medicas/>; Secretaria de Salud, *Directorio de Unidades Medicas de la Secretaria de Salud* (Secretaria de Salud).
[449] IMSS, *supra* note 432; ISSSTE, *supra* note 432 at 21–25; Secretaria de Salud, *supra* note 360.
[450] Secretaria de Salud, *supra* note 360; IMSS, *supra* note 432; ISSSTE, *supra* note 432 at 218–223.

SSA and, that therefore do not require affiliation to a social security program, most of the healthcare centres located in the areas where the Mayan communities are settled and administered by the ISSSTE and the IMSS and require such an affiliation. This is a major problem for the Mayas, because even though close to half of the population of the Yucatan Peninsula in general is entitled to the benefits of the public healthcare system, this percentage has decreased to less than 5% in the Maya communities specifically in the state of Yucatán and to 15% in the Maya communities in the state of Campeche.[451]

Furthermore, in some Maya communities, patients lack vehicles to be transported to the clinics and to specialized healthcare centres. Major surgeries and appointments with specialists can only take place in hospitals located in cities.[452]

Second, there is a problem of availability and affordability of medication and treatment. The medication and surgical materials available in the public healthcare centres in the Mayan communities are usually insufficient and restricted to target basic healthcare in most community clinics.[453] Dermatological treatment and medication is more likely to not be considered basic healthcare, and it is specialized.

[451] CDI, *supra* note 441 at 78.
[452] *Ibid* at 82–84.
[453] *Ibid* at 84.

5.2.3 Nahuas

The Nahuas are located in Guerrero, Hidalgo, Puebla, Veracruz, San Luis Potosí, Tlaxcala, and the State of Mexico.[454] They are identified by the region they inhabit.[455]

Nahua Region[456]

Their main economic activities are agriculture and animal husbandry.[457] One of their main agricultural-related innovations is the *milpa* system, which maintains a sustainable use of the land. These practices bring economic and commercial benefits as well as ecological and sustainable advantages to their communities.[458]

---

[454] INEGI, *supra* note 432 at 36.

[455] There are the Nahuas from the Balsas, the Nahuas from Michoacán, the Nahuas from the Huasteca, the Nahuas from the Milpa Alta, the Nahuas from the Mountains, the Nahuas from Puebla, the Nahuas from Texcoco, and the Nahuas from Tlaxcala.

[456] SIL, "Familia náhuatl", online: *SIL Mex* <http://www.mexico.sil.org/es/lengua_cultura/nahuatl>.

[457] Art with natural fibre, clay, papel amate, and leather and the commerce with their art are other economic activities. Esperanza Ignacio Felipe, *Nahuas de la Montaña.* (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2007) at 27; Juan Luna Ruiz, *Nahuas de Tlaxcala* (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2007) at 12–14.

[458] The milpa system is a crop growing system used in Mesoamerica that allows two years of cultivation and requires eight years of fallow or secondary growth to allow natural restore of the land's vegetation and fertility avoiding the use of artificial pesticides and fertilizers and promoting its sustainability. Luis M Arias, "'Milpa' Agroecosystems in Yucatan, Mexico | Agricultural Transition", (14 May 2012), online: *Agroecology.org* <http://ag-transition.org/?initiative=milpa-agroecosystems-in-yucatan-mexico>.

In terms of infrastructure, the Nahuas have some federal highways that connect the municipalities located on the coast. The ones situated in higher areas are connected by some small roads and rough dirt tracks.[459] Regarding access to water and drainage, 20.3% of homes have access to wells, 40.5% have outer piped water, and 46.7% do not have drainage.[460] Only those close to urbanized areas have tap water and drainage, and even those sometimes have problems of water scarcity, which are "solved" by getting water only on specific days.[461] Not all the homes have latrines.[462] These conditions make any healthcare treatment difficult to accomplish, particularly with regard to any skin-related treatment, where hygienic measures and habits are essential.

In terms of healthcare infrastructure, municipalities with large populations have several medical clinics that provide basic preventive services funded by the federal and local governments and the social security services agencies (ISSSTE and IMSS). The number of hospitals and clinics varies greatly depending on the community's degree of isolation. For instance, the municipality of Puebla in the state of Puebla, which holds one of the main cities of Mexico with no strong Nahua presence, has a large number of clinics, hospitals, and even specialty institutions administered by the SSA, the IMSS, and the ISSSTE. However, in the same state, the Nahua municipality of Zoquitlan, has only two

[459] Catherine Good Eshelman & Guadalupe Barrientos Lopez, *Nahuas del Alto Balsas* (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2004) at 11–12.
[460] INEGI, *supra* note 432 at 38.
[461] Metter Marie Wacher Rodarte, *Nahuas de Milpa Alta* (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2006) at 24; CDI, "Pueblos nahuas", (2018), online: *Atlas Los Pueblos Indígenas México INPI* <http://atlas.cdi.gob.mx/?page_id=8271>.
[462] Sandra Monzoy Gutierrez, *Nahuas de la Costa-Sierra de Michoacán* (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2006) at 14 & 27–29; Good Eshelman & Barrientos Lopez, *supra* note 459 at 28; Ignacio Felipe, *supra* note 457 at 56.

rural medicine units administered by the IMSS, one community hospital administered by the ISSSTE, and no healthcare centres administered by the SSA. None of the six Nahua municipalities in Veracruz has SSA hospitals or clinics and, whereas some of those municipalities have fifteen rural clinics administered by the IMSS and the ISSSTE, there are others with only two rural clinics. This is problematic because healthcare centres administered by the IMSS and the ISSSTE require patients to have a social security affiliation in order for them to access healthcare services and most Nahuas lack social security affiliation. The insufficient number of SSA healthcare centres available in or close to the Nahuas communities is neglectful of this situation, and affects the Nahuas' access to healthcare.[463]

Moreover, the staff of the rural clinics is usually comprised of a general practitioner or medical students on their social service rotation, and a nurse. These clinics commonly have insufficient drugs, medicines, and medical equipment. There are other rural clinics that do not even have staff at all.[464] For more specialized diseases or treatments, they have to go to the main cities of the state where there are specialized hospitals. Similar situations occur in the states of Hidalgo, San Luis Potosi, and Guerrero.[465]

[463] IMSS, *supra* note 432; ISSSTE, *supra* note 432; Secretaria de Salud, *supra* note 360.
[464] Only half of the healthcare centres in the region of the Nahuas of the Mountain have a general practitioner and deficient drugs and medicines. Ignacio Felipe, *supra* note 457 at 17.
[465] INEGI, *supra* note 432 at 36–41; Secretaria de Salud, *supra* note 360; IMSS, *supra* note 432; ISSSTE, *supra* note 432 at 102–127, 194–211, 224–238 & 287–302.

5.2.4 Actinic Prurigo in the Mazateca, Maya, and Nahua communities

Actinic prurigo is an autoimmune, non-fatal, and non-contagious skin disease. It consists of a rare form of photodermatosis that is characterized by pruritic symmetric skin lesions predominantly on the face (superciliary arches, eyebrows, malar areas, dorsum of nose and lower lip) chest, neck, and extremities as an allergic reaction to exposure to ultra violet light A and B. Even though relevant aspects of actinic prurigo and its prognosis are still unknown, ultraviolet light seems to trigger excessive TNFα production by keratinocytes (epidermal cells that produce keratin), which causes inflammation and skin lesions.[466]

The lesions are inflamed macules, papules, nodules, crusts, plaques and hyper-pigmentation on the skin that itch and usually appear hours or days after exposure to sunlight. In 45% of the cases, the skin lesions are accompanied by conjunctivitis,[467] hyperemia,[468] photophobia, tearing, hyper-pigmentation, and pseudopterygium[469] that may cause visual impairment.[470] The lesions on the lips, which appear in 65% of the actinic prurigo patients, include inflammation and pruritus, edema,[471] scales, fissures, crusts, and ulceration. In chronic cases, facial skin thickens and it can cause alopecia of the

[466] Estrada-G et al, *supra* note 316 at 893; Hannah D Pile & Jonathan S Crane, "Actinic Prurigo" in *StatPearls* (Treasure Island (FL): StatPearls Publishing, 2019).

[467] Conjunctivitis: "Swelling (inflammation) or infection of the membrane lining the eyelids due to exposure to virus and bacteria and other irritants like chemicals. Its symptoms include blurred vision, crusts on the eyelid, eye pain, gritty feeling in the eyes, increased tearing, itching of the eye, redness of the eye and photophobia." *U.S. National Library of Medicine,* online *s.v.* "conjunctivitis".

[468] Hyperemia: "An increase in the quantity of blood flow to a body part." *Farlex,* online *s.v.* "hyperemia".

[469] Pseudopterygium: A fold of conjunctiva that has become attached to the cornea as a result of injury or ulcer near the limbus." *Farlex,* online *s.v.* "pseudopterygium".

[470] Jorge E Arrese et al, "Effectors of inflammation in actinic prurigo" (2001) 44:6 J Am Acad Dermatol 957 at 957.

[471] Edema: "Swelling condition caused by fluid in body's tissues. It usually occurs in feet, ankles, and legs." *U.S. National Library of Medicine,* online *s.v.* "edema",.

eyebrows.[472] The appearance of the symptoms worsen in summer and sometimes spring. Common complications of actinic prurigo include secondary infections, impetigo,[473] and other irritant contagious dermatitis. Frequent relapses are common. Additionally, some actinic prurigo patients in Mayan communities have shown warts or papules inside their mouths and on their tongues as a symptom of focal epithelial hyperplasia. These warts seem to be associated with the type 13 of the human papilloma virus (HPV), which is highly contagious in environments without tap water and with poor hygienic conditions.[474]

Medical genetic studies suggest that it is very likely that actinic prurigo has a genetic component that, in combination with exposure to ultraviolet light A and B, causes the disease.[475] According to these studies, actinic prurigo has been observed to be predominantly found in Amerindians and mestizos carrying the gene HLA-DR4/DRB1*0407. The populations of Amerindians where this gene has been found and where actinic prurigo has observed to be more recurrent are Mazatecas, Nahuas, Mayas, and Chimilas located principally in Mexico, Colombia, Guatemala, Bolivia, Peru, and Honduras.[476] Some actinic prurigo cases have been found as well in the United States,

[472] María-Teresa Hojyo-Tomoka et al, "Diagnosis and treatment of actinic prurigo" (2003) 16:1 Dermatol Ther 40 at 380.

[473] Impetigo is a skin disease caused by streptococcus or staphylococcus bacteria characterized by a single or multiple itchy blisters filled with pus and rash on face, lips, arms, and legs and swollen lymph nodes near the infection. *U.S. National Library of Medicine,* online *s.v.* "impetigo",.

[474] Maria R González-Losa et al, "Multifocal epithelial hyperplasia in a community in the Mayan area of Mexico" (2011) 50:3 Int J Dermatol 304 at 304–309; Cristina García-Corona et al, "HLA-DR alleles associated with skin warts induced by human papillomavirus infection" (2010) 49:12 Int J Dermatol 1376 at 1376–1379.

[475] Hojyo-Tomoka et al, *supra* note 419; Hojyo-Tomoka et al, *supra* note 472; Jane M McGregor et al, "Genetic Modeling of Abnormal Photosensitivity in Families with Polymorphic Light Eruption and Actinic Prurigo" (2000) 115:3 J Invest Dermatol 471; Tp Millard et al, "A candidate gene analysis of three related photosensitivity disorders: cutaneous lupus erythematosus, polymorphic light eruption and actinic prurigo" (2001) 145:2 Br J Dermatol 229; Pile & Crane, *supra* note 466.

[476] Hojyo-Tomoka et al, *supra* note 472; M Duran De Rueda, Jaime E Bernal & Clara Patricia Ordonez, "Actinic Prurigo at Sea Level in Colombia" (1989) 28:4 Int J Dermatol 228; Alfonso Suárez et al,

Canada, Great Britain, and North of Argentina. One of the reasons for the global spread of actinic prurigo is the immigration of some of the Amerindian and mestizos, carrying the relevant gene to those countries.[477] Another reason is that actinic prurigo has also been linked to the antigens HLA-A24 and HLA-Cw4 common in Cree from Saskatchewan[478] and the allele DRB1*14 found in the Inuit of Canada (.1%-4%).[479] Notwithstanding the high percentages related to the frequency with which the gene HLA-DR4/ DRB1*0407 is found in actinic prurigo patients, only 3.5% of the Amerindian population and less than 1% of the Mexican mestizo population is afflicted by the disease.[480]

Even though the disease can appear at any age, its onset usually occurs during childhood (one third of patients are children). It most predominantly afflicts women (ratio 2:1).[481] The seriousness of the lesions depends on the stage of the disease, the intensity of the ultraviolet light, the time of the day on which the patients expose themselves to sunlight, and the amount of time of exposure. The severity of the disease also depends on the latitude and altitude where the actinic prurigo patients reside, because the intensity of the ultraviolet light varies depending on the location.[482] These facts are particularly troublesome for the Mayas, Nahuas, and Mazatecos, due to the recurrence of the HLA-DRB1*0407 gene observed in these populations, the location of their residence (high altitudes), and their

---

"Association of HLA subtype DRB1*0407 in Colombian patients with actinic prurigo" (2006) 22:2 Photodermatol Photoimmunol Photomed 55.

[477] Marni C Wiseman et al, "Actinic prurigo: Clinical features and HLA associations in a Canadian Inuit population" (2001) 44:6 J Am Acad Dermatol 952; Paula Boggio et al, "Prurigo actínico: A propósito de un caso" (2006) 104:6 Arch Argent Pediatría 530.

[478] D P Sheridan et al, "HLA typing in actinic prurigo" (1990) 22:6 Pt 1 J Am Acad Dermatol 1019.

[479] Wiseman et al, *supra* note 477.

[480] Man, *supra* note 316 at 51.

[481] Boggio et al, *supra* note 477 at 530; Emma Salford Royal, *Actinic Prurigo* (United Kingdom: Salford Royal NHS Foundation Trust, 2010) at 2.

[482] Arrese et al, *supra* note 470 at 957.

daily activities (agriculture and animal farming, which require them to spend a great number of hours outdoors, under direct sunlight, and during the most harmful hours of the day).

There is no cure for actinic prurigo; however, some of its effects, such as the lesions, can be controlled. For instance, sun exposure at certain times of the day should be avoided, particularly between 11 am and 3 pm. Additionally, thalidomide can be used to treat some of the effects, as it helps to reduce the production of tumour necrosis factor alpha and reduces the inflammations of most lesions. [483] Patients suffering from actinic prurigo, apart from pregnant women, are prescribed thalidomide tablets (generally one tablet a day) for at least two months to treat the lesions.[484] Immune-suppressors are also prescribed in the most acute cases. Additionally, antihistamines, topical steroids, and anti-inflammatory creams, such as corticosteroid, are recommended to help reduce the rash and itching. In chronic cases, methotrexate, a drug used in treatment of cancer and autoimmune diseases to inhibit cellular reproduction is prescribed as well. Finally, sunscreens must be used to prevent the rash from developing. The treatment for the conjunctivitis is 2% cyclosporine A. Complications, such as secondary infections or eczema, are treated with oral antibiotics or topical Burow[485] solution.[486]

[483] Estrada-G et al, *supra* note 316; Pile & Crane, *supra* note 466.
[484] Salford Royal, *supra* note 481 at 3; Granados Arriola, *supra* note 357.
[485] Burow's solution: "A liquid preparation containing aluminum sulfate, acetic acid, precipitated calcium carbonate, and water, used as a topical astringent, antiseptic, and antipyretic for a wide variety of skin disorders. Also called aluminium acetate solution." *Medical Free Dictionary,* online *s.v.* "Burow's solution".
[486] Hojyo-Tomoka et al, *supra* note 472; Hojyo-Tomoka et al, *supra* note 12; Salford Royal, *supra* note 481; Pile & Crane, *supra* note 466.

In addition to the immediate measures and medication mentioned above, long-term precautions are considered essential. Some of these precautions include daily protection from the sun exposure through the use of protective articles of clothing (such as sunglasses, hats, umbrellas, and long sleeve shirts). Sunscreens provide additional protection in addition to these measures, but they are not a substitution. Staying under outdoor shade (i.e. provided by trees) or indoors, but close to windows, does not provide adequate protection, because ultraviolet light is not properly filtered.[487]

There are up to 20 places where the disease can be diagnosed through a clinical examination and a skin or lip biopsy that costs around $80 USD. The diagnostic test is not patented. The places where actinic prurigo can be diagnosed and treated are healthcare centres located in Mexico City, San Luis Potosí, and Jalisco. The treatment of actinic prurigo in Mexico is usually provided through the public healthcare system, although there are some private practices as well that could provide treatment. [488] The thalidomide used in the treatment is usually prescribed for two-months periods. The cost of one box of 50 tablets is around USD $100.[489] Even though thalidomide was invented and first patented in the 1950s, there still are associated patents and patent applications[490] and there is not yet a generic version. The medication is only provided at no charge for patients classified as level 1, which is the level reserved for people with no fixed address (i.e. homeless). The patients classified in the subsequent levels pay different fees in accordance with their socio-

[487] Hojyo-Tomoka et al, *supra* note 472; Hojyo-Tomoka et al, *supra* note 12; Salford Royal, *supra* note 481.
[488] Granados Arriola, *supra* note 357.
[489] "Talizer 100mg c 50", online: Farmacias San Pablo <https://www.farmaciasanpablo.com.mx/medicamentos/especialidades-medicas/s---t/talizer-50-tabletas-caja/p/000000000030330002>.
[490] Patent search at the IMPI's database using the keyword "talidomida".

economic level. Indigenous Peoples are usually classified as level 2, which requires them to pay a small amount for their medication, tests, and their medical appointments.[491] However, given that inhabitants of rural areas and Indigenous communities commonly have poor medical coverage and that thalidomide is a controlled drug in Mexico, they also have to pay for travel expenses to go to specific, usually distant, healthcare centres to have their appointments, get diagnosed, get their prescriptions, and obtain their medication. Only some of the Nahua (none of the Maya or Mazateca) communities are located close to those centres. Another aspect to consider in regard to Indigenous Peoples' access to healthcare is the time they have to wait to actually receive healthcare services. The insufficient resources in the public healthcare system in comparison with the large population and the population's needs make the appointments few and far between. In other words, similar to the situation described with respect to the P'urhépechas of chapter four, the geographical isolation and the low income prevalent in the Nahua, Maya, and Mazateca communities are conversion factors that need to be kept in mind when determining whether they in fact have access to healthcare services.

Even if the Indigenous patients manage to get treatment for their actinic prurigo, there are a number of problems resulting from a merely palliative approach to the disease (i.e. simply controlling the lesions and implementing long term precautions). On the one hand, the current treatment requires the patients to use thalidomide for a minimum period of two months. This is problematic because of the known thalidomide's teratogenesis and

[491] Guadalupe Soto Estrada, Miguel Angel Lutzow Steiner & Rafael Gonzalez Guzman, "Rasgos generales del sistema de salud en México." in Rafael Gonzalez Guzman, Laura Moreno Altamirano & Juan Manuel Castro Albarran, eds., *Coleccion Salud Publica Para Estudios Medicos Vol 1 La Salud Publica y El Trabajo En Comunidad* (Mexico: McGraw Hill, 2010) at 155.

other negative side effects (e.g. peripheral neuropathy) when used for long periods of time. Using thalidomide periodically, even if it is for only for two months every time an onset of actinic prurigo takes place, is therefore not recommended.[492]

On the other hand, avoiding sun exposure, even just at the times of the day where ultra violet light A and B are strongest, means that actinic prurigo patients will not be able to do any agriculture, animal farming, or any other outdoors activity. This could greatly affect the patients', the patients' families', and the patients' communities' economic conditions, given that not being able to work will reduce their families' cash income and their communities' economic activities, and overall diminish their quality of life. Suggesting Mazatecos, Mayas or Nahuas to devote to an economic activity that avoids sunlight is not a simple (feasible) solution and could greatly affect not only their chosen lifestyles (capabilities and functionings), but also their quality of life in general.

Moreover, Indigenous patients will probably discontinue their treatment prematurely, given that considering their low socio-economic conditions, it would not be surprising if they could not afford the follow-up treatment. Likewise, they may rather sell the remaining medication once they stop feeling sick in order to have an additional source of income.[493]

---

[492] Vinay Chaudhry et al, "Characteristics of bortezomib- and thalidomide-induced peripheral neuropathy" (2008) 13:4 J Peripher Nerv Syst JPNS 275; V Chaudhry et al, "Thalidomide-induced neuropathy" (2002) 59:12 Neurology 1872; Linda Mileshkin et al, "Development of neuropathy in patients with myeloma treated with thalidomide: patterns of occurrence and the role of electrophysiologic monitoring" (2006) 24:27 J Clin Oncol Off J Am Soc Clin Oncol 4507; Neil Vargesson, "Thalidomide-induced teratogenesis: History and mechanisms" (2015) 105:2 Birth Defects Res 140.

[493] Roberto Estrada et al, "Specialized dermatological care for marginalized populations and education at the primary care level: is community dermatology a feasible proposal?" (2012) 51:11 Int J Dermatol 1345 at 1348.

Finally, simply ignoring and not treating the symptoms of actinic prurigo or letting the disease relapse can gravely affect the life of those afflicted by it in two ways. First, the severity and visibility of the lesions may cause a very negative impact on the patients' social and emotional life. This greatly impacts their psychological, emotional, and physical well-being. Second, an untreated or recurrent case of actinic prurigo is likely to result in complications, such as secondary infections, impetigo, and other irritant contagious dermatitis, creating thus a health problem in the whole community.

5.3 Research and Development

5.3.1 Research Projects

Actinic prurigo has been researched for decades by researchers from Mexico, Colombia, Argentina, Spain, Belgium, United Kingdom, United States, Australia, among many other countries. The focus, as with most diseases, has been on whether its onset is associated with the genetics of those afflicted by it, the comparison of the evolution in different age, geographical or racial populations, and the response to a number of treatments.[494] Mexico has offered a particularly interesting niche for research on actinic prurigo, as the disease has been associated with the alleles HLA-DR4 and HLA-DRB1*0407, both found in Mexican mestizos and Indigenous Peoples. Specifically, the results of studies involving Mexican patients have shown that 92.8% of actinic prurigo

[494] Suárez et al, *supra* note 516; Rueda, Bernal & Ordonez, *supra* note 516; Boggio et al, *supra* note 517; Wiseman et al, *supra* note 517; Hojyo-Tomoka et al, *supra* note 12; Hojyo-Tomoka et al, *supra* note 512; Zuloaga-Salcedo et al, *supra* note 442.

patients have the HLA-DR4 allele and 80.7% the HLA-DRB1*0407 allele.[495] Colombia, Guatemala, Bolivia, Peru, and Honduras are other countries with actinic prurigo patients who carry these genes.[496]

This part of the case study focuses on two medical genetics research projects that examine actinic prurigo and its prevalence in the Mexican mestizo population and in the Indigenous People's in Mexico, suggesting that such prevalence is associated with the presence of the alleles HLA-DR4 and HLA-DRB1*0407.

5.3.2 Specific Scientific Findings

The first research project, "HLA-DR4 Allele Frequencies on Indian and Mestizo Population from Mexico", corroborates the link between actinic prurigo and the HLA-DR4 allele in American populations, including Mexicans. There are currently fifty known variants of this allele[497] (thirty-two at the time of the study); given that they are specific to particular ethnic groups and populations, discovering those variants can help to identify the ethnic group to which the subject/patient belongs. This project included 228 healthy Mexican individuals who carry the HLA-DR4 allele. Out of those 228, 99 were Mestizos from Mexico City, 71 Mazatecos from Huahutla de Jimenez and San Mateo Yoloxóchitl in the state of Oaxaca, and 58 Nahuas. In this study, the HLA-DR4 allele, which is associated with a predisposition to actinic prurigo, was found to be prevalent in 47 out of

[495] In studies involving Colombian patients, 97.5% of actinic prurigo patients presented the HLA DRB1*0407. Suárez et al, *supra* note 476 at 56; Zuloaga-Salcedo et al, *supra* note 420.
[496] Boggio et al, *supra* note 477 at 530.
[497] Granados Arriola, *supra* note 357.

99 Mestizos, 69 out of 71 Mazatecas, and 31 out of 58 Nahuas.[498] Since the HLA-DR4 has been associated with rheumatoid arthritis and actinic prurigo, identifying this allele can help to better understand the pathogenesis of those diseases and to more effectively diagnose and treat them in a timely manner.[499]

The second research project, entitled "Actinic Prurigo: An Update",[500] suggests that the prevalence of actinic prurigo in Mexicans results from a genetic predisposition. A number of research projects have focused on finding a link between actinic prurigo and the expression of a MHC (major histocompatibility complex). This particular research project studied 29 Mexican actinic prurigo patients and a control group of 100. Out of all the actinic prurigo patients studied (29), 93.1% (27) were carriers of the HLA-DR4 and 86.2% of HLA-A28. In contrast, out of the subjects of the control group, the percentages were 57% and 22% respectively.[501] The conclusion reached in this study was that class I and/or class II MHC antigenes are involved in the pathogenesis of actinic prurigo.[502]

5.3.3 Non-Scientific Details and the Involvement of Patents

Both research projects that comprise this second part of the case study include several co-authors, with Granados being one. Granados' collaboration on both research projects included the participation of the same colleagues as in the three research projects

[498] Vargas-Alarcón et al, *supra* note 12.
[499] Granados Arriola, *supra* note 357.
[500] Hojyo-Tomoka et al, *supra* note 12 at 383.
[501] *Ibid* at 382.
[502] *Ibid* at 383.

of the previous part of the case study for the collection of samples, the various angles of interpretation and analysis, and the anthropological work.

None of the researchers obtained or even applied for a patent associated with their research. The researchers' incentives to get involved in research projects involving actinic prurigo included scientific curiosity and an interest in improving the Indigenous community's well-being. Their main scientific/professional goals were to publish articles, get involved in further collaborations, and become National Researchers.[503] The only form of intellectual property associated with the research projects was copyright over the publications resulting from the research.

Given that the researchers/collectors working with Granados were the same as in the first part of the case study, benefit sharing practices in these research projects included similar services, namely basic, simple healthcare and medical services, medication that would treat their actinic prurigo, results of the analysis made, including glucose, triglycerides, and cholesterol levels, blood type, blood pressure, and their percentage of Indigenous ancestry, as well as driving them to the nearest healthcare centre when needed.[504] Indirect commercial benefits for the community, such as paying for the researchers' stay or food or temporarily employing members of the community, was also a form of benefit sharing.[505]

[503] Granados Arriola, *supra* note 357; Menjivar Iraheta, *supra* note 397; UNAM, *supra* note 399; Acuña Alonzo, *supra* note 397; Ballesteros Romano, *supra* note 397.
[504] Granados Arriola, *supra* note 357; Acuña Alonzo, *supra* note 397; Ballesteros Romano, *supra* note 397; UNAM, *supra* note 399.
[505] INCMNSZ, *supra* note 397.

The resources to fund Granados' collaborations to both research projects and those of his team were also public: CONACYT grants and UNAM's resources. Like in the first part of the case study, there were no private funds and no partnerships with the national or international private industries reported.[506]

None of the interviewed researchers performed a state of the art background check regarding existing patents associated with any of the elements of the actinic prurigo research projects. None of the researchers were contacted by any patent holder preventing them from engaging in any research project. This is noteworthy given the 49 patents associated with actinic prurigo and the genes and antigens studied in the research projects granted by the IMPI that I mention below.

Finally, based on patents granted by the IMPI, the national research area does not seem to consider patents a priority. In the search I performed[507] at the IMPI's patent database, I found 4 patents related to pruritic conditions, 4 patents concerning actinic conditions, 5 associated with the HLA-DR4 receptor, and 36 related to the HLA antigene. These patents were granted on inventions that cover: methods and processes, compositions of matter, and products used in treating pruritic and actinic conditions. The patents on methods and processes refer to inventions that create substances, antibodies, and proteins

[506] Granados Arriola, *supra* note 357; Menjivar Iraheta, *supra* note 397; UNAM, *supra* note 399; Acuña Alonzo, *supra* note 397; Ballesteros Romano, *supra* note 397.

[507] As in the first part of the case study, the systematic search was done using the search engine of the IMPI's patents database. The keywords used included: "prurigo actinico," "prurigo," "actinico," "HLA DR4," and "HLA" alone and in combination with each other. The search was conducted during the first six days of May 2014 and verified for updates on the first six days of December 2015 and the last days of May 2019. I only included patents granted between 1994 and 2018.

necessary in processes that induce the expression of HLA-DR4 receptor and the HLA antigene used in genetic diagnostic tests and drugs associated with actinic prurigo (thalidomide). The patents on compositions of matter cover substances, proteins, molecules, antigenes, and antibodies, either isolated from the body or artificially created, as well as their derivatives, which interact with the genes and receptors on which the projects focus. The patents on products encompass medication (thalidomide). However, all of the patents mentioned above are owned by foreign research centres and institutions, being those located in the United States, Germany, France, Australia, South Korea, and Japan the ones who hold the most patents in the field. All the 49 patents retrieved were still valid by December 2018.

5.3.4 Future Research

Research focusing on actinic prurigo in Mexican populations is still ongoing. The focus of some of this research is on Mexican mestizos, Mexican Indigenous Peoples in Mexico, and on comparing Mexican populations with populations of other countries.[508] Granados and the people with whom he collaborated in the research projects of this part of the case study have continued their research on actinic prurigo and have expanded it to analyze the way in which their findings can correlate with other diseases, such as HPV, and with other Indigenous populations.[509] They are also collaborating on projects that apply

[508] Katya Pulido Diaz et al, "Actinic Prurigo in a Mexican Patient: Case Report" (2014) 117:2 Oral Surg Oral Med Oral Pathol Oral Radiol e136 at See for instance:; So Yeon Paek et al, "Skin diseases in rural Yucatan, Mexico" (2012) 51:7 Int J Dermatol 823; Ana MO Miranda et al, "Actinic prurigo of the lip: Two case reports" (2014) 2:8 World J Clin Cases WJCC 385.

[509] Sofía Bernal-Silva et al, "HLA-DRB1 Class II antigen level alleles are associated with persistent HPV infection in Mexican women; a pilot study" (2013) 8:1 Infect Agent Cancer 31; García-Corona et al, *supra* note 474; Cristina García-Corona et al, "Association of HLA-DR4 (DRB1*0404) with human papillomavirus infection in patients with focal epithelial hyperplasia" (2004) 140:10 Arch Dermatol 1227.

and expand their previous findings to anthropological studies that look at the Mexican genetic diversity from evolutionary-adaptive and historical-demographical perspectives.[510] Then, they use these perspectives to try to explain and predict the epidemiological courses of certain diseases and set the basis for further biomedical and immunological innovation.[511]

In none of these subsequent projects have the interviewed researchers applied for patents, nor do they plan to apply. Their incentives have continued to be scientific curiosity and an interest of helping the studied communities. Their funding resources have also continued to originate from governmental agencies and hosting institutions.

However, the disease still lacks a cure and its correlation with other diseases such as HPV is still not fully understood. This requires further research and therefore, further funding. A good way to ensure funding would be to attract diverse sources, including those of the private sector. Attracting the private sector through the patent system may be difficult, however, given that actinic prurigo is not prevalent in populations with profitable markets. A disease that lacks a profitable market does not easily attract private investment

[510] Proyecto Candela, *supra* note 272; University College London, *supra* note 272.

[511] Andrés Moreno-Estrada et al, "Human genetics. The genetics of Mexico recapitulates Native American substructure and affects biomedical traits" (2014) 344:6189 Science 1280; Rodrigo Barquera & Julio Granados Arriola, "La Diversidad Biologica en los Haplotipos del Sistema HLA en las Poblaciones Mestizas de Mexico." (2013) 20:58 Cuicuilco Revista de la Escuela Nacional de Antropologia E Historia 197; Rodrigo Barquera et al., "Una primera aproximación a la generación de un mapa inmunogenético de la población mexicana" (2016) 16:0 Estudios de Antropologia Biológica, online: <http://www.revistas.unam.mx/index.php/eab/article/view/56706>; Fuzuki Mizuno et al, "Complete mitogenome analysis of Indigenous populations in Mexico: its relevance for the origin of Mesoamericans" (2014) 59:7 J Hum Genet 359.

because, there are low chances of profiting from commercializing the medical products and/or the patents associated with them.

5.4 Final Remarks

There is a constant interest in researching the etiology of actinic prurigo. This interest stems from the severity of the lesions and scars that the disease causes,[512] the effect that avoiding sunlight would have on the patients' lifestyles,[513] and the importance of identifying the genetic factor(s) in order to understand the disease's etiology and possibly find a more efficient and safer cure.[514] Despite this scientific and medical interest in actinic prurigo, the disease still lacks a cure. The current treatment only treats the symptoms in the short term and requires that the actinic prurigo patients avoid direct daylight during the most productive hours of the day.

The studies of actinic prurigo patients with Mexican mestizo and Indigenous ancestry that I discussed in this chapter suggest a relation between the HLA-DR4 gene, frequently found in Mexicans, and a predisposition to actinic prurigo. These cases are particularly relevant for two reasons. First, they provide the opportunity to determine the aforementioned genetic predisposition. Second, they also provide the chance to assess the magnitude of the effect that avoiding sunlight would have on the Indigenous communities' lives.

---

[512] Hojyo-Tomoka et al, *supra* note 472; Hojyo-Tomoka et al, *supra* note 12.
[513] Martha C Valbuena, Sandra Muvdi & Henry W Lim, "Actinic Prurigo" (2014) 32:3 Dermatol Clin 335.
[514] Vargas-Alarcón et al, *supra* note 12; Hojyo-Tomoka et al, *supra* note 472; Hojyo-Tomoka et al, *supra* note 419.

Agricultural activities have a substantial importance for the Mazatecas, Mayas, and Nahuas. This shows the need for further research and development to find a treatment that does not require the avoidance of daylight.

Patents, like in the first part of the case study, did not noticeable play a role in the research projects. The interviewed researchers did not consider them an incentive or a deterrent with regard to their projects. Despite this not being completely unexpected given that the interviewed researchers were the same for the research projects of both parts of the case study, it is still interesting to observe that the researchers' practices remain the same throughout the years (the projects took place in different years, from 1995 to 2010), in spite of the diseases being different (TB having a more profitable market than actinic prurigo), and regardless of the other co-authors of the articles being different. Furthermore, this seemed to be the case also for other national researchers or research centres, as I found only a few patents associated with actinic prurigo and they were all owned by foreign companies, universities or research centres. Patents did not seem to be the source of funding for any of the research projects either, as they were all publicly funded.

Nonetheless, patents did prevent generics from entering the market. The treatment prescribed for actinic prurigo requires the use of thalidomide for relatively long periods (2 months). The cost of the treatment is very high for patients belonging to Indigenous Peoples (as well as for people living under the poverty line) to afford it by themselves. Therefore, they depend on the public healthcare system to provide them with this treatment. However,

conversion factors such as their geographical isolation, combined with the inefficiencies and insufficiencies of the public healthcare system, make providing and accessing services difficult. For these same reasons, even if a cure or a more efficient treatment for actinic prurigo were found in the future, the Mazatecas, Mayas, and Nahuas, like other Indigenous Peoples in Mexico, may not have access to it and therefore, may not benefit from the innovative medical products.

Conclusions to Section 3

The objective of the two chapters that make up the case study was to provide two illustrative examples of how the combination of vulnerable populations, specific and concrete conditions surrounding R&D activities involving those populations as research subjects, those populations' access to healthcare, and the role that patents played, interact. This level of specialization provided a more concrete and visual image of the way in which the circumstances and conditions (e.g. poverty, isolation, malnutrition, etc.) in which vulnerable populations live (i.e. their conversion factors) can affect the impact that the different systems, programs, and policies (e.g. patent system and healthcare system) have on people's lives (e.g. their health). Furthermore, it contributed to a clearer view and understanding of the importance of people's ability to choose their own lifestyles (i.e. functionings) (e.g. being healthy) and of providing (or at least not complicating) the possibilities (i.e. capabilities) of attaining those choices. It also provided a snapshot of the role that patents and other circumstances played in actual research projects to serve simply as point of reference.

With the foregoing in mind, each chapter focused on medical research involving genetics and access to healthcare in Mexico. They involved a specific team of researchers with different backgrounds (immunologists, anthropologists, chemists, geneticists, administrative staff) affiliated with different hosting institutions (public hospitals, public research centres, and public universities in Mexico City). Each chapter focused on a disease with a genetic component: tuberculosis and actinic prurigo with two different effects: resistance in the case of tuberculosis and predisposition in the case of actinic prurigo. The research projects involved as well specific Indigenous populations: P'urhépechas, Mazatecas, Mayas, and Nahuas as participants to the medical research projects and as individuals from vulnerable populations trying to access healthcare services.

With respect to their activities of R&D, most of the interviewed researchers did not consider the patent system to have provided an incentive to get involved in their research projects. Furthermore, since they admitted to not being concerned with the existence of previous patents and were not contacted by any patent holder to prevent them from engaging in any research activity, they did not consider patents to be a deterrent from participating in a specific research area either. However, they mentioned being aware of the asserted advantages of patents for private investment and the risks for further research and collaboration. While the interviewed researchers whose background was technology transfer and administration were more enthusiastic about the advantages of patents for future research and development, those directly involved in the medical research and the Indigenous Peoples were more concerned with the risks. These awareness and concerns were not based on personal experience, but on reflection on the discussions about the patent

system they are aware exist. Finally, all of the projects in which the interviewed researchers have participated are still in the basic research stages; neither has translated into clinical commercializable products. Despite these findings being interesting, it is important to keep in mind that the opinions collected intended simply to provide a greater insight into the conduct and context of an actual research project and therefore, they should not be considered representative of the vast research community, as they refer to the activities of a very small group of researchers.

With respect to access to healthcare, the four Indigenous Peoples herein discussed exhibited worrisome levels of extreme poverty and isolation. This extreme poverty and isolation translated into conditions of extremely low socio-economic levels, and deplorable healthcare, all of which deeply affect these vulnerable populations' basic capabilities. Regarding the deplorable healthcare, the inadequate access to healthcare suffered by these Indigenous Peoples has been the result of a number of interacting factors, including ineffective health and socio-economic policies and faulty protection regulation of Indigenous Peoples. However, there has been another factor: costly and unaffordable medical products. Medical products, such as diagnostic tests, drugs, and therapies that are too expensive are not included in the public healthcare system.

As discussed in chapter three, patents tend to make medical products expensive. Having the exclusive right to use, make, sell, and import the invention and to prevent others from doing so, allows the patent holder to set the price for the invention and to control, or at least discourage, competitors. Patents can also prevent generics, as they can only be

commercialized once the patents expire. This effect was observed in my case study. In the first part of the case study, the patents of the first generation of antibiotics used to treat tuberculosis are expired. These antibiotics have generic versions and their prices are a lot lower than those of fifth generation antibiotics, whose patents were still valid at the time of my research and do not have generic versions. The public healthcare system covers mainly generic medication, with only few exceptions. If medical products are not included in the public healthcare system, it is very likely that the P'urhépechas will be unable to afford them, given their socio-economic conditions. This shows that the patent system may in fact worsen the already difficult access to healthcare that vulnerable populations, such as the P'urhépechas have.

Section 4

Chapters 6, 7, 8 and 9. Justification of Patent System in Health-Related Innovation in Mexico

Introduction to Section 4

There are two subjects that are associated with how the patent system is justified in health-related innovation: inventive activity and access to healthcare. In my previous chapters, I have described circumstances specific to Mexico that are connected to both subjects.

The deficient healthcare conditions I found in the P'urhépecha, Mazateca, Nahuan, and Maya communities (chapters four and five) as well as in almost half of Mexico's population (chapter two) may stem from the population's poverty and/or the government's ineffectual socio-economic policies that fail to ensure that these populations have a decent quality of life. Therefore, proper socio-economic policies and public funding could help alleviate some of the problems surrounding deficient nutrition, inappropriate hygienic habits, inadequate healthcare infrastructure (e.g. hospitals, clinics, and medical equipment), and certain aspects of insufficient healthcare services (e.g. medication supply and staff availability). However, the population's poverty and Mexico's faulty socio-economic policies are not the only factors in deficient access to healthcare services. As I have been demonstrating in the previous chapters, the patent system can affect access to healthcare services as well.

Patented medication tends to be more expensive than non-patented medication. This results in most patented medication being excluded from the public healthcare system. Since close to half of the population in Mexico lives under the poverty line, most rely on the public healthcare system, and therefore will have access to mostly non-patented medication. Non-patented medication includes drugs that were either never patented (because their inventors decided to not obtain patents or because the invention could not be patented due to non-compliance with the necessary requirements) or whose patents already expired. Generics belong to this last category. Even though generics are generally very useful, previous generation generic drugs may not be as effective in curing a disease as are currently patented drugs, given that the latter tend to be more up-to-date with mutations in pathogens, the evolution of the pathogens that they treat, and with newly developed resistances. This was, for instance, the case of the P'urhépechas in the first part of my case study (chapter four), who only had access to the first and second generation of antibiotics (generics) to cure their tuberculosis, and therefore more commonly relapsed or developed drug-resistant tuberculosis. As a result, I argue that, as necessary as is the implementation of proper policies to improve the population's economic conditions, nutrition, hygiene, and healthcare infrastructure, it is not sufficient to improve access to healthcare. For this reason, in this section I will go into a deeper analysis on the terms in which the patent system regulation and implementation also contribute to the unavailability and inaccessibility of necessary medication and diagnostic tools.

Likewise, as described in Mexico's patent legislation and policies (e.g. Industrial Property Law and IMPI's objectives) as well as governmental plans, policies, and strategies

(e.g. National Plan of Development, CONACYT funding policies, and SNI program), the purpose of Mexico's patent system is to promote innovation for the benefit of society. This benefit serves as the justification for granting the exclusive rights that compose the patent system. Mexico's pharmaceutical industry is comprised of national and foreign companies. National companies focus on generics, biological products, and similares, while foreign companies concentrate on innovative drugs (chapter three). All these types of products are available in the Mexican market. There remains, however, a concern with respect to diseases endemic to Mexico and that lack a profitable market. This was the case of the actinic prurigo in the Nahua, Mazateca, and Maya communities (chapter five), which lacks an effective treatment.

Then, the problem is that it is unclear what constitutes "benefit." Concerning medical innovation, is the mere existence of innovative products and their availability on the market enough to consider them beneficial for society, irrespective of who can access it? Or should ensuring that the majority of the population has the ability to access the patented invention constitute that "benefit" that would justify granting and enforcing patents on medical innovations? In my first chapter, I proposed that utility/welfare, for purposes of justifying the patent system, should be determined assessing to what extent people have the opportunity to actually achieve their functionings and capabilities and to improve their quality of life. In this final section, I apply this definition of utility/welfare to health-related innovation and I argue that upholding the need to ensure universal access to necessary (either patented or non-patented) medication, treatment, and diagnostic tools

should constitute the "benefit" that the patent system is supposedly aiming to achieve in innovations involving medical applications.

This last section comprises four chapters: six, seven, eight and nine. In the first chapter of this section (chapter six), I analyze the effects that the patent system may have on innovation in medical genetics as a source of better healthcare. I also look at the effects that the patent system may have on access to healthcare. This analysis examines the benefits and the concerns as discussed in the literature. These benefits and concerns serve as a blueprint for chapter seven, where I analyze which of these effects can be corroborated in Mexico based on the case study of chapters four and five and the details of Mexico's population and healthcare and patent systems presented in chapters two and three. In chapter eight, I set the theoretical basis for the discussion in my last chapter regarding the elements that would justify the patent system in Mexico in health-related innovation. I do this by applying the concepts and justifications of utilitarianism and capability approach that I described in chapter one to the concerns and benefits of the patent system discussed in chapters six and seven. Finally, in chapter nine, I propose a definition of "utility/welfare" that contains the elements that would justify the patent system in Mexico in health-related innovation and finish by suggesting exploring the use more open and collaborative innovation models to better achieve that "utility/welfare".

Chapter 6 Patent System, Health-Related Innovation, and Access to Healthcare

Discussions regarding the patent system revolve around several topics, including procedural issues, most adequate scope of protection, effectiveness and productivity, appropriate fields or areas of applicability, and concerns and benefits. Except for those on procedural issues, these discussions contribute to finding a justification of the patent system.

In this chapter, I identify and explain the main benefits and concerns regarding the patent system in health-related innovation as they are discussed in the literature. Corroborated benefits and concerns make up relevant capabilities and functionings and thereby, the utility/welfare that I suggest should be used to determine whether the patent system is justified in Mexico in the health-related innovation.

6.1 Benefits of the Patent System on Health-Related Innovation and Access to Healthcare as Discussed in the Literature

The first benefit that the patent system is said to bring and which justifies its current regulation and implementation is the improvement of people's health. The pharmaceutical and biotechnology industries claim that the current patent system is essential for them to be willing and able to engage in R&D and create medical products that improve health.[515] They argue that the exclusive rights to make, use, sell, and import their invention granted

[515] Gold et al, *supra* note 2; Andrew Ward, "GSK to relax intellectual property and help developing world - FT.com", *Financial Times* (31 March 2016), online: Financial Times <http://www.ft.com/cms/s/0/903cc52e-f729-11e5-803c-d27c7117d132.html#axzz492RqZPsJ>.

by the patent system allow them to recoup their original investment and make an additional profit.[516] Moreover, patent holders are also able to reinvest part of the money they obtain from their patents into further R&D. The potential to recoup their original investment, to make a profit, and to have a source of funds to reinvest in further R&D becomes an economic incentive[517] for those already in the field to continue investing and for the newcomers to start doing it.[518] This reasoning is applicable to health-related R&D.[519]

The second benefit that some supporters of the patent system claim it brings, therefore justifying its use, refers to the way in which the patent system facilitates information markets and therefore, collaboration. The patent system is said to allow the information and knowledge associated with the invention to be "packaged" in units (i.e. patents) and have a value assigned. This packaging can facilitate the transaction of intellectual inputs (e.g. assignments or licenses) and the division of profits, which can facilitate collaboration among different parties and agents.[520] Collaboration among different parties and agents in general is likely to prevent duplication of efforts, shorten the time of the innovation process, facilitate sharing costs, enable better quality control, and

[516] Bubela, FitzGerald & Gold, *supra* note 218 at 3; Svatos, *supra* note 20 at 114.

[517] These economic incentives assume that investors and inventors act under the rational intention to maximize their economic well-being. Trebilcock, *supra* note 6 at 125.

[518] Kieff, *supra* note 1 at 698, 699 & 703; Shanker A Signham, "Competition Policy and the Stimulation of Innovation: TRIPs and the Interface Between Competition and Patent Protection in the Pharmaceutical Industry" (2000) 26 Brooklyn J Int Law 363 at 367–370.

[519] Gold et al, *supra* note 2; Janet Hope, *Biobazaar: The Open Source Revolution and Biotechnology* (United States of America: Harvard University Press, 2009) at 70; Commission on Intellectual Property Rights, Innovation and Public Health, *WHO | Public Health, Innovation and Intellectual Property Rights* (Switzerland: World Health Organization, 2006) at 19–20; Granados Moreno & Joly, *supra* note 227 at 285; Subhashini Chandrasekharan, Amy L McGuire & Ignatia B Van den Veyver, "Do recent US Supreme Court rulings on patenting of genes and genetic diagnostics affect the practice of genetic screening and diagnosis in prenatal and reproductive care?" (2014) 34:10 Prenat Diagn 921 at 921.

[520] Hope, *supra* note 519 at 107–108.

allow a more efficient use of resources.[521] The benefits that collaboration may bring could then lead to better, faster, and more diversified innovative health-related products and services. Therefore, since patents are said to facilitate information markets, they are also deemed by some to indirectly facilitate collaboration and to bring the benefits associated with the latter. However, as I will further discuss in sections below, the collaboration that the patent system generally promotes is limited to that which upholds a proprietary framework such as commercialization,[522] open innovation,[523] and some forms of public-private partnerships[524,525] and among people or organizations that patent holders have specifically authorized as collaborators because they comply with the conditions (e.g. royalties, terms of collaboration, cross licensing) they impose.

Likewise, that the patent system may encourage newcomers to invest in R&D and maintain current innovators may also result in increased competition. Increased competition could be considered beneficial for innovation and for access to healthcare for

---

[521] Hope, *supra* note 561; US Department of Justice, *Antitrust Guidelines For The Licensing Of Intellectual Property | ATR | Department of Justice* (United States of America: U.S. Department of Justice, 1995) at 28; *ibid* at 22; Bubela, FitzGerald & Gold, *supra* note 234 at 1.

[522] Traditional commercialization refers to the process by which new products, processes, and knowledge can be commercially exploited through the use of intellectual property rights, licensing agreements, and spin off companies in order to extract economic value from them. Yann Joly et al, "The Commercialization of Genomic Research in Canada" (2010) 6:2 Health Policy 24 at 24.

[523] Open Innovation is a model of R&D that, through the use of intellectual property rights, encourages and enables constant collaboration and participation of different parties incorporating ideas, strategies, information, research tools, and resources that are internal and external to the company. The purpose of the collaboration promoted in this model is to accelerate the R&D process, expand the markets, and maximize the revenues. The commercial purpose of this model (expansion of markets and maximization of revenues) differentiates it from open science and open source models. Granados Moreno & Joly, *supra* note 211 at 287.

[524] Public-Private Partnerships are arrangements between entities of the public and private sectors to collaborate sharing their resources (e.g. knowledge, data and samples, clinical expertise, infrastructure, economic fund, etc), risks, and responsibilities in order to make the innovation process more efficient, less costly, and faster. This is particularly useful in bench to bedside innovation processes. The entities can be national and international. *Ibid*.

[525] Commission on Intellectual Property Rights, Innovation and Public Health, *supra* note 519 at 20; Granados Moreno & Joly, *supra* note 211 at 287.

four reasons. First, a larger number of competitors may encourage all of them to improve their products (e.g. a drug that would treat a condition in a shorter timeframe or a diagnostic test that would cover more strains or variants of a disease or more associated genes) in order to strengthen their market share. Second, a large number of competitors looking at each other's inventions to improve their own products may also unveil defects or shortcomings on those inventions. For instance, competition may reveal that a genetic test created by a competitor is inaccurate or it may reveal unknown side effects of a competitor's drug. Third, the prices of the innovative medical products may become lower if there are several similar products competing in the market.[526] Fourth, competition can lead to a more efficient innovation process where resources are better used and the innovation timeline is shorter. The explanation is that in a competitive environment, parties are likely to want to be the first ones to finish the invention. In this sense, they may try to adopt measures or strategies, including maybe collaboration with other parties during the pre-competitive stages, in order to accelerate the innovation process and acquire a stronger position against other competitors.[527] In summary, competition can lead to an efficient allocation of innovative medical products among the general public by helping to maintain lower prices, by contributing to a faster creation and supply of medications and diagnostic tools, and by providing incentives for manufacturers to improve existing medications and diagnostic tools.[528]

[526] Commission on Intellectual Property Rights, Innovation and Public Health, *supra* note 519 at 54 & 128–129; Chandrasekharan, McGuire & Van den Veyver, *supra* note 519 at 921.
[527] U.S. Department of Justice, *supra* note 521 at 12 & 22; Chandrasekharan, McGuire & Van den Veyver, *supra* note 519 at 921.
[528] U.S. Department of Justice, *supra* note 521 at 2; Canadian Competition Bureau, *supra* note 6 at 9.

The patent system is also considered beneficial for innovation because it creates, maintains, updates, and extends the relevant sources of knowledge (prior art). The requirement stated by the patent system for applicants to describe their invention thoroughly so as to enable a person skilled in the art to understand, reproduce, and use the invention is thought to create, maintain, update, and extend these sources of knowledge. This created knowledge expands the current prior art from the moment the patent application is published.[529] The patent system also contributes to the prior art by establishing that after the expiration of the patent, the invention and the knowledge associated with it become part of the public domain.[530]

These positive effects could benefit society in two ways. First, despite the fact that some companies will in fact lose profits and their competitive advantage and disappear, a thriving state of innovation can propel and advance industry. This boost on the industry can in itself advance the economy of the country given the increase of commercial activities and the creation of jobs that it may bring about.[531] Second, and more importantly, innovative industries can generate products that may improve people's lives by making

[529] Commission on Intellectual Property Rights, Innovation and Public Health, *supra* note 519 at 20; Granados Moreno & Joly, *supra* note 211 at 285.

[530] Bernier, *supra* note 34 at 103–104; E Richard Gold et al, "The unexamined assumptions of intellectual property: adopting an evaluative approach to patenting biotechnological innovation" (2004) 18:4 Public Aff Q 299; Edwin Mansfield, *Intellectual Property Protection, Direct Investment, and Technology Transfer: Germany, Japan, and the United States*, Edwin Mansfield, ed. (Washington D.C.: International Finance Corporation and World Bank Publications, 1995); Signham, *supra* note 518; Keith Maskus, *Intellectual Property Rights in the Global Economy* (Washington D.C.: Institute for International Economics, 2000) at 143–170; Scott F Kieff, "Property Rights and Property Rules for Commercializing Inventions" (2001) 85 Minn Law Rev 697; F Scott Kieff, "IP Transactions: On the Theory & Practice of Commercializing Innovation by F. Scott Kieff :: SSRN" (2005) 42:3 Houst Law Rev 727.

[531] Robert J Stimson, Roger R Stough & Brian H Roberts, *Regional Economic Development: Analysis and Planning Strategy*, 2nd ed. (New York, United States of America: Springer Science & Business Media, 2006) at 4; Vincent K Omachonu & Norman G Einspruch, "Innovation in Healthcare Delivery Systems: A Conceptual Framework" (2010) 15:1 Innov J Public Sect Innov J 1 at 2; Svatos, *supra* note 20 at 140.

certain tasks more efficient or aspects of people's life more comfortable or more enjoyable.[532] Particularly with respect to medical and health-related innovation, innovation can improve healthcare services and therefore people's health and life expectancies.[533] For instance, innovative R&D may result in treatments against limiting, debilitating, communicable, or deadly conditions, drugs with fewer side effects or that overcome the resistance developed by certain bacteria, diagnostic tests that detect a condition that would be difficult to diagnose otherwise, new tests that are more accurate or that are more comprehensive, medical devices that make medical intervention more precise and less intrusive, genetic tests that cover more anomalies, or personalized medicine that better adapts to the patient's particular conditions. In innovation in medical genetics, innovative products and services such as diagnostic tests could contribute to timely identification of a condition or a risk of developing a condition that has a genetic component and allow doctors to prevent it or at least control it. This diagnosis could be done with symptomatic and asymptomatic patients.

Other innovative products and services, such as genetic therapies or personalized medicine, could help to treat diseases more effectively. Personalized medicine is a practice of medicine that takes into account the individual's genetic profile in order to influence medical decisions concerning the prevention, diagnosis, and treatment of a disease.[534] It uses a genetic test to detect whether the patient has the specific genes responsible for the processes of production of the biomarkers (e.g. enzymes) that regulate the analysis and

[532] Stimson, Stough & Roberts, *supra* note 531 at 4.
[533] Omachonu & Einspruch, *supra* note 531 at 2–3.
[534] *National Human Genome Research Institute,* online *s.v.* "personalized medicine".

processing of drugs. Clinicians can interpret this information and predict the potential reaction that patients may have to a certain medication, compound or dosage based on the presence of a specific biomarker in their genomes. This can help clinicians to prescribe the drug, dosage or treatment that is more likely to have the desirable effect. It may also help to avoid or reduce side effects. Therefore, a targeted treatment is expected to improve the patient's health in a more effective, efficient, and possibly cheaper way. These characteristics are what make personalized medicine beneficial, not only for individual patients, but also for governmental healthcare policies, as it can in fact save the public healthcare system a lot of resources by avoiding waste via unnecessary or even detrimental treatments.[535]

6.2 Concerns Regarding the Patent System on Health-Related Innovation and Access to Healthcare as Discussed in the Literature

6.2.1 Concerns Raised Regarding Health-Related Innovation

The most commonly heard concern regarding the patent system and innovation is the emergence of a tragedy of the anti-commons and the underuse of resources and underdevelopment of certain areas and technologies that it may cause. The term "anti-commons" surfaced as an opposite reaction to the tragedy of the commons. In a tragedy of the commons, it is assumed that many people who share a resource (e.g. the ocean) and could freely use it would in fact overuse it (e.g. overfish or pollute it), thus affecting everyone else who could have access to it. Private property is considered a good way to

[535] Granados Moreno & Joly, *supra* note 211 at 289–290; Chandrasekharan & Cook-Deegan, *supra* note 237; Kesselheim & Shiu, *supra* note 248.

limit this overuse because, given the owners' vested interest in maintaining the resource and its economic value, they are expected to actively enforce actions to prevent the resource's overuse from taking place.

In a tragedy of the anti-commons, scarce resources can be underused if they have many owners who can block each other's use.[536] In an R&D environment, this underuse could occur because the scarce resources (e.g. research tools) are patented, and thereby owned by many different parties. This is called a patent thicket. A patent thicket is defined as a "dense web of overlapping intellectual property (in this case, patents) that a company (or a researcher) must hack its way through in order to actually commercialize new technology."[537]

The tragedy of the anti-commons prompted by a patent thicket can occur because inventors/developers may feel deterred from doing R&D in areas or on methods and products where the research tools or upstream products have multiple and overlapping patents for two reasons. First, this may occur because these inventors/developers are required to obtain a license from any person or company who holds a patent over an invention or knowledge that is required in the development of a new downstream invention. Identifying all the patent holders, determining the extent of their patents, overcoming all the necessary negotiations, and paying the pertinent transaction costs to obtain a license can easily become very burdensome, expensive (even unaffordable sometimes), and

[536] Heller, *supra* note 2; Heller & Eisenberg, *supra* note 2.
[537] Shapiro, *supra* note 2 at 122.

lengthy.[538] Second, they could be deterred from doing R&D in overly patented areas due to the fear of being sued in the future. In research areas composed of products or methods with multiple patents, the process of clearing all the potential patents can be very convoluted. Innovators/developers may be unaware of the existence of some patents or they may fail to accurately determine the extent of other known patents and therefore be unclear on whether their own R&D is infringing them. In this case, the over-owned resources could very likely be underused and the associated area, product or method underdeveloped.[539] These two hindering effects could therefore result in fewer researchers, universities, and companies working on further developing a patented technique, method, research tool (e.g. biomarker, cDNA, gene sequence) or compound or on improving or correcting a flaw in the patented invention. Another concern is that, even if the developers/innovators proceed with the complex patent landscaping and licensing process, the associated high costs and long timelines become unavoidable opportunity costs, as the resources and time invested to overcome a patent thicket, could be used instead in developing other products.[540]

[538] Commission on Intellectual Property Rights, Innovation and Public Health, *supra* note 561; Hope, *supra* note 561 at 39 & 43–45; Heller & Eisenberg, *supra* note 2; Timothy Caulfield et al., "Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies" (2006) 24:9 Nat Biotechnol 1091 at 2; Arti K Rai, "Evolving Scientific Norms and Intellectual Property Rights: A Reply to Kieff" (2001) 95:2 Northwest Univ Law Rev 707 at 707; Bernier, *supra* note 34 at 137; Svatos, *supra* note 20 at 126.

[539] Gold et al, *supra* note 2 at 2; Shapiro, *supra* note 2 at 122–123; Amy Kapczynski, "Addressing Global Health Inequalities: An Open Licensing Approach for University Innovations" (2005) 20:2 Berkeley Technol Law J 1032 at 1053; Svatos, *supra* note 20 at 124–127.

[540] Hope, *supra* note 561 at 29; Chandrasekharan, McGuire & Van den Veyver, *supra* note 561 at 921; Sarah E Ali-Khan & E Richard Gold, "Gene patents still alive and kicking: their impact on provision of genetic testing for long QT syndrome in the Canadian public health-care system" (2017) 19 Genet Med 1253.

The aforementioned negative effects may not be as harmful in a mature industry as they can be in a growing one.[541] Patents are more likely to have the positive effect of encouraging innovation if there is a clear distinction between use and production of the invention and of the associated knowledge. This is more likely to occur in a mature industry because much of the knowledge and technology created and used is understood, learned, and organized into codified and tangible patterns. However, the distinction between use and production of knowledge, tools, and technology in an incipient industry such as medical genetics is not clear because there is still a lot of what we do not know about this field (e.g. which genes are associated with which condition, how do those genes interact with each other and with other elements,[542] etc.).[543]

Furthermore, the effects mentioned above are more likely to occur in research areas and products heavily based on cumulative innovation.[544] Even though this is regularly the case in most science-oriented innovation, the area of medical genetics could be particularly perceived as being at risk of developing tragedy of the anti-commons, as it was argued in the Myriad Genetics controversy.[545] Some of the research tools and upstream products in medical genetics research include genes, proteins, other biomarkers, reagents, DNA sequences, cDNA, expressed sequence tags (ESTs), cell lines, CRISPR technology,

[541] Hope, *supra* note 561 at 82–83 & 86; Dan Hunter, "Cyberspace as Place and the Tragedy of the Digital Anticommons" in Paul Schiff Berman, ed., *Law and Society Approaches to Cyberspace* (London: Routledge, 2017) 81.
[542] Aled Edwards, *Why biomedical philanthropy supports redundant science* (Toronto, TEDxToronto, 2016).
[543] Hope, *supra* note 519 at 84; Jonathan M Barnett, "The Anti-Commons Revisited" (2015) 29 Harv J Law Technol 127; Hunter, *supra* note 541.
[544] Shapiro, *supra* note 2 at 119–120.
[545] E Richard Gold & Julia Carbone, "Myriad Genetics: In the eye of the policy storm" (2010) 12:4 Suppl Genet Med S39 at 10–11.

methods, or devices.[546] The actual number of patents claiming human genes or gene sequences is actually uncertain. In 2014, it was estimated that the U.S. Patents and Trademarks Office (USPTO) had granted more than 60,000 DNA related patent applications.[547] In that same year, another study asserted that there were over 15,000 patent claims over one simple nucleic acid including close to 6,000 involving human gene sequences.[548] Another study stated that there were over 4,900 gene patents in August 2012, making up about 14% of the human genome.[549] The great number of patents over gene sequences combined with the uncertainty regarding the validity and extent of those patents make the patent landscaping and licensing processes particularly burdensome, complicated, and costly.

The most discussed example by authors and activists has been that of diagnostic tests. According to a survey sent to laboratories from the U.S. Association for Molecular Pathology on conducting DNA-based genetic tests in the early 2000s, 53% of them said that patents or licenses had prevented them from developing new clinical genetic tests.[550] A similar argument was made in the case of Myriad's patents over the BRCA1 and BRCA2 genes and the diagnostic tests to detect the genetic susceptibility for breast and ovarian

[546] Richard L Wang, "Biomedical Upstream Patenting and Scientific Research: The Case for Compulsory Licenses Bearing Reach-Through Royalties" (2008) 10:1 Yale J Law Technol 251 at 280; Lawrence Horn, "Patent pools for CRISPR technology" (2017) 355:6331 Science 1274; Jorge L Contreras & Jacob S Sherkow, "Patent pools for CRISPR technology—Response" (2017) 355:6331 Science 1274.

[547] Chandrasekharan, McGuire & Van den Veyver, *supra* note 561 at 922; Kennedy Institute of Ethics Georgetown University & Duke Institute for Genome Sciences and Policy, "DNA Patent Database U.S.", (18 December 2015), online: Georgetown University <https://dnapatents.georgetown.edu/>.

[548] Gregory D Graff et al, "Not quite a myriad of gene patents" (2013) 31 Nat Biotechnol 404 at 407; Chandrasekharan, McGuire & Van den Veyver, *supra* note 519 at 922.

[549] Chandrasekharan, McGuire & Van den Veyver, *supra* note 561 at 922.

[550] Mildred K Cho et al, "Effects of patents and licenses on the provision of clinical genetic testing services" (2003) 5:1 J Mol Diagn JMD 3 at 5.

cancer,[551] and in the lawsuit filed by Children's Hospital of Eastern Ontario ("CHEO") challenging the legality of the gene patents used in diagnostic tests to detect the genetic susceptibility to long QT syndrome.[552] Having more researchers or companies working on a particular test or biomarkers from different angles or with different techniques could expedite and enrich the development of a new genetic test that screens for the presence or absence of a particular gene in a more accurate or less invasive way than the previous patented one. They could also develop a test that is more comprehensive and includes other genes and biomarkers or that diagnoses other disorders or that predicts reactions to drugs.[553] These benefits could either take longer or not materialize at all if the above-mentioned hindering effect occurs and there are fewer researchers and companies working on the field.

However, it is worth mentioning that despite the aforementioned concerns, which are amply discussed in the literature and academia, the empirical evidence about the effects of the patent system on innovation is ambiguous and inconclusive, and it changes depending on the country, the industry, and even the product.[554] For instance, studies involving the French and Australian medical industries failed to find considerable anti-

[551] Gold & Carbone, *supra* note 545 at 12–13; Bita Amani, "Patents, the Charter, and a Healthy Dose of Rights in Wrongs: The Poison is the Elixir of Life, Liberty and Security of the Person" (2007) 57 Univ N B Law J 162 at 165.

[552] CBC News, "U.S. human gene patent 'like patenting water or air,' Canadian hospital CEO says", *CBC News* (3 November 2014), online: CBC News <http://www.cbc.ca/news/health/u-s-gene-patents-patient-care-stymied-in-canada-hospital-claims-1.2820211>; Ali-Khan & Gold, *supra* note 582.

[553] Chandrasekharan, McGuire & Van den Veyver, *supra* note 519 at 921.

[554] Bhaven Sampat & Heidi L Williams, *How Do Patents Affect Follow-On Innovation? Evidence from the Human Genome*, Working Paper 21666 (United States of America: National Bureau of Economic Research, 2015); Bronwyn H Hall, "Business and Financial Method Patents, Innovation, and Policy" (2009) 56:1 Scott J Polit Econ 443 at 450; E Richard Gold, Matthew Herder & Michel Trommetter, *The Role of Biotechnology Intellectual Property Rights in the Bioeconomy of 2030*, OECD International Futures Project on "The Bioeconomy to 2030: Designing a Policy Agenda" (OECD, 2007) at 4.

commons effects in innovation regarding diagnostic tests.[555] In the U.S., on the other hand, it was reported that on the years following the U.S. Supreme Court's decision that invalidated Myriad's BRCA1 and BRCA2 patents ("U.S. Myriad's decision"), laboratories started offering genetic testing for the BRCA mutations at half the price of Myriad's tests, thus reducing barriers to patients' access to BRCA genetic testing; several laboratories included the BRCA testing as part of larger cancer panels; more laboratories shared their data in public databases; and more published variants of uncertain significance began to be studied, which has improved their interpretation.[556] Overall, some of these changes that followed the invalidation of Myriad's patents have resulted in actions leading to more innovation and better access to healthcare, so despite this not being evidence of an anticommons or a patent thicket, it shows that the absence of certain patents can in fact promote innovation.

In Canada, where the U.S. Myriad's decision did not have an effect, gene patents continue to exist having an impact on diagnostic tests, impeding equitable and cost-effective genetic testing. This impact has been observed with respect to the LQTS tests. The LQTS gene patent holders stated that genetic testing involving their patent on the LQTS associated genes had to be performed by their licensee in the U.S. This meant that patient samples from Canada had to be shipped to that licensee in the U.S. This process

[555] Dianne Nicol & Jane L Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry*, SSRN Scholarly Paper ID 2583508 (Rochester, NY: Social Science Research Network, 2003); Stéphane Lhuillery & Etienne Pfister, "R&D cooperation and failures in innovation projects: Empirical evidence from French CIS data" (2009) 38:1 Res Policy 45; Gold et al, *supra* note 2.

[556] My Gene Counsel, "4 Years Post-Gene Patents: How Has Life Changed In The Genomics World?", (13 June 2017), online: *My Gene Counsel - Post Genetic Testing* <https://www.mygenecounsel.com/2017/06/13/2017-6-11-4-years-post-gene-patents-how-has-life-changed-in-the-genomics-world/>.

was considered costly because it included not only the expenses associated with the shipping and the costs for the test, but also those related to the approval process by the corresponding healthcare authorities. Furthermore, the possibilities of building local genetics capacity and research opportunities were deemed diminished. Many of these concerns were addressed in the agreement reached between CHEO and the LQTS patent holders, which states that any non-profit entity providing services within Canada's public healthcare system can freely obtain a license to test for the LQTS associated genes.[557]

Another concern about the patent system is the harmful impact that it may have on competition.[558] The harm that an abusive exercise of patent rights may cause on competition can occur at two levels: the goods market and the innovation market. A goods market refers to the market that enables the ability to obtain goods. The patent system may impact the goods market in two ways. First, the patentee can affect the existence/creation of innovative products. Patentees can unilaterally decide whether to license or whom to license the use of the knowledge/information/techniques associated with the patented invention. If patent holders have a patent on inventions that constitute research tools and they also have market power,[559] they have the ability to control or, at least influence, the number of direct competitors in further downstream R&D. This situation can affect the goods market, as it can hinder the entry of competitors into the relevant market and

[557] Ali-Khan & Gold, *supra* note 540.

[558] Raúl E Molina-Salazar, Eloy González-Marín & Carolina Carbajal-de Nova, "Competencia y precios en el mercado farmacéutico mexicano" (2008) 50 Salud Pública México S496; Svatos, *supra* note 20 at 117–120.

[559] Market power is defined as the ability that a goods/services provider has to maintain prices above competitive levels or to control the availability of close substitutes for a considerable period of time due to having the possibility to control or deny competitors entry to the relevant market. Canadian Competition Bureau, *supra* note 6 at 9, 12–13; U.S. Department of Justice, *supra* note 521 at 4.

influence the number of close substitutes available, thus increasing the market concentration in the hands of the patentees.[560] Second, an abusive use of the patent system may also affect the goods market by limiting the public's access to the innovative product. However, since this concern is more related to access to healthcare, I will discuss it in much more detail in the following section. Suffice it to say at this point that an abusive exercise of patent rights can give patentees the ability to set an unaffordable and unfair price for the patented inventions. This ability is maximized in the absence of competitors.[561] A price that is high enough so as to make the medication, diagnostic tools, and therapies unaffordable could seriously limit the access to these products for many patients.[562]

An innovation market refers to the market that enables the ability to innovate, either in terms of developing new goods or improving the existing ones.[563] The patent system may harm competition in an innovation market by limiting access to research tools that are necessary for further development. In other words, it can affect the democratization of innovation[564], which intends to empower innovators from everywhere in the world, small

[560] Canadian Competition Bureau, *supra* note 6 at 14–21; Chandrasekharan, McGuire & Van den Veyver, *supra* note 519 at 922; Hope, *supra* note 519 at 19.

[561] U.S. Department of Justice, *supra* note 521 at 18; Chandrasekharan, McGuire & Van den Veyver, *supra* note 519 at 922; Hope, *supra* note 519 at 19; Aaron S Kesselheim, Carolyn L Treasure & Steven Joffe, "Biomarker-Defined Subsets of Common Diseases: Policy and Economic Implications of Orphan Drug Act Coverage" (2017) 14:1 PLOS Med e1002190 at 7; Svatos, *supra* note 20 at 117.

[562] U.S. Department of Justice, *supra* note 521 at 7; Canadian Competition Bureau, *supra* note 6 at 9.

[563] U.S. Department of Justice, *supra* note 521 at 10–11.

[564] The concept of democratization of innovation starts with the democratization of knowledge or information, which is defined as the acquisition, sharing, and spread of knowledge or information amongst the common people (i.e. anyone) rather than only privileged elite groups (e.g. academics or licensees). The process of democratization of knowledge has been prompted by the printing press, the Internet, and digitalization technologies, and has expanded to the democratization of technology and innovation. An important effect of this democratization is that it has the potential to counteract inequality, exclusion of the masses, and concentration of financial and intellectual wealth in the hands of a minority. Hope, *supra* note 519 at 104; Henri Colt & Silvia Quadrelli, "Democratization of Medical Knowledge and Technology: Brief Commentary on Implications for Medical Education" (2006) 1:4 Simul Healthc 238.

and large, from public and private sectors.[565]The patent system may harm competition or democratization in an innovation market because, as part of the rights granted by the patent system, patentees have the ability to decide whether to grant a license and the terms under which they will license their patented research tools (e.g. cDNA, gene sequences, biomarkers, etc.). Limited access to research tools can negatively impact the pace, extent, and quality of innovation with respect to a particular medical product, a medical or genetic area, or the whole industry, as patentees may foreclose or make it difficult or more expensive for other researchers to engage in activities of R&D in the field.[566] In the area of medical genetics, the lack of competition in the innovation market may prevent, for instance, the creation of more accurate diagnostic tests or the development of tests that look at multi-gene disorders.[567]

A third concern related to the patent system is a potential delay in the innovation process. Patents over research tools require that any potential developer/innovator intending to develop an invention using those research tools negotiate and obtain a license from all the relevant patent holders. In cases where there are many overlapping patents and a patent thicket is created, this process can become convoluted and therefore lengthy, tedious, and expensive. The reason for this is that potential developers/innovators, in order to be able to legally commercialize their inventions, are expected to identify all the patents that the new invention could infringe, contact all the corresponding patent holders, and

[565] Hope, *supra* note 519 at 104; Colt & Quadrelli, *supra* note 564 at 238; Sarah E Ali-Khan et al, "Defining Success in Open Science" (2018) 2:2 Mni Open Res 1.
[566] U.S. Department of Justice, *supra* note 521 at 8, 10–11; Canadian Competition Bureau, *supra* note 6 at 9 & 19; Hope, *supra* note 519 at 19.
[567] Chandrasekharan, McGuire & Van den Veyver, *supra* note 519 at 921; Gold & Carbone, *supra* note 545 at 20; Granados Moreno & Joly, *supra* note 211 at 293.

negotiate a license with each one of them. This process could take a very long time and even require the employment of multidisciplinary experts that understand the science behind the invention as well as the patent drafting process in order to elucidate a patent landscape.[568]

Furthermore, even if potential developers/innovators did most of their necessary R&D claiming that these activities fall under the research and experiments exemption,[569] all these negotiations would still have to be done before the product is commercialized. In this case, the availability of the innovative medical product in the market could be delayed until the negotiations to obtain licenses are settled.[570] This delay could also occur if the potential developers/innovators decided to invent around the patented research tool (if possible), as most alternatives chosen in order to circumvent these patented research tools would most probably be less efficient.[571] Likewise, innovation would be delayed if innovators/investors decided to wait for the patents covering important research tools to expire (20 years after the filing date).

Another concern refers to the costs of engaging in activities of R&D. In addition to the standard expenses of R&D (infrastructure, salaries of researchers and staff, regulatory costs, etc.), developers/innovators facing a vast number of third-party-owned patents associated with their inventions have to cover the royalties for the different patent holders,

[568] Shapiro, *supra* note 2 at 122; Gold et al, *supra* note 2 at 2; Hope, *supra* note 519 at 39; Svatos, *supra* note 20 at 117–120.
[569] See section 3.3.2.1.1 Patents for more information on this exemption.
[570] Shapiro, *supra* note 2 at 125; Hope, *supra* note 519 at 39.
[571] Heller & Eisenberg, *supra* note 2 at 700; Svatos, *supra* note 20 at 120–122.

and in some cases, the employment of an expert who elucidates the relevant patent landscape. The complete costs can become quite substantial.[572] The amount of money that developers/innovators may have to pay as royalties could be even higher than expected if they have already designed, placed into production, or finished their inventions using the patented research tools, as their position to negotiate lower royalty fees with these patent holders is likely to weaken.[573] High costs to innovate can be problematic because they may discourage many small and medium size innovators/investors from engaging in costly R&D.[574]

For example, in an analysis focused on anti-tuberculosis therapy in the U.S.[575], the authors found in 2013 six U.S. patents, two European patents, and twelve WIPO patents associated with diagnosis of tuberculosis, and five U.S. patents, four European patents, and eleven WIPO patents related to anti-tuberculosis therapy.[576] Likewise, the patent landscape related to non-invasive prenatal testing (NIPT)[577] in the U.S. in 2012 included thirty-four patents and ninety-nine applications owned/filed by different national and international companies and universities.[578] All these patents and patent applications cover different

[572] Svatos, *supra* note 20 at 124–127.
[573] Shapiro, *supra* note 2 at 125; Gold et al, *supra* note 2 at 3; Chandrasekharan, McGuire & Van den Veyver, *supra* note 519 at 922.
[574] Svatos, *supra* note 20 at 126.
[575] Ananya Singh et al, "Current status of anti-tuberculosis therapy: a patent analysis" (2014) 9:1 Recent Patents Anti-Infect Drug Disc 25.
[576] *Ibid*.
[577] Noninvasive Prenatal Testing (NIPT) is a test that allows genetic testing of cell-free fetal (cff) DNA to detect the chances of having a baby with trisomy 21 (Down syndrome), 13 (Patau syndrome), 18 (Edward syndrome) or some sex chromosome abnormalities by analyzing maternal blood. This test can be performed five weeks after conception and without any risk of hamring the fetus. Ashwin Agarwal et al, "Commercial landscape of noninvasive prenatal testing in the United States" (2013) 33:6 Prenat Diagn 521; Vardit Ravitsky & Raphaelle Dupras-Leduc, "Emerging issues in medicine reproductive technologies" in Yann Joly & Bartha Maria Knoppers, eds, *Routledge Handbook of Medical Law and Ethics* (United Kingdom: Routledge, 2015) 223.
[578] Agarwal et al, *supra* note 577.

methods, products, and compositions of matter that are associated with the diagnosis and treatment of regular and drug resistant tuberculosis in one case and the detection of genetic diseases/disorders in cell-free fetal DNA in the maternal blood in the other. They are owned/filed by national and foreign companies/universities in both cases and have different expiration dates. Developers/innovators developing or improving current medical devices or products related to tuberculosis or NIPT in the U.S. would have to determine the scope of at least these patents and the claims they include. The patent landscape, particularly in a rapidly-evolving area like medical genetics, is usually complex and dynamic.[579] Hence, any developers/innovators would also have to verify any recent patents and patent applications. Once they have identified which ones are associated with their inventions, they have to negotiate licenses with each of them. This process will inevitably lengthen the product pipeline and increase the associated costs for the development of a more effective anti-tuberculosis therapy or an NIPT that detects more accurately any of the trisomies 13, 18 or 21. The patent landscape I just described in both cases may result in longer timeframes to develop innovative tuberculosis treatments and less invasive NIPT and in fewer and more expensive options.

Another concern is the focus of the pharmaceutical industry on the so not necessarily socially valuable "me too drugs." "Me too drugs" are drugs that are structurally similar to already existing drugs with slight insignificant differences.[580] There are two aspects about these drugs that create an incentive for pharmaceutical companies to develop

[579] Hope, *supra* note 519 at 54–57.
[580] Marcia Angell, *The Truth About the Drug Companies* (United States of America: Random House Publishing Group, 2004) at 75.

them. First, given that these drugs are intended to serve a similar purpose as the original innovative drugs, they have proved to have a utility (to cure a disease or to treat the symptoms of a specific condition) and have a very likely profitable market with channels of distribution and a group of consumers. Consequently, the chances of a market failure are lower than in innovative products and services. The second aspect is that the small differences between these drugs and the original innovative drugs on which they are based can give rise to new 20-year patents of exclusive commercial exploitation.[581] These drugs could have two positive effects. The first one is that they could improve people's access to necessary drugs and treatments by increasing the number of similar products available in the market, thereby decreasing the drugs' prices. The second positive effect that upcoming "me too drugs" could have is that the drugs' novelty or specific benefit could be that they have fewer side effects or that they have more localized or specifically targeted effects (e.g. a painkiller that targets specific types of pain or specific types of migraines).[582] Nonetheless, the main criticism is that investors and inventors devote considerable resources (e.g. monetary, intellectual, time, etc.) to research and development on these drugs instead of innovative products and services, affecting thus the pace of innovation.[583] The benefits of "me too drugs" on medical innovation and on people's health in general then seem to be limited and meagre. In this case, even though the decision that inventors and investors make of focusing their resources and efforts on the R&D of "me too drugs" can be prompted partially by the potentially ensured market, the patent system is also

[581] Hope, *supra* note 519 at 54.
[582] Marc A Rodwin, "Conflicts of Interest, Institutional Corruption and Pharma: An Agenda for Reform" (2012) 40 J Law Med Ethics 511 at 513; Joshua J Gagne & Niteesh K Choudhry, "How Many 'Met-Too' Drugs is Too Many?" (2011) 305:7 J Am Med Assoc 711 at 711.
[583] Angell, *supra* note 580 at 74–93; Gagne & Choudhry, *supra* note 582 at 711.

considered to be an important incentive, as it will extend the market and development exclusivity over the product or the research tool or compound used in the final product.

The sixth concern refers to neglected diseases. The patent system can contribute to certain diseases or areas being neglected in R&D because the economic incentives that it creates, along with those of the market, are deemed to encourage companies to focus their resources on diseases that have a profitable market. Diseases or strains of diseases endemic to developing or underdeveloped countries are unlikely to have a profitable market. Actinic prurigo discussed in chapter five is an example. As I mentioned earlier, there are other incentives and other sources of funding that could promote and support research on neglected diseases, mainly at the basic research stage. However, basic research must translate into clinical applications to be of benefit to patients and, given the complexity, length and high costs of this stage, most of the time, the involvement of biotechnology and pharmaceutical companies is needed or at least desirable.[584] Therefore, unless there are other incentives besides patents that persuade biotechnological and pharmaceutical companies to centre their R&D on these diseases, clinical applications on these diseases will probably be neglected and their treatments delayed, underdeveloped or never developed.[585] Similarly, there is a concern that the patent system could contribute to insufficient funds for basic research. The patent system provides incentives to work on clinical applications because, as I mentioned in chapter three, one of the requirements for an invention to be patentable is to have an industrial application. Basic research comprises information and knowledge that, despite its importance, is useful in stages prior to the

[584] Granados Moreno & Joly, *supra* note 211 at 281–282.
[585] Rai, *supra* note 5 at 208; Maurer, Rai & Sali, *supra* note 5.

development of inventions with an industrial application. If members of the private sector focus their resources to products that are patentable, these resources are unlikely to be allocated to basic research.[586]

The seventh concern associated with the patent system is that it may prompt a practice of secrecy and lack of collaboration among researchers, universities, and companies. Secrecy could occur for the following two reasons. First, the patent system formally encourages disclosure and dissemination of the knowledge and information associated with the invention by requiring patent applicants to include a detailed description of the invention in their applications. However, given that the patent system requires the invention to be new and non-obvious for it to be patentable and it is based on a first-to-file policy, inventors (e.g. researchers, universities, and companies) are very likely to keep their inventions secret until they file their patent applications, as a way to prevent others from filing first. This strategy would include avoiding any mentioning of the invention in articles, conferences, workshops, meetings, etc., until they are ready to file their patent applications (or within the twelve months grace period).[587] Second, researchers, universities, and companies may decide to not share their contributions for fear of providing evidence of any patent infringement that they may be knowingly or

[586] Svatos, *supra* note 20 at 122–124.

[587] Adam B Jaffe & Josh Lerner, *Innovation and Its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What to Do About It* (United States of America: Princeton University Press, 2004) at 30 & 156; Commission on Intellectual Property Rights, Innovation and Public Health, *supra* note 561 at 41; Granados Moreno & Joly, *supra* note 227 at 283; Arti K Rai et al., "Pathways across the valley of death: novel intellectual property strategies for accelerated drug discovery" (2008) 8:1 Yale J Health Policy Law Ethics 1 at 25; Constance Bagley & Christina D Tvarnø, "Pharmaceutical Public-Private Partnerships : Moving From the Bench to the Bedside." (2014) 4:2 Harv Buisness Law Rev 373 at 384; Wang, *supra* note 588 at 353; Svatos, *supra* note 20 at 127.

inadvertently committing.[588] These practices of secrecy and of no disclosure/sharing result in a lack of collaboration with third parties. They also contradict the long-used principles and policies of open science. Secrecy may lead to inefficient, slower, and costly innovation because without collaboration it is likely that there will be duplication of research and inventors will be unable to build on knowledge/information already generated.[589] It can also hinder the possibility of identifying mistakes or defects in the existing inventions or prevent or delay the creation of improved or better versions of them, as it is likely that fewer people (researchers and inventors) and fewer resources will focus on the invention and its functionality.[590]

The last concern raised in the literature regarding the current patent system is an inefficient and absurd use of resources. The costs for obtaining a patent can go from USD $700 to USD $10,000, depending on the length and difficulty of the process.[591] In addition to these costs, patent holders have to pay a yearly maintenance fee in order to keep their patents active and valid and registration fees for every license granted.[592] The strong emphasis put on the importance of obtaining patents and the current practices of patent infringement lawsuits in certain fields in countries like the U.S., have led to a tendency to use patents defensively.[593] Companies build large patent portfolios with strategic value to

[588] Gold & Carbone, *supra* note 545 at 44.
[589] Hope, *supra* note 519 at 72–75; Fisher, *supra* note 20 at 180; Granados Moreno & Joly, *supra* note 211 at 286.
[590] Horn, *supra* note 546 at 1274; Contreras & Sherkow, *supra* note 546 at 1274.
[591] Instituto Mexicano de la Propiedad Industrial, "Servicios Tarifa de Invenciones, Modelos de Utilidad, Diseños Industriales y Esquemas de Trazado de Circuitos Integrados", online: *Instituto Mexicano de la Propiedad Industrial* <http://www.impi.gob.mx/servicios/Paginas/TarifadeInvencionesdeDisenodeCircuitos.aspx>; Hope, *supra* note 561 at 92.
[592] Instituto Mexicano de la Propiedad Industrial, *supra* note 591.
[593] This phenomenon is called by some the "knowledge game." Hope, *supra* note 519 at 89; Peter Drahos &

fight and neutralize competitors. These patents are not used to facilitate the company's R&D, but to obtain licensing revenues from competitors,[594] discourage competitors from entering the field of innovation,[595] block competitors from exploiting their own inventions,[596] or avoid and discourage potential lawsuits initiated by their competitors.[597] All the resources invested in these patenting strategies could be better used on R&D that would result in innovation that benefits society. The employment of excessive funds to obtain multiple licenses from different patent holders in cases where an invention is at the centre of a patent thicket is another way in which resources are misused.

6.2.2 Concerns Regarding Access to Health-Related Innovation and Healthcare

The patent system may hamper access to healthcare by enabling patent holders to either set the prices of patented medications, diagnostic tools, and therapies so high as to make them inaccessible or to complicate their supply or improvement. As briefly

---

John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (United Kingdom: Earthscan, 2002).

[594] For instance, companies may engage in strategies like patent stacking (which means obtaining many patents over different aspects of one invention) or obtaining submarine patents (which means obtaining patents but only enforcing them once users/competitors have become dependent on the patented invention/technology). Hope, *supra* note 519 at 90; Knut Blind, Katrin Cremers & Elisabeth Mueller, "The Influence of Strategic Patenting on Companies' Patent Portfolios" (2009) 38:2 Res Policy 428 at 429.

[595] Companies may obtain so many patents associated with one invention that they create a patent thicket. Hope, *supra* note 519 at 90; Blind, Cremers & Mueller, *supra* note 594 at 429.

[596] In this case, companies can engage in strategies such as clustering (obtaining patents around their own core patents), bracketing (obtaining patents around competitors' core patents), blitzkrieg (obtaining many patents over similar products or compositions of matter), blanketing (obtaining patents over minor modifications in every step of manufacturing processes), flooding (obtaining patents over minor variations on the technology developed by a competitor), fencing (obtaining patents to block certain lines of research), and surrounding (obtaining patents that manage to block the effective commercial exploitation of a competitor's core patent). Hope, *supra* note 519 at 90; Blind, Cremers & Mueller, *supra* note 594 at 429.

[597] Companies build a large portfolio of patents in order to be able to negotiate with or discourage potential plaintiffs in case they want to initiate a patent infringement lawsuit against them as they could use those patents to countersue these plaintiffs. Hope, *supra* note 519 at 90; Blind, Cremers & Mueller, *supra* note 594 at 429.

mentioned in the previous section, this may occur through an abusive exercise of the exclusive rights granted to patent holders. By being the only ones who can manufacture, sell or import the patented medication, diagnostic tool or therapy, patent holders can set the commercialization terms of these inventions, including particularly the price for which patented inventions will be offered to the public.[598] If the price is so high that patients are unable to privately afford those medical products and services or that the public healthcare system cannot include them in the medical services they provide, the patent system is contributing to this lack of access to healthcare services. Moreover, patent holders may have an even stronger control over the price of their inventions when, in addition to exercising their patent rights to set the commercialization terms, they can influence/control the entry of new competitors in the market. If the invention (or the knowledge or information associated with it) constitutes a research tool that is essential for further development in the field, patent holders may influence the entry of competitors by either not licensing their patented technology/knowledge or by setting very burdensome/costly licensing terms. In either case, patent holders may be able to prevent or discourage any potential competitor from developing products that would be considered close substitutes. A reduced number of competitors can strengthen the leeway that the patent holder may have to set a price.[599]

[598] Gold et al, *supra* note 2; Atanu Saha et al, "Generic Competition in the US Pharmaceutical Industry" (2006) 13:1 Int J Econ Bus 15; Commission on Intellectual Property Rights, Innovation and Public Health, *supra* note 561; Ellen F M t'Hoen, "The Global Politics of Pharmaceutical Monopoly Power" (Medecins Sans Frontiers); Gaelle Krikorian, "L'accès aux génériques : enjeux actuels et propriété intellectuelle", (4 October 2005), online: *OSI Bouake* <http://osibouake.org/?L-acces-aux-generiques-enjeux>; Svatos, *supra* note 20 at 117–118.

[599] Gold et al, *supra* note 2 at 2.

However, the conclusiveness of the evidence that the patent system has an impact on the price of innovative medical products varies depending on the product and on the country. For instance, the evidence regarding the influence of the patent system on the high prices of drugs and therapies is more conclusive than in diagnostic tools. The evidence also varies depending on the specific country and on whether the focus is on high, middle or low-income countries.[600] In medical genetics, an example of this situation would be the BRCA 1 and BRCA 2 genetic tests created, patented, and commercialized by Myriad to detect the risk of hereditary breast and ovarian cancer. In Canada, in the early 2000s, Myriad's test cost CDN$3,800, whereas a similar test created and provided by the public healthcare system cost CDN$1,200. After Myriad's failed attempts to negotiate with the provincial governments,[601] the Canadian public healthcare system upheld its policies - which did not match Myriad's business platform- and kept ensuring that its patients had access to the test, regardless of Myriad's cease and desist letters. However, given that the U.S. population does not have the same public healthcare system as Canada and that insurance companies do not always cover the test, there are sectors of the U.S. population who are likely to be unable to afford the test and therefore to access it.[602]

On the other hand, the exclusive rights to make or use the invention (or the knowledge, information or research tools associated with it) or to authorize others to do so can also affect people's access to proper healthcare by enabling patent holders to influence the availability of health-related innovative products and services. This can happen in many

[600] *Ibid* at 1–3.
[601] For more details on the Canadian case, see Gold & Carbone, *supra* note 545.
[602] Jonathan R Foote et al, "Cost Comparison of Genetic Testing Strategies in Women With Epithelial Ovarian Cancer" (2017) 13:2 J Oncol Pract 115 at 121 & 123; Gold & Carbone, *supra* note 545 at 47.

ways. First, if patent holders have the exclusive rights to manufacture, sell, and import the patented invention; they are the only ones who can either supply that product in the market or determine who else can contribute to that supply. A limited number of inventors/developers/investors contributing to the supply of a particular medical product or service could lead to that product or service shortage. This shortage could prevent patients from having access to those products and services, thus affecting their access to proper healthcare.[603] For instance, Myriad used its patents to implement a business model in the U.S. by which it required that every full-sequencing BRCA1/BRCA2 diagnostic test be exclusively done in its laboratory. It allowed, however, that follow-up single mutation tests could be done in any of the 13 laboratories that it had licensed. In order to maintain this model, Myriad sent cease and desist letters to competing laboratories providing the test as it claimed those laboratories were infringing its patents.[604] With this practice of being the sole provider of this test in the U.S., Myriad prevented many patients from having access to a timely diagnostic test because Myriad's tests were too expensive and many insurance policies did not cover them and because it was too much of a hassle to send the blood samples to Myriad and wait for the only laboratory to perform the test.[605]

Second, patent thickets combined with an abusive exercise of patent rights may give rise to an environment characterized by the tragedy of the anti-commons and reduced competition. If this environment discourages innovation in one field or in relation to one

[603] Julie Clague, *supra* note 3 at 185–188; Fran Quigley, "Escaping Big Pharma's Pricing With Patent-Free Drugs", *New York Times* (18 July 2017), online: New York Times <https://www.nytimes.com/2017/07/18/opinion/escaping-big-pharmas-pricing-with-patent-free-drugs.html>; Bubela, FitzGerald & Gold, *supra* note 234.
[604] Gold & Carbone, *supra* note 545 at 5–8.
[605] Chandrasekharan, McGuire & Van den Veyver, *supra* note 519 at 922.

medical product, consequently different or more suitable options (e.g. a panel of a diagnostic test that encompasses more genetic disorders or that assesses other determining factors that better fit the needs or conditions of the patient) or improved versions (e.g. a less invasive procedure, more accurate or cheaper) of that existing product are less likely to be developed, or at least, are more likely to be delayed. Any limitation, delay or impediment in the development of these alternatives or improved products affects their availability in the market and thereby the population's access to proper or better healthcare. [606] Myriad's business practices described above also prevented the creation of other tests that could provide a second opinion.[607]

A third way in which the patent system may hinder access to healthcare through affecting the availability of innovative medical products and services is by limiting collaboration. In the previous section, I mentioned that supporters of the patent system argue that, given that patents facilitate information markets, they can also be deemed to facilitate collaboration. However, I also highlighted that this collaboration is mostly aligned with proprietary models and it is limited to occur only among those who the patent holders specifically authorize as collaborators (i.e. those who meet the conditions they impose). This can be problematic for the following reasons. The process of R&D in the pharmaceutical and biotechnology industries is lengthy, complex, and costly.[608] However, collaboration can help to solve these problems in different ways, thereby spurring

[606] Gold et al, *supra* note 2 at 2.
[607] Chandrasekharan, McGuire & Van den Veyver, *supra* note 519 at 922.
[608] Hope, *supra* note 561 at 152; Stephen H Friend & Thea C Norman, "Metcalfe's law and the biology information commons", (5 April 2013), online: *Nature Biotechnology* <https://www.nature.com/articles/nbt.2555> at 298.

innovation. First, collaboration among different researchers and companies can help the parties involved in the innovation process to share the costs and risks of the different stages of the R&D process, thus reducing the resources needed to develop a product.[609] Second, it can shorten the innovation timeline, as many tasks and stages of the innovation process can be divided and shared among those researchers and companies and also duplication of efforts can be avoided.[610] Third, collaboration can help to improve the quality of the invented products by finding mistakes or flaws in them faster or simply making them better, given that there would be more researchers who will be able to test and further develop those products from different angles, backgrounds, and circumstances.[611] The more people/centres/companies collaborate, the more efficient the innovation process gets and the more attractive it is for other actors to join in. Reduced collaboration, on the other hand, may prevent all the above-mentioned benefits and lead to a shortage or delay in the supply of innovative medical genetics products and services. In some diseases, it can even result in no innovative medical products at all, as the costs and risks of engaging in the development of certain products are too high to be commercially worth it. Therefore, limited collaboration could affect the availability of necessary medical genetics products, thereby hindering access to proper healthcare.

---

[609] Hope, *supra* note 519 at 135; Granados Moreno & Joly, *supra* note 211 at 286; E Richard Gold, "Accelerating Translational Research through Open Science: The Neuro Experiment" (2016) 14:12 PLOS Biol e2001259.

[610] Granados Moreno & Joly, *supra* note 227 at 286; Timothy Caulfield, Shawn HE Harmon & Yann Joly, "Open science versus commercialization: a modern research conflict?" (2012) 4:2 Genome Med 17 at 5; Edwards, *supra* note 584; Aled Edwards, "To spark medical innovation, Canada should embrace Open Science", *The Globe and Mail* (7 January 2017), online: The Globe and Mail <https://www.theglobeandmail.com/report-on-business/rob-commentary/to-spark-medical-innovation-canada-should-embrace-open-science/article33533010/>; Svatos, *supra* note 20 at 130.

[611] Eric S Raymond, *The Cathedral & the Bazaar: Musings on Linux and Open Source by an Accidental Revolutionary* (Cambridge: O'Reilly Media, 2001) at 12; Dirk Riehle et al, "Open Collaboration Within Corporations Using Software Forges" (2009) March/April IEEE Softw 52 at 53–54.

In addition to potentially diminishing the availability of innovative medical genetics products and services in the terms explained above, the patent system may also affect access to healthcare by reducing, delaying or impeding the development of generics. Generic drugs are usually between 20% and 90% cheaper than patented medication.[612] For instance, whereas the patented antiretroviral therapy for HIV costs USD $15,000 per patient a year in the U.S., its generic version made in India costs USD $99.[613] There are two factors that contribute to this difference in prices between generic and patented drugs. The first is that generic drugs do not need to undergo clinical trials as new drugs do. This reduces the costs of R&D, as generic developers do not have to invest in lengthy and costly clinical trials, which as a result, tends to reduce the final price of the drug. The second factor is that anyone can engage in the R&D of an unpatented drug without the need to negotiate and obtain the authorization of the patent holder(s) and the number of products that can compete against each other is likely to increase. On the one hand, this reduces the costs of R&D, as those engaging in the development of generics do not have to invest resources negotiating licenses and paying the corresponding royalties, which similarly to what occurs with the first factor, tends to reduce the final price of the drug. Moreover, having an increased number of products that can compete against each other decreases the leeway that a sole manufacturer could have to unilaterally set the price of the final product.[614]

[612] Dunne et al, *supra* note 135 at 1.
[613] Gold et al, *supra* note 2 at 3; Dylan Mohan Gray, *Fire in the Blood* (2013).
[614] Hope, *supra* note 519 at 65 & 107; Krikorian, *supra* note 598.

The patent system reduces, delays or impedes the development of generics in two ways. The first is through the 20-year-long exclusive rights to manufacture, use, sell, and import that it grants to the patent holder.[615] In this case, the development and commercialization of any generic associated with a patented drug will be delayed for at least those 20 years. However, this effect is expected given the nature and purpose of the patent system: to grant exclusive exploitation rights in order to provide inventors/investors economic incentives to engage in R&D and innovation. Furthermore, in reality, during most of this 20-year period, the drug is most probably being under development. The second way is by extending the period of exclusivity with new patents over slightly modified inventions. In this case, the problem results from an abuse of the patent system on behalf of the patent holder and from a faulty patent office that fails to enforce a stricter criterion for novelty and non-obviousness. By reducing, delaying or impeding the development of generics in the terms described above, the patent system enables and prolongs costly and often unaffordable medical products and services, which hinders access to proper healthcare for many people. The most known case has been the AIDS crisis in African countries in the late 1990s and early 2000s.[616] In the early 2000s, the yearly antiretroviral treatment per person cost USD $10,000. At this time, the drugs were patented and only the patent holders were allowed to make and sell them. Once the patent expired, new manufacturers, mainly in Brazil, India, and Thailand, started producing generic versions. This competition onset brought the price of the most commonly used

[615] This term of 20 years can be extended in certain jurisdictions such as in the U.S., Canada, the European Union, and Japan due to delays in the patenting or regulatory approval processes.

[616] Gray, *supra* note 655; Medecins Sans Frontiers, "The impact of patents on access to medicines", online: *Medicins Sans Frontiers* <https://www.msfaccess.org/our-work/overcoming-barriers-access/article/1360>; Gold et al, *supra* note 2 at 3; Krikorian, *supra* note 640.

antiretroviral treatment down to USD $70 per year.[617] It is nonetheless worth mentioning that this concern is less likely to be true with respect to gene patents, as these patents are less likely to be able to be improved or modified.

Finally, an innovation setting strongly based on patents could also prevent R&D on domestic health-related priorities in countries whose local innovation ecosystem is not as well developed. R&D based on patents focuses on areas or fields where innovation is needed in the case of public research centres, or on products that are likely to have a profitable market in the cases of private companies. In the latter case, the absence of a profitable market in a developing country is likely to lead R&D many agents of that country to focus on different products, areas, or countries, thus neglecting the endemic illnesses and the products actually needed in these countries.[618] R&D in developed countries is likely to centre on the diseases and disorders endemic to their own countries. Many of those diseases and disorders are likely to be found in developing countries as well, so the innovation in developed countries could also benefit patients in developing countries. However, there are certain diseases or disorders that are only found in developing countries, either because they are determined by the genetics of their population (e.g. actinic prurigo) or by their environment (e.g. malaria), or because they have already been controlled (or even locally eradicated) in developed countries (e.g. poliomyelitis).[619] Even though biotechnology and pharmaceutical companies and researchers in developing

[617] Medecins Sans Frontiers, *supra* note 616.
[618] Commission on Intellectual Property Rights, Innovation and Public Health, *supra* note 519 at 23; Svatos, *supra* note 20 at 121–124.
[619] Mark Miller, Scott Barrett & D A Henderson, "Control and Eradication" in Dean T Jamison et al., eds., *Disease Control Priorities in Developing Countries*, 2nd ed (Washington (DC): World Bank, 2006); "WHO | Malaria", online: *WHO* <http://www.who.int/mediacentre/factsheets/fs094/en/>; María-Teresa Hojyo-Tomoka et al, "Diagnosis and treatment of actinic prurigo" (2003) 16:1 Dermatol Ther 40.

countries may focus on the diseases endemic to their geographical location, treatments, therapies and diagnostic tests for these diseases may still not be developed on-time or even not developed at all. Pharmaceutical and biotechnology companies and research centres in developing countries usually have a less technologically and scientifically developed infrastructure and more limited resources than those in developed countries. If the companies and research centres of developed countries neglect the diseases or conditions that are endemic in developing countries because they are not profitable and the companies and research centres from developing countries do not have the infrastructure or the resources to do R&D on those diseases on their own, it could probably result in delayed, less advanced, or otherwise insufficient R&D, and therefore affect the supply of the necessary treatments, therapies, and diagnostic tools. An example of this situation is the meningitis vaccine. Meningitis A is common in African countries. In the 1990s, the disease caused the death of approximately 100,000 people. Meningitis C, on the other hand, is common in the U.K. During the same period, this type of meningitis caused the death of 1,000 people. Despite the fact that meningitis type A was causing more deaths, while three vaccines against meningitis C were developed, tested, approved and available in 2001, the vaccine for meningitis A had not been developed, even though the individual components and technology existed. Part of the problem of developing a vaccine for this type of meningitis was that this type of meningitis was endemic in a territory with an indigent market unable to pay the prices that the population with meningitis A was able to pay. In view of this, in 2001, the Bill and Melinda Gates Foundation awarded PATH a ten-year grant to start a partnership with the Meningitis Vaccine Project to advance the development, production, testing and introduction of this vaccine against type A

meningitis. This partnership brought together SynCo Bio Partners, the Serum Institute of India Limited, and the Center for Biologics Evaluation and Research, each one of which contributed with their components and conjugation technology to develop this vaccine. For this partnership, several nonexclusive, sublicensable licenses were negotiated regarding the partner's patented components and technologies. The vaccination campaign in Africa against meningitis A was finally implemented in 2010.[620]

The patent system is supposed to provide a fair balance between providing an incentive to innovate and access to health-related products in order to be justified. The effect that the patent system may have on the availability of the medical products and services and/or the access to them in the instances described above hinders access to healthcare in a number of ways. The most obvious is that if patients cannot access the medication or treatment they need, the healthcare they are receiving is suboptimal and their health will most likely deteriorate. The same will occur if patients (or potential patients) cannot access the most accurate or efficient diagnostic tests, as the ability to identify their actual diseases, disorders or predisposition to them is reduced or delayed. Another way in which limited availability of or access to medical products affects healthcare is when patients can only access a limited number of options of diagnostic tests, drugs or treatments, because they may not be able to obtain a second opinion in a diagnosis, or they may not have access to most suitable or opportune treatment. In the following chapter, I

[620] SC Brooke et al, "How Public-Private Partnerships Handle Intellectual Property: the PATH Experience" in A Kratiger, RT Mahoney & L Nelson, eds., *Intellectual Property Management in Health and Agricultural Innovation Handbook of Best Practices* (Oxford: MIHR, 2007) 1755; "Fact Sheet n. 141| Meningococcal meningitis", (2015), online: *WHO* <http://www.who.int/mediacentre/factsheets/fs141/en/>.

focus my analysis on the impact that the current patent system has had specifically in Mexico's health-related innovation and healthcare. My analysis evaluates whether the concerns I just discussed actually occur in Mexico and thereby will help me determine whether the patent system achieves the expected balance and therefore whether it can be justified.

Chapter 7 Impact of Patents on Health-Related Innovation and Healthcare in Mexico

In practice, the above-mentioned benefits and concerns materialize differently in every country, region or context. The reason is that the actual effects that the patent system may have on innovation and healthcare depend on the environment and context provided.[621] The analysis that I undertake in this chapter aims to provide evidence about which of the concerns and benefits amply discussed in the literature, which I described above, in fact occur in Mexico. This analysis is based on the information contained in chapters two, three, four, and five. My findings will make up the relevant capabilities and functionings and thereby, the utility/welfare that I suggest should be used to determine whether the current patent system is justified in Mexico with respect to health-related innovation.

7.1 Impact of Patents on Health-Related Innovation in Mexico

The regulation of the patent system in Mexico described in chapter three is very similar to the regulations in the U.S., Canada, France and Germany.[622] Among other political and commercial reasons, this similarity stems from international trade agreements, particularly the TRIPs (Trade-Related Aspects of Intellectual Property Rights) Agreement, that set minimum standards worldwide for intellectual property protection requiring

[621] Gold, *supra* note 103 at 191–194.

[622] *Germany: Patent Act (as amended up to Act of December 17, 2008)*, 5 May 1936 [*Germany: Patent Act (as amended up to Act of December 17, 2008)*] sec. 16; *Canadian Patent Act*, June 1985 [*Canadian Patent Act*] sec. 44; *U.S. Patent Act. Title 35*, 1976 [*U.S. Patent Act. Title 35*] sec. 154 (2); "France: Code de la propriété intellectuelle (version consolidée au 25 avril 2016)", online: WIPO <http://www.wipo.int/wipolex/en/text.jsp?file_id=403397> sec. L611-2.

developing and developed countries to provide the same protection models, despite the flexibilities in place.[623] In a nutshell,[624] Mexico's patent system provides a 20-year period of protection and a set of exclusive rights that are mainly the same as in these countries. It also states similar requirements and exceptions for a patent to be granted. Likewise, it provides comparable users' rights and cases for compulsory licenses. In addition, many of Mexico's governmental policies have had the expressed purpose of promoting innovation and of bringing about all the social benefits that are said to be associated with it.[625] Despite this similarity, it is difficult to assert that the patent system has had an impact that resembles that in developed countries.

First, despite the foregoing characteristics and facts of the patent system in Mexico, the country does not have a local innovative and developed area of medical R&D as developed countries with equivalent patent systems have. As I mentioned in chapter three, out of the 200 pharmaceutical companies in Mexico in 2011, 46 were multinationals. These foreign companies had 68% of the total market. Out of the top ten companies, nine are foreign multinationals and one was Mexican.[626] Furthermore, most of Mexico's pharmaceutical and biotechnological companies focus their activities on the development and improvement of biological products, similares, and generics,[627] rather than on innovative products.[628] In the public sector, despite the specialization, current activities are

[623] United Nations Development Programme, *supra* note 145 at 141–149.
[624] For a more detailed description of the patent regulation in Mexico, see chapter three section 3.2.1.
[625] For more information, see section 3.2.2 in chapter three, where I mention the objectives of the IMPI, the content of the National Plan of Development, and the details of the programs of the CONACYT and the SNI to promote innovation using the patent system as one of the means to achieve this.
[626] Guzman, *supra* note 137 at 115.
[627] For a detailed definition and distinction of these terms, see footnote 7 in the Introduction.
[628] Moise & Docteur, *supra* note 277 at 34–35.

mainly focused on basic research without having yet reached its translation into any marketable product.

On the other hand, the current patent regulation complies with the international standard of protection. As result, as I described in chapter three, it has incentivized most of the main transnational pharmaceutical companies to establish their manufacturing laboratories in Mexico. This situation has created an important employment market; it has generated the circumstances to transfer know-how and facilitate capacity building from these companies to the Mexican researchers being employed in these companies; and it has stimulated some economic growth in the country. Moreover, these transnational companies have made innovative medical products and services available in the Mexican market.

Second, patents do not seem to be very prominent among Mexican researchers, companies, and research institutions. As I also mentioned in chapter three, 97% of the patents in Mexico are owned by companies, centres, and individual inventors from France, Germany, Japan, Switzerland, United Kingdom, and the United States.[629] Out of the 17,184 patent applications filed in 2017, only 1,334 were filed by Mexican companies/centres/researchers. Likewise, out of the 8,510 patents granted in the same year, only 407 were granted to Mexican companies/centres/researchers. US companies and inventors filed 8,370 applications and 3,950 were granted to them.[630] Among the main list of main patent holders before the IMPI, there are twelve Mexican universities and only one

[629] Margain b), *supra* note 297; Margain a), *supra* note 297; Margain c), *supra* note 297.
[630] Margain c), *supra* note 297 at 6 & 9.

company. The U.S. has over 130 companies in the list.[631] The companies with the highest number of patents are Pfizer, Pharmacia, GlaxoSmithKline, Eli Lilly, Merck, Johnson, Abbot, and Bayer. [632] This patenting pattern also occurs in other jurisdictions, such as WIPO, the European Patent Office, the United States Patents and Trademarks Office, and the Japanese Patent Office, where Mexico has one of the lowest numbers of patent applications. [633] One circumstance that could contribute to this situation is that the focus of Mexico's private health-related industry is generics, generics with an innovative element added, similares or biocomparables, [634] all of which by definition, usually lack novelty, an essential element to obtain a patent. However, the above-mentioned patenting numbers are not exclusive to health-related innovation, but instead refer to all innovative and research areas.

In connection with the described patenting pattern in Mexico's innovation, a circumstance that could be interesting to explore in a deeper and more systematic manner is the approach that inventors take towards the patent system (i.e. obtaining patents, enforcing patents, respecting third parties' patents, etc.) and the role that the latter plays in encouraging their research and innovation. The researchers I interviewed for the case study in chapters four and five, for example, did not seem influenced or lured by the possibility of obtaining patents, as they had not filed or obtained any patents in the course of their

[631] *Ibid* at 13–18.
[632] Guzman, *supra* note 137 at 137.
[633] Malkin et al, *supra* note 265 at 103.
[634] Solleiro Rebolledo, *supra* note 307; INMEGEN, *supra* note 405; Menjivar Iraheta, *supra* note 397; Granados Arriola, *supra* note 357; Acuña Alonzo, *supra* note 397.

careers up to the date on which I conducted my interviews. Whether this view is widely shared among researchers in Mexico would be an interesting follow-up project.

Third, it is difficult to determine whether the patent system has accelerated the pace of innovation in the area of medical research, increased the reinvestment of companies into R&D, or impacted the industry's growth in Mexico, mainly because I cannot know how fast the pace of innovation could have been, if there had not been patents given the many factors and variables that come into play in the innovation process.[635] However, I did find that, despite the regulation and implementation of the patent system being similar to that of countries where innovation in the field has flourished and the continued scientific enthusiasm for the area, much of the state of the art in Mexican research institutions that focus on innovative medical genetics is still in the stage of basic research. For instance, as mentioned in the chapter three, the INMEGEN, created in 2000, genotyped part of the mestizo population as part of the MGDP. The first stage of this project ended in 2009.[636] The Genoteca Indigena that started in 2008 in the UNAM has not finished its first stage.[637] Both projects have resulted in a number of publications, inter- and extra- institutional collaborations, and associated projects, all of which imply an important scientific and academic advancement in the field.[638] Furthermore, both projects have been granted important amounts of funding and have attracted the interest of some members of the

[635] Svatos, *supra* note 20 at 131.
[636] Silva-Zolezzi et al, *supra* note 270.
[637] "Facultad de Química UNAM- Recibe la FQ donativo de Fundación Coca Cola para conformar la Genoteca Indígena", online: *Facultad de Quimica UNAM* <http://www.quimica.unam.mx/cont_espe2.php?id_rubrique=12&color=526C11&id_article=3362>.
[638] INMEGEN, *supra* note 311; INMEGEN, "Publicaciones Científicas - Instituto Nacional de Medicina Genomica", (24 October 2011), online: *Instituto Nacional Medicina Genomica* <http://www.inmegen.gob.mx/es/investigacion/publicaciones-cientificas/>.

private sector. Likewise, Mexico allows patents over most of the inventions associated with both projects. However, none of these projects has yet translated into a clinical product except for the BRCA1 and BRCA2 genetic testing the INMEGEN provides for some hospitals and for which has applied for two patents. It could be interesting to explore other projects as a point of reference with respect to their pace of development and the role that patents play in that development.

Fourth, with respect to the much-discussed tragedy of the anti-commons, it is also difficult to determine whether health-related innovation in Mexico suffers from this problem. Within the limitations of my research, even though all of the researchers I interviewed for the case study mentioned being aware of the potential risks of a tragedy of the anti-commons caused by existing or future patents, this scenario did not seem to have occurred yet, at least in their personal experience. On the one hand, as I mentioned in chapters four and five, none of these researchers seem to be concerned about third parties' patents, so they do not have a culture of doing a background check before starting a new project. On the other hand, they do not seem to have been contacted by patent holders regarding a potential patent infringement.[639] Therefore, none of the researchers I interviewed had ever had to abandon a project, nor had they encountered delays in the course of their research due to third parties enforcing their patents. In other words, none of them had ever experienced any first-hand tragedy of the anti-commons effect in their own research. However, it is worth noticing that none of these researchers had yet reached the

[639] INMEGEN, *supra* note 405; INMEGEN, *supra* note 397; Solleiro Rebolledo, *supra* note 307; Ballesteros Romano, *supra* note 397; Granados Arriola, *supra* note 357; Menjivar Iraheta, *supra* note 397; INCMNSZ, *supra* note 397; UNAM, *supra* note 399; Acuña Alonzo, *supra* note 397.

stage in their research where resulting medical products were ready to be commercialized. Patents are usually enforced after the alleged infringing invention is commercialized, for two reasons. First, patent holders may not be aware of the alleged infringement to their patents before the third party actually commercializes the invention.[640] Second, many patent holders consider it a better negotiating strategy to wait until the allegedly infringing product is finished and ready to be commercialized (or in other terms, locked into the patented technology) to enforce the patent. This is because, at this moment, potential infringers would have already made a big investment on the product, and therefore their negotiation position to set royalties or any other licensing terms would not be as strong.[641] In other words, the conditions that would prompt patent holders to enforce their patents (i.e. commercialization of potentially infringing products), and that would therefore trigger the effects associated with the tragedy of the anti-commons and harms to the innovation and goods markets, were not present in the circumstances surrounding my interviewees. Expanding this analysis to the circumstances and experiences of a larger number of researchers would provide a more representative and definitive conclusion on the potential presence of a tragedy of the anticommons.

Besides the individual opinions and conjectures I just presented, I did not find any concrete evidence in the literature that would lead to conclude either the presence or the absence of an anti-commons in Mexico in health-related innovation or in any other area.

[640] Robert P Merges & Richard R Nelson, "On the Complex Economics of Patent Scope" (1990) 90:4 Columbia Law Rev 839; Wendy H Schacht, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology* (United States of America: Congressional Research Service, 2009).

[641] Brian J Love, "An Empirical Study of Patent Litigation Timing: Could a Patent Term Reduction Decimate Trolls Without Harming Innovators?" (2013) 161 Univ Pa Law Rev 1309 at 1317; Hope, *supra* note 519 at 61.

The literature I found for other jurisdictions in fact shares this uncertainty. While there are several authors asserting the absence of the negative effects of the anti-commons,[642] there are others who argue that these effects have in fact manifested in certain areas.[643] Therefore, the anti-commons hypothesis remains to this day unproven.

Finally, in general, the patent system does not seem to have an impact on the researchers/companies/centres' decision to collaborate, whether positive or negative. Collaborations and partnerships are mostly encouraged for economic and efficiency purposes. This encouragement commonly stems from governmental, institutional, and industry's policies, governmental development plans, and even recent legislation focusing on the creation and regulation of public-private partnerships (PPPs). Collaborations of research centres and universities usually involve other universities (public and private, national and international), public research centres, governmental agencies, and some national companies.[644] The patent system does not seem to play an important role in these collaborations, given that with few exceptions, most of the academic researchers/centres do not hold patents and neither do the national companies, as they mainly focus on the generics market.[645] However, collaborations and partnerships involving international pharmaceutical and biotechnology companies show some differences. Even though these

[642] Barnett, *supra* note 543.
[643] Dan Hunter, "Cyberspace as Place and the Tragedy of the Digital Anticommons" in Dan Hunter, *Law and Social Approaches to Cyberspace* (London: Routledge, 2017) 81.
[644] INMEGEN, "Instituto Nacional de Medicina Genómica - Vinculacion - Convenios Marco", (16 August 2017), online: INMEGEN <http://www.inmegen.gob.mx/es/vinculacion/convenios-marco/>; INMEGEN, "Instituto Nacional de Medicina Genómica - Vinculacion - Convenios Específicos", (16 August 2017), online: INMEGEN <http://www.inmegen.gob.mx/es/vinculacion/convenios-especificos/>; Javier Jasso, "Innovación y colaboración universidad-empresa en la industria biofarmacéutica en México." in *Vinculacion de las Universidades con los Sectores Productivos. Casos en Iberoamerica*, 1st ed. (Mexico: UDUAL, 2016) 125.
[645] Margain c), *supra* note 297; Margain b), *supra* note 297; Margain a), *supra* note 297.

collaborations are still motivated by economic and efficiency-based incentives, these companies pursue obtaining patents more than the public centres or national companies for profit purposes. These patents however, are individually owned by each of these companies and their listed inventors are mostly foreigners without showing any impact or playing any role in the creation or development of the collaborations or partnerships.[646] Likewise, collaboration and partnerships in the community of researchers who participated in my case study seem to be most commonly prompted by the researchers' scientific interests and not by patents. As expressed in the interviews, the different parties involved in the R&D process of the research projects comprised in my study share information with the sole purpose of achieving their scientific/academic goals, publications, and grants, as opposed to pursuing or engaging in an information market. The terms of such collaborations are set keeping this objective in mind and negotiated by the same academic researchers as individuals, without a clear concern for any profit. The main aspect of intellectual property discussed in those collaborations is usually over the copyright associated with the resulting publications, without any special attention paid to patents. These collaborations have taken place mainly among academic researchers without any substantial interaction with the private sector.[647] As with the other subjects where I have discussed the opinions and experiences of the researchers I interviewed, expanding the sample of interviewees in order to include a higher number and a more diverse background of researchers would lead to a more complete picture of the role of patents in promoting collaborations and partnerships.

[646] Margain c), *supra* note 297; Margain b), *supra* note 297; Margain a), *supra* note 297.
[647] Solleiro Rebolledo, *supra* note 307; INMEGEN, *supra* note 405; Menjivar Iraheta, *supra* note 397; Granados Arriola, *supra* note 357; Acuña Alonzo, *supra* note 397.

7.2 Impact of Patents on Access to Health-Related Innovation and Healthcare in Mexico

The first effect that patents may have on access to healthcare in Mexico is due to the high prices that patented inventions may have. Regardless of any price control policy[648] in place, patented drugs, diagnostic tests, and therapies in Mexico are considerably more expensive than those in their generic or biocomparable versions or those directly performed by the public healthcare system.[649] For instance, supradol is a non-steroidal anti-inflammatory patented drug used for acute pain, whose price is between USD $4.5 and $7.5 for four tablets of 30mg. The price of its generic version fluctuates between USD $1.13 and $2.26 for fifteen tablets of 275-300mg of naproxen/paracetamol and USD $0.70 and $1.5 for ten tablets of 10mg of ketorolac.[650] The prices for other important patented medications are USD $34 for ten tablets of Tamiflu, a medication against influenza and USD $64.5 for 28 tablets of Plavix, a medication against heart diseases and strokes. The generic versions for those medications are USD $16 for 10 tablets of oseltamivir (generic version of Tamiflu) and USD $16 for 28 tablets of clopidogrel (generic version of Plavix).[651] Likewise, as I described in chapter four, the cost for the whole treatment (six to nine months with generic antibiotics (first and generation) is approximately of USD $800.

---

[648] See below for details on this price control policy.

[649] Molina-Salazar, González-Marín & Carbajal-de Nova, *supra* note 558.

[650] Sharai Isabel Abaroa Silva, "Medicamentos genéricos y de patente ¿Cuánto cuestan?", (Abril 2015), online: *Procuraduria Federal del Consumidor PROFECO* < https://www.vocero.com.mx/salud/medicamentos-diferencia-de-precios/>.

[651] "Tamiflu 10 Cápsulas Caja | Antibiótico | Tipo | FSP Sitio Web", online: Farmacias San Pablo <https://www.farmaciasanpablo.com.mx/es/MXN/Todas-las-Categor%C3%ADas/Medicamentos/Supervisi%C3%B3n-m%C3%A9dica/S---T---U/Tamiflu-10-C%C3%A1psulas-Caja/p/000000000004160190>; "Plavix 28 Tabletas Caja | SANOFI | Apego | FSP Sitio Web", online: <https://www.farmaciasanpablo.com.mx/es/MXN/Todas-las-Categor%C3%ADas/Medicamentos/Supervisi%C3%B3n-m%C3%A9dica/P---Q---R/Plavix-28-Tabletas-Caja/p/000000000007990056>.

One month of treatment with bedaquiline and linezolid (patented antibiotics of the fourth and fifth generation) can reach USD $700.

In Mexico, the Ministry of Economics is in charge of setting maximum prices for patented medication pursuant to article 31 of the General Health Law. This control applies only to patented medications, without any effect on generics or medications whose patents expired, or on patented diagnostic tools. The highest price allowed in the market for patented medications takes into account the average price of that medication within the previous three months in the six countries with the biggest influence in that medication's world market.[652] The maximum price can be set as high as up to 72% above the international prices used as references.[653] Despite this attempt to control medications' prices, Mexico has the highest prices of medication and medical products in Latin America.[654] The maximum price of patented medication in Mexico is set jointly by the different pharmaceutical companies based on the prices set for that medication in other countries without much regard to the price control mechanism described above. The difference in prices between patented and generic drugs is commonly justified and accepted because of the investment that companies need to do in order to develop those innovative drugs, tests, and therapies. This justification is not only academic or commercial, but institutional/governmental as well.[655] However, the prices for diagnostics, medication, and

[652] Molina-Salazar, González-Marín & Carbajal-de Nova, *supra* note 558.

[653] The price of generic medication is not legally or institutionally controlled because it is expected that the competition brought about by the expiration of patents and the resulting multiple manufactures will naturally reduce it. *Acceso a Medicamentos y Propiedad Intelectual: Actores e Interacciones* (online: Organizacion Panamericana de la Salud, 2011) at 14.

[654] Molina-Salazar, González-Marín & Carbajal-de Nova, *supra* note 558.

[655] The National Chamber of the Pharmaceutical Industry (Camara Nacional de la Industria Farmaceutica-Canifarma), the Ministry of Economy, and the Consumer Protection Agency assert that in the last 15 years, there has been a 40% increase of the population's life expectancy in Mexico as a result from the

therapies seem to depend more on the ability of the manufacturer to set them than on the costs associated with their development.[656]

High-priced patented medication can affect access to healthcare. A high price can affect access to healthcare in the following terms. As mentioned in chapter two, the public healthcare system expenditure in medication is distributed 56% of the total public healthcare system's expenditures are used to buy patented drugs (which accounts for 10% of the total medication provided by the public healthcare system), 29% of the expenditure for generics (which accounts for 73% of the total medication provided), and 15% for unidentified medication (which accounts for 17% of the total medication provided).[657] If the price for patented medication is too high, the public healthcare system will either reduce the needed patented drugs it can cover with the assigned budget or it will devote more funds to obtaining patented drugs and reduce the budget for generics. Likewise, high-priced patented drugs can reduce the ability of those resorting to the private healthcare system, because they may not be able to afford them. This can also be problematic for those with private healthcare insurance, as insurance companies are likely to exclude expensive drugs from coverage. In these cases, patients may be prevented from going through the prescribed treatment, or at least from completing it. The negative impact on access to healthcare is even more harmful when there is no generic version of a needed medication, treatment or diagnostic test, as without this option, an unaffordable high price can totally prevent patients from accessing the necessary medication or diagnostic treatment and damage the

innovation and R&D in the pharmaceutical industry. Abaroa Silva, *supra* note 650.

[656] Kesselheim, Treasure & Joffe, *supra* note 561 at 7.

[657] Guzman, *supra* note 137 at 116.

patients' health. Therefore, in this case, the patent system can affect access to healthcare not only by allowing high prices in medication, making it thus unaffordable and inaccessible, but also by impacting the timely availability of generics.

A similar situation occurs with respect to genetic diagnostic tests. Access to the BRCA1 and BRCA2 diagnostic tests for hereditary ovarian and breast cancer can be considered an example. Myriad had four patents in Mexico based on patent applications filed in accordance with the Paris Cooperation Treaty. These patents covered the BRCA1 and BRCA2 genes and their mutations, the methods and materials used to isolate and detect those genes and mutations, and the diagnostic method to determine a predisposition to develop ovarian or breast cancer linked to the aforesaid genes and mutations.[658] These patents expired in 2015 and 2016.

A few years before the expiration of the patents, the BRCA1 and BRCA2 diagnostic tests cost USD $3,500 in Mexico and were done exclusively in the United States by Myriad. Today, after the expiration of the patents and after the 2013 U.S. Supreme Court's decision on Myriad, most of the commercial tests are still done overseas by foreign laboratories in either Spain or the United States, and cost between USD $1,600 and USD$ 2,000.[659] This

[658] "Metodo para Diagnosticar una Predisposicion para Cancer de Pecho y Ovario", Mark H Skolnick et al., USPCT/US95/10220, February 1998; "Gen de Susceptibilidad de Cancer de Pecho y Ovario Enlazado con 17Q", Mark H Skolnick et al., USPCT/US95/10203, February 1998; "Mutaciones en Vivo y Polimorfismos en el Gen de Susceptibilidad al Cancer de Pecho y Ovario Enlazado con 17Q", Donna M Shattuck-Eidens et al., Mex 9701075, PCT/US1995/010202, November 11, 1995; "Gen de Susceptibilidad de Cancer Mamario Ligado al Cromosoma 13", Sean V Tavtigian et al., Mex 9804878, PCT/US1996/019598, 17 December 1996.

[659] Color Genomics one of the companies that provide this direct-to-consumer test. It uses saliva instead of blood and even though the company claims there is a doctor available to answer questions, there is no proper genetic counseling regarding the explanation of the results, their interpretation, and the relevance of the many unknown mutations. Color Genomics, "Common Questions - Color Provider Platform",

price includes the costs associated with sending the samples to those countries. Even though the price decreased in recent years and it is close to the actual cost, it is still unaffordable for a great sector of Mexico's population. In the public sector, the National Institute of Oncology and the INMEGEN are the only two institutions that offer the BRCA1 and BRCA2 diagnostic tests. In addition to offering the tests, they also began to sequence the BRCA genes and do research with them.[660] The incipient local innovation, manufacture, and practice of the tests contributes to this high price, as the additional costs associated with the out-of-the-country shipping cannot be avoided and limited competition on the provision of the test prevails.[661]

The problems described above are particularly serious in a country such as Mexico, where 43.6% of its national population and 75% of its Indigenous population live below the national poverty line.[662] For instance, if close to half of the country's population live with no more than USD $177-113 or USD $85-66 a month depending on whether they live in urban or rural communities and in moderate or extreme poverty,[663] it is easy to assume that it would be impossible for any those living in these conditions to be able to afford a treatment of Tamiflu, Plavix, Bedaquiline or Linezolid if it is not covered by the public

online: *Color Genomics* <https://www.color.com/providers/questions>.

[660] "México cuenta con estudio genético para predecir cáncer", *Alto Nivel* (19 June 2013), online: Alto Nivel <http://www.altonivel.com.mx/36524-mexico-cuenta-con-estudio-genetico-para-predecir-cancer/>; Researcher from the INMEGEN, *BRCA1 & BRCA2 Diagnostic Tests* (2017).

[661] Medica Sur Hospital, *Information provided by the private Medical Laboratory of Medica Sur Hospital.* (February 21, 2017); Angeles Hospital, *Information provided by private Medical Laboratory of Angeles Hospital* (February 21, 2017).

[662] The World Bank, "Mexico | Data", online: *World Bank Mexico* <http://data.worldbank.org/country/mexico>; Wilson, *supra* note 149; "Banco de Informacion INEGI", online: *Instituto Nacional de Estadistica y Geografia* <http://www3.inegi.org.mx/sistemas/biinegi/?e=31&m=0&ind=1005000040>; Valadez, *supra* note 171; Cardenas Elizalde et al, *supra* note 171 at 42.

[663] Wilson, *supra* note 149; Gobierno Federal, *Plan Nacional de Desarrollo 2012-2018* (Presidencia de la Republica, 2012); note 662.

healthcare system, to undergo a breast/ovary diagnostic test or to get the necessary treatment in case the diagnostic test requires it. In this respect, it is important to remember that in 2015, close to 25% of its population did not have access to public healthcare services, leaving them with the sole possibility of private healthcare services.[664] The limited or inexistent access to Plavix (the medication against heart diseases and strokes) could be particularly harmful, as ischemic heart diseases is one of the two leading causes of death in the country.[665] A similar concern could be raised regarding the unaffordable BRCA1 and BRCA2 diagnostic tests, as breast cancer is the second leading cause of death associated with cancer in Mexico after lung cancer. This is because even though the test only identifies the risk, being able to assess the risk on time and act at the opportune moment can save lives, spare unnecessary surgeries or treatments, and make public and private expenditures more efficient.[666] In these cases, it is difficult to find these innovative medical products and services useful and beneficial, as those who need them the most cannot afford them, despite being available in the market.

Authors are concerned that the patent system may also have an effect on access to healthcare by having a negative impact on the pace of innovation and manufacture.[667] A low pace in any of these two processes reduces the availability of innovative drugs,

[664] Gobierno Federal, *supra* note 663 at 44; INEGI, *supra* note 8; "Censo de Poblacion y Vivienda 2010. Mexico en Cifras", online: *INEGI* <http://www3.inegi.org.mx/sistemas/mexicocifras/>; "Censo de Poblacion y Vivienda. Consulta General", online: *INEGI* <<http://www.inegi.org.mx/lib/olap/consulta/general_ver4/MDXQueryDatos.asp?proy=cpv10_pt>.

[665] World Health Organization, *Mexico: WHO Statistical Profile* (online: World Health Organization, 2015); World Health Organization, *Estadisticas Sanitarias Mundiales 2012* (online: World Health Organization, 2012).

[666] Instituto Nacional de Estadistica y Geografia (INEGI), *Estadistica a Proposito del Dia Mundial de la Lucha Contra el Cancer de Mama* (2015).

[667] Julie Clague, *supra* note 3; Bubela, FitzGerald & Gold, *supra* note 218; Gold et al, *supra* note 2; Quigley, *supra* note 603; Medecins Sans Frontiers, *supra* note 616; Svatos, *supra* note 20 at 129–130.

diagnostic tests, and therapies. The exclusive rights to make, use, sell, and import the patented invention or to authorize others to do so control the availability of drugs and diagnostic tools. If the patentee decides to refuse licensing or to impose unattainable terms to the use of patented research tools, the creation of more similar or improved products may be reduced or delayed. If this occurs, the general supply of medication and diagnostic tools may be affected. An example of this situation in Mexico took place in February 2016. In that month, Mexico suffered a national shortage of Tamiflu, a medication used against influenza.[668] Tamiflu has 57 patents in 28 countries owned by Roche.[669] Specifically in Mexico, Roche has one patent.[670] Tamiflu is available worldwide only through six designated suppliers. In Mexico, it is only available through Roche. At the time of the shortage, Roche's patent over Tamiflu was valid.[671] This meant that only Roche could manufacture, distribute, and sell Tamiflu in Mexico. Because of the patent, there were no generic or other alternative versions available. The shortages were particularly serious in Mexico City, the State of Mexico, Nuevo Leon, and Jalisco, all states with the biggest cities in the country.[672]

The situation and examples I describe above focus on access to drugs and therapies that, except for the Myriad case, have no genetic component. However, these

[668] "Salud da ultimátum a Roche por desabasto de Tamiflu", *Excelsior* (28 February 2016), online: Excelsior <http://www.excelsior.com.mx/nacional/2016/02/28/1077855>.
[669] "Tamiflu generic launch, patent expiration information", online: *Drug Patent Watch* <//www.DrugPatentWatch.com/p/tradename/TAMIFLU>.
[670] The patent found is MX/a/2008/008386 granted to Roche in June 2011 with international priority date of December 18, 2006.
[671] Considering the priority dates stated in the patent application filed before the IMPI, it expired in December 2016.
[672] "Escasez de tamiflu es porque fue mal recetado: Cofepris", *Milenio* (29 February 2016), online: Milenio <http://www.milenio.com/politica/tamiflu-medicamento-tamiflu-escasez-tamiflu-recetan-mal-tamiflu-Cofepris_0_692330980.html>.

circumstances can be extended to genetic-based medication, diagnostic tools, and therapies. Granting patents over gene sequences, biomarkers, or cDNA as compositions of matter could provide patent holders exclusive rights over their inventions (e.g. the process to determine the presence of an abnormal or mutated gene in a diagnostic test and over the diagnostic test kit) and over research activities associated with the patented isolated gene sequences, biomarkers, and/or cDNA.[673] In these cases, unless they are covered by the public healthcare system, those who cannot afford the genetic tests and/or the personalized therapies will not benefit from genetic-based preventive or personalized medicine, even if they exist in the market. Consequently, the population that is unlikely to benefit from these innovative and specialized products and services will include not only those living under the poverty line, but also many middle-class patients. The limited innovation, manufacture, and supply of the BRCA1 and BRCA2 diagnostic tests for hereditary ovarian and breast cancer can be considered an example of this situation in Mexico, as these limitations influence the tests' price, affecting not only people living below the poverty line, but sectors of the country's middle class as well.

Overall, there have certainly been some benefits associated with the products and services resulting from the R&D in the health-related industry. However, it is difficult to assert that these products and services have, without a doubt, been promoted by the patent system or to what extent it has contributed to their creation. This is due to the fact that there are a number of factors that play a role in the innovation process.[674] In the case of Mexico, this is even more difficult to assert because the national pharmaceutical industry focuses

[673] Granados Moreno & Joly, *supra* note 211 at 283.
[674] Svatos, *supra* note 20 at 130–131.

on generics, products that by their own nature, cannot be patented. Having said this, the current patent system has in fact generated some benefits (e.g. economic growth and job market, technology/know-how transfer; and creation and availability in Mexico of innovative medical products and services) brought about by attracting foreign pharmaceutical and biotechnology companies into the country. These benefits or outcomes have definitely improved the lives of many people in Mexico and therefore, could constitute a valuable utility. However, in addition to these benefits, the patent system has also contributed to very serious problems with respect to access to healthcare (e.g. expensive medication, delay in the availability of generics until after patents expire, suboptimal standard healthcare) for a very large part of Mexico's population. These problems greatly affect the capabilities and the functionings of this part of the population. The actualization in Mexico of both, the benefits and the concerns, bears the question: do the benefits outweigh the problems so as to assert the patent system brings a utility/welfare that justifies it. This is the question that I explore in the last chapter.

Chapter 8 Bases to Justify the Patent System in the context of Health-Related Innovation and Access to Healthcare in Mexico

As I described in chapter three, Mexico's current patent system seems to be justified on utilitarian terms by being deemed a source of incentives to promote innovation. Some of the limitations implemented (e.g. users' rights and exclusions from patentability) as well as some of the criticisms and concerns raised are based on principles of justice and equal distribution and aim to justify and limit the patent system in terms of its efficiency, merit, fairness, justice or equality.

The grounds, focus, arguments, and passion of the debate justifying the existence of the patent system, the extent of protection granted, and situations of enforcement usually vary depending on the area of innovation. For instance, justifying the patent system in innovation pertaining to engineering or information technologies commonly focuses on efficiency, efficacy, fairness and merit.[675] In these cases, the justification of the patent system tends to centre on whether patents provide the inventors and investors with the necessary incentives to invest time, resources, and efforts into innovation. It is also argued that it is fair for investors to recoup their investments and for inventors to be able to profit from their efforts and talent. In contrast, the justification of the patent system involving specifically inventions in health-related innovation focuses on and discusses other additional grounds and concerns. These grounds and concerns should and usually do centre not only on ensuring efficiency in promoting innovation in the field, but, because of the

[675] Merges & Nelson, *supra* note 640; Kieff, *supra* note 530.

association of the inventions to healthcare, should also centre on whether it can ensure equal access to those inventions.[676]

Health has been defined as "a state of complete physical, mental, and social well-being, and not merely the absence of disease or infirmity."[677] A state of health in these terms would lead to normal functioning.[678] This state allows people to function in society, get educated, work, be productive, benefit from the available opportunities and situations, develop meaningful and positive interactions, and overall appreciate life. Anything that moves away from this state of health and normal functioning is likely to negatively affect all those aspects in a person's life.[679]

Health depends on several factors. Some of these factors include nutrition, living and working conditions, individual biological conditions, and access to preventive, curative, and rehabilitative products and services, among others.[680] As mentioned in chapter two and shown in chapters four and five, poverty is likely to limit and even prevent people from having proper nutrition, living conditions, and access to preventive, curative, and rehabilitative products and services. In other words, poverty can negatively affect a person's normal functioning and enjoyment of life.[681]

---

[676] Bernier, *supra* note 34.
[677] Preamble of the *Constitution of the World Health Organization*, *supra* note 101.
[678] The use of "functioning" in the phrase "normal functioning" should not be understood in terms of the capability approach. Instead, it should be interpreted as fulfilling the purpose natural to or intended for a human being.
[679] Sen, *supra* note 23 chapter 1; Bernier, *supra* note 34 at 6 & 54–55.
[680] Norman Daniels, *Justice and Justification: Reflective Equilibrium in Theory and Practice* (Cambridge: Cambridge University Press, 1996) at 214.
[681] Bernier, *supra* note 34 at 57–58.

Innovation pertaining to medical genetics contributes to proper preventive, curative, and rehabilitative products and services. When poverty limits or prevents access to medical and medical genetics products and services, it is negatively affecting people's health and normal functioning. Given that the patent system can influence the price and supply of innovative medical and medical genetics products and services, it can affect those products and services' availability and accessibility and thereby harm people's health. It is this last potential negative effect that gives grounds for using a capability approach to assess whether the patent system can be justified in medical and medical genetics innovation in addition to whether it efficiently and effectively creates incentives to innovate.

In this chapter, I apply the terms and concepts of utilitarianism and capability approach described in chapter one specifically to the concerns and benefits described in chapters six and seven regarding health, health-related innovation, and healthcare. The outcome is a more targeted theoretical basis to then determine in the last chapter the elements that would justify the patent system in Mexico in health-related innovation and conclude how convenient I consider it to be and what could be worth doing about it.

8.1 Utilitarianism and the Patent System in Health-Related Innovation

8.1.1 Utilitarian Justification of the Patent System in Health-Related Innovation

As I mentioned in chapter one, according to utilitarianism, the patent system is usually justified in utilitarian terms because patents are considered to foster innovation. First, patents are expected to provide inventors and investors with an economic incentive

to devote their resources and efforts to funding the infrastructure, as well as the technological, financial, and human resources necessary to innovate.[682] Second, the patent system is considered to foster innovation by promoting competition among the different parties involved in the R&D process, thereby encouraging the improvement of products and services.[683] The third way in which the patent system is said to foster innovation is by creating, maintaining, updating, and extending the current scientific and technical knowledge (prior art or state of the art) through the patent applicant's disclosure requirement.[684] The patent system is also said to foster innovation by facilitating collaboration among the different parties and in the different stages of the R&D process. It does so by allowing intellectual inputs (e.g. knowledge associated with inventions) to be packaged in "tangible" easy to transfer units: patents.[685,686]

Fostering innovation justifies the patent system in utilitarian terms because that innovation is expected to benefit society in two ways. Innovative activities are likely to lead to products and services that improve people's lives, thereby leading to societal well-being and welfare.[687] Particularly in innovation in medical genetics, examples of these innovative products and services can be diagnostic tests and personalized treatments. Both

[682] Kieff, *supra* note 1 at 698, 699 & 703; Signham, *supra* note 518 at 367–370; Bubela, FitzGerald & Gold, *supra* note 218 at 3.
[683] Commission on Intellectual Property Rights, Innovation and Public Health, *supra* note 519 at 20, 54, 128–129; U.S. Department of Justice, *supra* note 521 at 12 & 22; Canadian Competition Bureau, *supra* note 6 at 9; Chandrasekharan, McGuire & Van den Veyver, *supra* note 519 at 921.
[684] Bernier, *supra* note 34 at 103–104; Gold et al, *supra* note 530; Mansfield, *supra* note 530; Signham, *supra* note 518; Maskus, *supra* note 530 at 143–170; Kieff, *supra* note 530; Kieff, *supra* note 530.
[685] Hope, *supra* note 519 at 107–108.
[686] For a more detailed explanation of the ways in which the patent system fosters innovation, refer to chapter six Benefits of the Patent System on Medical Genetics-Related Innovation and Access to Healthcare.
[687] Loon, *supra* note 6 at 202–203; David S Olson, "Taking the Utilitarian Basis for Patent Law Seriously: The Case for Restricting PatentableSubject Matter" (2009) 82 Temple Law Rev 181 at 183.

products can contribute to the timely identification of a condition and to improvements to the patient's health and quality of life in a more effective, efficient, and possibly, cheaper way. Hence, the rationale specifically with respect to health-related innovation in general is that if the patent system provides the economic incentives that encourage pharmaceutical and biotechnology companies to invest large amounts of money and efforts for the required infrastructure and the long development process (basic research, development and clinical translation, and safety approval[688]) that bring about these innovative medical products and services, and if these products and services improve people's health, then the patent system can improve people's health and thereby create an important utilitarian good.[689]

The second way in which the patent system can be justified in utilitarian terms is based on the patent system's economic impact. Innovative activity can boost the economy of the region and even of the whole country. Successful cases of innovation are likely to bring about economic benefits to the company or research centre from which the innovation originated. These benefits tend to expand and strengthen that company or research centre. Not only does this expansion allow the company or research centre to employ more people,

[688] The innovation process of medical products is usually long and expensive. The development process of drugs, diagnostics or therapies begins with basic research phase, which is usually performed in the public sector, such as public research institutions and universities. This stage is followed by the discovery phase in which developers seek and test materials, substances, and combinations with therapeutic or diagnostic value. The following stage is called development. In this stage, researchers test the compounds in terms of their metabolism, absorption, diagnostic efficacy, and toxicity for human consumption. This stage, also known as clinical trials, is one of the longest and most expensive. The next stage is the governmental approval, which tests for the safety, efficacy, and quality of the product. The final stage is the delivery, which is when the product is put in the market and made available to the public. The drug development process is said to cost USD $800 million and last 14 years. The diagnostics development process is said to cost USD $150 million and last 10 years. US Food and Drug Administration, "The Drug Development Process - Step 1: Discovery and Development", online: <http://www.fda.gov/ForPatients/Approvals/Drugs/ucm405382.htm>; Commission on Intellectual Property Rights, Innovation and Public Health, *supra* note 519 at 17–18.

[689] David B Resnik, "DNA Patents and Scientific Discovery and Innovation: Assessing Benefits and Risks" (2001) 7:1 Sci Eng Ethics 29; Kieff, *supra* note 530.

but in fact, it also requires it to do so. In this case, companies will then employ a higher number of people. The more people employed, the more people who are likely to have an income, and therefore the resources to be able to consume products and services. Likewise, the more people employed and the more companies in production, the more products and services that are likely to be put in the market. Therefore, this situation by itself is likely to boost the economy in that region since it is creating jobs, purchasing power, market products, and trade.[690] This effect expands outwards.

A successful innovative company and an active market could well attract other players. One of these other players can be other companies that either want to share part of the market or want to collaborate with the originally established companies. Skilled workers could also be attracted to move to the region where the successful innovative company is located, looking to be employed or be part of the innovation process and be trained in it. Universities may also want to help forge the new generation of human capital and keep the current one in a cutting-edge state. These demographics and corporations are likely to promote the creation of innovation hubs. A great number of companies can encourage each other to compete in prices and in quality or specialization of the products and services they offer. This would foster innovation and competitive prices. The people living in these regions are likely to have competitive salaries that would improve their purchasing power and therefore allow them to consume the products and services created and provided by the companies, maintaining thus an active market. Therefore, these

[690] Kristina Lybecker, "IP Protection is Key to U.S. Job Creation| Patents & Patent Law", (23 March 2015), online: *IP Watch dog.com Patent Law* <http://www.ipwatchdog.com/2015/03/23/ip-protection-is-key-to-u-s-job-creation/id=55978/>.

innovation hubs could foster medical innovation, boost competition, stimulate the market, and overall favour the economy of the industry, the region and of the country. Since patents are said to encourage and enable investors and inventors to participate in innovation, they are seen as one of the factors that can contribute to the formation of innovation hubs, and therefore to the industry's, region's or the country's economic development, which would be considered by some utilitarians as welfare.[691] Therefore, in utilitarian terms, the patent system creates welfare for society by contributing to this economic development.

6.1.2 Shortcomings of a Utilitarian Justification of the Patent System in Health-Related Innovation

As generally mentioned in chapter one, my main concern about a purely utilitarian and mainly economic justification of the patent system is the meaning, proof, and extent of the concept of "welfare." Accepting the justification of the patent system based on the utilitarian "utility/welfare" that the patent system is assumed to create (i.e. promote innovation) could be problematic in several ways. The first problem is that the actual impact that the patent system has on the pace or the process of innovation, the region's or the country's economy, and people's health is very difficult to measure.[692]

The parties involved in innovation processes are very diverse. Their motives to engage in these processes change depending on the industry, the company, the person, and the country. Patents may indeed attract inventors and investors, but they are definitely not

[691] Posner, *supra* note 6 at 119–135.
[692] Robert Cook-Deegan & Christopher Heaney, "Patents in genomics and human genetics" (2010) 11 Annu Rev Genomics Hum Genet 383 at 16.

the only incentive. Therefore, it is impossible to conclusively determine to what extent the patent system has contributed to the innovation activity in a certain area, industry or country. Particularly in Mexico, there are many researchers and some research centres devoting their activities to medical research and innovation. However, many of those researchers do not seem to make patents a priority, and in fact many of them do not even seem to pursue them. Similarly, research centres, universities, and Mexican native companies do not own many patents either.

The second problem is that the effects that the patent system is supposed to provide may turn out to be contrary or at least different to the ones expected. For instance, the patent system allows for information and technology to be "packaged" in convenient tradable units that could facilitate collaboration. The innovation that the patent system is also supposed to encourage and the resulting research and technology hubs could also be expected to promote collaboration. However, the requirement that the invention be new and non-obvious in order for it to be patentable may prompt practices of secrecy and hinder collaboration, as inventors may choose to maintain their research undisclosed until they are ready to file a patent.[693] Patent thickets may also cause[694] another outcome that would be different to the one expected: underdevelopment of a certain area or technology due to the underuse of a heavily patented research tools or products or the inefficient use of resources

[693] Rai et al, *supra* note 587 at 25; Bagley & Tvarnø, *supra* note 587 at 384; Wang, *supra* note 546 at 353; Hope, *supra* note 519; Horn, *supra* note 546 at 1274; Contreras & Sherkow, *supra* note 546 at 1274; Fisher, *supra* note 20 at 180.

[694] Patent thickets are a dense web of overlapping patents associated with a product, research tool or technology usually owned by a number of different parties that a company (or a researcher) must hack to commercialize new technology. See chapter six, section 6.2.1 for a full description of patent thickets and their effects.

devoted to determine the terms and extent of the protection covered by patents and to negotiate the necessary licenses.[695]

Likewise, the incentives granted by the patent system are supposed to encourage innovation that would bring about welfare to society; however, in reality, they may steer innovation away from useful areas. For instance, in many situations, a considerable part of the R&D in the pharmaceutical industry has focused on products that are not necessarily socially valuable: "me too drugs."[696] Despite their positive effects (i.e. competitive prices and fewer side effects or more targeted action, which can be deemed an important source of welfare), investors and inventors still devote considerable resources (e.g. monetary, intellectual, time, etc.) to research and development on these drugs instead of innovative products and services, affecting thus the pace of innovation.[697]

Another case in which it is unclear how to determine the true benefit of the type of innovation developed by companies and research centres and encouraged in some way by the patent system is that of beauty products, such as those against baldness, aging, obesity, cellulitis, etc. The market for products that counteract any of these conditions is usually composed of people who are likely to consume these products regardless of their prices, which makes for a very profitable and reliable market. This type of inelastic market provides an economic incentive for pharmaceutical and biotechnology companies to devote

[695] Hope, *supra* note 519; Bagley & Tvarnø, *supra* note 587 at 384; Wang, *supra* note 546 at 353; Horn, *supra* note 546 at 1274; Contreras & Sherkow, *supra* note 546 at 1274; Rai et al, *supra* note 587 at 25.
[696] "Me too drugs" are drugs that are structurally similar to already existing drugs with slight insignificant differences). For more details on "me tto drugs" and their effects see chapter six, section 6.2.1.
[697] Angell, *supra* note 580 at 74–93; Gagne & Choudhry, *supra* note 582 at 711.

significant resources to the R&D associated with these products and to pursue and control as much market share as possible. The patent system contributes to achieving both by providing exclusivity on the use and commercialization of the innovative technology and the products developed.

The large amounts of funds that pharmaceutical and biotechnology companies spend in marketing and advertising instead of in R&D is considered another waste of resources encouraged, at least indirectly, by the patent system.[698] Nine of the world's top ten pharmaceutical companies spend more resources (some even double) in marketing and advertising than in R&D. The company that spent the most being Johnson & Johnson allocated USD $17.5 billion to marketing and advertising while it only devoted USD $8.2 billion to R&D in 2013.[699] The better position that a drug, diagnostic or treatment obtains in the market, the more value that the associated patent will have. A valuable patent will lure more potential licensees into pursuing a license, and therefore lead to a more lucrative and more advantageous exploitation of the patent rights. The medical product's market value as well as the value that the associated patent has will result in higher profits for investors and patent holders. These profits are the reason for which the patent system may contribute to pharmaceutical and biotechnology companies devoting those many resources to marketing and advertising. A potentially positive effect of marketing is that the drug's uses and effectiveness may be made known to doctors and patients.

---

[698] Marketing and advertising includes promotion, packaging, and distribution. Marc-André Gagnon & Joel Lexchin, "The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States" (2008) 5:1 PLoS Med e1; Svatos, *supra* note 20 at 122.

[699] Ana Swanson, "Big pharmaceutical companies are spending far more on marketing than research", *Washington Post* (11 February 2015), online: Washington Post <https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/>.

Despite the potential positive effects of three cases –the "me too drugs", beauty products, and the marketing and advertising budget- the patent system may yet have a negative effect on health-related innovation. Instead of promoting innovation that would benefit society, the patent system encourages investors to divert resources to drugs that may not provide any additional benefit to the one already provided by existing drugs, to products that focus on aesthetic conditions, and to marketing, all of which are activities whose welfare could be easily questioned, especially in the light of several under researched and untreated life threatening diseases and life changing conditions.[700]

The case of neglected diseases or underfunded basic research is another undesirable situation, also attributable to a certain extent to the patent system, in which the welfare that the patent system is supposed to bring can be questioned. The patent system contributes to this situation because the economic incentives that it creates, along with those of the market, are deemed to encourage companies to focus their resources on diseases or areas that have a profitable market. The welfare that the patent system is expected to bring in terms of healthcare is the promotion of innovation of medical products and services that would improve people's health. This welfare should not be conditional on the disease, condition or area having a profitable market.

[700] Gagne & Choudhry, *supra* note 624; Marc-André Gagnon, "How a National Drug Plan Would Benefit Canadians", *Huffington Post* (12 August 2013), online: Huffington Post <https://www.huffingtonpost.ca/marcandre-gagnon/canada-national-drug-plan_b_3430031.html>; Marc-André Gagnon, "What my Critics Don't Get About Drug Policy", *Huffington Post* (2 September 2013), online: Huffington Post <https://www.huffingtonpost.ca/marcandre-gagnon/drug-policy-canada_b_3536203.html>.

In addition to the effects on the areas of innovation and marketing, the biggest problem with asserting that the patent system is justified in utilitarian terms relates to the impact of the patent system on access to medical innovations. The patent system may help to promote R&D in health-related innovation and benefit countries' industries, technological/scientific advancements, and economies. However, it may also harm access to healthcare in the terms described above (e.g. unaffordable prices, limiting competition, hindering and delaying supply, further developments, and generics/biocomparables). An economic benefit in health-related innovation, however, should not be enough to justify the current patent system and its prevailing implementation.[701] A justification that only promotes economic benefits, disregarding the focus of the innovation or failing to ensure fair and equal access to the inventions in the medical sphere, can have a very serious consequence: it can put people's lives at risk.[702] Moreover, unfair and unequal access to medical inventions allows the socio-economic gaps within the population to extend to people's health, particularly that of the most vulnerable populations, affecting their quality of life and even whether they live or die.

Upholding the welfare of the majority of a society as the aim and justification of a law or system is reasonable and desirable,[703] but only if the concept of welfare is not mainly defined in economic terms, as the patent system's justifications seem to be based on. "Welfare" is linguistically defined as the "state of doing well, especially in respect to good

[701] Stamatia A J Piper, *The emergence of a medical exception from patentability in the 20th century* (Ph.D., University of Oxford, 2008) [unpublished] at 84; Bita Amani, "'Of at Least Equal Importance': (Intellectual Property) Rights Mapping with a Moral Compass" (2018) 31:1 Intellect Prop J 105 at 116; Amani & Coombe, *supra* note 28 at 164.
[702] Amani, *supra* note 551 at 213; Amani, *supra* note 701 at 116 & 118.
[703] Kymlicka, *supra* note 26 at 12.

fortune, happiness, well-being or prosperity,"[704] it refers to "human good" gained by a person for their life to be considered to go well.[705] Good health is uncontroversially constitutive of human well-being. The reason is that people with good health are enabled to function effectively and pursue the type of life they want.[706]

The definition in practice of "utility/welfare" for purposes of a utilitarian justification is what I think is wrong in the current regulation and policies of the patent system. The utility or welfare that justifies the current regulation and policies of the patent system focuses on the economic incentives that patents provide for inventors and investors to engage in R&D activities that result in innovation. The rationale is that an ecosystem of innovation characterized by patents leads to the growth of industries, the improvement of countries' economies, the advancement of scientific and technological fields, and the benefits associated with all of the above that society as a whole may enjoy. Specifically, in the field of healthcare, the main benefit would be that people would have increased possibilities of improving their health by being able to have access to the innovative medical products available in the free market. Furthermore, the aforementioned benefits that any member of society may enjoy and that make those members better off, do not make anyone worse off, which is essential in terms of welfare economics.[707] In these terms, society is better off because anyone can have access to medical innovations available in

[704] *Merriam-Webster, s.v.* " Welfare".
[705] Arneson, *supra* note 97.
[706] Julie Clague, *supra* note 3 at 178.
[707] Welfare economics is a branch of economics that evaluates economic policies in terms of the effects they have on society's well-being, it is assumed that society is better off if one individual is better off without making anyone worse off. Fabienne Peter & Timothy Evans, "Ethical Dimensions of Health Equity" in Timothy Evans et al., eds., *Challenging Inequities in Health: From Ethics to Action* (United States of America: Oxford University Press, USA, 2001) 25 at 29; Mack, *supra* note 10 at 65; *(s.v.) "welfare economics"*, online ed.

the free market. No one is worse off because the existing patients do not get sicker because there are new innovative products and even if some of these patients do not have access to the innovative medical products, their condition is not worse than before the products were created.[708]

The main problem with this conception of welfare is that a justification based on an economic incentive that is expected to promote innovation may lead to praising innovation as an end in itself. It may lead society to consider innovation in any area (even those of the "me too drugs," beauty products or any other profitable area or product) as desirable. It may lead to R&D that neglects certain areas of medical research because they do not have a guaranteed profitable market. It may lead to a society that has a number of innovative treatments available in the market, such as genetic diagnostic tests, gene therapies, personalized treatments based on pharmacogenetics, but that are only accessible to very few. This perspective disregards the fact that innovation is not an end in itself, but a means to an end. As I have mentioned before, I am aware that the patent system is neither the cause of these problems nor the only incentive for innovation. However, the policies that countries (governments, authorities, and societies) adopt regarding innovation (such as Mexico) and the justifications of those policies that define welfare in economic terms give prominence to the patent system as the most important and effective kind of incentive to promote innovation. This prominence vindicates the current patent regulation, its enforcement, and its associated policies, and contributes to the aforementioned problems and disregards or underestimates the seriousness of their impact.

[708] Allan Gibbard, "Health Care and the Prospective Pareto Principle" 94:2 Ethics 261 at 264–266; Trebilcock, *supra* note 6.

Development should not be measured solely in economic terms. Economic growth, technological advancement, and innovation are important, but as means to an end, as the capability approach suggests. Development should be measured in broader terms and look at the impact it has on people's lives; the freedoms, capabilities and functionings they have in their lives; the extent to which these capabilities and functionings empower them to live their lives.[709] This should extend to the freedoms, capabilities, functionings, and lives of those in the most adverse circumstances. The end goal of innovation and development should be society's well-being. In health-related innovation, this well-being should be measured in the improvement of people's health. Consequently, for the patent system to be justified, it should do a better job at ensuring that the innovation it is supposed to encourage also promotes R&D on neglected diseases or on any other condition or area that does not have a profitable market. It should also do a better job of improving, or at least not making it harder to provide, universal, fair, and equitable access to the innovative medical products and services created, based not on whether the patient can afford it (as the current free-market does), but on whether the patient needs it. This last point is particularly important because, good health is an essential element of human well-being. Good health allows people to work and be productive, to function effectively, to enjoy life, and flourish.[710]

[709] Julie Clague, *supra* note 3 at 177; N Daniels, "Justice, health, and healthcare" (2001) 1:2 Am J Bioeth AJOB 2.
[710] Julie Clague, *supra* note 3 at 178.

8.2 Exceptionality of Health

The focus of this dissertation on the creation of and access to health-related innovations, as opposed to the impact that the patent system may have on other innovative areas, stems from the importance that health has for humanity. As I have argued earlier, health is a determining factor between life and death and of people's quality of life, which is why accessing the highest attainbale standard of health is one of the fundamental rights of every human being.[711] Health can determine the extent to which people can take advantage of the opportunities available to them, and thus influence their socio-economic situation.[712] For instance, as I explained in chapter two, the impact of a state of good or poor health can be observed in students' learning abilities and therefore their capacity to obtain a well-paying job or in people's availabilities to actually work and maintain a steady and adequate income. Having access to healthcare services enables people to be healthy, to work, be educated, be part of a community, etc. It also enables people to have the life they value. More importantly, health possesses a special link to life itself. Lack of health or to access to healthcare can bring serious physical and psychological suffering, substandard lives, and in more severe cases, it can result in death.[713] This link to life itself is what determines the exceptionality of health, what makes health-related innovation differ from innovation in other industries, what calls for different rules of access, and why welfare or utility needs to be redefined when assessing the convenience of the patent system in this field. With this in mind, the availability and access to healthcare services should not be determined by free market rules. Availability and access to health and healthcare services

[711] *Constitution of the World Health Organization*, *supra* note 101.
[712] Bernier, *supra* note 34 at 49–50.
[713] Amani, *supra* note 551 at 213.

should be fairly distributed. In other words, access to healthcare should be a moral requirement[714] that takes precedence over any preference like maximization of profit or economic growth.

8.3 Capability Approach and the Patent System in Medical Genetics

Considering the exceptionality of health, a more adequate justification of the patent system in health-related innovation should consider the capability approach's functionings and capabilities to define the concept of "welfare." Using a utilitarian approach that upholds the welfare of the majority of a society as the aim and justification of a law or system is reasonable and desirable. However, using a definition of "utility/welfare" that is reduced to economic terms may lead to actual unequal distribution of this welfare. Instead, the capability approach can help to define the concept of welfare in terms that ensure that this definition means actual and equal access to the innovative medical products and services that the patent system is supposed to encourage to be created.

As mentioned in chapter one, the capability approach is a normative framework created to evaluate and determine a person's well-being, and therefore useful to assess the impact that laws, policies or social changes may have on people's well-being, poverty or inequity.[715] To make this assessment, the capability approach focuses on the actual freedom or opportunity (capabilities) that people have to choose and achieve what to do in order to lead the life they want (functionings).[716] People's well-being increases when

[714] Kymlicka, *supra* note 26 at 29.
[715] Robeyns a), *supra* note 3 at 94.
[716] Sen, *supra* note 23 at 75 & 87; Julie Clague, *supra* note 3 at 178.

obstacles are removed and those people are enabled to do whatever they choose in order to live the kind of life they want.[717]

This approach challenges the idea that welfare, human well-being or human development could be measured solely by people's income or wealth. Income, wealth, economic growth, technological advancement, social institutions, and primary goods are only means to an end. In this case, the end is to provide proper access to health in order to enable people to be healthy. This end is what would ensure people's freedom to choose and attain the type of life they consider valuable. According to the capability approach, laws and policies should achieve this for all citizens, as opposed to just a few.[718]

Human development, as discussed in the Human Development Report, is about enabling human beings' freedoms to pursue the lifestyles they value (i.e. functionings and capabilities). This enablement is what constitutes human well-being. While economic growth and maximization of income and profit are means to human development, they are not the end.[719] In addition to the link of health with life itself that I explained while discussing its exceptional or unique nature, health is key to prosperity. It constitutes a determinant factor for human beings to be or do what they want. It could also allow and help human beings to do what they are expected to do in society. In other words, good health is an end in itself and a means to be able to work and be educated.[720] This is why

[717] Sen, *supra* note 23 at 75; Robeyns a), *supra* note 3 at 94.
[718] Jean Drèze & Amartya Sen, *India: Development and Participation* (Great Britain: Oxford University Press, 2002) at 3; Nussbaum, *supra* note 88 at 39–40 & 57; Nussbaum, *supra* note 88 at 70.
[719] United Nations Development Programme, *supra* note 145 at 1–2.
[720] Robeyns a), *supra* note 3 at 95; Julie Clague, *supra* note 3 at 178.

the capability approach is relevant while discussing health-related innovation. In fact, Nussbaum specifically considers life (i.e. to live a life of normal length) and health to be central human functional capabilities and asserts that they should be the aim of every law and policy.[721] Therefore, laws and policies that regulate, ensure, or are in any way associated with providing healthcare services should only be justified if they treat health in these terms.

As mentioned in chapters six and seven, the patent system can have and actually has an impact (positive or negative) on access to healthcare by encouraging, delaying or limiting innovation in medical R&D or by enabling patent holders to control the use of or access to their innovative medical products and services (through licenses and prices). The capability approach helps determine the impact that the patent system in health-related innovation could have on people's access to healthcare by evaluating whether patent laws or policies enable, limit or jeopardize people's capabilities to be healthy by determining if access to the necessary healthcare services is affected as a consequence of the enforcement of said laws and policies.[722] It justifies looking at whether patients who need those innovative medical products and services have the freedom and actual possibility to access them, thereby increasing their chances of having good health. In this case, having those innovative medical products and services in the market would not be enough if the price for those products and services is unaffordable by those who need them the most or if they

[721] For Nussbaum's full list of central human capabilities see chapter one section 1.2.1. Nussbaum, *supra* note 74 at 78–80; Sen, *supra* note 78 at 77–80; Nussbaum, *supra* note 88; Nussbaum, *supra* note 23 at 34.
[722] Robeyns a), *supra* note 3 at 96.

are physically/geographically inaccessible (i.e. they are not available in the only clinic near the patient).

In view of this, the patent system would be justified when used to promote and facilitate innovation related to medicine if it ensured that patients who needed access to innovative medical products and services could actually have that access, or if it at least did not contribute to limiting it. Grounding timely access to the innovative medical products or services on the basis of medical necessity is what would constitute the well-being or welfare generated by the patent system, as it would be this accessibility to necessary healthcare that would in turn provide the functioning of health and the capability of choice for a valuable life.

Chapter 9 Discussion: Health, Innovation, Patents, Mexico, and Suggested Solutions

Throughout the previous chapters, my focus has been on the impact that the patent system may have on the creation of and access to health-related innovations, as opposed to the impact that the patent system may have on other innovative areas and I have suggested that this differentiation stems from the importance that health has in people's lives. I have also discussed the main benefits and concerns associated with the patent system in health-related innovation, specifically identifying those that occur in Mexico. I have then argued that many of those concerns derive from justifying the patent system, on purely utilitarian bases and I have therefore suggested using the capability approach to make a more complete and appropriate theoretical basis to counterbalance some of those problems, specifically in health-related innovation. Using the capability approach, throughout my dissertation, I have highlighted where the socio-economic circumstances of Mexico's population and those of the Mexican Indigenous Peoples act as conversion factors and where achieving people's capabilities and functionings is essential toward improving their quality of life.

In this final chapter, I propose a definition of "utility/welfare" that I deem appropriate (based on principles of the capability approach: capabilities, functionings, conversion factors). I then use this definition to examine whether the actual impact that the patent system has on medical innovation creates welfare to Mexico's society. I finish this chapter suggesting that more open and collaborative innovation models, such as licensing models, public-private partnerships, and open science, be further researched and

considered as potential options to innovation in medical genetics as a way to increase the chances of ensuring welfare or benefit for society in terms of the capability approach principles.

9.1 The Utility/Welfare of Patents in Mexico

Based on the principles and elements discussed in chapter eight, the utility/welfare that I have suggested be used to justify the patent system in health-related innovation has two components: that it promotes innovation and that it promotes access to the innovative healthcare products and services, or at least, that it does not limit one or the other. Both components are important because only together it is possible to assert that people are empowered to achieve their health-related capabilities and functionings, and therefore, assert that the patent system contributes to the improvement of quality of life, to human development.

The first element touches on the most traditional utilitarian concept of utility: improving people's lives by creating and making available in the market innovative and useful medical products in an eficient and effective way as well as increasing economic growth. The second element is mostly based on the concepts of funtionings and capabilities of the capability approach: universally enabling people to choose the life they want and to live accordingly.

9.2 Implications of the Patent System on Health and Innovation in Mexico

In order to determine whether the patent system brings about welfare to health-related innovation in Mexico I look for the two elements of the above-mentioned definition of "utility/welfare" in impact on the patent system in the context of Mexico's innovation ecosystem and healthcare system as described in the previous chapters.

First, regarding the impact of the patent system on the promotion of innovation, despite the above mentioned ambiguity[723] of the worldwide empirical evidence,[724] as I described in chapter three, Mexico's pharmaceutical and biotechnological industries and specialized research centres lack the underlying advanced technological and scientific infrastructure and the resources - particularly monetary - to translate basic research into clinical applications. These conditions make it more difficult, more expensive, and longer to develop a clinical innovative product.[725] This could explain why the pharmaceutical and biotechnological industries in Mexico focus on generics, biocomparables, and similares[726] and the research centres have not been able to translate their basic research into the clinical setting. The fact that Mexico's pharmaceutical and biotechnological industries focus on these products and the research centres on basic research almost completely eliminates the possibility of any of these Mexican companies or institutions becoming a direct competitor to the innovative foreign companies. Given that the aforesaid necessary economic,[727]

[723] Hall, *supra* note 554 at 450; Gold, Herder & Trommetter, *supra* note 554 at 4.
[724] See for instance: Cook-Deegan & Heaney, *supra* note 692 at 399; Sampat & Williams, *supra* note 554; Heidi L Williams, "Intellectual Property Rights and Innovation: Evidence from the Human Genome" (2013) 121 J Polit Econ 1; Fiona Murray & Scott Stern, "Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis" (2007) 63:4 J Econ Behav Organ 648.
[725] Sales Heredia, *supra* note 113 at 45.
[726] For a detailed definition and distinction of these terms, see footnote 7 in the Introduction.
[727] Examples of this type of economic conditions include sufficient monetary funds and a market within

technological/scientific,[728] and social[729] conditions with which the patent system is supposed to promote innovation cannot be found in Mexico as I described in chapters two and three, the patent system has not shown to have any of the positive effects of encouraging and enabling local pharmaceutical and biotechnological industries or research centres to produce much original innovation of their own. Not having much original health-related innovation of their own could explain the low numbers of patents owned by Mexican companies, academic institutions, and research centres.

This situation forces Mexico's pharmaceutical and biotechnological industries and research centres to rely on the R&D activities done by foreign companies. This means that it is the foreign companies who decide which areas/products will be developed. Given that it is these companies who own the highest number of patents, and bearing in mind that the incentive provided by patent is economic, it is to be expected that their decisions about which areas to develop will be based on whether those areas will have a profitable market in which their patents will be useful. Consequently, non-profitable areas will likely be overlooked, regardless of whether members of the Mexican population would benefit from their development.[730] This could explain the absence of an effective treatment for actinic prurigo, a non-fatal, non-epidemic, and non-widely spread disease that affects mainly members of Indigenous Peoples (mainly in Mexico) who cannot personally afford its treatment and which is not a priority in the public healthcare system.

---

which the goods and services can in fact be offered and bought.

[728] Underlying infrastructure and researchers with particular training are two examples of this type of technological/scientific conditions.

[729] Some examples of these social conditions are population with decent socio-economic conditions and reliable and accessible healthcare system that will integrate the innovative products and ensure their access.

[730] Commission on Intellectual Property Rights, Innovation and Public Health, *supra* note 519 at 23.

On the other hand, as I mentioned in chapter seven, the presence of the top foreign multinational pharmaceutical and biotechnology companies in Mexico enables technology and know-how transfer in favour of Mexican researchers and availability of innovative medical products and services in the national market. Since many of the patents granted by the IMPI in the health-related innovation field are owned by these foreign companies, it is reasonable to assume that the patent system has contributed to these companies setting up their manufacturing and offices in Mexico and therefore, to the aforesaid benefits associated with them.

However, even with innovative medical products and services available in the market, Mexico lacks adequate social conditions (e.g. population with decent socio-economic conditions and reliable and accessible healthcare system that will integrate the innovative products and ensure their access) to ensure that its population has actual access to necessary health-related innovation resulting from the patent system. As mentioned in chapter two, despite Mexico's economy being ranked relatively high,[731] close to half of Mexico's population (including 75% of the Indigenous Populations) lives under the poverty line, cannot afford private healthcare services, and therefore relies on the public healthcare system. However, Mexico's public healthcare system is already underfunded and deficient. It is also worth remembering that in 2015, close to 25% of Mexico's population did not even have access to public healthcare.[732] High levels of poverty and a

[731] "Mexico - WolframAlpha", online: *WolframAlpha* <http://www.wolframalpha.com/input/?i=mexico>; (accessed May, 20, 2016) "Mexico. CIA The World Factbook", online: CIA <https://www.cia.gov/library/publications/the-world-factbook/geos/mx.html> (accessed May, 20, 2016).
[732] INEGI, *supra* note 8.

deficient public healthcare system act as negative conversion factors and, as such, are likely to prevent people from having access to the necessary healthcare services and to a dignified quality of life, in spite of possibly having the innovative drugs, therapies, and diagnostic tools available in the market and of clinically creating a demand for them.

Most R&D related to health directly touches people's health and lives.[733] Therefore, equality in access to healthcare needs to include not only essential medicines, but also innovative medical and medical genetics products and services, such as vaccines, drugs, diagnostic tests, personalized therapy.[734] Access to essential medicines can be a factor between life and death. However, access to any of the innovative products that are not considered "essential medicines" can still be the difference between being healthy and being sick and suffering, and eventually between life and death.[735] For instance, access to genetic diagnostic tests that can detect a genetic disease or anomaly in a timely manner, or that can detect a predisposition to developing a disease in asymptomatic individuals, can help to either obtain the necessary treatment on time or to even take preventative measures (e.g. change of diet, daily habits or surgery) to avoid or minimize the chances of developing chronic diseases and in some cases even a fatal disease such as cancer. Likewise, access to personalized medicine can help to effectively target a specific ailment, avoid unnecessary side effects, and diminish the possibility of a relapse.

[733] Cook-Deegan & Heaney, *supra* note 692 at 388.
[734] *Ibid*.
[735] Bernier, *supra* note 34 at 51; Amani, *supra* note 551 at 213.

Similarly, even though the P'urhépechas, Mazatecas, Nahuas, and Mayas discussed in chapters four and five who suffer from actinic prurigo and tuberculosis will not likely die from their diseases, not having access to effective treatments against their conditions prevents them from fulfilling their habitual and desired activities and lifestyles. For instance, in the case of the P'urhépechas, not having access to the most effective antibiotics is likely to prevent the tuberculosis from actually being eradicated from their bodies, thereby preventing them from having the energy to learn in school, from succeeding in the job they choose, and from having better chances of improving their socio-economic conditions. In the case of the Mazatecas, Nahuas, and Mayas, not having access to a more effective treatment against actinic prurigo that does more than treat the symptoms prevents them from being outdoors during sunny days and consequently from working on agricultural activities. It is true that it may be the case that there are actinic prurigo patients who do not wish to work on agriculture, but this should be their choice. They should have the freedom to choose the occupation they consider valuable. Moreover, being able to be outdoors on a sunny day impacts people's lives in more than their occupation: it allows them to have a normal, mentally and physically healthy life. In this case, the problem is not merely of access to existing treatment, but of R&D, since up to today, there is not an effective treatment.

Patents contribute to the aforementioned poor access to healthcare by allowing the patentee to set an increased price on the innovative and most efficient medications, diagnostic tools, and therapies. These increased prices, which depend more on the ability

of the manufacturer to set them than on the costs associated to their development,[736] affect the private access to the innovative medical products. They also affect their public supply, as the public healthcare system has limited resources. If patents are bound to make healthcare services (e.g. diagnostics, medications or treatments) more expensive, half of the population will be even less capable of affording the necessary healthcare services. Furthermore, the public healthcare system will either have to provide more generic or non-expensive patented drugs, diagnostics, and therapies or it will provide the more innovative patented products and services and have its coverage capacity considerably diminished. It is also worth mentioning that the provisions mentioned in chapter three that Mexico has in its legislation about compulsory licensing in cases of a national emergency or extreme urgency or abuse of patent rights, as well as policies about price control in medications or research and experiments exceptions, are insufficient to ensure timely access to effective medications, accurate diagnostic tests, and affordable personalized medicine. In fact, there have been no compulsory licenses granted in Mexico, even though there have been a number of unsuccessful attempts to obtain HIV/AIDS drugs. The attempts have been unsuccessful because of the difficulty in defining "shortage of medicine" or "health crisis" in the compulsory license application.[737] This means that, even if the patent system contributed to some extent to the creation and availability of innovative medical products that are more effective than the generic ones, and even if these products are medically needed, if the same patent system contributed to these products being so expensive that neither the patient nor the public healthcare system will be able to purchase them, then the patent system hinders access to healthcare for vulnerable populations and therefore, it

[736] Kesselheim, Treasure & Joffe, *supra* note 561 at 7.
[737] Moise & Docteur, *supra* note 277 at 11.

threatens their freedoms, opportunities, and lives. Hence, in terms of the definition of "utility/welfare" I suggest, the current patent system in Mexico does not bring about the benefits it should justify it.

I am not asserting that the current patent system is the sole factor responsible for the slow health-related innovation and its inequitable access in Mexico, as other necessary factors, such as other sources of funding, the existence of a profitable market, and prevailing infrastructure, strong universal public healthcare system, and stable socio-economic conditions are not present. However, considering the low patenting activity on behalf of Mexican researchers, institutions, and companies, I cannot conclude that the current patent system in fact creates incentives to promote the creation of a prolific local health-related innovation ecosystem in Mexico or that it promotes innovation on endemic diseases when they lack a profitable market. At the most, it attracts foreign biotechnology and pharmaceutical companies to establish offices and laboratories in Mexico to manufacture and commercialize drugs, diagnostic tests, and treatments for common and profitable conditions such as cancer, diabetes, and heart diseases. What is more pressing though is the negative impact that it does have on access to healthcare, particularly with respect to the issue of making drugs and treatments unaffordable to considerable sectors of the population. Furthremore, as I mentioned in chapters two, four, and five, there is already a very large socio-economic gap among the different sectors of Mexico's population with respect to water, income, living infrastructure, and nutrition that impacts people's lives and health. These inequalities hinder the capabilities and functionings of those who lack water, income, living infrastructure, and nutrition, as these conditions will limit their potential to

obtain a good job, and therefore to freely choose the life they consider valuable. Unequal access to healthcare determined by free market rules will only widen this gap by preventing people from affording proper living infrastructure, nutritious food, attending and succeeding in school, and maintaining a suitable job and source of income.[738] Considering the importance of providing universal access to proper healthcare as a means to ensuring people's capabilities and functionings, each country has the obligation to give consideration to health implications of their policies, including those of patents.[739]

9.3 Looking Ahead

The specific circumstances in Mexico regarding the innovation landscape, socio-economic conditions, healthcare services, the effects of the current patent system on health-related innovation and access to healthcare, and the importance of having access to healthcare, led me to question the way in which the patent system is in fact regulated, implemented, enforced, justified, and promoted. I do not suggest that Mexico get rid of the patent system for health-related innovation, for the following reason. Foreign pharmaceutical and biotechnology companies, who, despite not having a positive direct on promoting or enabling the advancement of the national industry, have an important place in the industry in Mexico in terms of availability of products as well as in terms of the country's labour and economy, vehemently claim to depend on patents. Getting rid of the patent system could greatly impact the presence and operations of these companies in Mexico, thus affecting the availability of the products and services that these companies

[738] Bernier, *supra* note 34 at 50–51; United Nations Development Programme, *supra* note 145 at 7.
[739] Commission on Intellectual Property Rights, Innovation and Public Health, *supra* note 519 at 10 & 21.

produce and market in Mexico, the jobs created by the laboratories that these have in the country, as well as the country's economy, given the importance that patent protection has in international trade agreements. However, I do advocate looking at some of the alternative options proposed in other cases of health-related innovation as well as in the case of other industries such as information technology to try to adapt to the specific circumstances and needs of Mexico and thereby prevent or, at least minimize, the negative effects I have found. The options I briefly review and that I suggest should be given further consideration and research share the objective of facilitating collaboration among different parties to the innovation process, which would be useful to promote innovation and enable access in view of the aforementioned conditions in Mexico. These options are licensing models (e.g. patent pools, cross licensing, and patent clearinghouses) public-private partnerships, and open science.

Patent pools, cross licenses, and patent clearinghouses are based on the pre-existence of patents. This means that, more than an alternative model of innovation process, they constitute a method in which patent rights can be negotiated and enforced in a more effective way. A patent pool is a set of agreements between patent holders to authorize one another or to third parties the use and exploitation of one or more of their patented inventions.[740] A cross licensing scheme is a bilateral license between two patent holders

[740] A modality of patent pools that could be relevant is the sovereign patent pool (also known as the sovereign patent fund). A sovereign patent pool is a patent pool created with state-backed funds to acquire intellectual property rights from third parties in order to license them to all national firms (defensively) or to some specific entities (offensively) as a way to meet national economic objectives. Warren Clarke, "A Worthwhile Intervention? The Potential Rile for a Sovereign Patent Fund in Canada", *Centre for International Governance Innovation* (25 April 2017), online: CIGI <https://www.cigionline.org/articles/worthwhile-intervention-potential-role-sovereign-patent-fund-canada>.

who grant each other a license for the use and exploitation of their patented inventions. A clearinghouse is a platform that matches patent holders and licensees in order to facilitate license agreements between them. A clearinghouse is also helpful in monitoring and enforcing the terms of use, collection of royalties, and mediation and arbitration of potential disputes.[741]

These licensing models have been used in other industries, where they have facilitated the use of standard technologies and enabled the advancement of technologies such as the DVD.[742] In medicine, patent pools have been suggested in the use of CRISPR technologies on non-exclusive, cost-effective, transparent, and non-discriminatory terms.[743]

The main advantage of these licensing models is that they facilitate collaboration in the innovation process, as they all aim to balance practices of commercialization and access to information or research tools. They allow negotiations costs between licensors and licensees to be low, as they frequently use typical licenses and provide developers with easy access to a set of patents associated with essential standard technologies and research tools in a single licensing transaction. This allows new innovative products to be effectively developed, bottlenecks to be avoided, and patent holders to be rewarded for their patented invention.

[741] Andrews, *supra* note 244; Esther van Zimmeren et al, "Patent pools and clearinghouses in the life sciences" (2011) 29:11 Trends Biotechnol 569; Granados Moreno & Joly, *supra* note 211.
[742] "DVD6C Patent Pool", online: DVD6C <http://www.dvd6cla.com/>.
[743] Horn, *supra* note 546.

The main drawback is that given that all these models are still based on patents and royalties, they may still have effects that are contrary to the democratization of innovation.[744] In all of these licensing models, patent holders can still set the terms and conditions they wish. These may still leave developers without a license to use the patented technology if they lack the resources to pay the royalties required. This means that the innovation process may still be slower or less diverse than broad royalty-free licenses.[745] This would be particularly undesirable in health-related innovation given the stage of development of much of the health sciences (and particularly, most of the medical genetics field) where there is still much about the field that remains unknown or not fully understood. Hence, the biggest challenge implementing these licensing models in health-related innovation is to be able to balance the need to cover/recoup the high costs of R&D (including the costs of clinical trials and regulatory approvals) and make a profit with maintaining fair, reasonable, and non-discriminatory terms of access that would encourage further development.[746]

A Public-Private Partnership (PPP) is an arrangement between entities of the public and private sectors to collaborate on sharing their resources (e.g. knowledge, data and samples, clinical expertise, infrastructure, economic funds, patient base etc.), risks, and responsibilities in order to make the innovation process more efficient, less costly, and faster. This model is based on the assumption that the innovation process is too complex, expensive, and long for any of the two sectors to efficiently engage in the innovation

[744] For more details on the democratization of innovation see chapter six, section 6.2.1
[745] Contreras & Sherkow, *supra* note 546 at 1274.
[746] *Ibid*.

process from early stages of basic research to the development and translation into "commercializable" applications.[747] The collaboration among PPPs is expected to become more efficient because sharing resources, responsibilities, and infrastructure allows them to avoid duplication of efforts, learn and take advantage of what their partners have done and learned, and therefore allocate their resources in more productive or specialized ways.[748] PPPs allow their partners to seek patents or other forms of intellectual property, which they share with the other partners. They also enable the implementation of an open science model.

In the medical setting, PPPs are used to develop and/or provide access to medical products such as drugs, vaccines, and diagnostic tests. This is particularly useful when trying to focus on a specific condition that is endemic to a particular region and which does not have a very profitable market or in order to overcome problems of access to healthcare due to issues of market failure.[749] They also aim to better understand diseases by studying their causes or associated factors (e.g. potential genetic component) and developing personalized treatments. The entities that are usually involved are philanthropic institutions, health authorities, public and private hospitals, research centres, public and private universities, pharmaceutical or biotechnological companies, not-for- profit organizations, patient associations, and information technology companies (e.g. cloud computing services to store, handle, organize, analyze, and make accessible massive

[747] Granados Moreno & Joly, *supra* note 211 at 287; Young Hoon Kwak, YingYi Chih & C William Ibbs, "Towards a Comprehensive Understanding of Public Private Partnerships for Infrastructure Development" (2009) 51:2 Calif Manage Rev 51.

[748] Palmira Granados Moreno, Yann Joly & Bartha Maria Knoppers, "Public–Private Partnerships in Cloud-Computing Services in the Context of Genomic Research" (2017) 4 Front Med, online: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC5247451/> at 1–3.

[749] *Ibid* at 3.

amounts of data for genomic research). Some examples include the Drugs for Neglected Diseases Initiative, the TB Alliance, the International AIDS Vaccine Initiative, MSSSNG, and the International Cancer Genome Consortium. Particularly in Mexico, PPPs have been used to provide healthcare services through the construction of and provision of equipment for thirteen hospitals throughout the country.[750]

PPPs can have a more positive effect on the democratization of innovation than the licensing models I mentioned above, as not only agents with the most resources will be able to participate in it. The democratization of the innovation process, as well as the support and means to focus on non-profitable conditions and to improve access to medical products and services caused by PPPs, benefit developing countries, as they are able to increase their chances to access the healthcare services they need. PPPs can also benefit developing countries, as the R&D in which they participate could increase the region's employment and distribution of goods, and promote the country's economic, scientific, and technological growth.[751]

Despite the benefits and some noticeable successful stories such as the DNDi,[752] PPPs can have certain challenges. The main challenge is the PPP's coordination and

[750] Ignacio Astorga et al, *10 Años de Asociaciones Público Privadas (APP) en Salud en América Latina Qué Hemos Aprendido?*, Serie de Notas Tecnicas de las Asociaciones Publicas Privadas en el Sector de la Salud en America Latina (Banco Interamericano de Desarrollo, 2016) at 38–43; A Llumpo et al, *Lessons from Latin America: The Early Landscape of Healthcare Public-Private Partnerships*, Healthcare Public-Private Partnership Series 2 (United States of America: Global Health Group, Global Health Sciences, University of California, and Price Waterhouse Cooper, 2015) at 33–45.

[751] Granados Moreno, Joly & Knoppers, *supra* note 748 at 3; Hope, *supra* note 519 at 104.

[752] The Drugs for Neglected Diseases Initiative is a non-for-profit collaborative organization that focuses on drug research and development on neglected diseases giving particular importance to patients' needs. The diseases on which the DNDi focuses include malaria, sleeping sickness, visceral leishmaniasis, paediatric HIV, mycetoma, filarial diseases, hepatitis C, and Chagas disease. Up to today, the

management. The difficulties in coordinating and managing the PPP stem from the partners' sometimes unrealistic expectations about the PPP's outcomes, the partners' different interests and goals, complications of the negotiation process itself, the legal and regulatory frameworks, the political setting and public opposition surrounding the focus of the PPP, and the length of the innovation process that would require the PPP to be maintained throughout the whole process.[753]

Open science is a model characterized by principles of open sharing of data, ideas and materials, fast dissemination of knowledge, research based on the accumulation of previous findings, and collaboration. It aims to stimulate scientific/technological progress, maximize the impact of research, enhance partnerships, and meet humanitarian goals by making research and data accessible to all.[754] The principles of this model are based on the idea that:

> "The only way in which a human being can make some approach to knowing the whole of a subject is by hearing what can be said about it by persons of every variety of opinion, and study all modes in which it can be looked at by every character of mind. No wise man ever acquired his wisdom in any mode but this…"[755]

organization has successfully made available treatments for malaria, sleeping sickness, leishmaniasis, paediatric HIV-TB, and Chagas disease. DNDi, "Drugs for Neglected Diseases Initiative - About Us", online: DNDI <https://www.dndi.org/about-dndi/>.

[753] Granados Moreno, Joly & Knoppers, *supra* note 748 at 3.

[754] Caulfield, Harmon & Joly, *supra* note 610; Gold, *supra* note 609 at 2; Guy Rouleau, "Open Science at an institutional level: an interview with Guy Rouleau" (2017) 18 Genome Biol 14 at 1.

[755] John Stuart Mill, *The Collected Works of John Stuart Mill, Volume XVIII - Essays on Politics and Society Part I*, On Liberty - Online Library of Liberty (New York: Henry Holt & Co, 1879) at 41; Hope, *supra* note 519 at 74.

The open science model has built on aspects, characteristics, and experiences of models in the software industry: Free Software[756] and Open Source.[757] Both models are characterized by transparency, peer review and feedback loops, low transaction costs and easy involvement, and a combination of formal and informal governing mechanisms.[758]

Some of the principles of open science (i.e. open sharing and fast dissemination) have been integrated into international policies and guidelines, such as the Organisation for Economic Cooperation and Development (OECD) Principles and Guidelines for Access to Research Data from Public Funding and the Organisation of the Human Genome (HUGO) Statement on Human Genomic Databases.[759] There have also been projects in medical genetics that have adopted the complete open science model. Examples of these

[756] Free software is a movement that rose in the software industry against proprietary restrictions on access to and use of source code (set of lines of code written, read, and understood by human beings that give instructions to a computer so it executes the orders given in that code). In accordance with this movement, users should be able to freely run, study, distribute, and modify the source of any program and to release the modified version (also known as derivative work) of such program. In addition to these principles, the free software model requires any modified version to be released under the same terms and conditions as the original software. Free Software Foundation, "What is Free Software", (1985), online: *GNU Org* <https://www.gnu.org/philosophy/free-sw.en.html>.

[757] Open source is a model that is very similar to free software in that it is based on the need to enable users to use, study, adapt, and distribute the source of code. The slight differences between them are the term used (the open source model explicitly intends to avoid the ambiguity of the term "free", which can be interpreted as "gratis" when in fact refers to "freedom") and the fact that open source licenses do not have to require that derivative works be distributed under the same terms. Open Source Initiative, "The Open Source Definition (Annotated)", (1998), online: *Open Source Org* <https://opensource.org/osd-annotated>.

[758] Hope, *supra* note 519 at 7–17.

[759] Caulfield, Harmon & Joly, *supra* note 610; Granados Moreno & Joly, *supra* note 211.

projects are the Structural Genomics Consortium (SGC)[760] and McGill University's Montreal Neurological Institute (MNI).[761]

One of the benefits of the open science model for innovation is making tools (e.g. knowledge, data, and research tools) available in a way that imposes no restrictions, being the selective and thoughtful eschewal of patent protection a common strategy to achieve this. This restriction-free way of providing access to knowledge, data, and tools allows partnerships to be enhanced, funding to be leveraged, entry costs to be low, networks of users and contributors to continuously increase in number and diversity, and transaction costs to be reduced (there is no need for technology transfer offices). All these benefits combined, if materialized, could accelerate the progress of science, which is likely to attract more researchers, governmental and not-for profit funders, academic institutions, and private companies, which could accelerate the progress of science even more.[762] A particularity of the partnerships that open science may enable is that, due to the principles it holds (egalitarianism, meritocracy, and self-organization), the contributors who are

[760] The SGC is a not-for-profit PPP that produces 3D structures of proteins and chemical tools that enable drug discovery. It releases its outputs and discoveries under the open science model: without any patent or any other intellectual property restrictions. While it started with six members in 2004, it currently has thirteen partners (out of which nine are pharmaceutical companies, such as Bayer, Merck, Novartis, and Pfizer) and has collaborations with more than 300 groups. In Canada, the SGC has produced and shared structures for over 1,500 proteins (approx. 15% of the human proteome) even before their self-set deadlines. Amy Donner, "A Conversation with Aled Edwards" (2014) Sci-Bus Exch 1 at 1.

[761] In 2016, the MNI launched a five-year experiment adopting the open science model across the whole institute and all of its laboratories. In accordance with its model, the MNI commits to publishing its research without restrictions, sharing experimental data, refraining from pursuing patents, and sharing biological samples and other resources from its biobank. The goal is to attract highly talented researchers and trainees enthusiastic about an open science model and improve the transparency, reliability, and impact of their research under this new model, accelerating the pace of discovery and benefiting patients all over the world. The project has attracted over $100-million in federal, provincial, and philanthropic donations, and it is hoped that it will contribute to the creation of a local knowledge/technology hub, as it is expected to draw companies and researchers to the Montreal area in order to fully benefit from the access to data, samples, and materials it offers. Gold, *supra* note 609 at 2; Rouleau, *supra* note 754 at 1.

[762] Donner, *supra* note 760 at 1 & 3; Gold, *supra* note 609 at 2–3.

attracted to projects adopting this model are very diverse in terms of their background and expertise; their interests, objectives, and expectations related to the projects; and the type of contributions they bring; as well as their motivation to get involved (some of them are even volunteers). This diversity is likely to bring different lenses and angles to the way in which problems are studied and tackled and solutions proposed, which are overall likely to provide more thorough results. These partnerships and the continuously increasing network of collaborators that the model favours allow for a constant peer review process, which can prompt higher quality control and reduce the possibility of duplication of efforts and waste of resources.[763]

In terms of access to healthcare, the open science model could contribute to making innovative medical products and services available in a shorter period of time, given that, the model could enable accelerated progress of science. The constant peer review and quality control is expected to improve the drugs, the tests or the therapies being developed. The partnerships and networks of collaborators enable researchers and institutions to engage in the R&D of drugs, diagnostic tests, and therapies that focus on conditions that may not be very appealing to companies because they lack a profitable market, but that may still be crucial to develop in a particular region. These companies do so because the resources, risks, responsibilities, knowledge, findings, and tools owned by the different collaborators and partners are shared, and therefore their own resources (e.g. time, money,

[763] Gold, *supra* note 609 at 2–3; Eric Low, Chas Bountra & Wen Hwa Lee, "Accelerating target discovery using pre-competitive open science—patients need faster innovation more than anyone else" (2016) 10 ecancermedicalscience, online: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4990051/>; Daniel L Shaw, "Is Open Science the Future of Drug Development?" (2017) 90:1 Yale J Biol Med 147.

and efforts) are used more efficiently and their own costs are reduced.[764] Furthermore, usually, academic institutions and partners from the public sector focus their activities and resources on basic research. Sharing the outcomes of all this basic research under the open science model allows collaborating private companies to use these findings and tools and develop their downstream clinical applications from there. This saves companies time and resources, which results in medical products and services being available earlier than under traditional proprietary models of commercialization. Moreover, the clinical applications that these private companies develop may also be used to treat diseases that do not have profitable markets. Likewise, even if those clinical applications were to only treat diseases that lacked a profitable market, the research outcomes and tools that these companies have access to under an open science model could also be useful to develop profitable clinical products and services. The aforementioned benefits can also occur in other areas of research during pre-competitive stages, and in some cases during clinical trials, and have particularly proved useful in drug discovery and drug repositioning.[765] Finally, given the reduced costs and more efficient allocation of resources, the expenses that researchers and developers (i.e. biotechnology and pharmaceutical companies) will have to invest and recoup will be lower, which could result in lower prices for the drugs, tests, and therapies developed, and therefore make them more accessible. However, even if this were not the case, the fact that more research institutions and companies can have access to the research

[764] Donner, *supra* note 802 at 1; Molly Morgan Jones et al, *The Structural Genomics Consortium. A Knowledge Platform for Drug Discovery* (United States of America: RAND Europe with the Institute on Governance, 2014); Manica Balasegaram et al., "An open source pharma roadmap" (2017) 14:4 PLOS Med e1002276 at 3.

[765] Morgan Jones et al, *supra* note 764 at 29–38; Balasegaram et al, *supra* note 764 at 3; Shaw, *supra* note 763 at 149–150; Edwards, *supra* note 5.

outcomes and tools and develop more medical products increases the chances of competition among those products, and therefore of lower prices for the consumers.[766]

The main challenge encountered in the projects that adopt the open science model is balancing the expectations and interests of the public and private funders in order to maintain their trust, involvement, and support to preserve and even improve the pace of discovery and innovation.[767] Another challenge is building the right infrastructure to be able to make meaningful data and materials accessible as well as to create mechanisms and indicators to measure and increase contributions in order to encourage more people and institutions to collaborate under this model.[768] A third challenge is addressing potential limitations or complications posed by third parties' existing patents on techniques, materials or methods used in open science projects and reconciling those patents with the open science model.[769] A fourth challenge is convincing and training more public and private researchers, institutions, governments, companies, and funders to consider adopting an open science model.[770]

[766] Phoebe H Li, "3D Bioprinting Technologies: Patents, Innovation and Access" (2014) 6:2 Law Innov Technol 282 at 297; Dean Baker, Arjun Jayadev & Joseph Stiglitz, *Innovation, Intellectual Property, and Development* (Azim Premji University, University of Cape Town, Fundação Oswaldo Cruz, and Escola Nacional de Saúde Pública, 2017); Dean Baker, "A free market solution for prescription drug crises" (2004) 34:3 Int J Health Serv Plan Adm Eval 517; Dean Baker, "The Upward Redistribution of Income: Are Rents the Story?" (2016) 48:4 Rev Radic Polit Econ 529.

[767] Donner, *supra* note 760 at 2; Morgan Jones et al, *supra* note 764.

[768] Ali-Khan et al, *supra* note 565; Rouleau, *supra* note 754.

[769] Rouleau, *supra* note 754 at 2–3.

[770] Guy Rouleau, *Freeing Science — From Software to Medicine* (Montreal, Canada, 2017); Dietmar Lampert et al, "New indicators for open science - Possible ways of measuring the uptake and impact of open science" (2017) 44J Res Technol Policy Eval 50.

All these models recognize that the implementation of the current patent system may, in fact hinder or at least complicate and delay, the innovation process and access to resulting products and services. Hence, they provide researchers, companies, industries, and countries with strategies and techniques to better and more effectively manage the different stages of the innovation process.

While determining the best innovation model for R&D in health-related in Mexico would be the subject of further research, given that this would depend on the specific circumstances of the product being developed, it is important for me to finish my dissertation highlighting the importance of bearing in mind the negative effects the implementation of the current patent system has had and may have on health-related innovation and access to healthcare in Mexico, and to highlight again the need for a more collaborative and open model.

The innovation process is already very expensive, long, and cumbersome. One quarter of a trillion dollars is spent on biomedical research every year. In 2016 in the U.S., the National Institutes of Health spent over USD $30 billion, and industry spent at least over USD $50 billion on R&D.[771] Development of new drugs can take anywhere between seven and fourteen years in addition to the decades of basic research.[772] Mexico does not have enough resources to undertake this kind of investment, but even if it did, resources

[771] Shaw, *supra* note 763; US Office of Budget, "FY2016 Budget in Brief - NIH", (6 February 2015), online: *HHS.gov* <https://www.hhs.gov/about/budget/budget-in-brief/nih/index.html>; Edwards, *supra* note 542; Pharmaceutical Research and Manufacturers of America, *PhRMA 2016 Biopharmaceutical Research Industry Profile* (United States of America: Pharmaceutical Research and Manufacturers of America, 2016).

[772] Pharmaceutical Research and Manufacturers of America, *supra* note 771; Hope, *supra* note 519 at 54.

should be allocated in more efficient ways that avoid duplication of efforts. Furthermore, knowledge in general, and health-related innovation in particular, is cumulative and cooperative in nature, so access and collaboration are necessary.[773] Even from a legal point of view, it can be argued that having access to the benefits of science constitutes a human right, as article 27(1) of the Universal Declaration of Human Rights recognizes a universal right to science: "Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits."[774] The advancement of medical sciences in Mexico would likely benefit from considering models of innovation that use the patent system to collaborate in a more open manner than the current traditional proprietary model.

Furthermore, considering the importance of health for anyone's well-being:

> "… genetics in medicine is not about knowledge for its own sake, but for the sake of sustaining wellness, improving health, relieving suffering, and enhancing human dignity. The challenge confronting us all, both future health professionals and members of society at large, is to make sure that the advances in human genetics and genomics knowledge and technology are used responsibly, fairly, and humanely."[775]

As I described throughout the previous chapters, Mexico's population suffers from a prevalent great socio-economic gap as well as from insufficient public healthcare system. Therefore, to justify the welfare that the patent system is supposed to bring with respect to

[773] Rouleau, *supra* note 770; Donner, *supra* note 760; Balasegaram et al, *supra* note 764; Hope, *supra* note 519 at 75.

[774] Bartha M Knoppers, "Broaden human-rights focus for health data under GDPR" (2018) 558:189 Nature, online: <https://www.nature.com/articles/d41586-018-05388-3>; *Universal Declaration of Human Rights*, *supra* note 101.

[775] Robert L Nussbaum, Roderick R McInnes & Huntington F Willard, "Ethical and Social Issues in Genetics and Genomics" in *Thompson Thompson Genet Med*, 8th ed. (Philadelphia, PA: Elsevier, 2016) 383 at 390.

health-related innovation and choose the most suitable innovation model for Mexico, this welfare should be framed in terms of the capability approach's principles of functionings and capabilities. This justification should consider access to the innovative medical products and services essential for any human being to be healthy insofar that they can have the equal opportunity to choose the lifestyle that they consider valuable.

PPPs and open science are attainable and promising models of innovation that would suit the specific circumstances of the innovation ecosystem in Mexico and not only stimulate the growth of health-related innovation, but also improve and enlarge the access to the benefits that would result from it. Whereas at an individual academic level there is an incipient interest on collaborative and open models, and there is even some legislation in place enabling the creation of PPPs,[776] Mexico formally and in reality, supports the implementation, enforcement, and reinforcement of a proprietary patent system. Most of this support occurs at a governmental and institutional level. However, this proprietary system has allowed large foreign corporations to control the entry, pace, direction of, and access to scientific, technological, and medical progress.[777] This formal support comes from international pressure to provide the same "protection" as the one provided in developed countries.[778] However, Mexico is not one of those countries and it disregards

[776] *Ley de Asociaciones Publico Privadas*, Diario Oficial de la Federacion, 16 January 2012 (Amended on April 21, 2016) [*Ley de Asociaciones Publico Privadas*].
[777] Hope, *supra* note 519 at 19 & 25.
[778] Kenneth C Shadlen, *Coalitions and Compliance: The Political Economy of Pharmaceutical Patents in Latin America* (United States of America: Oxford University Press, 2017) at 230; WTO et al, "How International IP Policy Reconfigured National Politics: An Interview With Prof. Ken Shadlen", (11 January 2018), online: *Intellectual Property Watch* <http://www.ip-watch.org/2018/01/11/international-ip-policy-reconfigured-national-politics-interview-prof-ken-shadlen/>; John M Curtis, *Intellectual Property Rights and International Trade: An Overview*, CIGI Papers 3 (Canada: Centre for International Governance Innovation, 2012) at 6–8; Owen Morgan, "Harmonisation of Intellectual Property: Issues in the South Pacific", (2010) 4:3 International Journal of Business and Globalisation 237 at 3; Assafa

the fact that Mexico's local health-related industry lacks the infrastructre and resources to engage in innovative R&D at the levels that the industry at developed countries do, which leaves the country in no position to have a decent and valuable share of the market. Combining this with Mexico's socio-economic and healthcare conditions leads to the conclusion that neither its pharmaceutical and biotechnological industries nor its population in fact benefit from this "protection." Therefore, health-related innovation in Mexico needs an R&D model featuring "peer review and feedback, low costs, and ease of engagement",[779] that allows for a collaborative innovation process, while simultaneously promoting (or at a minimum not obstructing) equal and universal access to innovative healthcare services. Above all, this model must account for those who are the most vulnerable: Indigenous Peoples and those who are highly impoverished. As Franklin D. Roosevelt said: "The test of our progress is not whether we add more to the abundance of those who have much, it is whether we provide enough for those who have little."

Endeshaw, "Harmonization of Intellectual Property Laws in Asean" (2005) 2:1 J World Intellect Prop 3 at 3.

[779] Hope, *supra* note 519 at 13–14.

Conclusions to Section 4

In this last section, I discussed the effects that the current patent system has had on Mexico's population's access to healthcare, focusing first on the impact that it has had on the creation of innovative medical products and services, as it would affect their availability, and second, on the population's access to those products and services. Based on this review, the current patent system has failed to properly spur local health-related innovation, and even worse, it has contributed to deficient healthcare access in Mexico.

Most of the health-related innovation in Mexico is done by foreign pharmaceutical and biotechnological companies, and it is these companies that have benefited the most from the patent system, as they own the majority of the patents granted. Meanwhile, Mexico's pharmaceutical and biotechnological companies focus on developing generics, similares, biocomparables, and biological versions of drugs, tests, and therapies for which they wait for the patents to expire. Publicly funded research centres and academic institutions still concentrate on basic research, and even in that area, governmental expenditure in R&D is below the percentage recommended for OECD countries. These circumstances have resulted in a local pharmaceutical and biotechnological industry that barely gets involved in original innovation, an innovation environment with low competition, high prices for innovative medical products and services, and several neglected endemic conditions.

With respect to access to healthcare, Mexico has a dual system where private healthcare services are allocated in accordance with free market terms. Since close to half

of the population lives under the poverty line, the public healthcare system is underfunded and insufficient, close to 25% of the population does not have access to the public healthcare system, and the already high prices of patented medical products and services are considerably higher than their generic versions, a very big sector of Mexico's population depends greatly on generics and cannot afford to have access to the innovative medical products and services. Hence, access to innovative medical products and services a luxury. Furthermore, a lengthy patent protection term affects their access to healthcare, as generic, similar, and biocomparable versions of the drugs, diagnostics, and treatments will take longer to be available in the market.

The above-stated conditions regarding the pace of local health-related innovation and access to healthcare in Mexico are not exclusively prompted by the patent system. Despite deficiencies in other relevant and related systems and governmental actions, the patent system does contribute to those conditions. The impact that the patent system has had on healthcare by affecting both the pace and direction of innovation in the field and the access to the innovative medical products and services in Mexico is the cause and basis for suggesting the use of the capability approach to determine whether the patent system has brought welfare to society in utilitarian terms. I argued that while I agree that a law or a policy would be justified if it creates welfare to society, this welfare cannot be restricted to innovation for the sake of innovation or economic growth, particularly when the innovation in question is related to healthcare. Welfare denotes a state of doing well in terms of good fortune, happiness, well-being or prosperity. Health is a key element of human's and therefore, society's well-being. Being healthy gives people the freedom to

choose the kind of life they want to live, including their choice of job, social relationships, activities, etc. Because of this, healthcare should not be accessible just for those who have the means to afford it; it should instead be universally accessible. Only if health is universally accessible can we actually say there is human development. Moreover, healthcare cannot just be comprised of essential drugs. Medical genetics and biomedical R&D have given rise to important healthcare products and services that can make a huge difference in people's lives and that can greatly benefit healthcare policies and resources. Personalized medicine is one of these. This makes innovative medical products and services such as those associated with genetics or personalized medicine not a luxury, but simply a matter of fair access to the necessary existing healthcare. The way in which the patent system in medical innovation is implemented and enforced has therefore to consider the actual impact (negative or positive) on the promotion of innovation in medical products and on people's access to them in order to conclude whether it is justified and convenient to maintain.

As I mentioned at the beginning of my conclusions for this section, I do not believe the current patent system (including its legislation, policies, and practices) has really benefited Mexico in promoting local health-related innovation or in improving the health of its population. However, while this should open the discussion about a potential reform to the patent regulation or at least to the relevant policies and practices in each country in health-related innovation, there are certain models that could better promote innovation while not neglecting the conditions of each innovation environment and more importantly, the need to ensure universal access to healthcare.

I suggested exploring innovation models outside the traditional proprietary model, such as PPP and open science, as they seem to better fit the needs of health-related innovation in Mexico. The SGC and the MNI are two open science-based projects that have been able to build an accessible platform of knowledge, samples, data, materials, and tools relevant for medical innovation and have maintained and continue to maintain a good and an even accelerated pace of scientific innovation.[780]

The potential benefits brought about by PPPs and open science (e.g. enhancement of partnerships, creation of knowledge hubs and stimulation of new research avenues, reduction of entry costs, integration of cross-disciplinary expertise, decreases in transaction costs (interoperability standards, legal instruments and counsel) and better allocation of resources) could facilitate the progress of basic research, the translation into clinical applications, and access by patients.[781] Mexico will absolutely benefit from this.

Innovation has scientific, economic, and social value.[782] The value of innovation is the potential contribution to society's social needs, [783] and the welfare it brings. The scientific and technological innovation that the patent system should encourage, and that therefore should be its own justification, should in fact create welfare. Healthcare aims to promote prevention, health promotion and improvement of individuals' and populations'

[780] Gold, *supra* note 609 at 3; Edwards, *supra* note 610.
[781] Gold, *supra* note 609 at 3–4.
[782] Donner, *supra* note 760 at 3.
[783] Commission on Intellectual Property Rights, Innovation and Public Health, *supra* note 519 at 27.

lives.[784] Therefore, regarding health-related innovation, welfare should be measured in terms of the health problems that it solves, in the number of lives that are saved or improved.[785]

[784] Lena Griebel et al, "A scoping review of cloud computing in healthcare" (2015) 15 BMC Med Inform Decis Mak, online: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4372226/> at 7.
[785] Edwards, *supra* note 542.

Conclusions

"[…] we ought to care about a *just IP* [patent] regime, and not *just the IP* [patent] regime".[786]

Innovation has value in scientific, economic, and social contexts.[787] In any of these contexts, the value of innovation is its potential to contribute to society's social needs, [788] and the welfare it brings. In other words, innovation is not, or at least should not be deemed, an end itself. Instead, it is a means to many ends. The scientific and technological innovation that the patent system should encourage, and that therefore should be its own justification, should be a means to an end and hence contribute to society's social needs and welfare.

Healthcare aims to provide disease prevention, health promotion and improvement of individuals' and populations' lives.[789] Healthcare is a means to being healthy. Being healthy gives people the freedom to choose the kind of life they want; it allows people to live the lives they want (e.g. have a satisfying job, obtain the necessary income, get involved in the community, etc.); it enables them to have a good quality of life. The innovation that the patent system in health-related areas is expected to promote should therefore promote preventing diseases, being healthy and improving people's lives. In other words, regarding health-related innovation, the goal or welfare that the patent system is supposed to bring should be measured in terms of the health problems that it solves, in the number of lives that are saved or improved.[790]

---

[786] Amani, *supra* note 701 at 118.
[787] Donner, *supra* note 760 at 3.
[788] Commission on Intellectual Property Rights, Innovation and Public Health, *supra* note 519 at 27.
[789] Griebel et al, *supra* note 784 at 7.
[790] Edwards, *supra* note 542.

The way in which the patent system would bring about the welfare that would justify it would be if it promoted innovation and access to the innovative healthcare products and services, or at least, that it did not limit one or the other. Both components are important because only together is it possible to assert that people are empowered to achieve their health-related capabilities and functionings, and therefore, assert that the patent system contributes to the improvement of quality of life, to human development.

No system operates in isolation. The way in which systems operate and therefore the extent of the impact they may have is affected by other systems with which they interact and by the conditions surrounding them. Consequently, when assessing the impact of the patent system on health-related innovation, it is essential to take into account the context and the conditions (e.g. country's regulations, policies, infrastructure, and socio-economic and scientific-technological conditions) in which the patent system is immersed and the other systems (e.g. healthcare) with which it interact. In this case, the socio-economic and scientific-technological conditions and the healthcare system specific to Mexico should therefore be taken into account.

In this context, I asked the question: "How can we tell when the patent system is benefiting or failing with respect to health-related innovation?" I focus this question on the specific case of Mexico, as an example of a developing country. In order to answer this question, I also addressed the following complementary questions: How have Mexico's current patent system (regulations, policies, and practices) and its promotion,

implementation, and enforcement influenced the country's health-related innovation environment? How have they impacted its population's access to healthcare in general? Has this impact resembled that in developed countries? Has it been beneficial for the country's local health-related innovation and access to healthcare?

I used the theoretical constructs of utilitarianism and the capability approach to frame my questions, analysis, and discussion. I used utilitarianism because it is one of the most commonly used theories to justify the patent system. An act, law or policy is justified in utilitarian terms if it offers or enables the maximization of utility: the greatest good (welfare) for the greatest number. The justification of the patent system in utilitarian terms is based on a balanced combination of rewards, dissemination, and access.[791] The exclusive rights that the patent system grants to patent holders are commonly considered to be the economic incentives that investors and inventors need and want in order to devote their resources, efforts, and time to innovation. The resulting innovative products and services are argued to contribute "utility/welfare" that leads to society's well-being.

However, "utility/welfare" is currently predominantly defined in economic terms and, while having a patent system that encourages innovation that is potentially beneficial (economically, technologically, and scientifically speaking) for society is positive, there have been a number of debates about this definition of utility/welfare.[792] Particularly regarding health-related innovation, justifying the patent system, on purely economic-

[791] Merges, *supra* note 20 at 2; Posner, *supra* note 28 at 58; Fisher, *supra* note 20 at 168; Hettinger, *supra* note 28 at 47–48.
[792] Fisher, *supra* note 20; Merges, *supra* note 20; Moore & Himma, *supra* note 20.

utilitarian bases has resulted in several negative outcomes. These include neglected diseases, more lengthy innovation processes, proliferation of me-too-drugs and beauty products, and most worrisome, highly-priced treatments, drugs, and diagnostics, which consequently lead to unequal access to healthcare and unfairly intensify the misfortunes of a considerable part of its population (i.e. the majority of the Indigenous Peoples in the country, the rural population, and overall, those living under the poverty line). The concepts, principles, and theoretical constructs of the capability approach: capabilities, functionings, conversion factors, means-ends can help to provide fuller definition of "utility/welfare" where various aspects of it are included. I proposed that for purposes of the patent system, "utility/welfare" be determined assessing to what extent the outcomes of the patent system enable people to have the opportunity to actually achieve their functionings and capabilities and to improve their quality of life. Hence, this definition includes not only economic and scientific/technological benefits, but also social ones. Based on this, with respect to health-related innovation, scientific/medical innovation, economic incentives, economic growth, and innovative products and services that the patent system generates can only be considered utility, and therefore advantageous, if they lead people to actually be healthy.

With the foregoing fuller definition of "utility/welfare", I argued that, while I agree that a law or a policy would be justified if it creates welfare to society, this welfare cannot be restricted to innovation for the sake of innovation or economic growth, particularly when the innovation in question is related to healthcare. Welfare denotes a state of doing well in terms of good fortune, happiness, well-being or prosperity. Health is a key element

of human's and therefore, society's well-being. Having good health enables people to live their lives as they considered appropriate or worthwhile. In other words, being healthy gives people the freedom to choose the kind of life they want to live, including their choice of job, social relationships, activities, etc. My conclusion then was that I do not believe the current patent system (including its legislation, policies, and practices) has really benefited Mexico in promoting local health-related innovation or in improving the health of its population. However, while this should open the discussion about a potential reform to the patent regulation or at least to the relevant policies and practices in each country in health-related innovation, there are certain models that concurrently could better promote innovation while not neglecting the conditions of each innovation environment and more importantly, the need to ensure universal access to healthcare.

My dissertation was composed of four parts: 1. Theoretical Framework, 2. Healthcare and Innovation in Mexico, 3. Case Study, and 4. Justification of the Patent System in Healthcare-Related Innovation in Mexico. The first part comprised one chapter. This chapter provided the theoretical framework to situate two aspects of my discussion. First, it framed the discussion on the actual impact that the current patent system has on promoting innovation in health-related innovation and on facilitating access to healthcare in Mexico. Second, it provided the philosophical basis to determine whether this impact on both health-related innovation and access to healthcare in fact, justifies the implementation and enforcement of Mexico's current patent system. I considered that using the theoretical constructs of capabilities, functionings, conversion factors, and means-ends proposed in capability approach to devise a more complete definition of utility within the theory of

utilitarianism in the terms I mentioned above was useful for purposes of analyzing whether Mexico benefited from the current patent system in health-related innovation.

The second part of my dissertation was composed of two chapters. In the first chapter of this section (chapter two), I focused on the conditions of access to healthcare in Mexico. I described the healthcare system in Mexico, the socio-economic conditions in which the majority of the most vulnerable population in Mexico lives, and the conditions of access to healthcare available to this population. My findings were that the healthcare system in Mexico is dual, which means it is public and private. Whereas the latter is unaffordable for more than half of the population, the former is insufficient and underfunded. Close to half of the population lives under the poverty line and therefore, depends on the public healthcare system. Indigenous Peoples are particularly in disadvantage because they suffer from extreme poverty, isolation, and discrimination, all of which act as negative conversion factors in terms of the capability approach. The way in which the patent system affects the healthcare system is through the insufficient funding of the latter and the high prices enabled by the former. Insufficient funding in the public healthcare system leads to limited resources to obtain and provide medication to patients. This means that the public healthcare system depends on the availability of generics and affordable innovative medical products and services to be able to provide the necessary treatment. Likewise, most of the population that uses the private healthcare system can also be affected by delayed or lack of generics or unaffordable patented medication, as many of them also have limited resources.

In the second chapter of this section (chapter three), I focused on the activities of R&D in health-related innovation in Mexico, including details of the country's pharmaceutical and biotechnology industries and its patent system. The regulation and policies of the patent system showed many similarities to the patent systems of developed countries such as the U.S. and Canada. They meet the standards of protection imposed internationally, as Mexico is signatory to the most important international patent treaties. Despite this, I found that the patent system has not truly promoted innovation among the national companies. It has, however, attracted foreign companies, which have been encouraged to innovate and manufacture those innovative medical products in Mexico. This has made these innovative medical products and services available in the Mexican market and it has also benefited Mexico's economy (national, regional, and industry's growth) and facilitated technology transfer and capacity building through employment. Nonetheless, given the negative conversion factors surrounding Mexico's population (poor socio-economic conditions) and healthcare system, the patent system has not really benefited access to healthcare, despite those products being in the market.

The third section of my dissertation contained my case study and it comprised two chapters. Each chapter focused on one disease and on the associated Indigenous People, including details on the socio-economic conditions of the Indigenous community, the circumstances in which they have access to healthcare, impact of the specific disease on their communities, details on the medical research projects in which the communities participated, and the extent of the involvement of the patent system in that disease and in the selected research projects. Chapter four focused on the P'urhépechas and their genetic-

based resistance to tuberculosis. Chapter five centred on the Mayas, Nahuas, and Mazatecas and their genetic-based predisposition to actinic prurigo. The two parts of my case study, despite being limited in scope, showed with concrete examples, the disadvantaged socio-economic reality of Indigenous Peoples and their inability to take advantage of the commodities available in the market, particularly with respect to any innovative medical product that may result from the patent system. It also showed concrete cases where a non-mortal disease can greatly affect someone's quality of life by either reducing the freedom (capability) of choosing a specific lifestyle or by affecting someone's health (functionings).

The fourth section of my dissertation was composed of four chapters. My objective in this section was to answer my research question "How can we tell when the patent system is benefiting or failing with respect to health-related innovation?" and determine whether the patent system in Mexico is beneficial and therefore justified in health-related innovation. To answer this question, I took into account the benefits and concerns attributed to the patent system and analyzed them in light of the information and conclusions gathered throughout my previous chapters. Chapter six contained the benefits and concerns associated with the patent system as discussed in the literature. This chapter provided a list of issues and advantages associated with the patent system to look for in Mexico. The anti-commons and patent thickets, competition, pace and delays in innovation, allocation of resources, secrecy, prices, collaboration, availability of medical products and services, endemic diseases, generics, and access to healthcare were among the issues discussed.

In chapter seven, I analyzed which of the issues mentioned in chapter six could be found in Mexico. I found that since the national pharmaceutical and biotechnology industry focuses on generics, biocomparables, and similares, patents do not play an important role in the activities of Mexican companies. However, the situation is the opposite in the case of foreign companies, who in fact focus on innovative medical products and hold most of the patents granted by the IMPI with respect to health-related innovation. In this sense, whereas the patent system did not seem to benefit local companies, it was advantageous for foreign companies. Despite this, I did not find indisputable evidence that would determine the extent to which the patent system served as an incentive even for these foreign companies. I did not find evidence of an anti-commons caused by the patent system in Mexico either. Nonetheless, I did find evidence of the issues associated with the impact that the patent system can have on access to healthcare. The exclusive rights that patents grant to their holders enable them to almost freely set the prices for their innovative medical products and services. I found that the prices of patented medication were a lot higher than those of generics. This situation affects access to both private and public healthcare services. Patents also had an impact on the availability of generics, as the latter can only be obtained once the 20-year patent rights expire. This negative effect on access to medication is particularly damaging in Mexico considering the socio-economic conditions of its population and the structure of its healthcare system.

In chapter eight, I applied the concepts and justifications of utilitarianism and capability approach that I described in chapter one to the concerns and benefits of the patent system discussed in chapters six and seven. This provided me with a specially tailored

theoretical framework to determine in the last chapter how can we tell if the patent system benefits or fails Mexico. In chapter nine, I concluded, based on my definition of "utility/welfare", that even if the patent system contributed to some extent to the creation and availability of innovative medical products that are more effective than the generic ones, and even if these products are medically needed, if the same patent system contributed to these products being so expensive that neither the patient nor the public healthcare system is able to purchase them, then the patent system hinders access to healthcare. Therefore, in terms of the definition of "utility/welfare" I suggested, the current patent system in Mexico does not bring about the benefits it should justify it.

Importance of my Research

My research has two main contributions. The first is its contextual approach: it is geographically focused on Mexico. Most of the existing studies discussing the impact of the patent system on health-related innovation do it from a theoretical perspective or based on the circumstances of developed countries, particularly of the U.S. Basing regulation, policies, programs, and strategies on circumstances (with the strengths, weaknesses, successes and failures) of a different country or region and disregarding the specific country's context can be problematic and misleading in terms of what would in fact benefit or harm that specific country. Therefore, in my research and analysis, I looked at Mexico's specific infrastructure, human resources, and actors in health-related innovation; its healthcare and patent system, governmental programs, regulatory frameworks (patents and healthcare), and pharmaceutical/healthcare market; as well as the socio-economic conditions of its population. Furthermore, despite its already acknowledged limitations, the

case study provided a deeper level of specificity illustrating some of the effects of the patent system on specific circusmtances.

The contextual approach combining the two levels of analysis (national and case study-specific) in my dissertation provided a presentation of Mexico's specific context. This served several purposes. It allowed for the identification of actual circumstances in which the innovation process occurs, the conditions in which healthcare services are provided and accessed, and the extent of the actual impact that the patent system has on both as it interacts with those circumstances. As such, it highlighted some of the conditions under which the relevant actors in the innovation process operate and the hurdles and specific requirements that the industry and the government have to confront and address in order to encourage and support sustainable progress. This then allowed me to develop an understanding of the role that the patent system plays in the innovation process in Mexico. For instance, the low levels of funding, the focus of the local pharmaceutical and biotechnology industries on biocomparables, generics, and similares (as opposed to innovative research), and the low numbers of patents applied for and owned by Mexican companies and researchers led me to conclude that the current patent system does not produce an overall positive effect on Mexico's local innovation. While the patent system seems to provide foreign researchers and companies with incentives to bring innovative medical products and services into the Mexican market, it does not have the same effect on national entities and individuals, as they do not pursue as many patents and they focus on the non-innovative approaches mentioned above (i.e. similares, biocomparable, and

generics). This increases Mexico's dependence on foreign advancement and technology and on the expiration of existing patents.

Likewise, it identified the socio-economic conditions and needs of Mexico's population, specifically regarding their ability to respond to any impact that the patent system has on the innovation process in health-related R&D and on the prevalent healthcare systems. Moreover, it allowed me to distinguish how the advantages and concerns discussed in other studies actually materialize in Mexico. For instance, the inadequacies of the public healthcare system and the severe conditions of poverty in almost half of the population shown in my research amplify the effects that the patent system can have on the price of innovative and patented medical products and services and therefore on access to healthcare, particularly on that of the majority of the Indigenous Peoples in Mexico.

These conditions and findings can incite and help to better inform relevant policy debates, allocate resources more efficiently, and increase the chances of achieving the necessary balance in the way the patent system is regulated, promoted, implemented, and enforced in order to allow Mexico's population to truly benefit. For instance, the analysis of the patent system in relation to the specific conditions surrounding Mexico's innovation ecosystem and access to healthcare can inform not only the debates about potential amendments to the regulation and enforcement of the current patent system, but also the convenience of adopting, as well as the most suitable approaches to adopt open models of collaboration.

Finally, Mexico's economic, social, health, and strategic policies and programs, as well as its economy and regulatory frameworks, can be very relevant and influential for the rest of Latin America and other developing countries, which share some of its culture, context, history, circumstances, and challenges. Therefore, the findings and suggestions included in my dissertation could prompt and guide similar studies in other Latin American countries and even influence and benefit some of these countries' own policies, frameworks, and programs to improve their own innovation and health outcomes.

The second contribution of my research lies on the fuller definition of "utility/welfare" it proposed. Considering the importance given to concepts such as capabilities, functionings, conversion factors, and means-ends in the attainment of a good quality of life, this definition is more ad hoc to analyze the patent system (and possibly other laws, acts, and policies) in developing countries.

Moving Forward and Looking Ahead

There are a few areas or issues stemming from my research that would be interesting to explore ahead. For instance, my research included many different factors, situations, actors and parties involved, and scenarios. However, as I mentioned throughout my dissertation, my research had certain limitations: namely, the size and focus of my case study with respect to the people interviewed and their affiliation to the public sector. Expanding the sample size of innovation actors to include the opinions and circumstances of more researchers and of researchers from different circles, areas of research, and communities would complement my research and would help to provide a full and more

accurate picture of the innovation process. This would be very useful in providing the perspective of groups that may have had different experiences. Furthermore, interviewing players from the private sector would give a more complete outlook of the innovation process, particularly since the process usually involves both sectors throughout all of its stages.[793]

Analyzing the effects of the patent system on the different stages of the innovation process could be another subject that could provide a complementary and more specialized perspective. For instance, projects focusing on pre-competitive stages (e.g. basic research) like the Structural Genomics Consortium mentioned in chapter nine have shown considerable levels of success using open models of collaboration such as open science, open access, and open source. However, this success has not been confirmed in stages of clinical translation. In fact, there have been serious concerns about the sustainability of these models in clinical translation mainly because of the competitive nature of this stage.[794]

Finally, further research on the use and implementation of open models of collaboration in general and particularly in developing countries could offer new perspectives on how to advance innovation in developing countries. Research on these subjects could bring new questions including for instance: which parameters could best

[793] Palmira Granados Moreno et al, "Open science precision medicine in Canada: Points to consider" (2019) FACETS, online: <http://www.facetsjournal.com/doi/10.1139/facets-2018-0034>; Linda A Hall & Sharmistha Bagchi-Sen, "A study of R&D, innovation, and business performance in the Canadian biotechnology industry" (2002) 22:4 Technovation 231 at 233.

[794] Palmira Granados Moreno, Yann Joly & Dylan Roskams-Edris, *Could Open Be the Yellow Brick Road to Innovation in Genomics in North America?* (Accepted for publication at McGill Journal of Law and Health, 2019).

measure the effectiveness of the patent system (and open models of collaboration) in other areas of innovation different from health-related innovation? Could any of the parameters found in other areas of innovation be applicable to health-related innovation? How do these parameters differ from developed to developing countries? What could encourage the more frequent use of open models of collaboration in developing countries?

The concerns and suggestions I made throughout my dissertation as well as the questions that could be raised through further research discussed above show that an optimal patent system should focus not only on the economic aspect of innovation, but also on the moral value of access. Consequently, the regulation and implementation of this optimal patent system should be mindful of both the effect that they may have on a given society and of the need to be open to adapting to a society's continuously changing specific needs.

Bibliography

Primary Sources

Mexican Legislation

Constitucion Politica de los Estados Unidos Mexicanos, Diario Oficial de la Federacion, 5 February 1917 (Amended on January 27, 2016) [*Constitucion*].

Ley Federal de los Trabajadores al Servicio del Estado, Diario Oficial de la Federacion, 28 December 1963 [*Ley Fed Trab Estado*].

Ley General de Salud, Diario Oficial de la Federacion, 7 February 1984 [*LGS*].

Ley de la Propiedad Industrial, Diario Oficial de la Federacion, 27 June 1991 (Amended on June 1, 2016) [*Ley de la Propiedad Industrial*].

Reglamento a la Ley de la Propiedad Industrial, Diario Oficial de la Federacion, 23 November 1994 (Amended on December 16, 2016) [*Reglamento a la Ley de la Propiedad Industrial*].

Ley del Seguro Social, Diario Oficial de la Federacion, 21 December 1995 [*Ley del Seguro Social*].

Ley del Instituto de Seguridad Social para las Fuerzas Armadas, Diario Oficial de la Federacion, 7 July 2003 [*Ley del ISS Fuerzas Armadas*].

Ley del Instituto de Seguridad y Servicios Sociales de Trabajadores del Estado, Diario Oficial de la Federacion, 31 March 2007 [*Ley del ISSSTE*].

Reglamento del Sistema Nacional de Investigadores, Diario Oficial de la Federacion, 21 March 2008 [*Reglamento del Sistema Nacional de Investigadores*].

Ley de Asociaciones Publico Privadas, Diario Oficial de la Federacion, 16 January 2012 (Amended on April 21, 2016) [*Ley de Asociaciones Publico Privadas*].

International Agreements

Universal Declaration of Human Rights, General Assembly of the United Nations Organization, 10 December 1948, GA Res 217 III UN CAOR 3d Sess Supp No 13 UN Doc A810 1948 [*Universal Declaration of Human Rights*].

International Covenant on Economic, Social and Cultural Rights, United Nations General Assembly, 3 January 1976 [*International Covenant on Economic, Social and Cultural Rights*].

Constitution of the World Health Organization, World Health Organization, 22 July 1946 (Last amended September 15, 2005) [*Constitution of the World Health Organization*].

Agreement on Trade-Related Aspects of Intellectual Property, WTO, 1 January 1995 [*Agreement on Trade-Related Aspects of Intellectual Property*].

Doha 4th Ministerial - Ministerial declaration, WTO, 14 November 2001 [*Doha 4th Ministerial - Ministerial declaration*].

Doha: Declaration on the TRIPs Agreement and Public Health, WTO, 14 November 2001 [*Doha: Declaration on the TRIPs Agreement and Public Health*].

Foreign Legislation and Case Law

U.S. Constitution, 4 March 1789 (Amended in 1992) [*U.S. Constitution*].

Germany: Patent Act (as amended up to Act of December 17, 2008), 5 May 1936 [*Germany: Patent Act*].

U.S. Patent Act. Title 35, 1976 [*U.S. Patent Act*].

Canadian Patent Act, June 1985 [*Canadian Patent Act*].

USMCA Free Trade Agreement, October 2018 [*USMCA Free Trade Agreement*].

Association for Molecular Pathology v Myriad, 569 U.S. 576 (2013) (US Supreme Court).

Secondary Sources

Monographs and Reports

Alter, Rolf & Janos Bertok, eds. *Estudios de la OCDE sobre Gobernanza Pública Estudio sobre la Contratación Pública del Instituto de la Seguridad y Servicios Sociales de los Trabajadores del Estado en Mexico* (Paris: OCDE, 2013).

Amezcua Luna, Jarco & Gerardo Sanchez Diaz. *Pueblos Indigenas en el siglo XXI: P'urhépechas*, 1st ed. (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2015).

Anderson, Elizabeth. “Justifying the Capabilities Approach to Justice” in Harry Brighouse & Ingrid Robeyns, eds., *Measuring Justice: Primary Goods and Capabilities* (United States of America: Cambridge University Press, 2010) 81.

Angell, Marcia. *The Truth About the Drug Companies* (United States of America: Random House Publishing Group, 2004).

Astorga, Ignacio et al. *10 Años de Asociaciones Público Privadas (APP) en Salud en América Latina Qué Hemos Aprendido?*, Serie de Notas Tecnicas de las Asociaciones Publicas Privadas en el Sector de la Salud en America Latina (Banco Interamericano de Desarrollo, 2016).

AWS. *Personalized Medicine and Genomic Research* (online: AWS <https://s3.amazonaws.com/awsemailuploads/uploads/Medical+Research+eBook+Final_Interactive+Version.pdf>).

Baez, Lourdes. *Nahuas de la Sierra Norte de Puebla* (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2004).

Baumol, William J. *Welfare Economics and the Theory of the State*, 2nd ed. (United States of America: Harvard University Press, 1965).

Bentham, Jeremy. *An Introduction to the Principles of Morals and Legislation* (London: Clarendon Press, 1781).

Bernier, Louise. *Justice in Genetics: Intellectual Property and Human Rights from a Cosmopolitan Liberal Perspective* (United Kingdom: Edward Elgar Publishing, 2010).

Bolivar Zapata, Francisco G et al. *Recomendaciones para el Desarrollo y Consolidacion de la Biotecnologia en Mexico* (Mexico: CONACYT - Academia Mexicana de Ciencias, 2003).

Bradley, John, David Johnson & Barbara Poher. *Medical Genetics* (United States of America: Blackwell Publishing Ltd, 2006).

Brooke, SC et al. “How Public-Private Partnerships Handle Intellectual Property: the PATH Experience” in A Kratiger, RT Mahoney & L Nelson, eds., *Intellectual Property Management in Health and Agricultural Innovation. Handbook of Best Practices* (Oxford: MIHR, 2007) 1755.

Burr, Claudia et al. *Guía para el Paciente Participativo* (Mexico: LID Editorial Mexicana, 2011).

Canadian Competition Bureau. *Enforcement Guidelines Intellectual Property* (Canada: Canadian Competition Bureau, 2016).

Cardenas Elizalde, Maria del Rosario et al. *La Pobreza en la Poblacion Indigena de Mexico* (Mexico: Consejo Nacional de la Evaluacion de la Politica de Desarrollo Social, 2014).

Castle, David, ed. *The Role of Intellectual Property Rights in Biotechnology Innovation* (United Kingdom: Edward Elgar Publishing, 2009).

Clague, Julie. "Patent Injustice" in Severine Deneulin, Mathias Nebel & Nicholas Sagovsky, eds., *Transforming Unjust Structures: The Capabability Approach* (Netherlands: Springer Science & Business Media, 2006) 177.

Comisión Nacional para el Desarrollo de los Pueblos Indígenas. *Acciones de Gobierno para el Desarrollo Integral de los Pueblos Indígenas. Informe 2009* (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2009).

———. *Monografía de los Purépechas or P'urhépechas*, 1st ed. (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2009).

———. *Programa para el Desarrollo de los Pueblos Indígenas 2009-2012.* (Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2010).

———. *Programa Especial de los Pueblos Indigenas 2014-2018* (Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2014).

Commission on Intellectual Property Rights, Innovation and Public Health. *WHO | Public Health, Innovation and Intellectual Property Rights* (Switzerland: World Health Organization, 2006).

Committee on the Judiciary of the United States. *Report of the President's Commission on the Patent System* (United States of America: Senate, 1967).

CONEVAL. *Informe de Evaluacion de la Politica de Desarrollo Social 2018* (Mexico: Consejo Nacional de Evaluacion de la Politica de Desarrollo Social, 2018).

———. *Estudio de Diagnostico del Derecho a la Salud 2018* (Mexico: Consejo Nacional de Evaluacion de la Politica de Desarrollo Social, 2018).

———. *Pobreza 2010. Informacion a Nivel Estatal: Michoacan 2010-2012* (Mexico: CONEVAL, 2010).

Cook-Deegan, Robert. "Gene Patents" in Mary Crowley, ed., *From Birth to Death and from Bench to Clinic. The Hastings Center Bioethics Briefing Book for Journalists, Policymakers and Campaign* (Garrison, New York: The Hastings Center, 2008) 69.

Cordourier Real, Gabriela & Rodolfo De la Torre Garcia, eds. *Informe sobre Desarrollo Humano de los Pueblos Indigenas en Mexico* (Mexico: Programa de las Naciones Unidas para el Desarrollo, 2010).

Daniels, Norman. *Justice and Justification: Reflective Equilibrium in Theory and Practice* (Cambridge: Cambridge University Press, 1996).

De la Torre Garcia, Rodolfo & Cristina Rodriguez Garcia. *Índice de Desarrollo Humano para las Entidades Federativas, México 2015. Avance Continuo, Diferencias Persistentes* (Mexico: Programa de las Nacionaes Unidas para el Desarrollo & Oficina de Investigacion en Desarrollo Humano, 2015).

Drahos, Peter & John Braithwaite. *Information Feudalism: Who Owns the Knowledge Economy?* (United Kingdom: Earthscan, 2002).

Drèze, Jean & Amartya Sen. *India: Development and Participation* (Great Britain: Oxford University Press, 2002).

European Patent Office. *Guidelines for Examination in the European Patent Office* (European Union: European Patent Office, 2016).

Fernandez Ham, Patricia et al. *Informe Sobre Desarrollo Humano de los Pueblos Indígenas de Mexico*, 1st ed. (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2006).

Fisher, William. "Theories of Intellectual Property" in Stephen R Munzer, ed., *New Essays in the Legal and Political Theory of Property* (United States of America: Cambridge University Press, 2001) 168.

Flores Reyes, Alfonso, Ildefonso Garcia Lara & Nora Hernandez Valdes. *Atlas de Infrastructura y Patrimonio Cultural de Mexico 2010* (Mexico: Consejo Nacional para la Cultura y las Artes, 2010).

Gelehrter, Thomas D, Francis S Collins & David Ginsburg. *Principles of Medical Genetics* (United States of America: Williams & Wilkins, 1998).

Gobierno Federal. *Plan Nacional de Desarrollo 2012-2018* (Mexico: Presidencia de la Republica, 2012).

Gold, E Richard, Matthew Herder & Michel Trommetter. *The Role of Biotechnology Intellectual Property Rights in the Bioeconomy of 2030*, OECD International Futures Project on "The Bioeconomy to 2030: Designing a Policy Agenda" (online: OECD, 2007).

Gold, E Richard et al. *Toward a New Era of Intellectual Property: From Confrontation to Negotiation - A Report by the International Expert Group on Biotechnology, Innovation and Intellectual Property*, SSRN Scholarly Paper ID 1260099 (Rochester, NY: Social Science Research Network, 2008) <https://papers.ssrn.com/abstract=1260099>.

Good Eshelman, Catherine & Guadalupe Barrientos Lopez. *Nahuas del Alto Balsas* (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2004).

Granados Moreno, Palmira & Yann Joly. “Intellectual Property and Innovation in Translational Medicine” in Martin Wehling, ed., *Principles of Translational Science in Medicine, 2nd ed.* (Boston: Academic Press, 2015) 281.

Guzman, Alenka. “The Challenges of Constructing Pharmaceutical Capabilities and Promoting Access to Medicines in Mexico under TRIPS” in Kenneth C Shadlen et al., eds., *Intellectual Property, Pharmaceuticals and Public Health* (United Kingdom: Edward Elgar Publishing, 2011) 110.

Holbrook, J Adam. “Are Intellectual Property Rights Quonta of Innovation?” in David Castle, ed., *The Role of Intellectual Property Rights in Biotechnology Innovation* (United Kingdom: Edward Elgar, 2009) 24.

Hope, Janet. *Biobazaar: The Open Source Revolution and Biotechnology* (United States of America: Harvard University Press, 2009).

Hunter, Dan. “Cyberspace as Place and the Tragedy of the Digital Anticommons” in Paul Schiff Berman, ed., *Law and Society Approaches to Cyberspace* (London: Routledge, 2017) 81.

Ignacio Felipe, Esperanza. *Nahuas de la Montaña.* (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2007).

INEGI. *Censo de Poblacion y Vivienda 2010.* (Mexico: Instituto Nacional de Estadistica y Geografia, 2011).

Jaffe, Adam B & Josh Lerner. *Innovation and Its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What to Do About It* (United States of America: Princeton University Press, 2004).

Jasso, Javier. “Innovación y colaboración universidad-empresa en la industria biofarmacéutica en México.” in *Vinculacion Las Universidades con los Sectores Productivos. Casos en Iberoamerica*, 1st ed. (Mexico: UDUAL, 2016) 125.

Jensen, Eric. *Teaching with Poverty in Mind* (United States of America: ASCD, 2009).

Kymlicka, Will. *Contemporary Political Philosophy: An Introduction* (United States of America: Oxford University Press, 2002).

Lanata, Claudio F. “Children’s Health in Developing Countries: Issues of Coping, Child Neglect, and Marginalization” in David Leon & Gill Walt, eds., *Poverty, Inequality and Health. An International Perspective* (United States of America: Oxford University Press, USA, 2001) 137.Leon, David & Gill Walt. *Poverty, Inequality and Health. An International Perspective* (New York: Oxford University Press, 2001).

Llumpo, A et al. "Lessons from Latin America: The Early Landscape of Healthcare Public-Private Partnerships, Healthcare Public-Private Partnership Series 2" (United States of America: Global Health Group, Global Health Sciences, University of

California, and Price Waterhouse Cooper, 2015) <https://globalhealthsciences.ucsf.edu/sites/globalhealthsciences.ucsf.edu/files/pub/public-private-partnerships-latin-america-full-report.pdf>.

Lopez Calva, Luis Felipe & Rodolfo De la Torre Garcia. *Informe sobre Desarrollo Humano México 2004* (Mexico: Programa de las Naciones Unidas para el Desarrollo, 2005).

———. *Informe sobre Desarrollo Humano México 2006-2007* (Mexico: Programa de las Naciones Unidas para el Desarrollo, 2007).

Lucchi, Nicola. *The Impact of Science and Technology on the Rights of the Individual* (Switzerland: Springer International Publishing, 2016).

Luna Ruiz, Juan. *Nahuas de Tlaxcala* (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2007).

Luna Ruiz, Xicohténcatl. *Mazatecos. Pueblos Indígenas del México Contemporáneo* (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2007).

Malkin, Daniel et al. *OECD Reviews of Innovation Policy: Mexico* (France: OCDE, 2009).

Man, Irene. "Actinic Prurigo" in James Ferguson & Jeffrey S Dover, eds., *Photodermatology* (United Kingdom: Manson Publishing, 2006).

Mansfield, Edwin. *Intellectual Property Protection, Direct Investment, and Technology Transfer: Germany, Japan, and the United States*, Edwin Mansfield, ed. (Washington D.C.: International Finance Corporation and World Bank Publications, 1995).

Margain a), Miguel Angel. *IMPI en Cifras 2013* (Mexico: IMPI, 2013).

——— b). *IMPI en Cifras 2015* (Mexico: IMPI, 2015).

———. c). *IMPI en Cifras 2017* (Mexico: IMPI, 2018).

Maskus, Keith. *Intellectual Property Rights in the Global Economy* (Washington D.C.: Institute for International Economics, 2000).

Merges, Robert P. *Justifying Intellectual Property* (United States of America: Harvard University Press, 2011).

Mill, John Stuart. *Utilitarianism*, 7th ed. (London: Longmans, Green, and Co, 1879).

———. *The Collected Works of John Stuart Mill, Volume XVIII - Essays on Politics and Society Part I*, On Liberty - Online Library of Liberty (New York: Henry Holt & Co, 1879).

Miller, Mark, Scott Barrett & D A Henderson. “Control and Eradication” in Dean T Jamison et al, eds., *Disesase Control Priorities in Developing Countries*, 2nd ed. (Washington (DC): World Bank, 2006).

Monzoy Gutierrez, Sandra. *Nahuas de la Costa-Sierra de Michoacán* (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2006).

Moore, George Edward. *Principia Ethica* (Cambridge: Cambridge University Press, 1959).

Murray, Christopher, Julio Frenk & Emmanuela E Gakidou. “Measuring Health Inequality: Challenges and New Directions” in David Leon & Gill Walt, eds., *Poverty and Inequality in Health. An International Perspective* (New York: Oxford University Press, 2001) 194.

Navarrete Linares, Federico. *Los Pueblos Indígenas de Mexico* (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2008).

Nussbaum, Martha. *Frontiers of Justice: Disability, Nationality, Species Membership* (Cambridge: Harvard University Press, 2006).

———. *Creating Capabilities. The Human Development Approach* (United States of America: Harvard University Press, 2011).

Nussbaum, Martha C. *Women and Human Development: The Capabilities Approach* (United States of America: Cambridge University Press, 2000).

Nussbaum, Martha & Amartya Sen, eds. *The Quality of Life* (United States of America: Oxford University Press, 1993).

Nussbaum, Robert L, Roderick R McInnes & Huntington F Willard. “Ethical and Social Issues in Genetics and Genomics” in *Thompson Thompson Genetics in Medicine*, 8th ed. (Philadelphia, PA: Elsevier, 2016) 383.

OECD. *In It Together: Why Less Inequality Benefits All - en - OECD* (Paris: OECD Publishing, 2015).

O’Neill, Onora. *Towards Justice and Virtue: A Constructive Account of Practical Reasoning* (United States of America: Cambridge University Press, 1996).

Organisation for Economic Co-operation and Development. *Frascati Manual: Proposed Standard Practice for Surveys on Research and Experimental Development* (OCDE, 2002).

Organizacion Panamericana de la Salud. *Acceso a Medicamentos y Propiedad Intelectual: Actores e Interacciones* (Organizacion Panamericana de la Salud, 2011).

Peter, Fabienne & Timothy Evans. “Ethical Dimensions of Health Equity” in Timothy Evans et al., eds., *Challenging Inequities in Health: From Ethics to Action* (United States of America: Oxford University Press, USA, 2001) 25.

Pharmaceutical Research and Manufacturers of America. *PhRMA 2016 Biopharmaceutical Research Industry Profile* (United States of America: Pharmaceutical Research and Manufacturers of America, 2016).

Pile, Hannah D & Jonathan S Crane. “Actinic Prurigo” in *StatPearls* (Treasure Island (FL): StatPearls Publishing, 2018).

Piper, Stamatia A J. *The emergence of a medical exception from patentability in the 20th century* (Ph.D., University of Oxford, 2008) [unpublished].

Presidencia de la Republica. *Plan Nacional de Desarrollo 2007-2012* (Mexico: Presidencia de la Republica, 2006).

———. *Plan Nacional de Desarrollo 2013-2018* (Mexico: Presidencia de la Republica, 2012).

———. *Plan Nacional de Desarrollo 2019-2024* (Mexico: Presidencia de la Republica, 2019).

Rai, Arti K. “Proprietary Rights and Collective Action: The Case of Biotechnology Research with Low Commercial Value” in Jerome H Reichman & Keith Maskus, eds., *International Public Goods and Transfer of Technology Under Globalized Intellectual Property Regime* (Cambridge: Cambridge University Press, 2005) 288.

Ravitsky, Vardit & Raphaelle Dupras-Leduc. “Emerging issues in medicine reproductive technologies” in Yann Joly & Bartha Maria Knoppers, eds., *Routledge Handbook of Medicine, Law and Ethics* (United Kingdom: Routledge, 2015) 223.

Raymond, Eric S. *The Cathedral & the Bazaar: Musings on Linux and Open Source by an Accidental Revolutionary* (Cambridge: O’Reilly Media, 2001).

Resnik, David B. *Owning the Genome: A Moral Analysis of DNA Patenting* (United States of America: State University of New York Press, 2004).

Ruz, Mario Humberto. *Mayas. Pueblos Indígenas del México Contemporáneo. Primera Parte* (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2006).

———. *Mayas. Pueblos Indígenas del México Contemporáneo. Segunda Parte* (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2006).

Sales Heredia, Francisco, ed. *Situación del Sector Farmacéutico en México*, 1st ed. (Mexico: Centro de Estudios Sociales y de Opinión Pública, 2010).

Schacht, Wendy H. *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology* (United States of America: Congressional Research Service, 2009).

Schumpeter, JA. *The Theory of Economic Development* (New York: Oxford University Press, 1961).

Schweitzer, Stuart O. *Pharmaceutical Economics and Policy* (New York: Oxford University Press, USA, 2007).

Secretaria de Gobernacion. *Plan Sectorial de Salud 2013-2018* (Mexico: Secretaria de Gobernacion, 2013).

Secretaria de Salud. *Programa de Accion: Tuberculosis* (Mexico: Secretaria de Salud, 2001).

———. *Programa Nacional de Salud 2007-2012.* (Mexico: Secretaria de Salud, 2007).

———. *Programa Sectorial de Salud 2013-2018* (Mexico: Secretaria de Salud, 2013).

Seidman, Irving. *Interviewing as Qualitative Research: A Guide for Researchers in Education and the Social Sciences* (United States of America: Teachers College Press, 2006).

Sen, Amartya. *Inequality Reexamined* (United States of America: Oxford University Press, 1992).

———. *Development as Freedom* (United States of America: Oxford University Press, 1999).

———. "Capability and Well-Being" in Martha Nussbaum & Amartya Sen, eds., *Quality of Life* (Oxford University Press, 1993) 30.

Shadlen, Kenneth C et al, eds. *Intellectual Property, Pharmaceuticals and Public Health* (United Kingdom: Edward Elgar Publishing, 2011).

———. *Coalitions and Compliance: The Political Economy of Pharmaceutical Patents in Latin America* (United States of America: Oxford University Press, 2017).

Shapiro, Carl. "Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting" in Adam B Jaffe, Josh Lerner & Scott Stern, eds., *Innovation Policy and the Economy* (United States of America: MIT Press, 2001) 119.

Silva-Zolezzi, Irma et al. *Mapa del Genoma de Poblaciones Mexicanas*, 2d ed. (Mexico: Instituto Nacional de Medicina Genomica, 2010).

Solleiro Rebolledo, Jose Luis & Alejandra Herrera Mendoza. “Conceptos Basicos” in Jose Luis Solleiro Rebolledo & Rosario Castanon, eds., *Gestion Tecnologica. Conceptos y Practicas* (Mexico: Plaza y Valdes, S.A. de C.V., 2008).

Soto Estrada, Guadalupe, Miguel Angel Lutzow Steiner & Rafael Gonzalez Guzman. “Rasgos generales del sistema de salud en México.” in Rafael Gonzalez Guzman, Laura Moreno Altamirano & Juan Manuel Castro Albarran, eds., *Coleccion Salud Publica Para Estudiantes de Medicina Vol 1: La Salud Publica y el Trabajo en Comunidad* (Mexico: McGraw Hill, 2010).

Stimson, Robert J, Roger R Stough & Brian H Roberts. *Regional Economic Development: Analysis and Planning Strategy*, 2nd ed. (New York, United States of America: Springer Science & Business Media, 2006).

Sumikura, Koichi. “Intellectual property rights policy for gene-related inventions - toward optimum balance between public and private ownership” in David Castle, ed., *The Role of Intellectual Property Rights in Biotechnology Innovation* (United Kingdom: Edward Elgar, 2009) 73.

United Nations Development Programme. *Indice de Desarrollo Humano en Mexico: Cambios Metodologicos e Informacion para las Entidades Federativas* (United Nations Development Programme, 2012).

———. *Human Development Report 2016* (United Nations Development Programme, 2016).

———. “Human Development Index (HDI) | Human Development Reports”, online: *U N Dev Programme* <http://hdr.undp.org/en/content/human-development-index-hdi>.

US Department of Justice. *Antitrust Guidelines For The Licensing Of Intellectual Property | ATR | Department of Justice* (United States of America: U.S. Department of Justice, 1995).

Valle Esquivel, Julieta. *Nahuas de la Huasteca* (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2003).

Vaver, David. *Intellectual Property Law*, 2nd ed (Canada: Irwin Law, 2011).

Wacher Rodarte, Metter Marie. *Nahuas de Milpa Alta* (Mexico: Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2006).

Wehling, Martin. “Introduction and Definitions” in Martin Wehling, ed., *Principles of Translational Science in Medicine. From Bench to Bedside*, 1st ed. (United States of America: Cambridge University Press, 2010).

Willet, Edward. *Genetics Demystified* (United States of America: McGraw Hill, 2006).

WIPO. *WIPO Report on Patents* (World Intellectual Property Organization, 2014).

World Health Organization. *Genomics and World Health. Report of the Advisory Committee on Health Research* (World Health Organization, 2002).

———. *Global Tuberculosis Report 2013* (France: World Health Organization, 2013).

———. *Global tuberculosis report 2016* (Switzerland: World Health Organization, 2016).

Yin, Robert K. *Case Study Research: Design and Methods* (SAGE, 2009).

Periodicals

Agarwal, Ashwin et al. "Commercial landscape of noninvasive prenatal testing in the United States" (2013) 33:6 Prenat Diagn 521.

Ali-Khan, Sarah E et al. "Defining Success in Open Science" (2018) 2:2 Mni Open Res 1.

Ali-Khan, Sarah E & E Richard Gold. "Gene patents still alive and kicking: their impact on provision of genetic testing for long QT syndrome in the Canadian public health-care system | Genetics in Medicine" (2017) 19 Genet Med 1253.

Amani, Bita. ""Of at Least Equal Importance": (Intellectual Property) Rights Mapping with a Moral Compass" (2018) 31:1 Intellectual Property Journal 105.

———. "Patents, the Charter, and a Healthy Dose of Rights in Wrongs: The Poison is the Elixir of Life, Liberty and Security of the Person" (2007) 57 U. N. B. L. J. 162.

Amani, Bita & Coombe, Rosemary J. "The Human Genome Diversity Project: The Politics of Patents at the Intersection of Race, Religion, and Research Ethics" (2005) 27:1 Law and Policy 152.

Andrews, Lori B. "Genes and patent policy: rethinking intellectual property rights" (2002) 3:10 Nat Rev Genet 803.

Arrese, Jorge E et al. "Effectors of inflammation in actinic prurigo" (2001) 44:6 J Am Acad Dermatol 957.

Bagley, Constance & Christina D Tvarnø. "Pharmaceutical Public-Private Partnerships : Moving From the Bench to the Bedside." (2014) 4:2 Harv Business Law Rev 373.

Baker, Dean. "A free market solution for prescription drug crises" (2004) 34:3 Int J Health Serv Plan Adm Eval 517.

———. “The Upward Redistribution of Income: Are Rents the Story?” (2016) 48:4 Rev Radic Polit Econ 529.

Baker, Meghan A et al. “The impact of diabetes on tuberculosis treatment outcomes: a systematic review” (2011) 9 BMC Med 81.

Balasegaram, Manica et al. “An open source pharma roadmap” (2017) 14:4 PLOS Med e1002276.

Barnett, Jonathan M. “The Anti-Commons Revisited” (2015) 29 Harv J Law Technol 127.

Barquera, Rodrigo et al. “Una primera aproximación a la generación de un mapa inmunogenético de la población mexicana” (2016) 16:0 Estudios de Antropologia Biológica, online: <http://www.revistas.unam.mx/index.php/eab/article/view/56706>.

Barquera, Rodrigo & Julio Granados Arriola. “La Diversidad Biologica en los Haplotipos del Sistema HLA en las Poblaciones Mestizas de Mexico.” (2013) 20:58 Cuicuilco Revista de la Escuela Nacional de Antropologia e Historia 197.

Bernal-Silva, Sofía et al. “HLA-DRB1 Class II antigen level alleles are associated with persistent HPV infection in Mexican women; a pilot study” (2013) 8:1 Infect Agent Cancer 31.

Blind, Knut, Katrin Cremers & Elisabeth Mueller. “The Influence of Strategic Patenting on Companies’ Patent Portfolios” (2009) 38:2 Res Policy 428.

Bloom, B R & C J Murray. “Tuberculosis: commentary on a reemergent killer” (1992) 257:5073 Science 1055.

Boggio, Paula et al. “Prurigo actínico: A propósito de un caso” (2006) 104:6 Arch Argent Pediatría 530.

Bubela, Tania, Garret A FitzGerald & E Richard Gold. “Recalibrating Intellectual Property Rights to Enhance Translational Research Collaborations” (2012) 4:122 Sci Transl Med 1.

Caulfield, Timothy et al. “Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies” (2006) 24:9 Nat Biotechnol 1091.

Caulfield, Timothy, Shawn HE Harmon & Yann Joly. “Open science versus commercialization: a modern research conflict?” (2012) 4:2 Genome Med 17.

Chandrasekharan, Subhashini & Robert Cook-Deegan. “Gene patents and personalized medicine - what lies ahead?” (2009) 1 Genome Med 92.

Chandrasekharan, Subhashini, Amy L McGuire & Ignatia B Van den Veyver. “Do recent US Supreme Court rulings on patenting of genes and genetic diagnostics affect the

practice of genetic screening and diagnosis in prenatal and reproductive care?" (2014) 34:10 Prenat Diagn 921.

Chaudhry, V et al. "Thalidomide-induced neuropathy" (2002) 59:12 Neurology 1872.

Chaudhry, Vinay et al. "Characteristics of bortezomib- and thalidomide-induced peripheral neuropathy" (2008) 13:4 J Peripher Nerv Syst JPNS 275.

Cheepsattayakorn, Attapon & Ruangrong Cheepsattayakorn. "Human genetic influence on susceptibility of tuberculosis: from infection to disease" (2009) 92:1 J Med Assoc Thail Chotmaihet Thangphaet 136.

Chemor Ruiz, Antonio, Anette Elena Ochmann Ratsch & Gloria Araceli Alamilla Martinez. "Mexico's Seguro Popular: Achievements and Challenges" (2018) 4:3 J Health Syst Reform 194.

Chiesa, Vittorio. "Strategies for Global R&D" (1996) 39:5 Res-Technol Manag 19.

Chiu, Kellia, Quinn Grundy & Lisa Bero. "'Spin' in published biomedical literature: A methodological systematic review" (2017) 15:9 PLOS Biol, online: <http://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.2002173>.

Cho, Mildred K et al. "Effects of patents and licenses on the provision of clinical genetic testing services" (2003) 5:1 J Mol Diagn JMD 3.

Claassen, Rutger. "Capability Paternalism" (2014) 30:1 Econ Amp Philos 57.

Clarke, Warren. "A Worthwhile Intervention? The Potential Rile for a Sovereign Patent Fund in Canada", *Cent Int Gov Innov* (25 April 2017), online: <https://www.cigionline.org/articles/worthwhile-intervention-potential-role-sovereign-patent-fund-canada>.

Colt, Henri & Silvia Quadrelli. "Democratization of Medical Knowledge and Technology: Brief Commentary on Implications for Medical Education" (2006) 1:4 Simul Healthc 238.

Contreras, Jorge L & Jacob S Sherkow. "Patent pools for CRISPR technology—Response" (2017) 355:6331 Science 1274.

Contreras-Loya, David et al. "Abasto y surtimiento de medicamentos en unidades especializadas en la atención de enfermedades crónicas en México en 2012" (2013) 55:6 Salud Pública México 618.

Cook-Deegan, Robert & Christopher Heaney. "Patents in genomics and human genetics" (2010) 11 Annu Rev Genomics Hum Genet 383.

Croda, Mariana Garcia et al. "Tuberculosis control in a highly endemic indigenous community in Brazil" (2012) 106:4 Trans R Soc Trop Med Hyg 223.

Curtis, John M. "Intellectual Property Rights and International Trade: An Overview", (2012) 3 CIGI Papers <https://www.cigionline.org/sites/default/files/no.3.pdf>.

Daniels, N. “Justice, health, and healthcare” (2001) 1:2 Am J Bioeth AJOB 2.

Diaz, Katya Pulido et al. “Actinic Prurigo in a Mexican Patient: Case Report” (2014) 117:2 Oral Surg Oral Med Oral Pathol Oral Radiol e136.

Donner, Amy. “A Conversation with Aled Edwards” (2014) Sci-Bus Exch 1.

Dunne, Suzanne et al. “A review of the differences and similarities between generic drugs and their originator counterparts, including economic benefits associated with usage of generic medicines, using Ireland as a case study” (2013) 14 BMC Pharmacol Toxicol 1.

Endeshaw, Assafa. “Harmonization of Intellectual Property Laws in Asean” (2005) 2:1 J World Intellect Prop 3.

Epstein, Charles J. “Medical Genetics in the Genomic Medicine of the 21st Century” (2006) 79:3 Am J Hum Genet.

Estrada, Roberto et al. “Specialized dermatological care for marginalized populations and education at the primary care level: is community dermatology a feasible proposal?” (2012) 51:11 Int J Dermatol 1345.

Estrada-G, Iris et al. “Evidence that thalidomide modifies the immune response of patients suffering from actinic prurigo” (2004) 43:12 Int J Dermatol 893.

Fitzgerald, Garret A. “Opinion: anticipating change in drug development: the emerging era of translational medicine and therapeutics” (2005) 4:10 Nat Rev Drug Discov 815.

Foote, Jonathan R et al. “Cost Comparison of Genetic Testing Strategies in Women With Epithelial Ovarian Cancer” (2017) 13:2 J Oncol Pract 115.

Friend, Stephen H & Thea C Norman. “Metcalfe’s law and the biology information commons”, (5 April 2013), online: *Nat Biotechnol* <https://www.nature.com/articles/nbt.2555>.

Gagne, Joshua J & Niteesh K Choudhry. “How Many ‘Met-Too’ Drugs is Too Many?” (2011) 305:7 J Am Med Assoc 711.

Gagnon, Marc-André & Joel Lexchin. “The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States” (2008) 5:1 PLoS Med e1.

Gallini, Nancy T. “The Economics of Patents: Lessons from Recent U.S. Patent Reform” (2002) 16:2 J Econ Perspect 131.

Ganachari, Malathesha et al. “Joint effect of MCP-1 genotype GG and MMP-1 genotype 2G/2G increases the likelihood of developing pulmonary tuberculosis in BCG-vaccinated individuals” (2010) 5:1 PloS One.

García-Corona, Cristina et al. “Association of HLA-DR4 (DRB1*0404) with human papillomavirus infection in patients with focal epithelial hyperplasia” (2004) 140:10 Arch Dermatol 1227.

———. “HLA-DR alleles associated with skin warts induced by human papillomavirus infection” (2010) 49:12 Int J Dermatol 1376.

Garfein, Richard S et al. “Latent Tuberculosis Infection in a Migrant Agricultural Community in Baja California, Mexico” (2011) 13:5 J Immigr Minor Health 940.

Garrido-Latorre, Francisco, Héctor Hernández-Llamas & Octavio Gómez-Dantés. “Surtimiento de recetas a los afiliados al Seguro Popular de Salud de México” (2008) 50:4 Salud Pública México S429.

Gibbard, Allan. “Health Care and the Prospective Pareto Principle” 94:2 Ethics 261.

Gold, E Richard. “The Reach of Patent Law and Institutional Competence” (2003) 1 Univ Ott Law Technol J 263.

———. “The unexamined assumptions of intellectual property: adopting an evaluative approach to patenting biotechnological innovation” (2004) 18:4 Public Aff Q 299.

———. “Are Patents Impeding Medical Care and Innovation?” (2010) 7:1 PLOS Med 1.

———. “Patents and human rights: a heterodox analysis” (2013) 41:1 J Law Med Ethics J Am Soc Law Med Ethics 185.

———. “Accelerating Translational Research through Open Science: The Neuro Experiment” (2016) 14:12 PLOS Biol e2001259.

Gold, E Richard & Julia Carbone. “Myriad Genetics: In the eye of the policy storm” (2010) 12:4 Suppl Genet Med S39.

Gomez Dantés, Octavio et al. “The health system of Mexico” (2011) 53:2 Salud Publica Mex 220.

González-Losa, Maria R et al. “Multifocal epithelial hyperplasia in a community in the Mayan area of Mexico” (2011) 50:3 Int J Dermatol 304.

Graff, Gregory D et al. “Not quite a myriad of gene patents” (2013) 31 Nat Biotechnol 404.

Granados Moreno, Palmira et al. “Open science precision medicine in Canada: Points to consider” (2019) FACETS, online: <http://www.facetsjournal.com/doi/10.1139/facets-2018-0034>.

Granados Moreno, Palmira, Yann Joly & Bartha Maria Knoppers. “Public–Private Partnerships in Cloud-Computing Services in the Context of Genomic Research” (2017) 4 Front Med, online: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC5247451/>.

Granados Moreno, Palmira, Yann Joly & Dylan Roskams-Edris. *Could Open Be the Yellow Brick Road to Innovation in Genomics in North America?* (Accepted for publication at McGill Journal of Law and Health, 2019).

Griebel, Lena et al. “A scoping review of cloud computing in healthcare” (2015) 15 BMC Med Inform Decis Mak, online: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4372226/>.

Guzmán-Montes, Gema Yolanda, Renata Heras Ovalles & Rafael Laniado-Laborín. “Indirect patient expenses for antituberculosis treatment in Tijuana, Mexico: is treatment really free?” (2009) 3:10 J Infect Dev Ctries 778.

Hall, Bronwyn H. “Business and Financial Method Patents, Innovation, and Policy” (2009) 56:1 Scott J Polit Econ 443.

Hall, Linda A & Sharmistha Bagchi-Sen. “A study of R&D, innovation, and business performance in the Canadian biotechnology industry” (2002) 22:4 Technovation 231.

Heller, Michael. “The Tragedy of the Anticommons: Property in the Transition from Marx to Markets” (1998) 111:3 Harv Law Rev 622.

Heller, Michael A & Rebecca S Eisenberg. “Can Patents Deter Innovation? The Anticommons in Biomedical Research | Science” (1998) 280:5364 Science 698.

Hettinger, Edwin C. “Justifying Intellectual Property” (1989) 18:1 Philos Public Aff 31.

Hojyo-Tomoka, María-Teresa et al. “Further evidence of the role of HLA-DR4 in the genetic susceptibility to actinic prurigo” (1997) 36:6 J Am Acad Dermatol 935.

———. “Diagnosis and treatment of actinic prurigo” (2003) 16:1 Dermatol Ther 40.

Hojyo-Tomoka, T et al. “Actinic prurigo: an update” (1995) 34:6 Int J Dermatol 380.

Horn, Lawrence. “Patent pools for CRISPR technology” (2017) 355:6331 Science 1274.

Huang, Judy et al. “Analyses of the NRAMP1 and IFN- γ R1 Genes in Women with Mycobacterium avium-intracellulare Pulmonary Disease” (1998) 157:2 Am J Respir Crit Care Med 377.

Jalife Daher, Mauricio. “TPP: amenaza para el mercado de genéricos”, (2 April 2016), online: <https://elmundodelabogado.com/revista/posiciones/item/tpp-amenaza-para-el-mercado-de-genericos>.

Joly, Yann. “Open Source Approaches in Biotechnology: Utopia Revisited” (2006) 59:2 Maine Law Rev 386.

———. “The Commercialization of Genomic Research in Canada” (2010) 6:2 Healthc Policy 24.

Joly, Yann, Angus Livingston & Edward S Dove. "Moving beyond commercialization: Strategies to maximize the economic and social impact of genomics research", (2012) 5 Policy Brief GPS-Genome Canada.

Kapczynski, Amy. “Addressing Global Health Inequalities: An Open Licensing Approach for University Innovations” (2005) 20:2 Berkeley Technol Law J 1032.

Kesselheim, A S & N Shiu. “The evolving role of biomarker patents in personalized medicine” (2014) 95:2 Clin Pharmacol Ther 127.

Kesselheim, Aaron S, Carolyn L Treasure & Steven Joffe. “Biomarker-Defined Subsets of Common Diseases: Policy and Economic Implications of Orphan Drug Act Coverage” (2017) 14:1 PLOS Med e1002190.

Kieff, F Scott. “IP Transactions: On the Theory & Practice of Commercializing Innovation by F. Scott Kieff :: SSRN” (2005) 42:3 Houst Law Rev 727.

———. “Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science – A Response to Rai and Eisenberg” (2000) 43 Northwest Univ Law Rev 698.

———. “Property Rights and Property Rules for Commercializing Inventions” (2001) 85 Minn Law Rev 697.

Knoppers, Bartha M. “Broaden human-rights focus for health data under GDPR” (2018) 558:189 Nature, online: <https://www.nature.com/articles/d41586-018-05388-3>.

Kwak, Young Hoon, YingYi Chih & C William Ibbs. “Towards a Comprehensive Understanding of Public Private Partnerships for Infrastructure Development” (2009) 51:2 Calif Manage Rev 51.

Lampert, Dietmar et al. “New indicators for open science - Possible ways of measuring the uptake and impact of open science” (2017) 44 J Res Technol Policy Eval 50.

Lhuillery, Stéphane & Etienne Pfister. “R&D cooperation and failures in innovation projects: Empirical evidence from French CIS data” (2009) 38:1 Res Policy 45.

Li, H T et al. “SLC11A1 (formerly NRAMP1) gene polymorphisms and tuberculosis susceptibility: a meta-analysis” (2006) 10:1 Int J Tuberc Lung Dis Off J Int Union Tuberc Lung Dis 3.

Li, Phoebe H. “3D Bioprinting Technologies: Patents, Innovation and Access” (2014) 6:2 Law Innov Technol 282.

Liu, W et al. “VDR and NRAMP1 gene polymorphisms in susceptibility to pulmonary tuberculosis among the Chinese Han population: a case-control study” (2004) 8:4 Int J Tuberc Lung Dis Off J Int Union Tuberc Lung Dis 428.

Loeza, Francisco et al. “Distribution of class I and class III MHC antigens in the Tarasco Amerindians” (2002) 63 Hum Immunol 143.

Loon, Ho Calvin Wai. “Utilitarianism and Patents: Justification and Change” (2010) 2:3 Asian Bioeth Rev 202.

Lopez Silva, Christian. “México retoma un liderazgo regulatorio sobre medicamentos biotecnológicos y biocomparables” (2012) 148:1 Gac Médica México 83.

Love, Brian J. “An Empirical Study of Patent Litigation Timing: Could a Patent Term Reduction Decimate Trolls Without Harming Innovators?” (2013) 161 Univ Pa Law Rev 1309.

Low, Eric, Chas Bountra & Wen Hwa Lee. “Accelerating target discovery using pre-competitive open science—patients need faster innovation more than anyone else” (2016) 10 ecancermedicalscience, online: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4990051/>.

Mack, Peter. “Utilitarian Ethics in Healthcare” (2004) 12:3 Int J Comput Internet Manag 63.

Marcon, Alessandro R, Mark Bieber & Timothy Caulfield. “Representing a ‘revolution’: how the popular press has portrayed personalized medicine” (2018) Genet Med Off J Am Coll Med Genet.

Martinez-Gamboa, Areli et al. “Molecular analysis of Mycobacterium tuberculosis strains with an intact pks15/1 gene in a rural community of Mexico” (2008) 39:8 Arch Med Res 809.

Maurer, Stephen M, Arti Rai & Andrej Sali. “Finding Cures for Tropical Diseases: Is Open Source an Answer?” (2004) 1:3 PLoS Med e56.

Mayoral-Zavala, A et al. “Actualización sobre los medicamentos biocomparables en la enfermedad inflamatoria intestinal: posición y recomendación en México” (2018) 83:4 Rev Gastroenterol México 414.

McGinnis, J Michael, Pamela Williams-Russo & James R Knickman. “The Case for More Active Policy Attention to Health Promotion” (2002) 21:2 Health Aff (Millwood) 78.

McGregor, Jane M et al. “Genetic Modeling of Abnormal Photosensitivity in Families with Polymorphic Light Eruption and Actinic Prurigo” (2000) 115:3 J Invest Dermatol 471.

Merges, Robert P & Richard R Nelson. “On the Complex Economics of Patent Scope” (1990) 90:4 Columbia Law Rev 839.

Mileshkin, Linda et al. “Development of neuropathy in patients with myeloma treated with thalidomide: patterns of occurrence and the role of electrophysiologic monitoring” (2006) 24:27 J Clin Oncol Off J Am Soc Clin Oncol 4507.

Millard, Tp et al. “A candidate gene analysis of three related photosensitivity disorders: cutaneous lupus erythematosus, polymorphic light eruption and actinic prurigo” (2001) 145:2 Br J Dermatol 229.

Miranda, Ana MO et al. “Actinic prurigo of the lip: Two case reports” (2014) 2:8 World J Clin Cases WJCC 385.

Mizuno, Fuzuki et al. “Complete mitogenome analysis of indigenous populations in Mexico: its relevance for the origin of Mesoamericans” (2014) 59:7 J Hum Genet 359.

Molina-Salazar, Raúl E, Eloy González-Marín & Carolina Carbajal-de Nova. “Competencia y precios en el mercado farmacéutico mexicano” (2008) 50 Salud Pública México S496.

Möller, Marlo & Eileen G Hoal. “Current findings, challenges and novel approaches in human genetic susceptibility to tuberculosis” (2010) 90:2 Tuberc Edinb Scotl 71.

Moreno-Estrada, Andrés et al. “Human genetics. The genetics of Mexico recapitulates Native American substructure and affects biomedical traits” (2014) 344:6189 Science 1280.

Müller, Olaf & Michael Krawinkel. “Malnutrition and health in developing countries” (2005) 173:3 CMAJ Can Med Assoc J 279.

Murray, Fiona & Scott Stern. “Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis” (2007) 63:4 J Econ Behav Organ 648.

Nájera-Ortiz, J C et al. “Demographic, health services and socio-economic factors associated with pulmonary tuberculosis mortality in Los Altos Region of Chiapas, Mexico” (2008) 37:4 Int J Epidemiol 786.

———. “The Poor Survival among Pulmonary Tuberculosis Patients in Chiapas, Mexico: The Case of Los Altos Region” (2012) Tuberc Res Treat 1.

Niño-Moreno, P et al. “P2X7 and NRAMP1/SLC11 A1 gene polymorphisms in Mexican mestizo patients with pulmonary tuberculosis” (2007) 148:3 Clin Exp Immunol 469.

Noble, Kimberly G et al. “Family income, parental education and brain structure in children and adolescents” (2015) 18:5 Nat Neurosci 773.

Noble, Kimberly G. “What Inequality Does to the Brain - Scientific American”, *Sci Am* (March 2017), online: <https://www.scientificamerican.com/article/what-inequality-does-to-the-brain/>.

Nussbaum, Martha. “Capabilities as Fundamental Entitlements: Sen and Social Justice” (2003) 9:2–3 Fem Econ 33.

Ogbogu, Ubaka et al. “Newspaper coverage of biobanks” (2014) 2 PeerJ e500.

Olson, David S. “Taking the Utilitarian Basis for Patent Law Seriously: The Case for Restricting PatentableSubject Matter” (2009) 82 Temple Law Rev 181.

Omachonu, Vincent K & Norman G Einspruch. “Innovation in Healthcare Delivery Systems: A Conceptual Framework” (2010) 15:1 Innov J Public Sect Innov J 1.

Morgan, Owen. "Harmonisation of Intellectual Property: Issues in the South Pacific", (2010) 4:3 International Journal of Business and Globalisation 237.

Paek, So Yeon et al. “Skin diseases in rural Yucatan, Mexico” (2012) 51:7 Int J Dermatol 823.

Parthasarathy, Shobita. “Whose Knowledge? What Values? The Comparative Politics of Patenting Life Forms in the United States and Europe” (2011) 44 Policy Sci 267.

Petersen, Alan & Ivan Krisjansen. “Assembling ‘the bioeconomy’: Exploiting the power of the promissory life sciences” (2015) 51:1 J Sociol 28.

Posner, Richard A. “Utilitarianism, Economics, and Legal Theory” (1979) 8:1 J Leg Stud 103.

———. “Intellectual Property: The Law and Economics Approach” (2005) 19:2 J Econ Perspect 57.

Possani, Lourival D. “The past, present, and future of biotechnology in Mexico” (2003) 21:5 Nat Biotechnol 582.

Rai, Arti K. “Evolving Scientific Norms and Intellectual Property Rights: A Reply to Kieff” (2001) 95:2 Northwest Univ Law Rev 707.

———. “Pathways across the valley of death: novel intellectual property strategies for accelerated drug discovery” (2008) 8:1 Yale J Health Policy Law Ethics 1.

Resnik, David B. “DNA Patents and Scientific Discovery and Innovation: Assessing Benefits and Risks” (2001) 7:1 Sci Eng Ethics 29.

Riehle, Dirk et al. “Open Collaboration Within Corporations Using Software Forges” (2009) March/April IEEE Softw 52.

Robeyns a), Ingrid. “The Capability Approach: a theoretical survey” (2005) 6:1 J Hum Dev 93.

Rodwin, Marc A. “Conflicts of Interest, Institutional Corruption and Pharma: An Agenda for Reform” (2012) 40 J Law Med Ethics 511.

Rouleau, Guy. “Open Science at an institutional level: an interview with Guy Rouleau” (2017) 18 Genome Biol 14.

Rueda, M Duran De, Jaime E Bernal & Clara Patricia Ordonez. “Actinic Prurigo at Sea Level in Colombia” (1989) 28:4 Int J Dermatol 228.

Saha, Atanu et al. “Generic Competition in the US Pharmaceutical Industry” (2006) 13:1 Int J Econ Bus 15.

Schurr, Erwin. “Is susceptibility to tuberculosis acquired or inherited?” (2007) 261:2 J Intern Med 106.

———. “The contribution of host genetics to tuberculosis pathogenesis” (2011) 86:1 Kekkaku 17.

Scott, Stuart A. “Personalizing medicine with clinical pharmacogenetics” (2011) 13:12 Genet Med 987.

Séguin, Béatrice et al. “Genomics, public health and developing countries: the case of the Mexican National Institute of Genomic Medicine (INMEGEN)” (2008) 9 Suppl 1 Nat Rev Genet S5.

Sen, Amartya. “Capabilities, Lists, and Public Reason: Continuing the Conversation” (2004) 10:3 Fem Econ 77.

———. “Human Rights and Capabilities” (2005) 6:2 J Hum Dev 151.

Shaw, Daniel L. “Is Open Science the Future of Drug Development?” (2017) 90:1 Yale J Biol Med 147.

Sheridan, D P et al. “HLA typing in actinic prurigo” (1990) 22:6 Pt 1 J Am Acad Dermatol 1019.

Shukla, Nitin & Tanushree Sangal. “Generic Drug Industry in India: The Counterfeit Spin” (2009) 14:3 J Intellect Prop Rights 236.

Signham, Shanker A. “Competition Policy and the Stimulation of Innovation: TRIPs and the Interface Between Competition and Patent Protection in the Pharmaceutical Industry” (2000) 26 Brooklyn J Int Law 363.

Silva-Zolezzi, Irma et al. “Analysis of Genomic Diversity in Mexican Mestizo Populations to Develop Genomic Medicine in Mexico” (2009) 106:21 PNAS 8611.

Singh, Ananya et al. “Current status of anti-tuberculosis therapy: a patent analysis” (2014) 9:1 Recent Patents Anti-Infect Drug Disc 25.

Sosa-Macías, Martha & Adrián Llerena. “Cytochrome P450 genetic polymorphisms of Mexican indigenous populations” (2013) 28:4 Drug Metabol Drug Interact 193.

Soto, María Elena et al. “Comparison distribution of HLA-B alleles in mexican patients with takayasu arteritis and tuberculosis” (2007) 68:5 Hum Immunol 449.

Strimbu, Kyle & Jorge A Tavel. “What are Biomarkers?” (2010) 5:6 Curr Opin HIV AIDS 463.

Suárez, Alfonso et al. “Association of HLA subtype DRB1*0407 in Colombian patients with actinic prurigo” (2006) 22:2 Photodermatol Photoimmunol Photomed 55.

Svatos, Michele. “Biotechnology and the Utilitarian Argument for Patents” (1996) 13:2 Soc Philos Policy 113.

Torres, Jose Luis et al. “Salud de la Población Indígena en México” in Felicia Marie Knaul & Gustavo Nigenda, eds, *Caleidosc Salud Investig Las Políticas Las Políticas Acción* (Mexico: Case Salud & Fundacion Mexicana para la Salud, 2003) 41.

Torres-Dosal, Arturo et al. “Indoor air pollution in a Mexican indigenous community: evaluation of risk reduction program using biomarkers of exposure and effect” (2008) 390:2–3 Sci Total Environ 362.

Torres-García, Diana et al. “Variants in toll-like receptor 9 gene influence susceptibility to tuberculosis in a Mexican population” (2013) 11 J Transl Med 220.

Trebilcock, Michael J. “An Introduction to Law and Economics.” (1997) 23 Monash Univ Law Rev 123.

Tridico, Anthony, Jeffrey Jacobstein & Leythem Wall. “Facilitating generic drug manufacturing: Bolar exemptions worldwide”, *WIPO Mag* (2014), online: <http://www.wipo.int/wipo_magazine/en/2014/03/article_0004.html>.

Valbuena, Martha C, Sandra Muvdi & Henry W Lim. “Actinic Prurigo” (2014) 32:3 Dermatol Clin 335.

Vargas-Alarcón, G et al. “HLA-DR4 allele frequencies on Indian and Mestizo population from Mexico” (2000) 61:3 Hum Immunol 341.

Vargesson, Neil. “Thalidomide‐induced teratogenesis: History and mechanisms” (2015) 105:2 Birth Defects Res 140.

Vela, Enrique. “Culturas Prehispanicas de Mexico”, *Arquelogia Mex* 53.

Vinkers, Christiaan H, Joeri K Tijdink & Willem M Otte. “Use of positive and negative words in scientific PubMed abstracts between 1974 and 2014: retrospective analysis” (2015) 351 BMJ h6467.

Waldron, Jeremy. “Superseding Historic Injustice” (1992) 103:1 Ethics 4.

Wang, Richard L. “Biomedical Upstream Patenting and Scientific Research: The Case for Compulsory Licenses Bearing Reach-Through Royalties” (2008) 10:1 Yale J Law Technol 251.

Waters, Ken. “Molecular Genetics” in Edward N Zalta, ed, *Stanf Encycl Philos*, fall 2013 ed. (online: Metaphysics Research Lab, Stanford University, 2013).

Wehling, Martin. “Translational medicine: science or wishful thinking?” (2008) 6 J Transl Med 31.

Williams, Heidi L. “Intellectual Property Rights and Innovation: Evidence from the Human Genome” (2013) 121 J Polit Econ 1.

Willis, Robert R. “International Patent Law: Should United States and Foreign Patent Law Be Uniform - An Analysis of the Benefits, Problems, and Barriers” (2009) 10:2 N C J Law Technol 283.

Wiseman, Marni C et al. “Actinic prurigo: Clinical features and HLA associations in a Canadian Inuit population” (2001) 44:6 J Am Acad Dermatol 952.

Zimmeren, Esther van et al. “Patent pools and clearinghouses in the life sciences” (2011) 29:11 Trends Biotechnol 569.

Zuloaga-Salcedo, S et al. “Class I and class II major histocompatibility complex genes in Mexican patients with actinic prurigo” (2007) 156:5 Br J Dermatol 1074.

Newspaper Articles

Alcantara, Liliana. “Surge Tuberculosis Farmacorresistente”, *El Universal* (24 January 2011), online: El Universal <http://www.eluniversal.com.mx/nacion/183207.html>.

CBC News. “U.S. human gene patent ‘like patenting water or air,’ Canadian hospital CEO says”, *CBC News* (3 November 2014), online: CBC News <http://www.cbc.ca/news/health/u-s-gene-patents-patient-care-stymied-in-canada-hospital-claims-1.2820211>.

Edwards, Aled. “To spark medical innovation, Canada should embrace Open Science”, (7 January 2017), online: The Globe and Mail <https://www.theglobeandmail.com/report-on-business/rob-commentary/to-spark-medical-innovation-canada-should-embrace-open-science/article33533010/>.

Gagnon, Marc-André. “How a National Drug Plan Would Benefit Canadians”, *Huffington Post* (12 August 2013), online: Huffington Post <https://www.huffingtonpost.ca/marcandre-gagnon/canada-national-drug-plan_b_3430031.html>.

———. “What my Critics Don’t Get About Drug Policy”, *Huffington Post* (2 September 2013), online: Huffington Post <https://www.huffingtonpost.ca/marcandre-gagnon/drug-policy-canada_b_3536203.html>.

Mariani, Mike. “The neuroscience of inequality: does poverty show up in children’s brains?”, *The Guardian* (13 July 2017), online: The Guardian <https://www.theguardian.com/inequality/2017/jul/13/neuroscience-inequality-does-poverty-show-up-in-childrens-brains?CMP=Share_iOSApp_Other>.

Matias, Pedro. “Irma, la indígena mazateca que parió en el patio de un hospital”, *Proceso* (4 October 2013), online: Proceso <http://www.proceso.com.mx/354510/irma-la-indigena-mazateca-que-pario-en-el-patio-de-un-hospital>.

Mere, Dayna. “Destacan Inventores Mexicanos”, *Reforma* (3 May 2016), online: Reforma <http://www.negociosreforma.com/aplicaciones/articulo/default.aspx?id=834230&v=impresion=1>.

Migueles, Ruben. “Sin acceso a salud, 32.6 millones de trabajadores: Inegi”, *El Universal* (15 November 2017), online: El Universal <http://www.eluniversal.com.mx/cartera/economia/sin-acceso-salud-326-millones-de-trabajadores-inegi>.

Molina, Hector. “En pobreza, 71% de los indígenas en México”, *El Economista* (9 August 2018), online: El Economista <https://www.eleconomista.com.mx/politica/En-pobreza-71-de-los-indigenas-en-Mexico-20180809-0145.html>.

Quigley, Fran. “Escaping Big Pharma’s Pricing With Patent-Free Drugs”, *N Y Times* (18 July 2017), online: New York Times <https://www.nytimes.com/2017/07/18/opinion/escaping-big-pharmas-pricing-with-patent-free-drugs.html>.

Saavedra, Diana. “Estiman lejano 1% del PIB a Ciencia”, *Reforma* (20 November 2013), online: Reforma <http://www.reforma.com/ciencia/articulo/722/1442233/?Titulo=estiman-lejano--1-del-pib-a-ciencia>.

Suarez, Alejandro. “Sin acceso a servicios de salud, 19.1 millones de personas - El Sol de México”, *El Sol de Mexico* (8 April 2019), online: El Sol de Mexico <https://www.elsoldemexico.com.mx/mexico/sociedad/sin-acceso-a-servicios-de-salud-19.1-millones-de-personas-3292147.html>.

Swanson, Ana. “Big pharmaceutical companies are spending far more on marketing than research”, *Washington Post* (11 February 2015), online: Washington Post <https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/>.

Ward, Andrew. “GSK to relax intellectual property and help developing world - FT.com”, *Financial Times* (31 March 2016), online: Financial Times <http://www.ft.com/cms/s/0/903cc52e-f729-11e5-803c-d27c7117d132.html#axzz492RqZPsJ>.

“AMLO announces new health system; Seguro Popular to be replaced”, *Mexico News Daily* (14 December 2018), online: <https://mexiconewsdaily.com/news/amlo-announces-new-integrated-health-system/>.

“Disputan farmacéuticas ampliación de patentes – Mexico”, *Bitácora Farmaceutica* (22 September 2009), online: Bitacora Farmaceutica <https://bitacorafarmaceutica.wordpress.com/2009/09/22/disputan-farmaceuticas-ampliacion-de-patentes-mexico/>.

“Escasez de tamiflu es porque fue mal recetado: Cofepris”, *Milenio* (29 February 2016), online: Milenio <http://www.milenio.com/politica/tamiflu-medicamento-tamiflu-escasez-tamiflu-recetan-mal-tamiflu-Cofepris_0_692330980.html>.

“Genoteca indígena recopila ADN de mexicanos”, *El Universal* (31 December 2013), online: El Universal <http://archivo.eluniversal.com.mx/ciencia/2013/genoteca-indigena-adn-mexicanos-82420.html>.

“México cuenta con estudio genético para predecir cáncer”, *Alto Nivel* (19 June 2013), online: Alto Nivel <http://www.altonivel.com.mx/36524-mexico-cuenta-con-estudio-genetico-para-predecir-cancer/>.

“Mujer da a luz en el pasto de una clínica en Oaxaca”, *Excelsior* (4 October 2013), online: *Excélsior* <http://www.excelsior.com.mx/nacional/2013/10/04/921864>.

“Salud da ultimátum a Roche por desabasto de Tamiflu”, *Excelsior* (28 February 2016), online: Excelsior <http://www.excelsior.com.mx/nacional/2016/02/28/1077855>.

Online Sources

Abaroa Silva, Sharai Isabel. “Medicamentos genéricos y de patente ¿Cuánto cuestan?”, (Abril 2015), online: *Procuraduria Federal del Consumidor PROFECO* <http://www.profeco.gob.mx/encuesta/brujula/bruj_2015/bol303_medi.asp>.

Arias, Luis M. “‘Milpa’ Agroecosystems in Yucatan, Mexico | Agricultural Transition”, (14 May 2012), online: *Agroecology.org* <http://ag-transition.org/?initiative=milpa-agroecosystems-in-yucatan-mexico>.

Armstrong Laboratorios. “Products Armstrong Laboratorios”, (2019), online: *Laboratorios Armstrong* <https://www.laboratoriosarmstrong.mx/armstrong/armstrong.html>.

Arneson, Richard. *Egalitarianism*, summer 2013 ed., Edward N. Zalta, ed. (online: Metaphysics Research Lab, Stanford University, 2013) <https://plato.stanford.edu/archives/sum2013/entries/egalitarianism/>.

Baker, Dean, Arjun Jayadev & Joseph Stiglitz. *Innovation, Intellectual Property, and Development* (Azim Premji University, University of Cape Town, Fundação Oswaldo Cruz, and Escola Nacional de Saúde Pública, 2017) online: <http://ip-unit.org/wp-content/uploads/2017/07/IP-for-21st-Century-EN.pdf>.

“Banco de Informacion INEGI”, online: *Instituto Nacional de Estadistica y Geografia* <http://www3.inegi.org.mx/sistemas/biinegi/?e=31&m=0&ind=1005000040>.

Biblioteca Digital de la Medicina Tradicional Mexicana. “La Medicina Tradicional de los Pueblos Indigenas de Mexico”, (2009), online: *Biblioteca Digital de Medicina Tradicional Mexicana* <http://www.medicinatradicionalmexicana.unam.mx/pueblos.php?v=p&t=purepecha&l=2>.

BREATH The Lung Association. “Tuberculosis | the lung association”, (6 September 2015), online: *BREATH Lung Association* <https://www.lung.ca/lung-health/lung-disease/tuberculosis>.

Burr, Claudia et al. *Ruta para Recibir Atencion Medica en el IMSS e ISSSTE* (Centro de Contraloria Social y Estudios de Construccion Democratica, 2013) online: <http://cciudadano.org.mx/cciudadano2/wp-content/uploads/2017/02/triptico3finalHR.pdf>.

“Búsqueda Patentes-- SIGA”, online: *IMPI Database* <http://siga.impi.gob.mx/content/common/busquedaSimple.jsf>.

“Censo de Poblacion y Vivienda 2010. Mexico en Cifras”, online: *INEGI* <http://www3.inegi.org.mx/sistemas/mexicocifras/>.

"Censo de Poblacion y Vivienda. Consulta General", online: *INEGI* <http://www.inegi.org.mx/lib/olap/consulta/general_ver4/MDXQueryDatos.asp?proy=cpv10_pt>.

CDC. "Neglected Tropical Diseases", (19 April 2017), online: *Center of Disease Control and Prevention CDC* <https://www.cdc.gov/globalhealth/ntd/>.

———. "TB | Fact Sheets - BCG Vaccine", online: *CDC* <https://www.cdc.gov/tb/publications/factsheets/prevention/bcg.htm>.

CDI. *Mayas de la Península de Yucatán* (Comisión Nacional para el Desarrollo de los Pueblos Indígenas, 2009) online: *CDI* <http://www.cdi.gob.mx/index.php?option=com_content&view=article&id=606:mayas-de-la-peninsula-de-Yucatán-&catid=54:monografias-de-los-pueblos-Indígenas&Itemid=62>.

———. "Mayas - Etnografía", (2018), online: *Atlas Los Pueblos Indígenas México INPI* <http://atlas.cdi.gob.mx/?page_id=894>.

———. "Mayas – Estadísticas", (2018), online: *Atlas Los Pueblos Indígenas México INPI* <http://atlas.cdi.gob.mx/?page_id=951>.

———. "Pueblos nahuas", (2018), online: *Atlas Los Pueblos Indígenas México INPI* <http://atlas.cdi.gob.mx/?page_id=8271>.

Centers for Disease Control and Prevention. "CDC | TB | Treatment", online: <http://www.cdc.gov/tb/topic/treatment/>.

CIA. "The World Factbook", online: *Central Intelligence Agency* <https://www.cia.gov/library/publications/the-world-factbook/fields/2012.html>.

Color Genomics. "Common Questions - Color Provider Platform", online: *Color Genomics* <https://www.color.com/providers/questions>.

Comisión Nacional para el Desarrollo de los Pueblos Indígenas. "Mazatecos Ha shuta Enima", (2009), online: *Comision Nacional Para El Desarrollo de los Pueblos Indigenas* <http://www.cdi.gob.mx/index.php?option=com_content&view=article&id=618:mazatecos-ha-shuta-enima-&catid=54:monografias-de-los-pueblos-Indígenas&Itemid=62>

CONACYT-Red OTT. "Red OTT - Nosotros", (3 July 2013), online: *CONACYT-Red OTT* <http://www.redott.com.mx/swb/ROTT/Nosotros>.

CONAPRED. "Discriminación en contra de la población indígena en México", (2012), online: *Consejo Nacional Para Prevenir la Discriminacion* <http://www.conapred.org.mx/index.php?contenido=noticias&id=798&id_opcion=273&op=448>.

Consejo Nacional de Ciencia y Tecnologia. “Sistema Nacional de Investigadores”, online: *CONACYT* <https://www.conacyt.gob.mx/index.php/el-conacyt/sistema-nacional-de-investigadores>.

Cultura Maya. “Ubicación Geográfica de la Cultura Maya”, (2018), online: *Cultura Maya* <https://culturalmaya.com/geografia/>.

DNDi. “Drugs for Neglected Diseases Initiative - About Us”, online: *DNDi* <https://www.dndi.org/about-dndi/>.

“DVD6C Patent Pool”, online: *DVD6C* <http://www.dvd6cla.com/>.

Edwards, Aled. *Why biomedical philanthropy supports redundant science* online: *TEDxToronto* (Toronto, 2016) <https://www.youtube.com/watch?v=Wtp7R97jz5k>.

———. *Freeing Science — From Software to Medicine* (Montreal, Canada, 2017) online: *McGill University* <https://www.mcgill.ca/neuro/channels/event/symposium-freeing-science-software-medicine-267911>.

“Fact Sheet n. 141| Meningococcal meningitis”, (2015), online: *WHO* <http://www.who.int/mediacentre/factsheets/fs141/en/>.

Facultad de Química - UNAM. “Recibe la FQ donativo de Fundación Coca Cola para conformar la Genoteca Indígena”, (2 September 2012), online: *Facultad de Química - UNAM* <https://quimica.unam.mx/recibe-la-fq-donativo-de-fundacion-coca-cola-para-conformar-la-genoteca-indigena/>.

“Facultad de Química UNAM- Recibe la FQ donativo de Fundación Coca Cola para conformar la Genoteca Indígena”, online: *Facultad de Quimica UNAM* <http://www.quimica.unam.mx/cont_espe2.php?id_rubrique=12&color=526C11&id_article=3362>.

Forbes. “The World’s Billionaires List”, (2017), online: *Forbes* <https://www.forbes.com/billionaires/list/#version:static_country:Mexico>.

“France: Code de la propriété intellectuelle (version consolidée au 25 avril 2016)”, online: *WIPO* <http://www.wipo.int/wipolex/en/text.jsp?file_id=403397>.

Free Software Foundation. “What is Free Software”, (1985), online: *GNU Org* <https://www.gnu.org/philosophy/free-sw.en.html>.

Gazcon, Felipe. “México es el que menos invierte en investigación y desarrollo: OCDE | Dinero en Imagen.com”, (23 November 2012), online: *Dinero En Imagen* <http://www.dineroenimagen.com/2012-11-23/11447>.

Gobierno Federal. *Indicadores Basicos de la Agrupacion Mazateco 2015* online: *Gobierno Federal*

<https://site.inali.gob.mx/Micrositios/estadistica_basica/estadisticas2015/pdf/agrupaciones/mazateco.pdf>.

Gomez-Dantes, Octavio et al. *WHO | A new entity for the negotiation of public procurement prices for patented medicines in Mexico* (Bulletin of the World Health Organization, 2012) online: *WHO* <http://www.who.int/bulletin/volumes/90/10/12-106633/en/>.

Gray, Dylan Mohan. *Fire in the Blood* (2013) online: <http://fireintheblood.com/>.

"Health Poverty Action", online: *Health Poverty Action* <https://www.healthpovertyaction.org/>.

Herchline, Thomas. "Tuberculosis Clinical Presentation", online: *EMedicine Medscape* <http://emedicine.medscape.com/article/230802-clinical#showall>.

Hoen, Ellen F M t'. "The Global Politics of Pharmaceutical Monopoly Power" online: *Medecins Sans Frontiers* <http://www.msfaccess.org/content/global-politics-pharmaceutical-monopoly-power>.

IMPI. "Servicios que ofrece el Tarifas: Invenciones, Modelos de Utilidad, Diseños Industriales y Esquemas de trazado de Circuitos Integrados", online: *Instituto Mexicano de la Propiedad Industrial* <http://www.gob.mx/impi/acciones-y-programas/servicios-que-ofrece-el-impi-tarifas-invenciones-modelos-de-utilidad-disenos-industriales-y-esquemas-de-trazado-de-circuitos-integrados>.

———. "Conoce el IMPI | ¿Qué es el IMPI?", online: *Instituto Mexicano de la Propiedad Industrial* <http://www.gob.mx/impi/acciones-y-programas/conoce-el-impi-que-es-el-impi>.

IMSS. "Directorio de las Instituciones del Instituto Mexicano del Seguro Social", online: *Instituto Mexicano del Seguro Social* <http://www.imss.gob.mx/directorio>.

Indígenas. "Etnografía del pueblo mazateco de Oaxaca - Ha shuta Enima", (20 October 2017), online: *INPI Instituto Nacional de Los Pueblos Indigenas* <http://www.gob.mx/inpi/articulos/etnografia-del-pueblo-mazateco-de-oaxaca-ha-shuta-enima>.

INEGI. "Mexico en Cifras", (2015 2008), online: *Instituto Nacional de Estadistica y Geografia* <http://www.beta.inegi.org.mx/app/areasgeograficas/>.

———. "Perfil Socio-demografico de la Poblacion que Habla Lengua Indigena." (2009) online: *Instituto Nacional de Estadistica y Geografia* <https://www.yumpu.com/es/document/view/15871099/perfil-sociodemografico-de-la-poblacion-que-habla-lengua-inegi>.

———. "Diferentes lenguas indígenas", (2015), online: *Instituto Nacional de Estadistica y Geografia* <http://cuentame.inegi.org.mx/hipertexto/todas_lenguas.htm>.

———. “Banco de indicadores”, (30 June 2016), online: *Banco Indicadores Instituto Nacional de Estadistica y Geografia* <http://www.beta.inegi.org.mx/app/indicadores/>.

———. “INEGI Cuadro Resumen. Indicadores Sociales”, (24 January 2018), online: *INEGI* <http://www3.inegi.org.mx/sistemas/temas/default.aspx?s=est&c=19004>.

———. “Base de Datos del INEGI”, online: *Instituto Nacional de Estadistica y Geografia* <http://www.inegi.org.mx/lib/olap/consulta/general_ver4/MDXQueryDatos.asp?proy=cpv10_pt>>.

———. “Servicios y Bienes en las Viviendas. Porcentaje de Viviendas Particulares Habitadas con Disponibilidad de Agua por Entidad Federativa 1990-2010.”, online: *Instituto Nacional de Estadistica y Geografia* <http://www3.inegi.org.mx/sistemas/sisept/default.aspx?t=mviv09&s=est&c=22242>.

INMEGEN. “Publicaciones Científicas - Instituto Nacional de Medicina Genomica”, (24 October 2011), online: *Instituto Nacional de Medicina Genomica* <http://www.inmegen.gob.mx/es/investigacion/publicaciones-cientificas/>.

———. “Líneas de Investigación - Instituto Nacional de Medicina Genómica”, (16 August 2017), online: *Instituto Nacional de Medicina Genómica* <http://www.inmegen.gob.mx/es/investigacion/lineas-de-investigacion/>.

———. “Instituto Nacional de Medicina Genómica - Vinculacion - Convenios Marco”, (16 August 2017), online: *Instituto Nacional de Medicina Genómica* <http://www.inmegen.gob.mx/es/vinculacion/convenios-marco/>.

———. “Instituto Nacional de Medicina Genómica - Vinculacion - Convenios Específicos”, (16 August 2017), online: *Instituto Nacional de Medicina Genómica* <http://www.inmegen.gob.mx/es/vinculacion/convenios-especificos/>.

———. “Estados Participantes at Mapa del Genoma de Poblaciones Mexicanas”, online: *INMEGEN* <http://genomamexicanos.inmegen.gob.mx/jornadasestados.htm>.

“Instituto Bioclon”, (2015), online: *Instituto Bioclon* <https://www.silanes.com.mx/instituto-bioclon.html>.

Instituto Mexicano de la Propiedad Industrial. “Servicios Tarifa de Invenciones, Modelos de Utilidad, Diseños Industriales y Esquemas de Trazado de Circuitos Integrados”, online: *Instituto Mexicano de la Propiedad Industrial* <http://www.impi.gob.mx/servicios/Paginas/TarifadeInvencionesdeDisenodeCircuitos.aspx>.

Instituto Nacional de Estadistica y Geografia (INEGI). *Estadistica a Proposito del Dia Mundial de la Lucha Contra el Cancer de Mama* (2015) online: *Instituto Nacional de Estadistica y Geografia* <http://www.inegi.org.mx/saladeprensa/aproposito/2015/mama0.pdf>.

———. “Educación. Michoacán de Ocampo”, online: *INEGI* <http://www.cuentame.inegi.org.mx/monografias/informacion/mich/poblacion/educacion.aspx?tema=me&e=16>.

ISSSTE. "Directorio de Unidades Medicas. ISSSTE (Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado, 2013)." online: ISSSTE

IWGIA. “Indigenous Peoples in Mexico”, online: *International Work Group for Indigenous Affairs* <http://www.iwgia.org/regions/latin-america/mexico>.

———. “Indigenous peoples in Latin America - a general overview”, online: *International Work Group for Indigenous Affairs* <http://www.iwgia.org/regions/latin-america/indigenous-peoples-in-latin-america>.

Kennedy Institute of Ethics Georgetown University & Duke Institute for Genome Sciences and Policy. “DNA Patent Database U.S.”, (18 December 2015), online: *DNA Patents* <https://dnapatents.georgetown.edu/>.

Kerstetter, Jim. “How much is that patent lawsuit going to cost you?”, (5 April 2012), online: *CNET* <https://www.cnet.com/news/how-much-is-that-patent-lawsuit-going-to-cost-you/>.

Krikorian, Gaelle. “L’accès aux génériques : enjeux actuels et propriété intellectuelle”, (4 October 2005), online: *OSI Bouake* <http://osibouake.org/?L-acces-aux-generiques-enjeux>.

Liomont. “Products Liomont”, (2019), online: *Liomont* <http://liomont.com.mx/portfolio/respiratorios/>.

Lopez Segundo, E. *Tuberculosis Pulmonar* (Mexico).

Lybecker, Kristina. “IP Protection is Key to U.S. Job Creation| Patents & Patent Law”, (23 March 2015), online: *IPWatchdogcom PatentLaw* <http://www.ipwatchdog.com/2015/03/23/ip-protection-is-key-to-u-s-job-creation/id=55978/>.

Maskus, Keith E. *Patents and Technology Transfer Through Trade and the Role of Regional Trade Agreements*, SSRN Scholarly Paper ID 2745455 (Rochester, NY: Social Science Research Network, 2016) <https://papers.ssrn.com/abstract=2745455>.

Mayo Clinic. “Tuberculosis Treatment”, online: *Mayo Clinic* <http://www.mayoclinic.org/diseases-conditions/tuberculosis/diagnosis-treatment/treatment/txc-20188961>.

Medecins Sans Frontiers. “The impact of patents on access to medicines”, online: *Medicins Sans Frontiers* <https://www.msfaccess.org/our-work/overcoming-barriers-access/article/1360>.

"Medicamentos Biotecnologicos Biocomparables. Definiciones", (24 October 2014), online: *Medicam Biotecnológicos Biocomparables* <https://biotecbiocomparables.wordpress.com/acerca-de/>.

"Mexico - WolframAlpha", online: *WolframAlpha* <http://www.wolframalpha.com/input/?i=mexico>.

"Mexico. CIA The World Factbook", online: *Central Intelligence Agency* <https://www.cia.gov/library/publications/the-world-factbook/geos/mx.html>.

Moise, Pierre & Elizabeth Docteur. *Pharmaceutical Pricing and Reimbursement Policies in Mexico* (2007), online: *OECD* < http://www.oecd-ilibrary.org/social-issues-migration-health/pharmaceutical-pricing-and-reimbursement-policies-in-mexico_302355455158>.

Moore, Adam & Ken Himma. *Intellectual Property*, winter 2014 ed., Edward N. Zalta, ed. (Metaphysics Research Lab, Stanford University, 2014), online: *Stanford University* <https://plato.stanford.edu/archives/win2014/entries/intellectual-property/>.

Morgan Jones, Molly et al. *The Structural Genomics Consortium. A Knowledge Platform for Drug Discovery* (United States of America: RAND Europe with the Institute on Governance, 2014), online: RAND.org <https://www.rand.org/content/dam/rand/pubs/research_reports/RR500/RR512/RAND_RR512.pdf>.

MSF México/América Central. "Los nuevos medicamentos para la TB sólo llegan al 2% de las personas que lo necesitan.", (3 December 2015), online: *MSF México/América Central* <http://www.msf.mx/article/los-nuevos-medicamentos-para-la-tb-solo-llegan-al-2-de-las-personas-que-lo-necesitan>.

My Gene Counsel. "4 Years Post-Gene Patents: How Has Life Changed In The Genomics World?", (13 June 2017), online: *My Gene Counsel - Post Genetic Testing* <https://www.mygenecounsel.com/2017/06/13/2017-6-11-4-years-post-gene-patents-how-has-life-changed-in-the-genomics-world/>.

NHGRI. "FAQ About Neglected Diseases", (14 May 2012), online: *National Human Genome Resesarch Institute NHGRI* <https://www.genome.gov/27531964/FAQ-About-Neglected-Diseases>.

Nicol, Dianne & Jane L Nielsen. *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry*, SSRN Scholarly Paper ID 2583508 (Rochester, NY: Social Science Research Network, 2003) <http://papers.ssrn.com/abstract=2583508>.

Noonan, Kevin E. "Falsehoods, Distortions and Outright Lies in the Gene Patenting Debate", (15 June 2009), online: *Patent Docs* <http://www.patentdocs.org/2009/06/falsehoods-distortions-and-outright-lies-in-the-gene-patenting-debate.html>.

"North America :: Mexico — The World Factbook - Central Intelligence Agency", (2018), online: *Central Intelligence Agency* <https://www.cia.gov/library/publications/the-world-factbook/geos/mx.html>.

OECD. "Compare your income - Perception of income inequality in OECD countries", (21 May 2015), online: *OECD* <http://www.compareyourincome.org>.

———. "Health expenditure and financing", (2017), online: *OECD Stat* <https://stats.oecd.org/Index.aspx?DataSetCode=SHA>.

———. "Research and development (R&D) - Gross domestic spending on R&D - OECD Data", (2018), online: *OECD Data* <http://data.oecd.org/rd/gross-domestic-spending-on-r-d.htm>.

Open Source Initiative. "The Open Source Definition (Annotated)", (1998), online: *Open Source Org* <https://opensource.org/osd-annotated>.

Organisation for Economic Co-operation and Development. "Health Expenditure and Financing", online: *OECD Stat* <http://stats.oecd.org/index.aspx?DataSetCode=HEALTH_STAT>.

PAHO. "Situacion de Control de la Tuberculosis en las Americas 2018" online: *Organizacion Panamericana de la Salud* <https://www.paho.org/hq/index.php?option=com_docman&view=download&category_slug=presentaciones-5882&alias=44088-dia-mundial-tuberculosis-2018-situacion-control-tb-americas-088&Itemid=270&lang=en>.

Perez Zazueta, Giselle. *Industria Farmaceutica* (ProMexico, 2013).

"Personalized Medicine", (7 October 2015), online: *National Insttitutes of Health* <https://www.nih.gov/about-nih/what-we-do/nih-turning-discovery-into-health/personalized-medicine>.

"Personalized Medicine: How the Human Genome Era Will Usher in a Health Care Revolution", (17 March 2012), online: *National Human Genome Research Institute* <https://www.genome.gov/13514107/Personalized-Medicine-How-the-Human-Genome-Era-Will-Usher-in-a-Health-Care-Revolution>.

Persson, Ingmar. "Prioritarianism" (2013), online: *Blackwell Publishing Ltd* <http://onlinelibrary.wiley.com/doi/10.1002/9781444367072.wbiee330/abstract>.

"Plavix 28 Tabletas Caja | SANOFI | Apego | FSP Sitio Web", online: *Farmacias San Pablo* <https://www.farmaciasanpablo.com.mx/es/MXN/Todas-las-Categor%C3%ADas/Medicamentos/Supervisi%C3%B3n-m%C3%A9dica/P---Q---R/Plavix-28-Tabletas-Caja/p/000000000007990056>.

"Probiomed", (2015), online: *Probiomed* <http://www.probiomed.com.mx/>.

Procuraduria Federal del Consumidor. "Boletin electronico: Brujula de Compra de PROFECO. Vacunas para Todos" online: *Procuraduria Federal del Consumidor* <http://www.profeco.gob.mx/encuesta/brujula/pdf-2008/Nuevas%20vacunas%20para%20todos.pdf>.

Proyecto Candela. "Proyecto Candela México - About", online: *Candela* <https://www.facebook.com/pg/CandelaMx/about/>.

Robeyns b), Ingrid. *The Capability Approach*, winter 2016 ed, Edward N. Zalta, ed. (online: Metaphysics Research Lab, Stanford University, 2016) online: *Stanford University* <https://plato.stanford.edu/archives/win2016/entries/capability-approach/>.

Rouleau, Guy. *Freeing Science — From Software to Medicine* (Montreal, Canada, 2017) online: *McGill University* <https://www.mcgill.ca/neuro/channels/event/symposium-freeing-science-software-medicine-267911>.

Salford Royal, Emma. *Actinic Prurigo* (United Kingdom: Salford Royal NHS Foundation Trust, 2010) online: *Salford Royal Foundation Trust* <http://www.srft.nhs.uk/for-patients/patient-leaflets/a-z-dept/?assetdet1043533=3409&categoryesctl1043533=161>.

Sampat, Bhaven & Heidi L Williams. "How Do Patents Affect Follow-On Innovation? Evidence from the Human Genome", (2015) Working Paper 21666 online: *National Bureau of Economic Research* <http://www.nber.org/papers/w21666>.

Sanfer. "Products and Operations Sanfer", (2019), online: *Sanfer* <http://www.sanfer.com.mx/compania/operaciones>.

"Sanofi - Genzyme Mexico", (27 February 2014), online: *Sanofi - Genzyme Mex* <http://www.sanofi.com.mx/l/mx/sp/layout.jsp?scat=FE714E51-3701-4B40-8EC3-7868B3487A48>.

Secretaría de Salud. "Seguro Popular", online: *Seguro Popular. Secretaria de Salud* <http://www.seguro-popular.gob.mx/>.

———. "Tuberculosis", online: *Secretaria de Salud* <https://www.gob.mx/salud/acciones-y-programas/tuberculosis>.

———. "Vacunas que integran el Esquema Nacional de Vacunación", online: *Secretaria de Salud* <http://www.gob.mx/salud/articulos/vacunas-que-integran-el-esquema-nacional-de-vacunacion>.

———. *Directorio de Unidades Medicas de la Secretaria de Salud* (Secretaria de Salud).

Secretaria de Salud de Michoacan. "Catalogo de Unidades Medicas. Secretaria de Salud de Michoacan", online: *Secretaria de Salud Michoacan* <http://salud.michoacan.gob.mx/index.php/clue>.

Secretaria de Salud de Oaxaca. “Directorio de Hospitales Oaxaca”, online: *Secretaria de Salud Oaxaca* <http://www.salud.oaxaca.gob.mx/directorio-de-hospitales/>.

Secretaria de Salud de Yucatan. “Directorio de Unidades médicas de Yucatán”, online: *Secretaria de Salud Yucatan* <http://salud.yucatan.gob.mx/unidades-medicas/>.

“Senosiain Laboratorios”, (2013), online: *Senosiain Laboratorios* <http://www.senosiain.com.mx/index.php?id=4>.

Senosiain Laboratorios. “Products Senosiain Laboratorios”, (2019), online: *Senosiain Laboratorios* <http://www.senosiain.mx/index.php?id=12&start=0>.

SIL. “Familia tarasca”, online: *SIL Mexico* <http://www.mexico.sil.org/es/lengua_cultura/tarasca>.

———. “Familia popoloca”, online: *SIL Mexico* <http://www.mexico.sil.org/es/lengua_cultura/popoloca>.

———. “Familia maya”, online: *SIL Mexico* <http://www.mexico.sil.org/es/lengua_cultura/maya>.

———. “Familia náhuatl”, online: *SIL Mexico* <http://www.mexico.sil.org/es/lengua_cultura/nahuatl>.

“Silanes”, (2019), online: *Silanes* <https://www.silanes.com.mx/>.

“Talizer 100mg c 50”, online: *Farmacias San Pablo* <https://www.farmaciasanpablo.com.mx/medicamentos/especialidades-medicas/s---t/talizer-50-tabletas-caja/p/000000000030330002>.

“Tamiflu 10 Cápsulas Caja | Antibiótico | Tipo | FSP Sitio Web”, online: *Farmacias San Pablo* <https://www.farmaciasanpablo.com.mx/es/MXN/Todas-las-Categor%C3%ADas/Medicamentos/Supervisi%C3%B3n-m%C3%A9dica/S---T---U/Tamiflu-10-C%C3%A1psulas-Caja/p/000000000004160190>.

“Tamiflu generic launch, patent expiration information”, online: *Drug Patent Watch* <//www.DrugPatentWatch.com/p/tradename/TAMIFLU>.

The World Bank. “Mexico | Data”, online: *World Bank Mexico* <http://data.worldbank.org/country/mexico>.

UNAM. “Coordinación de Innovación y Desarrollo - UNAM”, online: *UNAM* <http://www.innovacion.unam.mx/>.

———. “Coordinación de la Investigación Científica - UNAM”, online: *UNAM* <http://www.cic-ctic.unam.mx/cic/subsistema/institutos_centros/institutos_centros_general.cfm?vSiglasDep=CCADT>.

United Nations Development Programme. “Human Development Reports: Human Development Indicators: Mexico”, online: *United Nations Development Programme* <http://hdr.undp.org/en/countries/profiles/MEX>.

———. “Human Development Reports: Human Development Indicators: Syria”, online: *United Nations Development Programme* <http://hdr.undp.org/en/countries/profiles/SYR>.

———. “Human Development Reports: Human Development Indicators: Italy”, online: *United Nations Development Programme* <http://hdr.undp.org/en/countries/profiles/ITA>.

———. “Human Development Reports: Human Development Indicators: Malawi”, online: *United Nations Development Programme* <http://hdr.undp.org/en/countries/profiles/MWI>.

———. “Human Development Reports: Human Development Indicators: Cape Verde”, online: *United Nations Development Programme* <http://hdr.undp.org/en/countries/profiles/CPV>.

———. “Human Development Reports: Human Development Indicators: Czech Republic”, online: *United Nations Development Programme* <http://hdr.undp.org/en/countries/profiles/CZE>.

United Nations, Office of the High Commissioner of Human Rights. “What are Human Rights?”, (2017), online: *Office of the High Commissioner of Human Rights* <http://www.ohchr.org/EN/Issues/Pages/WhatareHumanRights.aspx>.

University College London. “Candela - Consortium for the Analysis of the Diversity and Evolution of Latin America”, (29 February 2016), online: *University College London* <http://www.ucl.ac.uk/candela>.

US Food and Drug Administration. “The Drug Development Process - Step 1: Discovery and Development”, online: *US Food and Drug Administration* <http://www.fda.gov/ForPatients/Approvals/Drugs/ucm405382.htm>.

US Office of Budget. “FY2016 Budget in Brief - NIH”, (6 February 2015), online: *HHS.gov* <https://www.hhs.gov/about/budget/budget-in-brief/nih/index.html>.

Valadez, Blanca. “En pobreza extrema, 39% de indígenas en México”, (9 August 2010), online: *Medios En Mexico* <http://mediosenmexico.blogspot.com/2010/08/en-pobreza-extrema-39-de-indigenas-en.html>.

“WHO | Malaria”, online: *WHO* <http://www.who.int/mediacentre/factsheets/fs094/en/>.

WHO. *Tuberculosis Profile: Mexico* (World Health Organization, 2017) online: *WHO* <https://extranet.who.int/sree/Reports?op=Replet&name=%2FWHO_HQ_Reports%2FG2%2FPROD%2FEXT%2FTBCountryProfile&ISO2=MX&LAN=EN&outtype=html>.

———. *Tuberculosis (TB)* (World Health Organization, 2018) online: *WHO* <https://www.who.int/news-room/fact-sheets/detail/tuberculosis>.

———. "The Doha Declaration on the TRIPs Agreement and Public Health", online: *WHO* <http://www.who.int/medicines/areas/policy/doha_declaration/en/>.

———. "Neglected Tropical Diseases", online: *WHO* <http://www.who.int/neglected_diseases/diseases/en/>.

Wilson, Christopher. "Mexico's Latest Poverty Stats", (12 August 2013), online: *Wilson Center* <https://www.wilsoncenter.org/article/mexicos-latest-poverty-stats>.

WIPO. *IP Litigation Costs* (World Intellectual Property Organization, 2010) online: *World Intellectual Property Organization* <www.wipo.int/wipo_magazine/en/pdf/2010/wipo_pub_121_2010_01.pdf>.

———. "WIPO Intellectual Property Statistics Data Center", (2014 2013), online: *World Intellectual Property Organization* <https://www3.wipo.int/ipstats/index.htm?tab=patent>.

———. *Who Filed the Most PCT patent applications in 2017?* (World Intellectual Property Organization, 2018) online: *World Intellectual Property Organization* <http://www.wipo.int/export/sites/www/ipstats/en/docs/infographic_pct_2017.pdf>.

Wolfram Alpha. "Mexico: Wolfram|Alpha", online: *Wolfram|Alpha* <www.wolframalpha.com/>.

World Bank. "Poverty headcount ratio at national poverty lines (% of population) | Data", (2016), online: *World Bank* <https://data.worldbank.org/indicator/SI.POV.NAHC?end=2016&locations=MX&start=2008&view=chart>.

———. "Mexico | Data : World Bank", (2019), online: *World Bank* <https://data.worldbank.org/country/mexico>.

———. "Rural population (% of total population) | Data", online: *World Bank Data* <http://data.worldbank.org/indicator/SP.RUR.TOTL.ZS>.

World Health Organization. *Estadisticas Sanitarias Mundiales 2012* (World Health Organization, 2012) online: *WHO* <http://www.who.int/gho/publications/world_health_statistics/ES_WHS2012_Full.pdf>.

———. *Tuberculosis. Fact Sheet* (World Health Organization, 2012) online: *WHO* <http://www.who.int/mediacentre/factsheets/fs104/en/>.

———. *Mexico: WHO Statistical Profile* (World Health Organization, 2015) online: *WHO* <http://www.who.int/gho/countries/mex.pdf>.

———. *Tuberculosis. Fact Sheet* (World Health Organization, 2017) online: *WHO* <http://www.who.int/mediacentre/factsheets/fs104/en/>.

———. "WHO definitions of genetics and genomics", online: *WHO* online: *WHO* <http://www.who.int/genomics/geneticsVSgenomics/en/>.

———. "BCG vaccine", online: *WHO* online: *WHO* <http://www.who.int/biologicals/areas/vaccines/bcg/en/>.

———. "The five elements of DOTS", online: *WHO* online: *WHO* <http://www.who.int/tb/dots/whatisdots/en/>.

World Health Organization, World Trade Organization & World Intellectual Property Organization. *Antimicrobial resistance – a global epidemic* (World Trade Organization, 2016) online: *WTO* <www.wto.org/english/news_e/news16_e/heal_29aug16_e.pdf>.

WTO et al. "How International IP Policy Reconfigured National Politics: An Interview With Prof. Ken Shadlen", (11 January 2018), online: *Intellectual Property Watch* <http://www.ip-watch.org/2018/01/11/international-ip-policy-reconfigured-national-politics-interview-prof-ken-shadlen/>.

"WTO | intellectual property (TRIPS) - TRIPS and public health: Compulsory licensing of pharmaceuticals and TRIPS", online: online: *WTO* <https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm>.

Dictionary entries

Medical Free Dictionary, online *s.v.* "Burow's solution".

U.S. National Library of Medicine online: *s.v.* "conjunctivitis").

U.S. National Library of Medicine online: *(s.v.* "edema".

Merriam-Webster online: *s.v.* "egalitarianism".

Merriam-Webster online: *s.v.* "equality".

Merriam-Webster online: *s.v.* "freedom".

Medical Free Dictionary, online *s.v.* "human genetics".

Farlex online: *s.v.* "hyperemia".

U.S. National Library of Medicine online: *s.v.* "impetigo".

Merriam-Webster online: *s.v.* "mestizo".

Farlex online: *s.v.* “pseudopterygium”.

National Human Genome Research Institute online: *s.v.* “personalized medicine”.

Merriam-Webster online: *s.v.* “second-line drug”.

Merriam-Webster online: *s.v.* “welfare”.

Encyclopedia Brittanica online: *(s.v.)* “welfare economics”.

Interviews

Interview of Acuña Alonzo, Victor. *Acuña’s Interview (ENAH-Laboratory of Molecular Genetics)* (June 19, 2012).

Interview of Ballesteros Romano, Monica Guadalupe. *Ballesteros’ Interview (ENAH-Laboratory of Physiology, Biochemistry and Genetics)* (June 20, 2012).

Interview of Granados Arriola, Julio. *Granados’ Interview* (June 19, July 31, Aug 2, and Aug 5, 2012).

Interview of Hospital Angeles. *Information provided by private Medical Laboratory of Angeles Hospital (email)* (February 21, 2017).

Interview of Hospital Medica Sur. *Information provided by the private Medical Laboratory of Medica Sur Hospital.* (February 21, 2017).

Interview of INCMNSZ. *INCMNSZ Nutrition Specialist’s Interview* (June 20, 2012).

Interview of INMEGEN. *INMEGEN Researcher’s Interview* (June 21, 2012).

Interview of INMEGEN. *INMEGEN’s Business Development Office* (June 21, 2012).

Interview of Researcher from the INMEGEN. *BRCA1 & BRCA2 Diagnostic Tests (email)* (February 20, 2017).

Interview of Menjivar Iraheta, Marta. *Menjivar’s Interview* (June 25, 2012).

Interview of Solleiro Rebolledo, Jose Luis. *Solleiro’s interview (UNAM)* (June 26, 2012).

Interview of UNAM. *UNAM’s Anthropologist’s Interview* (June 21, 2012).

Patents

"Mutaciones en Vivo y Polimorfismos en el Gen de Susceptibilidad al Cancer de Pecho y Ovario Enlazado con 17Q", Donna M Shattuck-Eidens et al., Mex 9701075, PCT/US1995/010202, November 11, 1995.

“Metodo para Diagnosticar una Predisposicion para Cancer de Pecho y Ovario”, Skolnick, Mark H et al., USPCT/US95/10220, February 1998.

"Gen de Susceptibilidad de Cancer de Pecho y Ovario Enlazado con 17Q", Mark H Skolnick et al., USPCT/US95/10203, February 1998.

"Gen de Susceptibilidad de Cancer Mamario Ligado al Cromosoma 13", Sean V Tavtigian et al., Mex 9804878, PCT/US1996/019598, 17 December 1996..