Cloatre, Emilie (2006) Actor-network theory and socio-legal objects: analysing TRIPS and pharmaceutical patents in the Republic of Djibouti. PhD thesis, University of Nottingham.

Actor-Network Theory and Socio-Legal Objects: Analysing TRIPS and Pharmaceutical Patents in the Republic of Djibouti

By Emilie Cloatre, LLM, MA.

Thesis submitted to the University of Nottingham

For the degree of Doctor of Philosophy, November 2005

ABSTRACT

This research analyses the role and action of the Trade Related Intellectual Property Agreements (TRIPS) and pharmaceutical patents in the public health network of Djibouti, by using an approach largely inspired by actor-network theory (ANT). In doing so, it addresses issues that run beyond the specificities of this case study and relate more broadly to the relevance of ANT to socio-legal analysis.

The relation between TRIPS, pharmaceutical patents and public health in developing countries has been a widely debated issue in the past decade. However, the field remains limited by a relative uniformity in the range of approaches and case studies chosen in existing research. This project aims to address some of these limits, by looking at the role of TRIPS and pharmaceutical patents in a small country with no local pharmaceutical industry, no pre-existing official system of intellectual property, and with a largely undocumented public health system.

Using ANT in this project allowed for the complexity of the mechanisms of both TRIPS and pharmaceutical patents to be highlighted. It participated in emphasising that they need to be understood as made of multiple, co-existing dimensions. By demonstrating how specific connections and associations have shaped what TRIPS and pharmaceutical patents are and do in the networks of

Djibouti, this research emphasises the artificiality of the dichotomy between social and legal, and proposes an understanding of social connections as symmetrical and co-dependent. It discusses the more general relevance of this approach to socio-legal research.

The example of Djibouti also allows for new questions to be raised in relation to the actual impact of TRIPS and pharmaceutical patents in "developing countries". In particular, it emphasises the need to return to a more balanced approach to the relation between pharmaceutical patents and health in poor countries.

Acknowledgements

I would like to thank my supervisors, Prof. Robert Dingwall, Prof. Tamara Hervey and Dr. Paul Street for all their help, advice and support during my PhD.

I am also most grateful to all those who helped me by reading and discussing aspects of my work, and those who introduced me to new, much needed vocabulary and helped me correct the most clumsy of my sentences.

The past three years – and even more so the last few months – would never have been as manageable without the great support that I enjoyed from my friends, in England and in France. Although I cannot thank everyone individually, I want to put a special note to Jemima Agyare and Juliette Salabert who have been the most efficient answer to any stress attack I might have had in the last few months. In the same way, and as always, I am very grateful to my family for simply caring and being there, and for always encouraging and supporting me.

I also need to thank everyone in Djibouti for making my fieldwork not only possible and instructive, but a highly enjoyable experience.

Finally, I need to give the biggest thanks to my partner, Pritesh Shah, for all his patience, care and support, which made the last three years not only possible, but also very happy times.

TABLE OF CONTENTS

INTRODUCTION

This research discusses the role and impact of pharmaceutical patents and the Trade Related Intellectual Property Agreement (TRIPS) on health networks in Djibouti. Based on actor-network theory (ANT), it provides an understanding of these two instruments as multi-dimensional and fragile systems, enrolled in a multiplicity of mobile and changing social networks. It emphasises their nature as "socio-legal objects"[1]. Overall, this research explains how the complexity of the links between TRIPS, pharmaceutical patents and health can best be understood by looking at the different roles and mechanisms of each instrument within the several networks of which they are part. The impact of these instruments on health can then be explained while acknowledging the complexity of the changes generated, as the result of the multiple actions and shapes of both TRIPS and pharmaceutical patents as complex actor-networks.

[1] Although the term will become clearer throughout the following chapters, the notion of "socio-legal objects" needs to be briefly explained. First, the term "socio-legal" is used throughout when designating TRIPS and pharmaceutical patents, as a way to emphasise the absence of dichotomy between what is sometimes understood as two "fields" or "dimensions", but is considered throughout this project as series of fluid and interrelated associations. Second, it should be emphasised that the term "object" should not be understood as pre-determining any form of "passivity" – partly because ANT puts forward the idea that any entity is always both acting and acted upon. Although the term "actant" used in some ANT writings could have more explicitly emphasised this idea, it was decided that the less "cryptic" notion of "socio-legal object" would be used throughout, while emphasising early in this project that this should not preclude their active role.

TRIPS and pharmaceutical patents in a least developed country

Although intellectual property has been a matter of national law and policy for a long time, the adoption of the TRIPS agreement in 1995 has created new international standards and requirements in the field. The adoption of TRIPS has generated important debates and disagreements amongst actors. Opposition to the text focused in particular on the potential risks and benefits that these new intellectual property (IP) standards would have for poorer countries.

Within TRIPS, pharmaceutical patents has been one of the most controversial areas, and has been taken up as a key ethical problem in a wide range of arenas. They have generated oppositional discourses and positions, in which TRIPS and pharmaceutical patents have been framed and understood in a fundamentally different way by different groups.

Broadly, the relation between TRIPS, pharmaceutical patents and health in poor countries has been fitted within two main sets of discourses. On the one hand, many have expressed the view that pharmaceutical patents in the form required by the TRIPS agreement would create obstacles to access to health. Based on the idea that stronger patents would have a negative effect on the availability of generic drugs, and therefore on the cost of medical treatment worldwide, this position explained how strengthening patents would make modern drugs unaffordable for people already in a critical health situation. This idea has been reframed in similar terms in the media, and has resulted in a

number of “health scandals” in which the North/South dimension of the conflict has often been stressed.

On the other hand, those supporting the TRIPS agreement have generally framed the link between pharmaceutical patents and health in poor countries in fundamentally different terms. They insist, in particular, on the idea that patents are necessary to maintain a high standard of research in the pharmaceutical field worldwide, and that weak pharmaceutical patents are therefore a danger to the availability of new drugs.

This key disagreement is also reflected in debates on the role of TRIPS in generating the development of a pharmaceutical industry in developing countries. While opponents to TRIPS have emphasised the idea that introducing patents at an early stage of development would hamper the initiation of a basic pharmaceutical industry, those defending the text have highlighted the need to implement patents to ensure that this basic industry could evolve into a research-based industry.

However, both sides of the debate leave a set of questions unanswered. Although they clearly illustrate two different versions of TRIPS and two different stories about pharmaceutical patents, they provide schematic and unspecific views of some of the links that can be made between the different relevant elements. In particular, the analysis they provide is essentially based on an understanding of current systems and future changes elaborated on the basis of written legal prescriptions. The potential for differences between the

content of legal prescriptions and social change is generally not addressed in most research in this field. Most literature rests, in addition, on deep assumptions about the needs of poor populations – such as the relation between health and modern drugs and the actual role of medication in the health networks of poor countries – and does not necessarily grasp the complexity and specificity of the different networks concerned.

A wide range of academic literature has developed in recent years, questioning the impact of TRIPS in developing countries in terms of public health and development. Examples of "developing countries" have generally been picked from amongst those states that most actively opposed TRIPS, which has resulted in the focus of research being essentially turned towards a few developing countries with a local generic industry, and with an official model of law in clear contradiction with that of TRIPS. One of the main stances taken is then to discuss whether the implementation of TRIPS and the subsequent revision of both patent law and public health and development strategies, would be likely to have negative impacts on the developing country chosen as an example. It is clearly understandable that most literature has in fact concentrated on the example of India, as one of the strongest opponents to TRIPS, and a country in which internal disagreements on the cost and benefits of TRIPS have emerged at an early stage. Although these early case studies have participated in presenting some of the issues raised in this particular set of countries, they have generated a range of arguments that are based on rather homogeneous assumptions in relation to the needs of "developing countries" in health and industrial development.

However, this literature overlooks the experiences of a number of states, and in particular overlooks the smallest and least developed countries. These countries have no existing pharmaceutical industry and rely exclusively on imports for their pharmaceutical market. Several of these are also in a legal situation completely different from that of larger developing states, and have no system of patents or intellectual property that pre-exists TRIPS.

These key differences make the situation of these small states worth investigating for several practical and theoretical reasons. Practically, least developed countries have come to the forefront of recent debates on TRIPS, following the discussions surrounding Paragraph 6 of the Doha declaration that will be explained in this research. The necessity to integrate safeguards that respond to the needs of countries with no local pharmaceutical industry within the TRIPS framework therefore became an important priority. However, the differences in the situation of small least developed states and large industrialised countries, on which most literature has concentrated, runs further than these practical issues. In particular, while countries like India need to reform laws in a field where positive policies have already been developed, and institutions created over a long period of time, states with no pre-existing IP system need not only to create a new law, but also to build expertise and create institutions. The task of generating a wholly new system in this way is fundamentally different from that of implementing written legal changes. One potential consequence of this lack of expertise and institutions, in particular, is a specific type of social understanding of TRIPS and pharmaceutical patents,

which might differ from that observed in countries where patents have been part of policy discourses for a long time. Other differences between states also need to be highlighted, and it is worth re-emphasising that the pharmaceutical market of each individual state is specific, and requires studying rather than assuming what pharmaceutical patents might mean for this market.

In this research, the need to understand the impact of the changes generated by TRIPS on health in a small least developed country, with no preexisting patent law and no local industry was therefore considered a priority. The research complements what has already been written on pharmaceutical patents and developing countries but also represents a necessary challenge to a field of research in which uniformity and simplification have sometimes been privileged over differences and complexity. Because little investigation has been carried out in the area on least developed countries, the focus of the research was defined as broadly as possible within the field of interest, in order to avoid making assumptions in advance.

The aim of this research is therefore to understand what TRIPS and pharmaceutical patents mean for public health in a small, least developed country, without existing laws in the field. It aims to study how each instrument was received and understood in the networks of this small state, what is their current role and impact and how this was expected to change with the legal implementation of TRIPS. It is also directed at understanding the modes of action of both instruments, and at offering a view of the nature and

mechanisms of these specific objects through social interactions. The focus of this research is therefore socio-legal in nature.

Focus of the research

In this research, the example of the Republic of Djibouti has been chosen. Djibouti represents an example of one of the poorest countries in the world, that is currently developing its first patent law following the adoption of TRIPS, and does not currently have any active form of pharmaceutical industry. It is also a state in which public health is a crucial issue, and there are a wide range of difficulties in this field. Although Djibouti was chosen as an example of a least developed country, it was accepted at an early stage that the pitfalls of existing simplifications of the field should be avoided, and that generalisation should therefore be kept to a minimum. To that extent, although this research is about the impact of TRIPS and pharmaceutical patents on health in a small least developed country, it does not claim to be about the impact of these instruments in "least developed countries". One of the main positions taken throughout this research is that claims made in this complex field – and in socio-legal research more generally – need to be empirically based, and that the situation of each network and society is unique.

The story of TRIPS and pharmaceutical patents in Djibouti soon became a story of contradictions and discrepancies. Written legal prescriptions became only a rather minor element of understanding what TRIPS and pharmaceutical patents as socio-legal objects were doing in practice in Djibouti. The

expectations that I had built from existing literature were revealed as flawed and were soon revised. This appeared to be due to two major elements: on the one hand, the networks of Djibouti were fundamentally different from those of countries more traditionally chosen as examples. On the other hand, the relation between written legal prescriptions and the social action of both TRIPS and pharmaceutical patents appeared to be more complex than existing literature represents. The story of TRIPS and pharmaceutical patents in Djibouti that could be told based on what they are supposed to do if taken as a set of written prescriptions, was fundamentally different from what was happening in reality. Comments made by informants about TRIPS and pharmaceutical patents were slightly in contradiction with some of the other results of the empirical work. Overall, what appeared throughout the research was not one story of TRIPS and pharmaceutical patents, but many different stories about them, or, rather, many versions of the same complex story. Similarly, understanding the relation between these instruments and health in Djibouti appeared to be more complex, and more flexible, than what has often been assumed by the different "sides" of the TRIPS debate. The links between TRIPS, patents and health appeared to result from a set of complex stories and relations. Based on the idea that these multiple aspects of reality are all part of the story to be told, this research will explain the different dimensions and the different sides of TRIPS and pharmaceutical patents in Djibouti, and what this means for the impact of both socio-legal objects on health.

The contrast between the different perspectives and the different stories told about TRIPS and pharmaceutical patents, and the originality of the type of

network chosen as case study called for a flexible form of analysis. The relevance of ANT to this research was based on different elements, including the complexity of the case study, the multiple versions and dimensions of TRIPS and pharmaceutical patents, and the involvement of a wide range of interrelated networks. Each of these elements related strongly to many of the ideas and concepts put forward by ANT. In addition, given that the aim is to understand and describe the situation on the ground in its complexity, and to grasp the co-existing realities of TRIPS and pharmaceutical patents in different networks, the ethnographic methods commonly used in ANT appeared most suitable. Although the use of ANT for socio-legal research is rather new and unexplored, its relevance to this particular research emerged at different stages of the project and allowed for a complete exploration of the issues raised by the case study.

Understanding TRIPS and pharmaceutical patents through actor-network theory

Emphasis on complexity, continuity and the fragility of social orderings has been one of the main elements of actor-network theory, and these appeared to be crucial dimensions in this research. The elements relate neatly to the complexity of the area under investigation, and the fragility of meaning of both TRIPS and pharmaceutical patents, as described in the background reading and emerging from the empirical research.

ANT – defined by Latour as the "sociology of associations"[2] – has been created as an alternative to traditional approaches to sociology that were based on an understanding of "the social". Based on the idea that there is no such thing as a stable and pre-determined social order, ANT prescribes the understanding of social orderings as changing sets of interrelations. By denying the possibility of determining a social context as a stable framework for analysis, ANT emphasises the need to understand mechanisms and connections within their inherent fragility. It defines and explains actor-networks as multi-dimensional systems that are constantly reshaped by the many networks in which they become enrolled, at the same time as they impact on these networks and participate in their re-ordering.

ANT also puts forward the crucial ideas of "continuity" and "symmetry", and calls for a uniform approach to the understanding of what have traditionally been defined as different spheres. These ideas have resulted in a challenge to several key dichotomies often used in other types of sociological analysis – such as nature/society, human/non-human. Networks come to be understood as heterogeneous systems from which pre-determined distinctions should be excluded.

Overall, from an ANT perspective, the role of sociologists is to retrace heterogeneous social networks in their entirety, and to question the relation between actor-networks, and the interrelation between their links and the movements of social orderings. In this research, these ideas were applied

[2] For example in Latour B. (2005) Reassembling the Social: an Introduction to Actor-network Theory, Oxford: Oxford University Press.

throughout to socio-legal research. The aim of the work undertaken, particularly empirically, was to understand the elements relevant to TRIPS, pharmaceutical patents and health in Djibouti, in their complexity, and to frame the pattern of their links and interdependency. The overall story became one in which TRIPS and pharmaceutical patents were enrolled and embedded in different networks that were shaping them in different ways, and in which the links between TRIPS, patents and health could only be understood as the intersection of these different actor-networks and as mobile and changing elements.

In this research, the complexity of understanding the role of TRIPS and pharmaceutical patents in relation to health is illustrated through their description as multi-dimensional objects. The role each object plays in relation to health is understood while acknowledging the different dimensions and effects generated through each network they have become enrolled into. The written creation and existence of both objects therefore becomes only one of the elements to consider when discussing the impact of TRIPS and patents on health. In order to carry out an analysis of each object it is necessary to grasp amongst others the commercial, political and practical dimensions of each object. These dimensions are part of their socio-legal nature, and are co-existing realities generated in particular networks. The role of each object, in relation to health, can then be understood by addressing TRIPS and pharmaceutical patents through the many versions of their reality provided by the different networks of Djibouti.

The story of TRIPS and pharmaceutical patents in this research is presented as challenging some of the assumptions that are inherent in understanding them as a simple and stable set of written prescriptions. The role and action of TRIPS and pharmaceutical patents is understood outside of the legal/social dichotomy, and offers a way to grasp the nature and role of each object without relying too heavily on assumptions as to the links between written rules and the role of socio-legal objects.

In addition to this particular understanding of both TRIPS and pharmaceutical patents, this research also has a more general aim in testing the relevance of ANT to socio-legal research. Through the particular example of TRIPS and pharmaceutical patents in Djibouti, it aims to provide an example of how ANT can prove useful to empirical research in the socio-legal field. It offers a conceptualisation of socio-legal objects as elements of complex networks more flexible than their textual dimension might suggest, and always subject to modification by the networks in which they are enrolled. This research therefore aims to locate itself within two distinct research areas, and builds its relevance from two different fields. First, it is a reply to existing literature on "TRIPS and developing countries", and reemphasises the differences and contrasts between the experiences of a wide range of states. Second, it elaborates on some key concepts of ANT to offer a particular approach to socio-legal research based on notions of continuity, flexibility and interdependency.

The research questions that this study will answer therefore revolve around the role and mechanisms of TRIPS and pharmaceutical patents in Djibouti:

What are the role and impact of TRIPS and pharmaceutical patents in health networks in Djibouti?

- What is the impact of TRIPS as official prescription in Djibouti?
- What is the role of pharmaceutical patents in shaping the pharmaceutical market of Djibouti?
- How can the action of TRIPS in other places impact on social orderings in Djibouti?
- How can understanding TRIPS and pharmaceutical patents as multi-dimensional actor-networks contribute to explaining their impact on health?

In order to answer these different questions, several elements need to be taken into consideration. Overall, the questions will be answered by describing the role and action of both TRIPS and pharmaceutical patents in three key networks in Djibouti – policy-making/the import system/the public health system. The study will question both the nature and modes of action of these instruments in each system, and each step will emphasise the potential discrepancies between the prescriptions of written law and the action of both socio-legal objects.

The research questions set for this project will be answered throughout eight chapters, including three background chapters and four empirically based chapters.

Chapter 1 will present the underlying doctrinal issues raised by TRIPS and pharmaceutical patents, and will explain the legal background on which this research has developed. It will introduce the pre-TRIPS situation worldwide with regard to pharmaceutical patents, and will locate Djibouti's legal situation within this field. It will then provide an introduction to the legal dispositions of TRIPS and explain why they have been so controversial with regard to developing countries. Finally, this chapter will explain the shaping of TRIPS as a public health issue in both academic literature and political discourses, and why this is important to understand the mechanisms of TRIPS.

Chapter 2 will offer a detailed introduction to ANT, and emphasise the key concepts that will be used throughout this thesis. It will explain the emphasis of the theory on symmetry, continuity and complexity, and how this can be applied in practice to empirically based socio-legal research. It will explain how ANT can assist in offering a new conceptualisation of TRIPS and pharmaceutical patents.

Chapter 3 will present the methodology used in this research, and explain why a case study based approach was chosen and how empirical research was carried out. It will present the sources used for data collection, and explain how

the potential limits of the methods chosen have been avoided or restrained in this project.

Chapter 4 will provide a background introduction to the Republic of Djibouti in relation to its public health, intellectual property system and pharmaceutical industry. It will provide the information necessary for the reader to understand some key elements of the issues that surround the fields investigated throughout. It will also begin to describe some of the networks that will be studied in the following data chapters, and present some of the key actors.

The following three chapters of the thesis will present the different dimensions of TRIPS and pharmaceutical patents as expressed in different networks, and will aim to define how both objects relate to health in Djibouti.

Chapter 5 will present TRIPS as prescription in a pharmaceutical patents policy network. It will analyse how TRIPS as written prescription has become enrolled in policy networks in Djibouti and will discuss its circulation amongst actors expected to constitute a "pharmaceutical patents policy-network". A first set of discrepancies between the written dimension of TRIPS and its role in social networks will be highlighted, by showing the contrast between the role of TRIPS within the office in charge of its written implementation and its role within larger policy networks. The impact of weak network connections on the circulation of TRIPS and on the shaping of TRIPS will be explained.

Chapter 6 will analyse the role of pharmaceutical patents within the pharmaceutical import network of Djibouti, and in relation to its pharmaceutical market in particular. It will demonstrate how, in spite of the absence of the official existence of patents in the country, they have become a central actor in the shaping of the local market. The modes of action of patents outside of national written law will be questioned, and this chapter will demonstrate how sets of commercial, personal and practical networks have participated in generating and maintaining this action.

Chapter 7 will discuss the role of TRIPS and pharmaceutical patents within the public health network of Djibouti, and will build on the findings presented in Chapter 5 and 6. It will emphasise how different understandings and the different dimensions of TRIPS and pharmaceutical patents have participated in creating complexity in this particular network, and why understanding the role of both objects in relation to health can only be achieved by looking at their nature outside of the official/written dimension. This chapter will start by questioning the links between patents, health and disease, on the basis of earlier discussion of the role of patents in the pharmaceutical market, and in relation to existing literature in the field. It will then move on to questioning the role of TRIPS and pharmaceutical patents in shaping health policies, in particular the need to understand TRIPS within wider international health policy networks. This will be done by reflecting on how two specific health programmes recently created in Djibouti can be read within the light of recent emphasis on access to generic drugs in poor countries. Overall, the links between TRIPS, patents and health will be presented by acknowledging the need to understand

both TRIPS and pharmaceutical patents as socio-legal objects. In order to understand the impact of both objects on health, their potentiality for acting further than written prescription in multiple networks needs to be fully understood and detailed.

Finally, the conclusion of this thesis will bring these different findings together to present a view of TRIPS and pharmaceutical patents as complex, multi-layered and multi-dimensional socio-legal objects. The relevance of the methods applied throughout for socio-legal research more generally will then be discussed, and the wider value of ANT for socio-legal research will be presented.

CHAPTER 1 - TRIPS, PHARMACEUTICAL PATENTS AND PUBLIC HEALTH IN "DEVELOPING COUNTRIES"

This chapter considers the issues raised by the impact of TRIPS and pharmaceutical patents on developing countries, and highlights some of the limitations of the way it has been discussed and understood in recent years. It introduces the doctrinal dimension of the issues at stake, and reflects on how different arguments have participated in providing different views about TRIPS and pharmaceutical patents. It explains how TRIPS and pharmaceutical patents have progressively become framed as public health issues, and why their public health impact has become the key element considered in relation to developing countries. Finally, it presents the need for further empirical research on the links between patents, TRIPS and public health in a wider range of countries, and explains how this study will fill some of the remaining gaps in existing literature.

In 1994 the Trade Related aspects of Intellectual Property rights (TRIPS) agreement was signed, as part of the measures taken in the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) to limit existing barriers to free trade. The distortions created by the widely non-harmonised nature of the existing IP system were considered as one of the elements that needed to be addressed. TRIPS introduced detailed and controversial international standards in the field of intellectual property, binding on every member of the newly created World Trade Organisation (WTO). The adoption of TRIPS was the result of several years of increasing pressure from industry towards a strong

protection of intellectual property worldwide[3]. It created a large amount of resistance and opposition in several fields – public health in particular, as will be explained below[4]. While TRIPS was originally thought of as an intellectual property and trade instrument, international opposition and discourses have made it a key actor in relation to public health in what has often been defined as the "developing world". This chapter explains how this instrument changed a number of relations and links between pharmaceutical patents, health and developing countries, and presents how these links are generally portrayed in the "post-TRIPS era".

This chapter begins by introducing the international regulation of patents, by first presenting the nationally determined system that pre-existed TRIPS. It emphasises the diversity of approaches to pharmaceutical patents in the pre-TRIPS system, and explains how these have traditionally been justified. This will highlight some of the key arguments that have been made about the potential benefits or risks of strong patent laws for many years and participate in understanding the opposition to TRIPS described throughout this chapter (Section 1). It then introduces TRIPS itself and its framing in international discourses, by reviewing the history of TRIPS, its content, and its progressive integration in public health networks (Section 2).

[3] Sell S. (2003) Private Power, Public Law, Cambridge: Cambridge University Press.

[4] See also Sell S. (2002) "TRIPS and the Access to Medicines Campaign", Wisconsin International Law Journal Summer 20(2) 481-522

SECTION 1: PATENTS BEFORE TRIPS – A VARIETY OF APPROACHES JUSTIFIED ON ECONOMIC GROUNDS

This section explains how pharmaceutical patents were regulated in the pre-TRIPS system. It discusses the legal concept of patents, before considering the specificities of the pharmaceutical field and how states had approached it up to TRIPS. It finally explains how the variety of national policies in the field up to TRIPS was justified by the diverging interests in this area.

1. NATURE AND MECHANISMS OF PATENTS – SOME BASIC CHARACTERISTICS

This section introduces the notion of patents and their mechanisms. It explains their rationale, and offers a brief overview of the social role of patents as traditionally understood. It begins by discussing the rationale for patents. It then explains how they have been regulated at international level until TRIPS. It provides a discussion of the common characteristics of the concept of patentability in different legal systems, and emphasises the complexity of the notion. Finally, it introduces some key elements in relation to the exploitation of patent rights and its limits.

Patents are considered both a social and economic tool. They represent a quasi-monopoly granted by states for a limited period of time on an industrial

invention, in exchange for publication[5]. In practice, they result in patentees being able to exclude others from using their invention commercially, for a period of time limited by law[6]. Although a patent does not offer inventors an immediate right to market their invention, as this right might be subject to other national laws[7], it guarantees them a commercial quasi-exclusivity from the moment the patent is granted. It is therefore a very strong advantage that will result in inventors being able to commercialise their invention for the highest price that the market will sustain, without being limited by competition. The duration of patents has varied according to different national laws. The new standards of international law defined by TRIPS impose a minimum of twenty years for patent rights in any field[8]. This is similar to what has been adopted for example in Europe[9] and the US[10] for several years. However, this has not been a fully universal practice, and many states had chosen to offer patents only for

[5] For different definitions of the concept, see for example: Holyoak and Torremans (2001, 3rd Ed) Intellectual Property Law, London: Butterworth; Grubb P. (1999) Patents for Chemicals, Pharmaceuticals and Biotechnology, Oxford: Oxford University Press; Domeij B. (2000) Pharmaceutical Patents in Europe, Cambridge (US): Kluwer Law International.

[6] See for example in the TRIPS agreement Article 28(1): "A patent shall confer on its owner the following exclusive rights:

(a) Where the subject matter of a patent is a product, to prevent third parties not having *the owner's consent from the acts of: making, using, offering for sale, selling or* importing for any of these purposes that product;

(b) Where the subject matter of a patent is a process, to prevent third parties not having *the owner's consent from the act of using the process, and from the acts of using,* offering for sale, selling or importing for these purposes at least the product obtained *directly by that process."*

[7] Such as health and safety regulations.

[8] TRIPS Article 33.

[9] See the European Patent Convention, Article 63.

[10] 35 US 154(2)

a shorter term[11], or to offer different durations in different fields of technology[12].

The rationale for the existence of patents has been widely debated within broader discussions on intellectual property. Most commonly, utilitarian arguments can be found to explain their role. In this perspective, intellectual property rights are perceived as necessary to social welfare[13]. If looking back at the history of patents and their original role in England in the Middle Ages, it is clear that the notion of public interest soon became central to the grant of patents[14]. Several elements are essential in understanding the relevance of patents for the public interest. First, and this was particularly important when patents were first created, patents were originally seen as an efficient way to "import" new technologies into a country[15]. Second, patents are always associated with a condition of disclosure. When a patent is granted, full details of the nature of the invention and ways of making it will be disclosed, and

[11] For example, Australian patents were granted for 16 years up to the Patents (WTO Amendment) Act 1994.

[12] For example the Indian 1970 patent act (Patent Act, 1970, 27 India A.I.R Manual 450 (1979) shortens the standard term of 14 years for patents to "5 years from the date of sealing or 7 years from the date of the paten*t, whichever is shorter"* for pharmaceutical process patents. (Article 53)

[13] See for example in the area of copyrights: Landes W. M. and Posner R. A. (1989) "An Economic Analysis of Copyright Law", Journal of Legal Studies 18(2) pp.325-363. See also the underlying approach in Bentham J. (1839) A Manual of Political Economy, New-York: Putnam.

[14] See the Darcy and Allin decision, (1602) Noy 173, 74 ER 1131. It confirmed for the first time the views of English courts that patent should not be granted only as a privilege but had to be dependent on public benefits.

[15] See Davies S. (1934) "The Early History of the Patent Specification", Law Quarterly Review (50) pp. 260-337

whatever was in the private knowledge of the inventor will become public knowledge[16]. Consequently, patents guarantee that public knowledge will be improved, which justifies the advantages given. While inventors see their inventions protected from counterfeit, public knowledge is improved by the disclosure of the details of this invention – and potential new developments can therefore be facilitated. The third argument relating to utilitarian theories for justifying patent law is often the one that is most centrally supported, or implicitly undertaken by authors in the field, and was largely put forward by lobby groups during the years leading to TRIPS: patents are a central incentive to research and development. Under this argument, the main aim of patents is to ensure that researchers are not discouraged from investing in research activities because of the risk of not recovering fully their investment. Patents provide a guarantee that inventors will have a wide margin of action in deciding the marketing price of their product, and participate in making research a rewarding activity. At national level, patents are therefore an important part of policies aiming at encouraging research and development activities[17]. However, it is important to emphasise that in addition to these economic arguments, intellectual property has sometimes been framed in terms of rights, and related to the natural origins of the right to property[18]. Although

[16] Publication is central to every patent system. See for example TRIPS Article 29.

[17] Drahos P (1996) A Philosophy of Intellectual Property, Dartmouth: Aldershot. For specific details on this, see discussion on the role of pharmaceutical patents in Section 2.

[18] For example: Shiffrin S. V. (2001) "Lockean Arguments for Private Intellectual Property", in Munzer S. R. (ed) New Essays in the Legal and Political Theory of Property, Cambridge: Cambridge University Press; Moore A. (1997) "Towards a Lockean Theory of Intellectual Property", in Moore A. Ed, Intellectual Property, Lanham: Rowman and Littlefield; Machlup F. and Penrose E. (1950) "The Patent Controversy in the 19th Century", The Journal of Economic History 10(1) p.1-29.

the theory behind these arguments has been opposed, in particular on the basis of the diversity of understandings of intellectual property worldwide, the history of TRIPS shows an increase in the use of the rights discourses in relation to intellectual property used by lobby groups.[19]

International regulation of patents

In terms of territoriality, patent systems are in principle organised at national level, each state deciding which set of rules to apply. A patent granted in one country is valid only on its territory, and patent applicants wanting to see their rights protected in different states will have to apply for as many patents, in principle. However, the lack of harmonisation of patent systems worldwide, and the procedural complexity of the system have both created difficulties for international trade, and a number of international agreements have been signed in order to limit the potential problems created. The first international development in the area of patent law was the Paris Industrial Property Convention, originally signed in 1883 by eleven countries. Membership to the Paris Convention has progressively increased since it was signed, and most countries worldwide are now signatories[20]. The convention requires member states to treat patent applicants from all nationalities in the same way – the "national treatment"[21] rule. In addition to this, the Convention contains

[19] Sell S. (2002) "TRIPS and the Access to Medicines Campaign", op. cit – when looking at the framing of patent law by the pharmaceutical lobby in particular, notions of "piracy" and "stealing" are frequently drawn upon when commenting on the law of states that have chosen to exclude pharmaceuticals from the patentability field.

[20] For a list, see the WIPO website at www.wipo.org/treaties/documents/english/pdf/d-paris.pdf

[21] Article 2(1).

important dispositions in relation to the question of "priority of applications", that will be looked at again below. It states that an applicant who has made an application in one of the member states will automatically get priority over later applications in other member states[22]. However, the content of the Paris Convention is essentially procedural, and remains far from the substantive harmonisation created by TRIPS, as will be explained below.

The second step towards an international harmonisation of patent systems was the Patent Co-operation Treaty, signed in 1970[23]. Its aim is to ease the administrative burden of patent applications[24], by providing a centralised system in which applicants can apply in one office for every national patent they want to be granted[25]. Applicants submit one application either to a national patent office or the International Bureau of the World Intellectual Property Organisation (WIPO)[26], and specify the list of member states in which they wish to apply for a patent[27]. This particular office investigates relevant aspects of the state of the art[28], and the application is published through the WIPO[29]. However, this system remains harmonised only as far as procedures are concerned, and the final substantive decision of whether or not to grant a patent is taken by each national patent office[30].

[22] Article 4(1)

[23] Full text of the treaty can be accessed at: http://www.wipo.int/pct/en/texts/pdf/pct.pdf

[24] Article 1

[25] Article 4(1)

[26] Article 2 (xv) and Article 2 (xviii)

[27] Article 3 (1)

[28] Article 15(1) and Article 15(2)

[29] Article 21(1)

[30] Article 27 (5)

It is useful at this stage to mention a further evolution in the international harmonisation of patents – in particular because it will be referred to throughout this section. Although until TRIPS no substantive rules had been created at international level in relation to patents, regional agreements have been signed that create this type of standards. The European Patent Convention (EPC), signed in 1973, is a good example of a strong regional system of harmonisation for intellectual property, and it is useful to explain its mechanisms[31]. The EPC has created the European Patent Organisation, in which the Patent Office (EPO) grants European Patents under the supervision of the Administrative Council[32]. It has set up a centralised system through which a patent applied for through the EPO will be valid in all EPC member states. However, as soon as the patent has been granted by the EPO, it becomes equivalent to a number, or "bundle" of national patents, and is submitted to further challenges at the national level only[33]. The main development created by the EPC, however, is to create harmonised substantive standards for patent systems in member states[34]. In addition to this and at European level, however, the most recent developments have been taking place in the European Union (EU), where attempts to create a newly integrated EU-level patent system are taking shape[35].

[31] Although the European Patent system is not the only regional IP system (the Organisation Africaine de la Propriete Intellectuelle and The African Regional Intellectual Property Organization are two other examples that could have been taken), its influence worldwide and its efficient development justify chosing it as the clearest example of regional integration for the purpose of this chapter.

[32] EPC Article 4.

[33] EPC Article 2.

[34] Articles 52 to 74.

[35] See for comments: http://www.eubusiness.com/imported/2003/03/104634

Overall, the international harmonisation of patent systems until TRIPS has been limited, and for many years the creation of international substantive standards has been limited to regional systems. However, in 1994, the Uruguay round of the GATT addressed the range of issues that have been seen as barriers to free trade worldwide – and this lack of harmonisation of IP systems, including patents, was one of the key issues discussed. This resulted in the signature of the TRIPS agreement, as part of the newly created WTO system. Although TRIPS will be discussed more in detail below, it is worth mentioning briefly at this stage that it represents a key step in the evolution of the international patent system, in that it creates a detailed set of substantive standards to be respected by all WTO member states. This was particularly crucial in relation to pharmaceutical patents, due to the variety of systems that existed when TRIPS was signed, as will be detailed in this chapter. However, before analysing more specifically the field of pharmaceutical patents, it is necessary to discuss further elements of patent law, in order to understand the content and mechanisms of patents, as well as the complexity of this particular legal area.

Patentability

Because patent systems have so far been nationally determined, it is difficult to provide a detailed overview of patentability criteria worldwide in this chapter. However, certain characteristics have been common to all patent systems – although they have often been applied, interpreted and delimited in different

ways. In particular, patents are only granted to inventions that are not explicitly excluded by national law[36], that are not contrary to "ordre public" or "public policy" and morality[37] and that are novel, inventive, and capable of industrial application[38]. In order to understand the essence of the concept of patents, it is useful to review the range of issues that have arisen in relation to the notion of patentability. In this section, the main criteria for patentability found in patent systems will be discussed, and the complexity of interpreting and applying them will be illustrated by examples borrowed from patent decisions essentially in the UK and the EPO. Although this does not claim to provide a full description of jurisprudential debates worldwide, it highlights some of the complexities of patent law, and introduces further elements necessary to understand what are patents and how they work according to written law.

Novelty

A patent can only be granted to an invention that is "new" – which means that it is adding something to the state of the art and therefore that it is not a claim

[36] This is the case for example of the exceptions presented in the UK Patent Act 1977 Section 1(2) or the EPC Article 52(2) – such as "discoveries, scientific theories and mathematical methods; aesthetic creations; schemes, rules and methods for performing mental acts, playing *games or doing business, and programs for computers; presentations of information."*; it is also the case of plant and animals, and processes for the production of these, excluding microbiological processes and their product (UK Patent Act 1977 Schedule A2 Paragraph 3(f) and EPC article 53(b).

[37] See for example EPC Art 53(a). The jurisprudence of the EPO has introduced the need to balance the risks to public order and morality with the potential benefits to be gained from the invention see Harvard/Onco-mouse (1990) EPOR 4.

[38] See UK Patents Act 1977 Article 1(1); EPC article 52; Bangui Agreement 1977 Article 2, for examples.

over a product or process already disclosed to the public[39]. The state of the art is evaluated both by comparison to existing publications – individual documents, to be interpreted according to the knowledge existing on the date of publication[40] – and to the use of particular products or processes.

Although it might appear as a straightforward concept at first consideration, the notion of state of the art has created intense legal debate, and understandings of the concept of novelty have varied both in national laws and court cases. Only a few elements need to be presented here as illustration of the difficulties of the concept.

The first element that has not been fully agreed on by states has been the geographical aspect of the notion of state of the art – where does something need to be known to be considered as "state of the art"? For a number of countries, the state of the art encompasses anything known anywhere in the world, even if it is in a form hardly accessible for patent applicants. This system has been adopted by the European Patent Convention[41] and had previously also been integrated to the system of some states, such as France, for many years[42]. In 1977, the UK adopted this form of approach in accordance with the law of the EPO[43]. However, until 1977, the British understanding of

[39] EPC Article 54 (1); See also 35 USC 102; UK Patent Act 1977 article 2(1)

[40] In the UK see General Tire& Rubber v. Firestone Tyre and Rubber (1972) RPC 457; in the EPO Tektronix/Scottky barrier diode (1995) EPOR 384.

[41] Article 54 (2).

[42] Code de la Propriete Intellectuelle, Art. L611-11.

[43] Patent Act 1977, Section 2(1) and Section 2(2).

public disclosure from a geographical perspective was different[44]. In order for a product or process to be considered as part of the state of the art, it had to have been disclosed to the public in the UK. The US has adopted an intermediary approach, and distinguishes between disclosure in the US and abroad when looking at the means for disclosure[45]. On the one hand, disclosure by any means, prior use or publication, would invalidate a patent if this has taken place in the US. On the other hand, for an invention to be considered as part of the state of the art for the purpose of US law because it was known abroad, the invention needs to have been published in written form in another country. Disclosure by prior use outside the US territory would not invalidate a US patent.

These different approaches have been subject to different criticisms. While on the one hand the approach adopted by the US has been criticised in relation to the patenting of inventions involving traditional knowledge[46], the European approach has sometimes been presented as unrealistic, in the sense that inventors might see a patent application rejected because of prior use in a small community on the other side of the world of which it was hardly possible for them to have heard. However, the risk of double patenting remains essential to keep in mind, and approaches extending their understanding of "state of the art" worldwide are therefore generally preferred[47].

[44] This was the case in the Patent Act 1949.

[45] 35 USC 102.

[46] Dutfield G. and Posay D. (1996) Beyond Intellectual Property, Towards Traditional Resources Rights for Indigenous People and Local Communities, Ottawa: International Development Research Centre.

[47] Torremans P. (2005) Intellectual Property Law, Oxford: Oxford University Press, pp. 54-55.

However, the complexity of the notion of novelty, and of the associated concepts of state of the art and public disclosure runs much deeper than this specific issue. In many circumstances, the difficulty faced by judges when dealing with the notion of novelty has been to determine how much of an invention had to have been disclosed in order for it to be disqualified from patenting possibilities. Although it is not directly relevant to the purpose of this research to provide full details on these issues, it is important to specify that they have been the focused of extensive case-law[48].

Finally, a last element linked to the concept of novelty is the question of priority of claims. Simply, it is the question of the value of patent claims that are not yet published when considering the state of the art. In particular, the concept of state of the art is, as just mentioned, linked to the question of availability to the public. To that extent, an unpublished patent claim, as it is not available to the public should not be considered as part of the state of the art. However, this could result in granting two patents on the same invention. Most states have answered this difficulty by considering that an unpublished patent claim should be part of the state of the art[49], and this has for example been so in the European Patent Convention[50]. In particular, this aims to avoid

[48] For examples from the UK and the EPO, see Thomson/Electron Tube T953/90 (1998) EPOR 415; Windsurfing international Inc vs Tabur Marine (1985) RPC 59; General Tire and Rubber Co v Firestone Tyre and Rubber Co (1972) RPC 457; Van Der Lely (L) NV v Bamfords (1963) RPC 61.

[49] In the UK, Patent Act 1977, Section 2(3); in France, Code de la Propriete Intellectuelle, Art. L611-11 to L611-13.

[50] EPC Article 54(3).

the conceptual and practical difficulties that granting two similar patents could have created.

Inventive step

The second central condition for patentability is the need for an "inventive step"[51]. This allows for a distinction to be made between what is a patentable invention, and what is a simple discovery that cannot be protected by patent rights. The question has arisen in particular both when inventors build on existing products or processes for their invention[52], and when they associate known products or processes in a new way[53]. Similarly, it can appear in relation to a new use of a known product[54].

The concept of inventive step has also created a wide range of debates and been at the centre of many court cases. The starting point of most debates is that for an inventive step, a new development should not be "obvious"[55]. The matter has thus become for courts to identify whether or not a new development was obvious. The reference for this question has generally been the "person skilled in the art"[56], considered as a person qualified in the field considered, knowledgeable but without inventive capacities. Depending on the

[51] EPC Article 56; UK Patent Act 1977, Section 3; 35 USC 103.

[52] For example Biogen Inc v Medeva plc (1997) RPC 1.

[53] Williams vs Nye (1890) 7 RPC 62; 35 USC 103; UK Patent Act 1977, Section 3.

[54] Burroughs Application (1974) RPC 147.

[55] See EPC Article 56.

[56] UK Patent Act 1977 Article 3; for application of the concept, see for example Windsurfing international Inc vs Tabur Marine (1985) RPC 59; Great Britain Ltd (1985) RPC 59 ; EPO Board of Appeal, decision T36/82, OJEPO 7/83.

type of inventions and on the field considered, the qualification of the referee can vary significantly, and in fields as specialised as new biotechnological developments it will be a highly qualified researcher[57].

However, this has raised new issues, and the fast evolution of high technologies has shadowed some doubts as to whether the notion of "person skilled in the art" was still viable in fields where the average worker is a highly skilled professional, and the example of the decision taken in the UK in *Genentech Inc's Patent*[58] is particularly illustrative in that respect. In this example, the court decided that a highly technical development was not to be considered as inventive, because other highly skilled teams could have achieved the result on which the patent claim was based. What has become particularly difficult, overall, is to imagine a fictional scientist who would know everything but invent nothing – and in highly technical fields it becomes particularly difficult to accept that the "average worker" is not inventive. This example demonstrates how in highly technical areas, the "average worker" has in fact become to be considered as gifted with inventive skills. The threshold of inventiveness could be raised so high that patents would become increasingly difficult to obtain in highly specialised fields. The exact weight of this particular decision should not, however, be stretched too far, and remains more

[57] Biogen Inc v Medeva plc (1997) RPC 1.

[58] *Genentech Inc's Patent* (1989) RPC 147; Mustill LJ in this case stated: " It is inventiveness that counts, and I cannot find it here in any degree that exceeds the amount of resource expected the amount of resource expected of a group mustering the skills, remarkable as they seem to the layman, ordinarily to be expected of persons skilled in this most difficult array of arts."

an exception than a general approach[59]. Even so, it is likely that further questions of this type will arise in the future until a clear adaptation of the approach to new fields of technology is found.

Industrial application

The last criterion used in patent law requires that the invention presented shall be of industrial use[60]. This can relate to any form of industry, and can relate to either making industrially the product considered or using industrially the process considered for a particular result. One of the key fields in which this has been a relevant issue has been the biomedical field, which can be read in association with the exclusion common to many patent laws of methods of treatment from their patentability field[61]. The notion of "treatment" itself, and the clear boundary between what can be considered as a "method of treatment" has raised jurisprudential debate, and the scope of the exception had to be delimited.[62]

[59] For a critique of the approach in this decision, see Torremans P. (2005) op. cit, pp.68-70.

[60] EPC Article 57; UK Patent Act 1977 Section 4(1); Code de la propriete intellectuelle francais, art 612-15.

[61] See for example the UK 1977 patent act, Section 4(2) and 4(3).

[62] In the UK, see for example Stafford-*Miller's application* (1984) FSR 258 in which a method for treating headlice is not considered as a "method of treatment", and *Bruker's application* (1988) OJ EPO 308, in which the EPO decided that a method for determining the presence of a disease could be patented.

Exercising patent rights – within their limitations

The exercise of patent rights resembles that of other property rights in many respects, and in particular because patents can be traded and transferred like tangible property rights[63]. In many cases, patent holders are not able to market their own invention. The best financial option open to them in order to see their invention become rewarding is to license their invention to others. The potentially most rewarding way to do so is to sign an exclusive license agreement with one specific licensee – although an agreement can legally be signed with several licensees. In this particular case, the rights granted to the patentee will be fully transferred to the exclusive licensee.

However, patents are not exactly similar to other forms of property. One of the differences is that patents are granted for the public benefit. Therefore, states maintain specific powers over patents, in order to ensure that the way they are used does not threaten the public interest. Compulsory licences are the most central tools kept by states to ensure that this is the case. They allow a government to permit a company to obtain a licence over a patented invention without the agreement of the patent holder, for reasons related to the public interest[64] and under some strict conditions. In addition to cases of national emergency (often symbolic of the relevance of compulsory licences), an example of such a reason is the national working requirement, and when a patent is taken out in a state and not industrially used in that particular country,

[63] See for example UK Patent Act 1977 sect. 30(1).

[64] For example India Patent Act 1970, Article 84(1). See also the concept of "licence of rights" under the Indian 1970 Patent Act – granted at the initiative of the patent office.

competitors can sometimes apply for compulsory licences on the ground that the patent is hampering the development of local capacities[65]. Compulsory licences have been allowed in most patent law systems[66], and in recent years became considered as a potentially useful safeguard in relation to public health, as will be developed when discussing TRIPS. However, in practice they have been used only exceptionally by developing countries, and that the price to be paid to inventors for their use is still an important element that could stop the poorest countries from using it[67]. In addition, it is worth mentioning that in many patent systems, governmental use can be exempt from patent rights – once again, this is related to the idea of public interest, and will only be done if it is proven to be in the public interest[68].

Finally, other limits exist to the rights granted by a patent, and in specific cases a person will be able to use commercially a patented product without the explicit consent of the patent owner. This is in particular so following the doctrine of exhaustion of rights. This doctrine has been at the centre of many debates in relation to public health in poor countries[69], and is therefore specifically relevant to this project. According to this doctrine, patentees cannot claim to use their exclusive rights any more once they have made their invention available on the market – whether national, regional or perhaps more

[65] See for example India Patent Act 1970, Article 83. See also Article 84 (1)

[66] See UK Patent Act 1977 section 48; Indian Patent Act Article 84.

[67] See for example Torremans P. (2005) op. cit pp. 98-100

[68] This is the case in India - India Patent Act 1970, Article 100.

[69] See for example Correa C. (2001) "Public Health and Patent Legislation in Developing Countries", Tulane Journal of Technology and Intellectual property (3) pp. 1-53; Heath C. (1997) "Parallel Imports and International Trade", The International Review of Industrial Property and Copyright Law, 28(5), pp. 623-632

controversially international[70]. Once an invention is transferred by sale, it is considered as available for re-sale, and the buyer can therefore market it again without penalty. The practical implication of this doctrine relates to the notion of parallel imports. Purchasers can decide whether it is financially more beneficial for them to buy a particular product from their own market or to import it from another country where it has been marketed by the patent holder, and where it might be available for a lower price[71]. We will see that this is particularly relevant in relation to public health and although the validity of this theory at international level has been questioned, the TRIPS agreement explicitly excludes the issue from WTO competencies[72].

2. PHARMACEUTICAL PATENTS IN THE PRE-TRIPS ERA: NATIONAL REGULATION OF PATENT POLICIES

This section describes how the specific area of pharmaceutical patents was regulated at national and international level before TRIPS, and emphasises the diversity of policies adopted by national states in this field. It explains how this diversity was justified by considering the role that patents play in processes of industrial development, and why this role is particularly debated in the pharmaceutical field. Overall, this section shows how pharmaceutical patents as a development tool have framed different policies in different countries, and

[70] The European Community is an example widely chosen to illustrate the question of exhaustion of patent rights, and has a complex jurisprudence in this area – for an early acceptance of the doctrine in relation to patents, see Centrafarm v. Sterling Drug, Case 15/74 (1975) ECR 1147.

[71] See Correa C. (2001) "op. cit; Heath C. (1997) op. cit.

[72] Article (6).

how opposite arguments have presented patents as useful or hindering instruments. This will provide the necessary background to understanding the role and significance of TRIPS, and how TRIPS has resulted in a shift in the understanding of pharmaceutical patents from a "development" issue to being a public health matter.

2.1 Pre-TRIPS system.

When looking at pharmaceutical patents in the pre-TRIPS era, existing literature on IPR generally highlights a broad division between the approaches of "developed" and "developing" countries. However, a wide range of approaches have existed across the world – even if a global tendency to extend the field of pharmaceutical patents in most industrialised states can be seen while less industrialised states have generally limited their role. Overall, states' policies have been established according to national interest and public benefit, and have therefore varied according to the situation of each particular state. For the purpose of this section, three main categories of approaches will be presented – states that have traditionally offered strong protection for pharmaceutical patents; states that have limited the extent of pharmaceutical patents within their national IP system; and states that have not developed any actual IP system at national level. Although this broad division does not reflect the diversity of approaches and the complexity of the worldwide context in relation to pharmaceutical patents, it is useful to portray some key differences in the policy aims justifying these different approaches.

Before entering into the description of the different legal systems in the field of pharmaceutical patents, it is useful to define the concept of "generic medicines", that will be referred to throughout this project, and to emphasise the two different meanings that are given to the term. Broadly speaking, generic drugs are the non-patented/non-branded version of a particular pharmaceutical product. However, this description can cover two different legal situations. First, generics can be understood as new versions of a drug that was under a patent now expired – or versions produced by non-exclusive licensees, for example following a compulsory licence. These can be legally marketed anywhere in the world – or, in case of compulsory licences, on the markets of the countries covered by the licence - provided that they meet health related criteria. The second type of situation, which has generated significant controversies, refers to the commercialisation of new versions of a drug that is still under patent in some countries, made in another country where pharmaceutical patents are not legally protected. It is this second type of situation that has produced the pre-TRIPS controversies, as well as the debates that have followed the adoption of TRIPS, as will be developed below.

In relation to the pre-TRIPS situation of states with regards to pharmaceutical patents, firstly, until now, several countries did not develop any form of patent system, either for pharmaceuticals or for other types of inventions. This was the case with Djibouti, as will be detailed further in Chapter 4. Patents were officially non-existent within the territory of these states – and still are for least developed states in this category that have not yet implemented TRIPS. In relation to pharmaceuticals, generic versions of drugs patented elsewhere could

thus be legally marketed on the territory of these states and the patent situation of specific pharmaceuticals did not have to be a consideration for any policy-maker or importer of drugs locally. We will see throughout this research that this lack of regulation did not necessarily mean that such drugs were in fact available, or that pharmaceutical patents were totally irrelevant to the public health system of the countries concerned. Indeed, definite and clear information on the state of affairs in a number of the least developed countries that potentially belong to this category is difficult to obtain. The example of Djibouti has shown that diverging information was available even from official sources[73]. It is therefore difficult to provide a definite list of countries that have followed this example. In addition, it could be argued that there might be more states without effective patent laws than there are states without a patent law officially existing. No empirical research exists in this field on many developing countries, and in particular most least developed countries, that could confirm whether laws adopted have been applied in practice. We will see that the situation in relation to copyrights in Djibouti is a clear example of the contrasts between existing and effective IP laws.

Within countries that have implemented a patent system, some states have adopted a particular approach in relation to pharmaceutical patents, which is directed at limiting the potentially negative effects of patents in the field that will be explained below. First, pharmaceuticals have been in some cases

[73] Contradictory information is therefore available from the WIPO website on http://www.wipo.int/eds/en/ccs/pdf/dj.pdf and http://www.wipo.int/about-ip/en/ipworldwide/pdf/dj.pdf

excluded from the patent field[74], and generic versions of any modern drug could thus be marketed (provided that other pharmaceutical regulations are respected). In a second case, pharmaceutical products could not be patented, while pharmaceutical processes remained patentable[75]. While a particular way of making a drug could be protected through patents, the drug itself could not be patented. Consequently, companies could develop new ways of making a specific drug and legally market it. This type of policy was designed to encourage the development of a local generic industry, and has been beneficial from that perspective in several countries[76], as will be explained below. In addition, the high competitiveness of the local industry ensured that the price

[74] See Patent regime in Brazil between 1971 and 1997 and for comments see Braune F. and Menezes N. J. (1998) "The Patentibility of Chemical, Biochemical, Pharmaceutical and Biotechnological Inventions in Brazil", Patent World (108) pp. 46-48; see also Bass N. (2002) "Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century", George Washington University International Law Review (34) pp. 191-222. In relation to the comparatively relevant examples, see the case of Thailand until 1992 Thai Patent Act, B. E. 2535 (1992) and for comments Park J. S. (1993) "Pharmaceutical Patents in the Global Arena: Thailand's Struggle between Progress and Protectionism", Boston College Third World Law Journal 13(1) pp. 121-154; China until 1992 – for comments see Jiang P. (2002) "Fighting the AIDS Epidemics: China's Options under the WTO TRIPS Agreement", Albany Law Journal of Science and Technology (13) pp. 223-248

[75] See for example the Indian 1970 Patent Act, Art.5; or the Egyptian system, Egyptian Patent Law No 132, 1949. For comments, see Al-Ali N. (2003) "The Egyptian Pharmaceutical Industry After TRIPS – a practitioner's view", Fordham International Law Journal, 26(2) pp. 274-314.

[76] Mayer C. S. (1998) "The Brazilian Pharmaceutical Industry Goes Walking from Ipanema to Prosperity: Will the New Intellectual Property Law Spur Domestic Economy?" Temple International and Comparative Law Journal (12) 377-389; See also for example Seeratan N. (2001) "The Negative Impact of Intellectual Patent Rights on Developing Countries: an Examination of the Indian Pharmaceutical Industry", *St Mary's Law Review on Minority Issues* (3) Spring 2001 pp.339-412; Karandikar S. M. (1994) Indian Drug Industry After GATT, Bombay: MVIRDC World Trade Centre; Redwood H. (1994) New Horizons in India: The Consequences of Pharmaceutical Patent Protection, Felixtowe: Oldwicks Press.

of drugs remained fairly low and helped widen access to drugs[77]. Finally, particular tools mentioned above, such as compulsory licences and parallel imports have been used by some of these states either in order to promote development[78] or in relation to public health[79]. We will see how critics of TRIPS have emphasised this aspect of this type of policy.

Finally, the tendency in other states, including in Europe, North America and Japan, after a certain stage of development was reached[80], was to widen progressively the scope of patents, and to limit any form of exclusions. In the pharmaceutical field, patents were allowed on products and processes[81]. Companies have sought the possibilities for patenting extended and have used many strategies in that regard. The results are often perceived as having potentially excessive consequences, where patents can be held virtually

[77] Keayla B.K. (1999) Pharmaceutical Industry and Patent System in India: A Case Study, in TRIPS Agreement on Patent Law: Impact on pharmaceuticals and health for all, New Delhi: Centre for the study of global trade systems and development.

[78]See for example the importance given to working requirements in the Indian Patent Act 1970, Article 83

[79] See for example the dispositions contained in the South African Medicines and Related Substances Control Act 1977 Art. 10, related to parallel imports as modified in 1997.

[80] See the history of Italy, Challu P. M. (1995) "Effects of the Monopolistic Patenting of Medicine in Italy since 1978", International Journal of Technology Management, 10(2/3) pp. 237-251

[81] Consequently the debate has now been moved to further questions as to the field of patentability such as new therapeutic uses - See Domeij B. (2000) op. cit, and for jurisprudential steps in this area Eisai/Second Medical Indication, G5/83 (1985) OJEPO 64; Wyeth Application (1985) RPC 545; Bristol-Myers Squibb Corpn v. Baker Norton Pharmaceuticals Inc (2001) RPC 1.

indefinitely if a company successively patents different elements of its invention.

It should be noted, however, that these positions are not necessarily exclusive, and that many states have widely reviewed their patent policies at specific stages – either because national needs had changed or because of new legal obligations, as is the case with TRIPS. In particular, a number of countries with a strong research-based pharmaceutical industry have only offered possibilities to patent pharmaceutical products once their national industry had reached a certain level of development – and had excluded pharmaceuticals from the patentability field for many years before that stage was reached[82].

From the 1980's, the non-generic pharmaceutical industry – located in a handful of countries – started lobbying against the approach of what they called "free-riders" – states and generic companies that were using what they considered to be "their" inventions[83]. In the United States in particular, the industry lobbied the government heavily into taking unilateral measures against countries that were deemed to have excessively weak protection for patents[84]. This growing pressure was not limited to the pharmaceutical field, although that industry was particularly pro-active. It needs to be understood as a whole, within an overall disagreement amongst governments, and between the

[82] The example of Italy mentioned above is often given. The case of the US is more generally a clear illustration of the way states have adopted patent laws during the industrial development (not only in the pharmaceutical field). For a historical description of US patent laws, see for example Sell S. (2003) Private power, Public Law op. cit, pp. 61-72.

[83] Sell S. (2003) Private Power, Public Law, op. cit.

[84] See Sell S. (2003) Private Power, Public Law, op. cit.

industry in different sectors and states, as to what should be considered as an "appropriate" IP regime. We will see in the next section how this growing pressure resulted in the negotiation and signature of the TRIPS agreement. At this stage, however, it is convenient to present some of the key reasons that have justified the variation in national policies presented above, in the field of pharmaceutical patents.

2.2 Pharmaceutical patents, research and development – arguments behind policy choices

As illustrated by the range of approaches presented above in the pre-TRIPS era, the regulation of policies in the field of pharmaceutical patents has been a debated and controversial issue. This section illustrates two key elements that explain why countries with a different industrial background have ultimately chosen fundamentally different approaches to pharmaceutical patents policies. It will emphasise the key arguments that have explained why some states chose a strong protection for pharmaceutical patents on their territory, while others have chosen to limit their impact.

Patents and pharmaceutical research

The central argument for defenders of patent law has been the role of patents as an incentive for research. In countries where research and investment has been encouraged, patent policy has played a determinant role, particularly in the pharmaceutical field. Overall, the significance of patents for research is highly

dependent on the cost of research and the cost of production. If the cost of research on a product is low compared to the cost of producing it, inventors will quickly recover their investment in research, and possible competitors will not be able to charge consumers much less than the original researcher. By opposition, if most of the costs involved in marketing a product come from research activities, and making the product itself is cheap, researchers will bear costs much higher than other producers, and the importance of limiting competition in order to recover the investment in research will be greater. The role of patents in limiting competition in this latter situation is thus said to be essential[85]. The pharmaceutical industry can be one of the clearest examples of this second situation[86]. While research on a new drug often requires high investments in terms of cost and time, producing the same drug by reverse engineering can be comparatively cheap and easy.

One of the reasons for the high cost of pharmaceutical research is that only a very limited part of research activities will offer marketing possibilities. Many new compounds developed during pharmaceutical research can never be marketed[87]. In addition, the many clinical trials and procedures necessary to

[85] Mansfield E., Schwartz M. and Wagner S. (1981) "Imitation Cost and Patent: an Empirical Study", Economic Journal (91) pp. 907-918.

[86] On the role of patents in pharmaceutical development, see for example Scherer F. M. (2000) « Le Systeme des Brevets et l'Innovation dans le Domaine Pharmaceutique », Revue Internationale de Droit Economique, 2000/1, Numero Special: Brevets Pharmaceutiques, Innovation et Sante Publique pp.109-124.

[87] Estimates have suggested that fewer than 1% of pharmaceutical compounds tested in the US reach human testing, and only 22% of those are successful in clinical trials – although estimates in this area need to be considered very carefully for obvious reasons, research in this area being often sponsored by the pharmaceutical industry. See Dimasi J. A. (1995) "Success

introduce a drug on the market make the development of any new drug particularly long and consequently costly[88]. In general, research on one particular drug involves years of highly specialised work, and many commercial failures, the cost of which must be recovered. In contrast, making a drug by reverse engineering is of limited cost and approval procedures are faster than for new drugs[89]. Marketing the reverse-engineered drug will then be possible if it can be proven that it is technically similar to the patented drug, and the many clinical trials followed by the original researchers will not need to be undertaken again. Authorization to put the drug on the market will of course be needed, but both research activities and marketing requirements will be much less costly for the generic competitor.

Overall, because they are able to avoid the cost of research into new drugs and limit their investment to production, generic companies are able to market drugs at much lower prices than companies which have developed the product through research. As a result, where pharmaceuticals are excluded from the field of patentability, researchers creating a new drug could face a situation where they have invested large amounts of money and time in a drug that can be cheaply reproduced by competitors. On a national scale, this could be a strong disincentive for companies considering investing in research, and

---

Rates for New Drugs Entering Clinical Testing in the US", Clinical Pharmacology and Therapeutics (58) pp. 1-14.

[88] Dimasi J. A., Hansen R and Grabowski H. (2003) "The Price of Innovation: New estimates of Drug Development Cost", Journal of Health Economics (22) pp. 151-185.

[89] Scherer F. M. (2000) op. cit.

economists have emphasised the crucial role of pharmaceutical patents in maintaining a strong research-based industry[90].

Even so, this understanding of the need for patents in the pharmaceutical field as crucial for research and investment could be questioned. In particular, the high profits made by the pharmaceutical industry could be seen as proving that the impact of patents runs further than what is in fact needed as an incentive for research and development. The need to conceive patents as a tool to be used in the public interest has been re-emphasised in that respect, and it can be argued that excessive opportunities for patenting could be essentially positive for private interests. In addition, the analysis and arguments provided above are only valid in countries where there is already a potential for research and investment. It is now useful to explain why many states have felt that it was not in their interest – or not yet in their interest – to introduce strong pharmaceutical patents systems.

[90] Crampes C. (2000) " La Recherche et la Protection des Innovations dans le Secteur Pharmaceutique", Revue Internationale de Droit Economique (1), Numero Special: Brevets Pharmaceutiques, Innovation et Sante Publique, pp. 125-145; International Federation of Pharmaceutical Manufacturers Associations, "The Question of Patents: the Key to Medical Progress and Industrial Development", Geneva; Mansfield, E. (1986), op. cit; Taylor C. T. and Silbertson Z. A. (1973) The Economic Impact of the Patent System, Cambridge: Cambridge University Press; Bale H.E. (1997) "Patent Protection and Pharmaceutical Innovation", New York University Journal of International Law and Politics, 29(1/2): 95-107 Kolker P.L. (1997) "Patents in the Pharmaceutical Industry", Patent World, January 1997, 34-37; Grabowski H. (2002) "Patents, Innovation and Access to New Pharmaceuticals", Journal of International Economic Law, 5(4): 849-860; Scherer F. M. (2000) op. cit.

Pharmaceutical patents and the development of a pharmaceutical industry

The situation of "developing" states in relation to patent rights has generated significant controversies[91]. Historically, patent systems were first created in European states, and exported subsequently to their colonies[92]. However, soon after the decolonization process, many newly independent states felt the need to re-adapt their patent systems to their national needs, and have proceeded to make wide revisions of their patent laws. In India, for example, the 1970 Patent Act was the product of these post-colonial revisions. The arguments put forward for those changes were both practical and theoretical. They mainly relied on the idea that, until a certain level of industrialisation was reached, a strong patent system may create more costs than benefits for the country concerned. In the case of most newly independent states, most of the patents conferred were given to nationals from European states and from the US, and

[91] Maskus K. E. (1998) "The Role of Intellectual Property in Encouraging Foreign Direct Investment and Technology Transfer", Duke Journal of Comparative and International Law 9:109-161; Sherwood R. (1990) Intellectual Property and Economic Development, Boulder: Westview Press; Griliches Z. (1984) Research and Development, patents and productivity, Chicago: university of Chicago Press; Walker C.E. and Bloomfield M. A. (1988), Intellectual Property and Capital Formation in the next decade, Landham: University Press of America; Primo B., Fink C. and Sepulveda C. (2000) "Intellectual Property Rights and Economic Development", World bank Discussion Paper no. 412, available at http://www.bvindecopi.gob.pe/colec/cbraga.pdf

[92] Drahos P. (2002) "Negotiating Intellectual Property Rights, Between Coercion and Dialogue", in Drahos P. and Mayne R. (eds), Global Intellectual Property Rights: Knowledge, Access and Development, London, Palgrave, pp. 161-182; Vaistos C. (1971) "Patents Revisited: their Function in Developing Countries", Science, Technology and Development pp. 71-97

the benefits for the local industry were questionable[93]. In a way similar to what had been done in many "developed" states in the past – the US being a clear example[94] – they considered that adopting more restricted forms of protections for patent rights would provide greater advantages to their own nationals and to their local industry.

Although this remained a debated issue, and the role of patents in economic development has been widely discussed[95], in particular in relation to foreign direct investment, this position has been defended particularly successfully in relation to the pharmaceutical field, where the potential benefits of introducing a patent system at a later stage of development can be particularly clearly illustrated. Being a very advanced type of industry in terms of research

[93] For data on patent applications in India before 1970, see for example Koshy S. (1995) "The Effect of TRIPS on Indian Patent Law: A Pharmaceutical Industry Perspective", Boston University Journal of Science and Technology Law (4) pp. 1-56.

[94] It is only from 1861 that US patent law stopped discriminating between US citizens and foreigners. Between 1790 and 1836, only US citizens could apply for US patents. Once foreigners were allowed to apply for patents, the cost of their application was much higher than that of US citizens. (See Sell S. (2003) Private Power, Public Law, op. cit. for a history of US patent law; see also Commission for Intellectual Property Rights (2002) Integrating Intellectual Property Rights and Development Policy, Chapter 1: Intellectual Property and Development, available at http://www.iprcommission.org/papers/pdfs/final_report/Ch1final.pdf

[95] Barro R. J. and Lee J.H. (1994) "Sources of Economic Growth", Carnegie Rochester Conference Series on Public Policy 40 pp. 1-46; Kondo E. (1995) "The Effect of Patent Protection on Foreign Direct Investment", Journal of World Trade (29) 97-122; Lee J.Y and Mansfield E. (1996) "Intellectual Property and US Foreign Direct Investment", Review of Economics and Statistics (78) 783-820; Markusen J. (2000) "Contracts, Intellectual Property Rights and Multinational Investments in Developing Countries", Journal of International Economics (16) 205-226.; Maskus K. E. (1998) "The role of intellectual property in encouraging foreign direct investment and technology transfer", op. cit.; Primo B. and Castern F. (1998) "The relationship between Intellectual Property Rights and Foreign Direct Investment", Duke Journal of Comparative and International law (9) 163-188; Vaistos C. (1971) op. cit.

infrastructures as well as in terms of investment, an innovative pharmaceutical industry has been developed in only a few countries. According to a WTO report, only ten countries have a "sophisticated pharmaceutical industry and a significant research base", and another seventeen have "innovative capabilities". Almost all "developing countries" – as classified by the WTO - are considered as having no pharmaceutical industry, or producing only finished products[96]. To the extent that such a limited number of countries have inventive capacities, and can thus be expected to offer an important part of their patents to their own nationals, the role of patents in the pharmaceutical field for the majority of states has been questioned. The debate in this field has been strongly grounded in the example given by some countries which now have a strong and competitive pharmaceutical industry, and had chosen in the past to exclude pharmaceuticals – or pharmaceutical products only - from the patentability field. Examples such as Switzerland, Italy[97], or India[98] are amongst the most commonly given. These different examples have proven that it can be economically beneficial for a country to limit pharmaceutical patents in order to give a sound basis to its local industrial capabilities, and to introduce pharmaceutical patents only when a certain level of innovative capacity has been reached. Aiming for the development of a generic industry

[96] WTO, Council for TRIPS, "Available information on manufacturing capacity for medicines", WTO Document IP/C/W/345.

[97] Challu P. M. (1995) op. cit.

[98] For example, Seeratan N. N. (2001), op. cit; Koshy S. (1995) op. cit; Henderson E. (1997) "TRIPS and the Third World: The Example of Pharmaceutical Patents in India", European Intellectual Property Review 19(11) pp.651-663.

can thus become a strategy for the progressive development of a future research capacity.

If a country is aiming for the development of a generic industry, the role of patents can obviously be constraining. In particular, it might not be in the interest of small companies starting up activities of production to see their activities limited to producing versions of drugs which have come out of patents. The first stage of development of a pharmaceutical industry is often limited to making drugs, before investment in research can be considered. To that extent, it might be more beneficial at an early stage for a local industry to be allowed to produce any modern drugs by reverse engineering than to be limited in this activity by a strong patent system. Ways of encouraging the development of a local industry in the pharmaceutical field included primarily the distinction between product and patents as well as further measures such as the introduction of a local working requirement. Policies in which a local working requirement was integrated were centrally aimed at ensuring that patents would bring benefits to the country concerned since those working within local industries would be trained to produce the particular product. Distinctions between products and processes, similarly, aimed to encourage local industries to develop new ways of manufacturing, without limiting the productive possibilities of non-research based companies. Country case studies[99] as well as wide economic analyses[100] were undertaken in this area,

[99] Coloma F., Gabrielli A. and Williamson C (1987) Efectos de las Patentes de Medicamentos sobre el Mercado Farmaceutico y su Impacto sobre la Salud y el Gasto Fiscal, Santiago: Instituto de Economia, Universidad Catolica de Chile; Kirim A.S. (1985) "Reconsidering Patents and Economic Development: a Case Study of the Turkish Pharmaceutical Industry",

reaching variable conclusions. Many of the arguments used by states with a strong pharmaceutical industry to emphasise the importance of patents for economic development could not in practice apply to states at a very different stage of development and at a very different stage of international competition.

These two sets of arguments can explain what have been two fundamentally diverging strands in patent policies worldwide. While, on the one hand, countries with a strong research-based pharmaceutical industry were willing to see pharmaceutical inventions strongly protected, countries with only a generic industry limited the potentially negative impact of strong patent rights on their industrial development. These diverging views and interests soon created conflicts and controversies between states. In addition to this, it is useful to reflect on what has justified the approach of countries like Djibouti that have not implemented any type of patent system so far. We will see through Chapter 5 in particular that this needs to be understood by stepping away from the arguments presented above. It can be thought of essentially as the result of

---

World Development 13: 219-36; Scherer F. M. (2000) op. cit; Weisburst S. (1995) "Economic Effects of Strengthening Pharmaceutical Patent Protection in Italy", International Review of Industrial Property and Copyright Law (26) 1009-24; Korenko G. (1999) "Intellectual Property Protection and Industrial Growth: a case study", Journal of World Intellectual Property (2) pp. 47-75; Lanjouw J.O. (1998) "The Introduction of Pharmaceutical Product Patent in India: Heartless Exploitation of the Poor and Suffering?" Yale University: Economic Growth Centre; LaCroix Sumner J. and Kawaura A. (1996) "Product Patent Reform and its Impact on Korea's Pharmaceutical Industry", International Economic Journal, 10(1), Spring 1996, pp. 109-124

[100] Maskus K. E. (2000) Intellectual property rights in the global economy, Washington D.C.: Institute for International Economics; Mazzoleni R and Nelson R.R. (1998) "Economic Theories about the Benefits and Cost of Patents", Journal of Economic Issues (32) pp. 1031-1052; Deardoff A. V. (1990) "Should Patents Protection be Extended to All Developing Countries?" The World Economy 13(4) 497-508.

indifference and lack of expertise in this particular field. As existing literature does not concentrate on the situation of these states, it will be discussed specifically through presenting the empirical findings of this study. First, however, the legal developments created by TRIPS need to be discussed, and the debates that TRIPS has opened in relation to public health need to be analysed. This is necessary to understand more clearly how TRIPS has in recent years become part of many discourses on access to health in developing countries.

SECTION 2: TRIPS AND THE FRAMING OF PHARMACEUTICAL PATENTS AS A PUBLIC HEALTH ISSUE

TRIPS has been at the forefront of international discourses in recent years, often in relation to public health. However, it is useful to emphasise that this shaping of TRIPS as a public health agreement is the result of a slow evolution of perceptions and discourses. In that respect, it is necessary to reflect on the origins of the text, and to highlight how it has progressively moved from being a trade and intellectual property instrument to become shaped as a public health actor. It will be emphasised, in particular, that this framing of TRIPS as a public health actor was essentially done on the basis of research carried out in a few specific states.

This section presents a short history of the negotiation of TRIPS, and emphasises in particular the role of the pharmaceutical industry in the process of negotiation. It then presents the key dispositions of TRIPS that are relevant

to the pharmaceutical field. It explains how TRIPS and pharmaceutical patents have become central in discourses on public health in "developing countries", and how their expected impact has been framed. Finally, it examines how this new framing has allowed for important debates on the possible use of safeguards in the light of the public health impact of TRIPS, and how the Doha declaration on TRIPS and public health was signed as a way to cope with the expected impact of TRIPS on health in developing countries.

1. LOBBYING AND NEGOTIATION OF TRIPS

The history of TRIPS is best understood as a long-term process that moved from state level to an international debate. Pressure from industry to create new IP standards that would be respected by countries worldwide arose in a number of key fields[101]. The pharmaceutical industry was particularly pro-active in that respect, and lobbied governments for several years in order to obtain a wider protection for their inventions. Overall, by jointly lobbying for a stronger protection of intellectual property worldwide, different sectors of the industry, essentially in Europe and North America, organised into a strong policy-network in which national governments became key players[102]. An example of the type of pressure that they exerted, and of the support they gained from their

[101] For a detailed comment on the role of industries in integrating IP to trade rules, see Sell. S. (2003) Private Power, Public Law, op. cit.

[102] Susan Sell's research identified the following lobby groups as crucial in the road leading to TRIPS: The International Intellectual Property Alliance, the Pharmaceutical Manufacturers association, the Chemical Manufacturers Association; National Agrochemical Chemicals Association; Motor Equipment Manufacturers Association; Auto Exports Council; Intellectual Propery Owners, Inc; The International Anti-counterfeiting Coalition and the Semiconductor Industry Association. Sell S. (2003) Private Power, Public Law, op. cit.

own government, can be found in the commercial action of the US against states with a "weak" IP system[103]. The pressure put on countries with weak IP protection, and in particular in the pharmaceutical field, was maintained for several years.[104]

However, this approach presented some weaknesses. In particular, some states resisted the pressure they were put under by commercial measures[105]. In addition to this, the legitimacy of unilateral commercial actions began to be questioned. It appeared clearer that the best way to ensure that minimum standards would be respected worldwide would be to create an international agreement in which these standards would be set. Progressively, pressure for such an agreement increased, and it was finally discussed in the Uruguay Round, as part of the questions that needed to be tackled in order to limit barriers to free trade.

In the Uruguay Round itself, disagreements between states on the most appropriate way to tackle patent issues and other intellectual property matters were debated until states came to an agreement on the appropriate standards for intellectual property. Considering the opposition from states that grew around TRIPS after its adoption, the fact that the agreement was signed by sovereign states on a voluntary basis might seem surprising. However, TRIPS had to be signed by any state willing to join the WTO. In addition, the negotiations that

[103] This was achieved by integrating IP systems to the scope of Section 301 of the US trade and tariff act.

[104] See Sell S. (2003) Private Power, Public Law, op. cit.

[105] India in particular maintained its system in relation to pharmaceutical patents.

took place at the Uruguay round are often characterised as a meeting in which only some voices could be heard[106]. Some therefore considered that the final outcome of the text seems to reflect more strongly the views of Europe, North America and Japan than the proposals of any other state or group of states. The process of adoption of TRIPS is often presented as having virtually excluded most states from the real decisions[107].

"The negotiations on TRIPS are often said to have begun properly in the second half of 1989, when a number of countries made proposals, or the first part of 1990, when five draft texts of an agreement were submitted to the negotiating group. A more sceptical view is that the negotiations were by then largely over. An even more sceptical view is to say that no real negotiation ever took place. Developing countries had simply run out of alternatives and opt*ions."*[108]

[106] Drahos P. (2002) op. cit. See also Correa C.M. (1997) The Uruguay Round and Drugs, WHO Task Force on Health Economics, Geneva, WHO, (WHO/TFHE/97.1); Raghavan C. (1990) Recolonization: GATT, the Uruguay Round and the Third World, Penang: Third World Network.

[107] The use of "circles of consensus" is at the centre of these criticisms. In particular, it has been considered that through this system only the US, Europe, Japan and Canada mattered in practice in the decision-making process. In addition, the use of different types of commercial pressure against key states such as India and Brazil is believed to have been a central feature of the negotiation of TRIPS. See Drahos P. (2002) op. cit ; on p. 171.

[108]Drahos P. (2002) op cit.

2. CONTENT OF THE TRIPS AGREEMENT: NEW STANDARDS FOR PHARMACEUTICAL PATENTS

The TRIPS agreement sets minimum standards that countries must respect in their national IPR system. However, it allows states a certain margin of action when implementing the text nationally:

"Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice."[109]

As TRIPS is part of the WTO system, enforcement mechanisms are provided through the WTO itself. The TRIPS council was created to facilitate dispute settlement and provide advice to member states[110].

The field of application of patent law is defined in Article 27(1):

"Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of article 65, paragraph 8 of article 70 and

[109] TRIPS Article 1.

[110] Article 68.

paragraph 3 of this article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced".

The usual conditions of patentability are therefore stated in TRIPS, and inventions can be deemed patentable in any field of technology. This second point is crucial in relation to pharmaceutical patents, as it makes national laws that exclude pharmaceutical patents from the field of patentability incompatible with TRIPS. Implicitly, the claims of the pharmaceutical industry to protect pharmaceutical inventions worldwide were thus satisfied at international level.[111] This particular disposition was at the centre of an important part of the debates at the Uruguay round, which highlights the importance that pharmaceutical patents – as well as protection for chemical and biotechnological inventions – played in the decision-making on this agreement. This disposition has been considered "the reason of being of the whole TRIPS *agreement"*[112]. Although this was originally conceived as a research and industry issue, subsequently it became shaped into a key public health matter.

The specific case of pharmaceutical patents is referred to in Article 70(8) – in relation to what has become widely known as the "mailbox requirements". This disposition creates specific obligations with regard to pharmaceutical patents, during the transitional period granted for implementation. In particular, it

[111] Otten A. (2000) « Les Brevets Couvrant les Produits Pharmaceutiques et l'Accord sur les ADPIC », Revue Internationale de Droit Economique, 2000/1. Numero Special: Brevets Pharmaceutiques, Innovation et Sante Publique pp.161-166

[112] Pires de Carvalho N. (2002) The TRIPS Regime of Patents Rights, London: Kluwer Law International.

requires states that did not provide patents in the pharmaceutical field when TRIPS was adopted to create a system that would allow inventors to submit a patent application before the end of the transitional period – although the patent itself would only be granted once the national law implementing TRIPS comes into place. The obligation of member states to respect the dispositions of TRIPS with regard to pharmaceutical patents is reinforced, and the clear intention of the creators of TRIPS to enforce pharmaceutical patents worldwide appears.

Specific exceptions to patentability are presented, in order to protect ordre public and morality in particular, including health[113], although the practical use that can be made of them has not yet been clarified. The political pressure for strong patent rights could to result in a restrictive understanding of these exceptions.

The rights conferred on a patent owner are presented in Article 28, and have the commercial consequences presented earlier in this chapter when discussing the concept of patents. In practice, they offer to patent holders a temporary commercial quasi-monopoly. It is economically a very strong right, as has been detailed above. On the other hand, the patentee has the obligation to disclose clearly his invention[114], as is traditionally the case. Patent rights should be conferred for at least twenty years[115], which is a reflection of the most pro-patent claims and legislations[116].

[113] Article 27(2).

[114] Article 29(1)

[115] Article 33.

In terms of deadlines for implementation, and after negotiation, developing states should have implemented TRIPS by 2000[117], although an extended period of 5 years was offered for introducing protection into fields of technology that were previously excluded – such as pharmaceuticals[118]. Least developed states were given until 2006 to implement TRIPS[119] –later extended by the Doha declaration, as far as pharmaceutical patents are concerned (discussed below)[120]. However, states have to comply immediately with the mailbox requirement mentioned above[121].

As a whole, the protection offered to patent holders through TRIPS seems to answer most of the claims of the pharmaceutical lobby. In particular, laws of countries having deliberately chosen to exclude pharmaceutical products from patentability on clearly defined grounds will now have to be revised in order to satisfy the new requirements. However, pressure from the industry on developing countries has continued after the signature of TRIPS, through a series of complaints put forward in the WTO. Pharmaceutical patents were at

[116] For example EPC Article 30; by opposition Australian patents for example were only 16 years until the Patents (WTO Amendment) Act 1994; The Indian Patent Act made pharmaceutical process patents valid for 7 years.

[117] Article 65 (2)

[118] Article 65 (4)

[119] Article 66 (1)

[120] This is specified in paragraph 7 of the Doha declaration.

[121] Article 70(8). As explained above, states have an obligation to provide a system through which patent applications can immediately be "posted", although the application does not need to be processed immediately.

the centre of these debates, and demonstrated the eagerness of the industry to see IP standards modified as extensively as possible in this area[122].

The actual impact of TRIPS in relation to pharmaceutical patents has been a widely debated issue in academic literature and the media alike. In particular, the potential consequences that TRIPS might be having on public health in poor countries has been at the centre of heated debates. The interrelation between TRIPS and public health raises important issues which developed a clearer focus of attention in the few years following the adoption of the text. The way TRIPS has become enrolled into public health discourses will now be discussed, before looking at how the safeguards offered by TRIPS have became "read" in relation to this public health dimension.

3. FROM INTELLECTUAL PROPERTY TO PUBLIC HEALTH

Although TRIPS was originally thought of as an intellectual property matter, and remains technically a set of regulations in this particular field, it soon became shaped as a public health actor in many discourses. The resistance to TRIPS by states and health activists that appeared in relation to access to medicines soon resulted in TRIPS becoming shaped into a key player in public health worldwide.

[122] Cases brought against India (Patent protection for pharmaceutical and agricultural chemical products 9th July 1996, DS50), Argentina (Patent protection for pharmaceutical products, 10th May 1999, DS171) and Brazil (Measures affecting patent protection 8th June 2000, DS199) are the most crucial examples given.

In the text of TRIPS itself, mention is made of public health a few times, as one of the issues with which intellectual property might need to be balanced. This is the case in Article 27.2, as mentioned before. The second example of this can be found in Article 8:

*"Members may, in formul*ating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with *this Agreement."*

Overall, it shows that member states acknowledged public health and nutrition concerns, as well as other interests of vital importance, but the article has a limited legal impact in increasing the margin of action left to states[123].

However, at the time of its adoption, TRIPS was still essentially perceived as mainly related to the industrial development aims with which intellectual property is traditionally associated, and did not have the health dimension that future developments would lend it. Soon after the adoption of TRIPS, opposition to the text started growing from new actors, and in particular from public health activists. These actors organised in a new, more efficient, manner

[123] Bloche G. (2002) "WTO Deference to National Health Policy: Towards an Interpretive principle", Journal of International Economic Law 5(4) pp. 825-848; WTO secretariat and WHO, WTO Agreements and Public Health, 2002.
WTO/WHO (2002) WTO agreements and public health, available at http://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf#search='WTO%20agreements%20and%20public%20health

and started lobbying and working on issues related to TRIPS. The key point of departure was the potential impact of pharmaceutical patents on the price of medication, and how this would worsen the health situation of people who were already in critical health conditions in poor countries.

Pharmaceutical patents and public health

By their very nature, and as mentioned earlier, patents allow producers to market their products for the price that the market will tolerate without having to consider elements of competition. In the absence of competition, prices are maintained much higher than if a larger number of producers were allowed on the market. In the pharmaceutical field, this means that drugs will be much more expensive than if they were produced by several competitors[124]. The potential impact of pharmaceutical patents on the cost of medication has become a highly controversial issue in recent years, which has been increased

[124] Velasquez G. (2000) « Medicaments Essentiels et Mondialisation », Revue Internationale de Droit Economique, 2000/1. Numero Special: Brevets Pharmaceutiques, Innovation et Sante Publique pp.38-44; Nogues J. (1993) "Social Costs and Benefits of Introducing Patent Protection for Pharmaceutical Drugs in Developing Countries", The Developing Economies, 31(1) pp. 24-53; Rozek R. and Berkowitz R. (1998) "the Effects of Patent Protection on the Prices of Pharmaceutical Products: is Intellectual Property Raising the Drug Bill in Developing Countries?" Journal of World Intellectual property (1) pp. 179-244; Subramanian A. (1995) "Putting some Numbers on the TRIPS Pharmaceutical Debate", International Journal of Technology Management (10) pp. 252-268; Watal J. (1999) op. cit; Marques M. B. (2000) "Brevets Pharmaceutiques et Accessibilite des Medicaments au Bresil", Revue Internationale de Droit Economique, (1) Numero Special: Brevets Pharmaceutiques, Innovation et Sante Publique pp. 97-107; Muennich F. E. (2000) « Les Brevets Pharmaceutiques et l'Acces aux Medicaments », Revue Internationale de Droit Economique, 2000/1. Numero Special: Brevets Pharmaceutiques, Innovation et Sante Publique pp. 71-81.

by the impact of specific health-related scandals[125]. The worsening AIDS crisis in many developing countries, and the difficulties experienced by poor populations in buying anti-HIV/AIDS drugs that are still under patents, have made the controversies around pharmaceutical patents stark. Similarly, the argument made by pharmaceutical companies for rights over their inventions has been challenged increasingly by contrary arguments in favour of the right to life. A narrative where the right to life and right to health prevailed was opposed to the narrative of right to property[126].

The debate around TRIPS has grown to include a range of health and development NGOs arguing for the need to improve access to medication on the one hand[127] and, on the other hand, drug companies insisting on the pressing necessity to improve IP standards in order to maintain a high level of

[125] The action of the pharmaceutical industry against the South African government in Pretoria can be seen as crucial in making the links between patents and health more broadly accepted in international discourses, and in increasing mobilisation against TRIPS – and against the pharmaceutical industry in developing countries. The example of the strong pressure put onto Brazil while the country was trying to implement a policy based on parallel imports and compulsory licences to keep the price and anti-HIV/AIDS as low as possible. Bass N. (2002) op. cit.

[126] Sell S. (2002) "TRIPS and the Access to Medicines Campaign", op. cit. See also Sell S. (2003) Private power, public law, op. cit.

[127] For example, MSF reports: Doha Derailed: a progress report on TRIPS and access to medicines, 27 August 2003, available at http://www.accessmed-msf.org/prod/publications.asp?scntid=27820031110385&contenttype=PARA&; TRIPS, Pharmaceutical Patents and Access to Medicines: Seattle, Doha and Beyond: 24 July 2003, available at: http://www.accessmed-msf.org/prod/publications.asp?scntid=24720031521553&contenttype=PARA&; See also Oxfam access to medicine campaign and press releases such as: Flawed WTO drugs deal will to little to secure future access to medicines in developing countries, 27 August 2003, available at: http://www.oxfam.org/eng/pr030830_wto_final.htm

research and investment[128]. Overall, the action of health activists soon started making the links between patents and health in developing countries appear as stable and rather simple – pharmaceutical patents were likely to make drugs more expensive, and therefore to have a negative impact on access to health. AIDS was presented as the clearest example of this "fact":

"… consumer and health groups on the front lines of the anti-HIV/AIDS pandemic mobilised to protest the high cost of HIV/AIDS drugs, the subsequent lack of access to the drugs, and the dangers of overly strong intellectual property protection as embodied in TRIPS. They presented an alternative framing of IP as a public health issue, not a trade issue."[129]

However, it should be emphasised at this stage that most studies or texts discussing the links between TRIPS, pharmaceutical patents and health were based on analyses of the situation of a few specific states – essentially industrialised states that had positively chosen to exclude pharmaceuticals from their patentability field before TRIPS came into place[130]. The example of these few countries became generalized within the notion of "developing states". Similarly, the public health and pharmaceutical needs of "developing countries" have mainly been described generalizing from those specific

[128] See for example Pharmaceutical Research and Manufacturers of America (Pharma) website for comments such as: Health Care in the Developing World dossier, available at: http://world.phrma.org/ and see specifically Intellectual Property and Access to Drugs at http://world.phrma.org/ip.access.aids.drugs.html

[129] Sell S. (2002) "TRIPS and the Access to Medicines Campaign", op. cit, on p. 497.

[130] See for example: Seeratan N. N. (2001) op. cit; Joni J. (2002) "Access to Treatment for HIV/AIDS: a Human Right Issue in the Developing World", Connecticut Journal of International Law (17) pp.273-280; Bass N. (2002) op. cit.

countries – including a large majority of states for which AIDS is the key public health priority at the moment. The specificity of the issue of AIDS as compared to other public health needs has not always been clarified, and the issue of "access to treatment" has often been portrayed as best illustrated by the questions raised by "access to anti-HIV/AIDS drugs"[131]. By contrast, this thesis re-emphasises the need to avoid undue generalisations, and to widen the range of situations looked at when discussing what TRIPS and pharmaceutical patents mean for public health in "developing countries". The example of Djibouti was chosen, as will be explained further in chapter 3, as a counter-example to the focus of most of the dominant literature discussed above.

The increasing public health dimension of TRIPS, and the new framing produced by resistant groups, resulted in an increasing pressure on states to address specifically the relation between TRIPS and public health in post-TRIPS negotiations. This was completed in Doha. The declaration on TRIPS and public health was the outcome of a gradual realisation that TRIPS had become an issue for networks larger than trade and intellectual property activists. In addition to this, a large academic legal literature has been devoted to analysing the safeguards offered by TRIPS that could be used to limit the potential impact of TRIPS on public health[132]. These different attempts to balance TRIPS and health requirements will now briefly be examined.

[131] For example Shoell S. (2002) "Why can't the Poor Access Lifesaving Medicines? An Exploration of Solving the Patent Issue*" Minnesota Intellectual Property Review* (4) pp. 151-182.

[132] Correa C.M. (1998) "Implementing the TRIPS Agreement in the Patent Field: Options for Developing Countries", the Journal of World Intellectual Property, 1(1), pp. 75-100; Scherer

4. BALANCING INTELLECTUAL PROPERTY RIGHTS AND HEALTH CONCERNS – SAFEGUARDS AND THE DOHA DECLARATION

The increasing concern for the public health aspect of TRIPS resulted in two elements. First, the possibility to use the safeguards offered by TRIPS in relation to public health was widely discussed, including in academic research. Second, the limitations of this possibility became apparent and resulted in the adoption of the Doha Declaration in 2001. This section will review the potential for protecting public health within the legal TRIPS framework that has been put forward by legal commentators. It will then present the Doha declaration and explain how it aimed to offer stronger guarantees that public health would not be affected by TRIPS. This will delimit the public health dimension of TRIPS, and explain how it has been discussed in discourses linking its legal dimension to its potential impact on health.

TRIPS safeguards: does the text of TRIPS offer a way to protect public health?

The main elements that have been put forward as potential safeguards to be used in relation to public health are compulsory licences and the remaining possibility to allow parallel imports. We will look at these in turn.

F.M and Watal J. (2002) "Post-TRIPS Options for Access to Patented Medicines in Developing Nations", Journal of International Economic Law 5(4): 313-319.

The text of TRIPS explicitly excluded parallel imports from the WTO field of decision[133]. Consequently, states have been strongly advised to make the theory of exhaustion of rights explicit in their national law.[134] This could prove essential in the pharmaceutical field, where parallel imports allow consumers to obtain patented drugs for the cheapest price that the patent holder has marketed it for[135], which can be crucial in relation to access to medication[136]. However, in recent years and in response to the lobbying of several NGOs, some pharmaceutical companies have agreed to make some of their modern drugs available in poor countries for a cheaper price than in others. To that extent, parallel imports should be limited so that those cheap drugs do not come back on the markets excluded from this advantage. The risk otherwise would be to discourage drug companies from offering their drugs at a cheap

[133] Article 6.

[134]Abbott F.A. (1998) "First Report to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation", Journal of International Economic Law (1) pp.607-636; Bale H.E. (1998) "The Conflicts between Parallel Trade and Product Access and Innovation: the Case of Pharmaceuticals", Journal of International Economic Law 4(1) pp. 637-653; Heath C. (1997) op. cit; Rozek R.P. (1992) "Parallel Trade in Pharmaceuticals: the Impact on Welfare and Innovation", Journal of Economic Integration 37(2) pp. 181-203.

[135] It prevents patent holders from marketing products for a higher price in a country where the market would be more beneficial if producers aimed, for example, at selling their product only to a rich minority. In the pharmaceutical field, this form of practice has sometimes existed in states where companies can aim either at a market of a very poor majority, which could buy the drug only at a very low price, or at a market of a very rich minority which could afford very high prices.

[136] Balasubramaniam K (2002) "Patents, Prices and Public Policy", in Drahos P and Mayne R (eds), Global Intellectual Property Rights: Knowledge, Access and Development, London: Palgrave MacMillan, pp. 90-107. See for example Correa C. (2001) "Public Health and Patent Legislation in Developing Countries", op. cit; Heath C. (1997) op. cit.

price to poor populations[137]. Currently, many states have allowed parallel imports in their national law[138]. Important debates remain, however, on this issue, combining politics and law – for example, the US have challenged laws specifically using parallel imports as a legal tool, as was the case in the Pretoria trial[139].

A key-safeguard offered by TRIPS that could be used in relation to public health is the compulsory license system. The conditions for a state to issue a compulsory licence legally under TRIPS are presented in Article 31[140]. One particularly debated element of Article 31 is paragraph (f), which states that compulsory licences shall be used mainly for domestic purposes. This paragraph has created important discussion in the pharmaceutical field in particular, and its interpretation and application has been contested by member states. In particular, in the terms of Article 31(f), it appears that a licence could not legally be given by a state with no pharmaceutical industry to a company in another country to respond to a health crisis. In that respect, the relevance of compulsory licences for most least developed states has been strongly undermined[141]. This has been discussed in and after Doha, as will be explained below.

---

[137] Hammer P. J. (2002) " Differential Pricing of Essential AIDS Drugs: Markets, Politics and Public Health", Journal of International Economic Law 5(4): 883-912.

[138] For example South Africa Medicine Act, op. cit.

[139] Sell S. (2003) Private Power, Public Law, op. cit (Chapter 6) ; see also Sell, S. (2002) "Industry Strategies for Intellectual Property and Trade: The Quest for TRIPS and Post-TRIPS Strategies", Cardozo Journal of International and Comparative Law 10(1) pp. 79-108.

[140] These include a limited scope and duration and the adequate remuneration of the patentee.

[141] Abbott F.M. (2002) "The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO", Journal of International Economic Law 5(2) pp. 469-

Additionally, based on the text of TRIPS, a further question has been raised as to whether or not the text of Article 30 could be read as opening a possibility to create an exception to the limitations of other compulsory licences in relation to health. Article 30 states: *"members may provide limited exceptions to the* exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking *account of the legitimate interest of third parties."*

Article 30 is an exception to patent rights that should, according to panel reports[142], be strictly limited. The three conditions for application – limited exceptions, no unreasonable conflict with a normal exploitation of the patent, no unreasonable prejudice to the interest of the patent owner taking into account the legitimate interests of third parties - are enumerated in the article and should be cumulatively applied. The use that can be made of this article in the context of pharmaceutical patents and in relation to compulsory licences is still unclear[143], and the answers provided partly in Doha, but mainly after the

505; Abbott F.M. (2002) "Compulsory Licensing for Public Health Needs: the TRIPS Agenda at the WTO after the Doha Declaration on Public Health", Quaker UN Office, Occasional Paper 9, available at http://www.accessmed-msf.org/upload/ReportsandPublications/25620021018167/fred%20abbott.pdf.

[142] Panel Report of the 7th June 2000: Canada – Patent Protection of Pharmaceutical Products, WTO document WT/DS114/R, 17th March 2000.

[143] The EC and developing countries in the WTO have emphasised the possibilities of using this article with a public health aim. WTO document WT/MIN(01)/DEC/2, 20th November 2001; WTO document IP/C/W/355, 24th June 2002.

meeting, to some of these questions have limited the need to investigate this option.

Overall, there are complex conditions that need to be satisfied for a compulsory licence to be taken under TRIPS. Combined with the high cost of compensation to be paid to the patentee, they are likely to limit the relevance of this safeguard for poor countries. We will see below how practical issues also need to be kept in mind when investigating this potential role for least developed states[144].

In addition, it might be said that legal arguments have often appeared to be less relevant than political issues. As pressure for implementation of the strongest standards of patent rights started growing, it appeared correspondingly unlikely that countries would be politically enabled to make use of any of these options[145].

[144] In addition to those crucial safeguards, a number of elements are believed to be of use for states willing to limit the immediate impact that pharmaceutical patents could have on their territory. The Bolar exception is one of those. It allows researchers to proceed to all steps leading to future marketing while an invention is still patented, in order to be able to commercialise a generic version straight after the patent expires. In the pharmaceutical field, procedures can be particularly lengthy, and this form of exception can thus be particularly valuable.

[145] Pretorius W. (2002) "TRIPS and Developing Countries: How level is the Playing Field?", in Drahos P. and Mayne R. (eds) Global Intellectual Property Rights: Knowledge, Access and Development, London: Palgrave; Bond P. (1999) "Globalization, Pharmaceutical Pricing and South African Health Policy: Managing Confrontation with US Firms and Politicians", International Journal of Health services, 29(4) pp.765-792.

The Doha Declaration on TRIPS and public health

In the few years following TRIPS, disagreement and debate remained in relation to the potential impact of the text on public health and the use that could be made of specific safeguards. In 2001, member states held a meeting in Doha, Qatar, in which an important part of the debates related specifically to the relationship between TRIPS and public health. The outcome was a declaration aimed at clarifying some specific elements[146].

The declaration is essentially political, and does not add any new legal element to the TRIPS system, other than new extended deadlines for developing and least developed countries in relation to pharmaceutical patents. In addition to this, a few specific elements are aimed at specifying more clearly how states should be enabled to make use of particular safeguards. In particular, paragraph 5(c) reaffirms the right of each member state to determine what constitutes a national emergency, which emphasises the power of decision of developing states in a controversial area[147].

[146] Abbott F.M. (2002) "The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO" op. cit.; Engelberg A.B. (2002) "Implementing the Doha Declaration – a potential strategy for dealing with legal and economic barriers to affordable medicines", www.cptech.org/ip/health/pc/engelberg.html.; Heywood M. (2002) "Drug Access, Patents and Global Health: "Chaffed and Waxed Sufficient", Third World Quaterly, 23(2): 217-231; Sherman P. B. and Oakley E. F. (2004) "Pandemics and Panacea: the World Trade Organization's Efforts to Balance Pharmaceutical Patents and Access to Drugs", American Business Law Journal, 41(2/3) pp. 353-411.

[147] The question of whether or not to integrate a list of diseases that could give rise to a national emergency in the text of the declaration created intense debates. While the US was particularly eager to create an exhaustive list of disease, developing countries fought to maintain a margin

As mentioned earlier, one particularly debated issue was that of the use of compulsory licences for countries with no manufacturing industry, and the impact of Article 31(f) in that respect. No agreement was reached on this issue at Doha, and paragraph 6 simply defers the issue to future meetings. However, on the 30th August 2003, an agreement was reached in the WTO on this particular matter[148]. The agreement waives the effects of Article 31(f) when countries with no pharmaceutical industry are involved – under a number of conditions. Consequently states with no pharmaceutical industry will be able to issue a compulsory licence on a particular drug, and will be entitled to allow producers in another state to make it for them and export it. The impact of this specific decision has been praised in the press internationally, and presented by the WTO[149] as a central step in solving access to drugs issues related to TRIPS. However, NGOs have emphasised that this impact is only partial, and that the number of conditions associated with the use of a compulsory licence in these circumstances would mean that states will be discouraged from using it in many circumstances[150].

---

of decision as wide as possible. The result is a compromise which, while emphasising on several epidemics, does not seem to present them as an exhaustive list.

[148] WTO Document IP/C/W/405, available at www.wto.int/english/tratop_e/trips_e/implem_para6_e.htm

[149] See for example http://www.wto.org/english/news_e/pres03_e/pr350_e.htm

[150] See Oxfam, 27th August 2003, "WTO patent rules will still deny medicines to the poor", available at: http://www.oxfam.org/eng/pr030827_wto_patents.htm and MSF, 27th August 2003, "Chairman's text brings new difficulties to WTO paragraph 6", available at: http://www.msf.org/msfinternational/invoke.cfm?component=article&objectid=77830ACA-8EC5-419A-82AB7D7ED6A2E1ED&method=full_html

This decision is unlikely to solve the central practical problem associated with the production of generic drugs for a very limited market. It is likely that companies will take a limited interest in producing drugs exclusively for a least developed state in a temporary health crisis. The incentive for a licensee to produce a generic version of a drug needs to be mainly market-based. If there is no sufficient market for the generic drug to be sold and bring benefits back to the company, it is unlikely that a producer would want to take up a license. Currently, in countries where there is no pharmaceutical patent system, a local generic industry has developed on the basis that the local market is important, and that exports are possible. From 2005, most countries with a generic industry had implemented protection for pharmaceutical products. In the case where a drug was to become urgently available in a least developed country without a manufacturing capacity, the use of compulsory licences could be considered, but the practical question of commercial viability would remain – combined with its practical feasibility, as will be discussed in the case of Djibouti.

In addition, the debate continues within the WTO, as this system is to be reviewed annually. As a whole, the Doha declaration has been an important text politically, and it is likely to help answer some questions regarding the relation between TRIPS and public health. It has also opened legal debates in this same field that are expected to be solved in the next few years.

CONCLUSION: TRIPS, PUBLIC HEALTH AND DEVELOPING COUNTRIES – NEEDS FOR FURTHER RESEARCH

Overall, the above analysis has presented the impact of TRIPS on pharmaceutical patents systems worldwide. The progressive framing of TRIPS as a public health issue has been explained, and the development of a strong literature aimed at analysing the legal options left to states for protecting their public health while respecting the prescriptions of TRIPS has been introduced. However, a large part of the value of the literature presented throughout rests on a few assumptions that might need to be challenged. In particular, the appropriateness of the views generally presented as the situation of all "developing countries" can be questioned. The fact that many of the views presented above were developed essentially by studying the situation of states with an existing generic industry, and with a patent system pre-existing TRIPS that will need to be revised, is crucial to keep in mind when considering how far the questions asked would remain pertinent in a different social network. In addition, most case studies that have analysed and questioned the role of TRIPS and pharmaceutical patents in relation to health have concentrated on countries with institutional and health related structures and problems of a specific nature, that might not be shared by other least developed countries. The limits and uniformity of existing literature, in addition, lie in the fact that it has been essentially doctrinal and concentrated more specifically on the dispositions of TRIPS and the written dimension of patent law than on

empirical analysis to understand the actual effects and mechanisms of TRIPS and pharmaceutical patents.

This research aims to compare the findings made in these few industrialised developing states with empirical data collected in a small least developed country. It seeks to question to what extent the issues that appeared in countries such as India, Brazil or South Africa would be shared by a state in a different legal, social, political and economic situation. This will be done by analysing the links between TRIPS, patents and health in the Republic of Djibouti. In order to do so, specific tools and methods will be needed. In this research, most of these tools have been borrowed from ANT, which now needs to be explained.

CHAPTER 2 - INTRODUCING ACTOR-NETWORK THEORY

The story of TRIPS in developing countries is a story that has been widely told. Or rather, one story of TRIPS in developing countries has been widely performed[151], and Chapter 1 introduced some of its key aspects. It is a story about TRIPS as a global text, as an instrument widely reshaping the international system of drugs, and having a series of more or less clearly defined expected outcomes on health in poor countries. But in many regards, this story is only one incomplete and imperfect version of what a complex object is doing in many places and many networks. This study aims to avoid some of the shortcuts that are widely performed by the dominant narrative on TRIPS and pharmaceutical patents. It aims to go back to a particular set of connections generated by and around TRIPS and by looking "down" into this set of connections, to question what this might be teaching us about TRIPS, about what it is doing, and about how these widely performed views of TRIPS and pharmaceutical patents as public health agents have arisen. It is directed at moving away from the assumption that studies on transnational law should aim to uncover a certain form of overall movement, to analyse a whole, and provide a framework for the parts to become clearer.

By contrast, this research remains very small. It is aimed at considering a limited set of local relations, and understanding what locality can teach us

[151] On the notion of performativity, see Law J. and Singleton V. (2000) "Performing Technology's Stories" published by the Centre for Science Studies, Lancaster University, Lancaster LA14YN, UK, at http//www.comp.lancs.ac.uk/sociology/soc036jl.html

about relations that have been so widely performed by commentators that they have become taken for granted as quasi-natural. This study is about relations, about understanding how relations shape TRIPS in Djibouti and how TRIPS transforms other connections and networks. It is also about pharmaceutical patents, about how they are performed in Djibouti, what they become and how they act. It does not claim to be "global" because it aims to understand a set of objects and relations that are limited and relevant to Djibouti. On the other hand, it is not truly local because none of these relations is isolated. Rather, these relations are all shaped by the integration of action taking place elsewhere, which generate the objects under scrutiny in a particular way.

The story of TRIPS and pharmaceutical patents that emerges from this analysis is complex. Both TRIPS and pharmaceutical patents appeared through traces that were unexpected and revealed their multiple dimensions, and it soon became clear that the complexity and mobility of social orderings were essential features of the phenomena under scrutiny.

As mentioned in the introduction, the story of TRIPS and pharmaceutical patents that will be provided throughout this research is inspired by ANT. This chapter explains some key ideas of this approach, and highlights how they have been influential in this research. This is a difficult task in part because the emphasis of ANT on change, flexibility, and the fragility of meaning make it almost self-contradictory to try to provide a specific understanding of the approach in explicit terms. However, this chapter aims to introduce some of its

ideas and concepts, and to consider how it can be useful for socio-legal research.

This chapter will address the role of ANT in this research in two main steps. First, it will provide an introduction to the main ideas and concepts, and will explain the meaning of this approach in terms of the way it understands social life and the role of sociologists (Section 1). Secondly, it will discuss how this project has used the key concepts of ANT in practice (Section 2). The specific issues raised by the links between methodology and ANT will be discussed in the next chapter, when explaining the methods chosen in this research.

SECTION 1: SOCIOLOGICAL RESEARCH AND MOBILITY OF ORDERINGS

ANT has challenged existing understandings of society in several ways. A key aspect of this approach lies in the views it puts forward of social networks as mobile and fragile sets of heterogeneous connections and associations. This section will emphasise this key aspect of the approach, and explain why it results in an understanding of social relations based on change, complexity and interdependency- and on the idea of interdeterminacy of the "social".

WHAT IS ANT?

Before introducing the key ideas of ANT, two points need to be tackled. First, the origins of ANT need to be introduced. Second, the difficulties of

identifying, defining and explaining ANT as one stable and unique object need to be presented.

Origins

ANT originated in the sociology of science and technologies. Its initial aim was to understand the life of scientific objects within and outside the laboratory[152]. Scientific objects were therefore the centre of the analysis, and ANT was developed as a sociological method to understand their role and modes of action. Since its first appearance in the late 1980's, ANT has evolved significantly and in different directions, and nowadays the term ANT covers a range of approaches with a common denominator. This introduction to ANT will aim to uncover this common denominator, and to illustrate the key aspects that have been used in this particular project. A key element for sociologists of science when developing ANT was to bring science back to the centre of their analysis, and to move away from the human-based type of analysis that had predominated in sociology. Actor-networks were thought of as a way to overcome some of the most central divisions of social theories, such as that of object/subject, structure/agency or human/non-human[153]. The theory aims to

[152] Latour, B. (1993) We Have Never Been Modern, Brighton; Harvester Wheatsheaf; Latour, B. (1987) Science in Action: How to Follow Scientists and Engineers Through Society. Milton Keynes: Open University Press; Latour, B. (1988) The Pasteurization of France. Cambridge, Mass.: Harvard University Press; Latour B. (1979) Laboratory Life: the Social Construction of Scientific Facts, Los Angeles: Sage Publications.

[153] Latour B. (2004) "On Recalling ANT", published by the Department of Sociology, Lancaster University, LA1 4YN, UK, at http://www.lancs.ac.uk/fss/sociology/papers/latour-recalling-ant.pdf , also published in an earlier version in as Latour B. (1999) in Law J. and Hassard J. (eds) Actor-network Theory and After, Oxford: Blackwells, pp.15-25.

analyse how the relative stability of a particular network can be achieved, and how it participates in the emergence of further actor-networks and connections[154]. It provides a new complex way of thinking about social relations through the definition of particular networks.

The term "sociology of association" used by Bruno Latour[155] to illustrate the focus of ANT is a useful way of understanding the most central elements of the approach. Derived from semiotics and the emergence of meaning from relations[156], ANT aims to understand how associations and connections make actors what they are, and act the way they do. It is based on the notion that nothing is truly stable and pre-defined, but always co-dependent on what surrounds it.

---

[154] Law J. (1992) "Notes on the Theory of the Actor-Network: Ordering, Strategy and Heterogeneity", published by the Centre for Science Studies, Lancaster University, Lancaster LA1 4YN, UK, at http://www.lancs.ac.uk/fss/sociology/papers/law-notes-on-ant.pdf,: "This theory – also known as the sociology of translation – is concerned with mechanics of power", p.1.

[155] Latour B. (2005) Reassembling the Social: an Introduction to Actor-Network Theory, Oxford: Oxford University Press.

[156] *"All entities, it says, achieve their significance by being in relation to other entities. This* means that in ANT entities, things, people, are not fixed. Nothing that enters into relations has fixed significance or attributes in and of itself. Instead, the attributes of any particular element in the system, any particular node in the network, are entirely defined in relation to other elements in the system, to other nodes in the net*work. And it is the analyst 's job, at least in* part, to explore how those relations – and so the entities that they constitute – are brought into *being."* Law J. (2000) "Networks, Relations, Cyborgs: on the Social Study of Technology", published by the Centre for Science Studies, Lancaster University, Lancaster LA14YN, UK, at http://www.comp.lancs.ac.uk/sociology/papers/law-networks-relations-cyborgs.pdf, on p. 4.

How to explain ANT?

One of the emphases of ANT, as will be developed below, is on the instability of the social and the fragility of meaning of social networks and objects. A consequence of this is the constant questioning of whether an object can ever be described in truthful terms, since it is always likely to change and be reshaped when enrolled in new networks. Numerous studies have emphasised this fragile character of objects, and John Law has questioned what this might mean in relation to descriptions of ANT itself[157]. How can ANT ever be described as a single approach, when its meaning and content is constantly reshaped by each network in which it is enrolled, with each performance of authors integrating it into their research? This is an important question, and the idea that it is probably impossible to provide one "true" version of ANT as a whole, while remaining faithful to some key ANT concepts, is undeniable. However, for the purpose of this research, it is necessary to try to highlight some key concepts of the version of ANT that has been enrolled in this study. Although "*traduction is also trahison"*[158], and the story of ANT given here only represents one version of ANT, this section will aim to explain some of the key ideas that have been used in this research. It will provide an introduction and some ideas of what ANT is in this particular project.

[157] See Law J. (1997) "Traduction/Trahison: Notes on ANT", published by the Centre for Science Studies, Lancaster University, Lancaster LA14YN, UK http://www.comp.lancs.ac.uk/sociology/stslaw2.html, Department of Sociology, Lancaster University

[158] See Law, J. (1997) "Traduction/Trahison: Notes on ANT" op. cit.

COMPLEXITY OF HETEROGENEOUS NETWORKS

When presenting ANT in its dimensions most relevant to this project, several specific elements need to be considered. First, the notion of "network" as used in this particular approach needs to be defined and explained. This will allow for a comment on one of the recurrent elements discussed in relation to ANT – its relation to the "structure/agency" debate. The notions of "heterogeneity" and "symmetry" will then need to be explained. The question of network stability, in its achievement and in the questions it raises in relation to notions of "failure" or power will be discussed. Finally, the relation between ANT and notions of space will be covered. Overall, what will be emphasised in this section are the ideas of mobility, complexity and fluidity put forward by ANT.

"Actor-network": Understanding the originality of the notion of network

Network theories as a whole have been highly popular in the social sciences from the 1950's[159]. They have also been considered in a wide range of disciplines, such as geography and International Relations[160]. The emphasis on

[159] See for example: Radcliffe-Brown A. R. (1952) Structure and Function in Primitive Society: essays and Adresses, London: Cohen and West; Barnes J. A. (1954) "Class and Committees in a Norwegian Island Parish", Human Relations (7) pp.307-312; Beshers J. M. and Laumann E. O. (1967) "Social Distance: A Network Approach", American Sociological Review (32) pp. 225-236; Bott E. (1957) Family and Social Networks, London: Tavistock Publications; Epstein A. L. (1961) "The Network and Urban Social Organization", Rhodes-Livingstone Journal (29) pp. 29-62.

[160] Beaverstock J.V., Smith R.G. and Taylor P.J. (2000) "World City Network: a new Metageography?", Millenial Issue of the Annals of the Association of American Geographers, 90, March 2000, pp. 123-134; Colonomos A. (2001) "Transnational Networks: Old Game, New Rules", in Smouts M.C. (eds) The New International Relations: Theory and Practice,

the need to understand connections between actors has been common to all approaches. The world is analysed as made up of inter-relations and any social system can be understood through the analysis of these connections, as well as in relation to the question of inclusions in and exclusions from particular networks. However, authors' relation to the structure/agency debate and their varied emphasis on the respective importance of the whole and the parts has in fact been highly different. In reality, a wide range of varied assumptions can be found within network theories, in spite of their common emphasis on connections as crucial to the understanding of society.

The danger of using the term "network" has been emphasised by ANT writers willing to explain the risk of following a dominant terminology and way of thinking – *"it also suggests that we are being caught up in a* hegemonic way of *representing and (...) performing the world"*[161]. However, it is useful at this stage to reflect on the specificity of the term "network" in ANT as compared to other sociological understandings. One of the main differences between the understanding proposed in ANT and other – including most recent - accounts of the meaning of the term, lies in the concept of stability. While many understandings of networks tend to refer to a rather stable set of connections, the emphasis of ANT was originally on the fact that what can appear as stable is in fact always a set of fragile associations. In addition to this, a key aim of the notion was originally to understand movement and changes, by

---

London: Hurst, pp. 112-125; Smith R. (2003) "World city Actor-networks", Progress in Human Geography 27(1) pp 25-44.

[161] Law J. (2000) "Networks, Relations and Cyborgs: on the Social Study of Technology", op. cit. on p. 5.

understanding circulations and transformations that reshape every set of associations in a dynamic way. Very recent changes, and in particular the increasing use of the term that has followed the development of the "information society"[162] are in clear contrast with this understanding, and the term network is now often understood as a set of connections through which information can circulate in an unmodified and stable way. *"Network at the* time clearly meant a series of transformations – translation, transductions -; now, on the contrary, it clearly means a transport without deformation, an *instantaneous, unmediated access to every piece of information."*[163] Although this criticism made of the term network by Latour essentially refers to its use in relation to cyber space and information technologies, broader implications can be drawn in relation to other sociological uses of the term network. Indeed, the concept of stability of relations and the building of long term relations between actors is found in many comments on networks. A clear example lies in the concept of policy-network that is widely used, and clearly refers to stable sets of connections that are built in order to generate a stable "whole" able to negotiate[164].

[162] See Castell M. (1996) The Rise of the Network Society: the information age, Cambridge, MA.: Blackwells Publishers.

[163] Latour B. (1999) "On Recalling ANT", op. cit. on p. 15

[164] For example: Rhodes R.A.W. (1990), "Policy-Networks, a British Perspective", Journal of Theoretical Politics, 2(3) pp. 292-316; Richardson J (2001), "Policy-Making in the EU: Interests, Ideas, and Garbage Cans of Primeval Soup", in Richardson J (ed) European Union: Power and Policy-making, London: Routledge, pp. 3-23.

Finally, in addition to this, the notion of network in ANT needs to be perceived as more than an "above-the-individual level" term, and refers both to the whole and the parts. Actor-networks are the gathering of connections and associations that create a particular entity that might appear as unified – as an "object" at one point in time - but remain fragile and potentially subject to re-ordering:

"The network pole of actor-network does not aim at all at designating a Society, this Big Animal. It designates something entirely different which is the summing up of interactions through various kinds of devices, inscriptions, forms etc, into a very local, very practical, very tiny locus." [165]

The concept of network, and, even more so, the notion of "actor-network", has generated important questions in relation to the traditional structure/agency debate that has largely mobilised sociologists. ANT does not as such locate itself on any "side" of the debate, and authors have dismissed this issue as irrelevant and inappropriate. However, it is important to specify how this dismissal was reached, as it is important for what it reveals about the notion of

[165] Latour B. (2004) "On Recalling ANT", published by the Department of Sociology, Lancaster University, LA1 4YN, UK, at http://www.lancs.ac.uk/fss/sociology/papers/latour-recalling-ant.pdf on p. 2. It should be noted, however, that Latour's definition of the term network in its most recent publication is slightly distinctive as compared to what appears here and in earlier literature. In particular, he emphasises the idea of "network" as a quasi-methodological tool than can help retracing connections under scrutiny. For more detail on this position, see Latour B. (2005) Reassembling the Social: an Introduction to Actor-network Theory, Oxford: Oxford University Press, p. 131. In this particular project, the term network is essentially used to refer to objects of study themselves rather than to the result of their observation, and borrows in that respect more clearly from earlier writings in ANT research.

network, as well as for other ideas that will be continually used throughout this project.

What has been presented as central to ANT analysis is the constant relations between the whole and the parts as well as the interdependency of actors and networks. In addition, the notion of power as flux that will be explained below is in clear contradiction to the idea of making a decision about whether structures or agency holds most power in social change. In ANT, the distinction between structure and agency is therefore largely irrelevant. ANT sidesteps the issue as the social order is constituted by a constant dynamic in which actors model networks and networks define actors – and in which all actors are also networks and all networks are themselves actors. The relation between actors and networks is more complex than in many studies emphasising the impact of structure over agency, as each network is only the result of other actor-networks' interactions[166]. Any association is therefore only understood as the result of further connections happening elsewhere and of the embedment[167] of multiple effects, associations and actors into what appears temporarily as a stable hybrid[168].

[166] Latour B. (1999) "On Recalling ANT", op. cit.

[167] The notion of embedment is widely used in ANT to refer to the unsaid integration of actors or concepts in particular actor-networks – for examples of its early use, see Law J. (1999) "Materialities, Spatialities, Globalities", published by the Centre for Science Studies, Lancaster University, LA14YN, UK, at http//www.comp.lancs.ac.uk/sociology/soc029jl.html or Law J. (1997) "Topology and the naming of complexity", published by the Centre for Science Studies, Lancaster University, LA14YL, UK, at http://www.comp.lancs.ac.uk/sociology/papers/law-topology-and-complexity-pdf. It will be used and illustrated throughout chapters 6 and 7.

[168] The notion of "hybridity" is borrowed from Latour B. (1993) We Have Never Been Modern, op. cit.

Consequently, social analysis should not have – and cannot claim - to be either micro or macro, but should aim to understand social relations as mobile along specific networks, without ever being conceived as specific to a certain "level" of scrutiny:

"*Actor and network (...) designates two faces of the same phenomenon, like* wave and particles, the slow realization that the social is a certain type of circulation that can travel endlessly without ever encountering either the micro-level – there is never an interaction that is not framed – or the macro-level – there are only local summing".[169]

Materiality and heterogeneous networks

One of the most central claims of ANT is that sociology needs to be understood as a science of continuity and symmetry, and ANT authors therefore challenge some of the dichotomies traditionally accepted in sociology. The starting point of this challenge is the critic of the gap between nature and society. Originating in Latour's early work[170], this idea emphasises the continuity of what has traditionally been portrayed as two distinct spheres, and the idea that, while nothing is ever purely social, nothing is ever purely natural either. Nature and scientific "facts" are all socially biased, and can only be understood through their links with society – society makes science and influences what become

[169]Latour B. (2004) "On Recalling ANT", published by the Department of Sociology, Lancaster University, LA1 4YN, UK, at http://www.lancs.ac.uk/fss/sociology/papers/latour-recalling-ant.pdf on p. 3.

[170] Latour B. (1993). We Have Never Been Modern, op. cit; Latour B. (1988) The Pasteurization of France. Cambridge, MA.: Harvard University Press.

seen as natural facts. Similarly, society cannot be conceived separately from a natural, material world, and every aspect of social life is shaped by constant interrelations with materiality. Rather than understand nature and society as two distinct elements, sociologists therefore need to understand nature/society as the continuity of each other, and as fully interdependent.

More specifically, the idea of continuity has resulted in a challenge to the divide between humans and non-humans. Translated in ANT terms through the notion of heterogeneity, this idea emphasises the fact that social networks are all constituted of, and co-dependent on, both humans and non-human elements[171]. Materiality is central to society, and covers a range of elements: objects, bodies and quasi-objects, such as information and media.[172] Without contesting the specificities of human beings as thinking actors, ANT argues that without materiality there would be no social relations, no "society" and that any form of human interaction necessarily relies on material elements to such an extent that they can be said to "exist" only through them. Consequently, in order to analyse social events of any kind, one needs to consider not only the role of humans but also that of non humans in shaping events and relations.

[171] See for example Latour B. (1999) "On Recalling ANT", op. cit. (or similarly in the version of this text published in 2004.)

[172] See Latour on quasi-objects in Latour, B. (1993) We Have Never Been Modern, op. cit.. See also on materiality Law J. (1999) "Materialities, Spatialities, Globalities", op. cit: "Materiality is about stuff, the stuff of the world. Straightforwardly, we can imagine three kinds of stuff. *First, there are objects. (...) But [stuff] is also about bodies too* – for bodies are material -. *(...)* So objects and bodies are stuff. They are material. But so too are information and media, and *this is our third category of materiality",* on p.2.

"This is a radical claim because it says that these networks are composed not only of people, but also of machines, animals, texts, money, architectures – any *material that you care to mention. So the argument is that the stuff isn't only* human. It is all these other materials too. Indeed, the argument is that we *wouldn't have a society at all if it weren't for the heterogeneity of the net*works of the social. So in this view the task of sociology is to characterise these networks in their heterogeneity, and explore how it is that they come to be patterned to generate effects like organisation, inequality and power."[173]

The central consequence of the "indeterminacy of actors" is that any particular actor, human or non-human, within a network could become influential at any stage, depending on their own actions and that of the network.[174]

Translation and power

When studying networks and objects, a necessary step is to understand what makes them what they are – what makes their shape stay still for a while, so that they can become a defined matter of inquiry. Therefore, we now need to come back to the key question raised by ANT – how do sets of connections turn into apparently stable actors; how are networks created? In other words,

[173] Law J. (1992) "Notes on the Theory of Actor-network: Ordering, Strategy and Heterogeneity", op. cit. on p. 3.

[174] Callon M. (1997) "Actor-network Theory – the Market Test", published by the Department of Sociology, Lancaster University, LA14YL, UK, at http://www.comp.lancs.ac.uk/sociology/papers/callon-market-test.pdf : "The most important is that ANT is based on no stable theory of the actor; in other words it assumes the radical *indeterminacy of the actor. For example, neither the actor's size nor its psychological make*-up nor the motivations behind its actions are predetermined", on p.2.

how do networks manage to stabilise and hold together their different components? By contrast, what makes networks crumble and what makes objects or technologies "fail" or differ from what their creators were expecting them to be?

These questions call for two sets of answers. The first will look at the issue of network creation and stability. The second, rather than explaining "failure", will question the concept of failure itself, and offer an alternative understanding for the unexpected action of technologies in society, and the unexpected shape that specific networks choose to adopt. Finally, this will take us to a discussion of the notion of power in ANT, where the circulating nature of power in this approach will be re-emphasised.

Network creation and stability

ANT uses the term "translation" to describe the moment through which a set of entities turns into what appears as a single, unified network, and consequently becomes a stable – and successful – network. The network can itself then become conceived as a whole, as what John Law calls a "punctualised actor":

"This, then, is the core of the actor-network approach: a concern with how actors and organisations mobilise, juxtapose and hold together the bits and pieces out of which they are composed; how they are sometimes able to prevent those bits and pieces from following their own inclinations and making off; and how they manage, as a result, to conceal for a time the process of translation

itself, and so turn a network from a heterogeneous set of bits and pieces each with its own inclinations, into something that passes as a punctualised actor."[175]

One of the key questions of ANT thus becomes to know how translation occurs – and the relation between translation, action and power. Several elements can be put forward, that have to do both with the nature of the actors concerned, and with strategies developed by networks. However, what makes a strict and definite listing of what participates in network stability a difficult task, is the idea of interdependency and fragility of networks, as well as the fact that, while some theories could have discussed the nature and stability of materials as an accepted element, this remains purely circumstantial in ANT. Therefore, a key element in the success of translation processes is the relative stability, or durability of relevant materials. Whether materials are strong and stable enough to participate in the stability of a given network, although crucial, is itself relational, as the stability of these materials is in fact fully dependent on the links they establish with others. Similarly, the potential of materials to move across space-time, while retaining their own shape, is essential in allowing successful translations to occur in many cases.[176] In particular, the role of these materials in allowing for delegation from "centre" to parts has been highlighted as a crucial element of successful networks.[177] Other key elements needed for successful translation relate to strategies and orderings, as

[175] Law J. (1992) "Notes on the Theory of Actor-network", op. cit., on p.6.

[176] See the concept of "immutable mobiles" in Latour B. (1990) "Drawing Things Together" in M. Lynch and S. Woolgar (Eds.) Representation in Scientific Practice. Cambridge, Mass, MIT Press, pp. 19-68.

[177] Law J. (1999) "Materialities, Spatialities, Globalities", op. cit.

well as the need for networks to develop ways to adapt to future changes and new enrolments and circumstances. In addition, anticipation is central within the network, and key actors need to be able to expect and address the potential divergence of other actors from the overall action of the network.

A relevant question when dealing with translation is its relation to power. This requires an explanation to briefly explain the position of ANT on power. One key element is that translation and the creation of relatively stable networks should be understood more as the origin, rather than the consequence of, a certain type of power. Power in ANT can never be fully retained – it does not exist as a definite and stable element, but is expressed by circulating through connections and associations. It does not pre-exist these connections in any way, cannot be considered to "belong" to any particular actor, but remains a fluid type of circulation through networks and associations. To that extent, connections create the circulation and expression of power, and power will be expressed in a particular way depending on the set of connections that are taking shape. "ANT is all about power - power as a (concealed or misrepresented) effect rather than power as a set of causes"[178]

Overall, by translating into what appear as punctualised networks, associations adopt a shape that can be taken for stable, although they are always exposed to the risk of seeing their parts drift away, and the network, as it was known, "falling apart".

[178] Law J. (1992) "Notes on the Theory of Actor-network", op. cit. on p.6.

"Networks patterns that are widely performed are often those that can be punctualised. This is because they are network packages – routines – that can, if precariously, be more or less taken for granted in the process of heterogenous engineering. In other words, they can be counted as resources, resources that may come in a variety of forms: agents, devices, texts, relatively standardised sets of organisational relations, social technologies, boundary protocols, organisational forms – *any or all of these. (...) Punctualisation is* always precarious, it faces resistance and may degenerate into a failing network"[179].

This citation bring us a discussion of the concept of "failing network", and to question how ANT evolved into challenging this notion itself, and opposing to it the idea that change in network configurations should be understood as unavoidable transformation rather than failure. It will help us understand the concept of co-existing realities put forward more recently in ANT, and the argument that the contrasts between expectations and happenings in relation to translation should not necessarily be understood as synonymous with failure.

Network failure and co-existing realities.

Most ANT literature has concentrated on examples of "successful" translations, and has been devoted to explaining a posteriori the relative stability of particular networks. The issue of the potential "failure" of networks has been

[179] Law J. (1992) "Notes on the Theory of Actor-network", op. cit. on p. 5.

less explored[180]. One possible reason for this is the fact that discrepancies between expectations and networks action have often been explained through the idea of co-existing realities, rather than in terms of failure. This section aims to explain the difficulties of using the concept of failure in ANT studies, and to introduce how the idea of co-existing realities is more appropriate in describing the potential contrasts between expectations and outcomes.

A useful way to discuss the concept of co-existing realities is to refer back to the original field of ANT, and to discuss how this can be most clearly understood when dealing with technologies. The creation of a particular technology is often associated with a set of aims and expectations from its creators. These expectations are partly built around the idea that the technology will work in a certain way, and will create a range of relations with other actors that will participate in it, working in the way foreseen by its creators. Certain types of networks will emerge, and shape the action and role of a given technology in social networks. However, in many cases, this set of relations will not be exactly as planned, and the technology will therefore not necessarily act in the way expected. This can result in minor discrepancies between expectations and realities, but can also result in the technology appearing as doing something fundamentally "different" from what it is supposed to do. A good example of this is given by Marianne de Laet and

[180] For examples of stories of failing networks, see Law J. (2000) "Ladbroke Grove, or How to Think about Failing Systems", published by the Centre for Science Studies, Lancaster University, UK, at http//www.comp.lancs.ac.uk/sociology/papers/law-ladbroke-grove-failing-systems.pdf or Star, S. L. (1991) "Power, Technologies and the Phenomenology of Conventions: on being Allergic to Onions", in Law J. (ed) A Sociology of Monsters, London: Routledge, pp. 26-56.

Anne-Marie Mol[181] when looking at the "Zimbabwean Bush Pump". They analyse the changes that this technology goes through once implemented in the African village for which it was designed, and observe how the absence of key actors that were necessary to the stability of the network as originally conceived resulted in the pump being transformed by each network in which it was enrolled. One of the questions raised by this case study is whether the transformed versions of the bush pump in Zimbabwe mean that the original version of the pump failed, or whether it has taken a new shape, that it has been adapted in ways unexpected by its creators that are nevertheless fully part of the same object's reality. Similarly, by emphasising the various "definitions" that could be provided of this particular technology and emphasising the difficulty of defining clearly its boundaries with specific networks, the authors emphasise the inherent fluidity of this particular object, and therefore highlight some of its potential complexities. The ideas put forward in this case study in relation to the fluidity and indeterminacy of technologies is taken up again in several studies[182]. Overall, studies in ANT emphasise the idea that the contrasts between expectations and actions should not be understood as a failure of a system, but as the expression of another aspect of a multi-dimensional object. This new aspect, even if unforeseen by its creators, is nevertheless part of a reality that needs to be studied on its own[183].

[181] de Laet, M. and A. Mol (2000) "The Zimbabwe Bush Pump: Mechanics of a Fluid Technology", Social Studies of Science (30) pp. 225-263.

[182] For example: Akrich, M. (1993) Inscription et Coordination Socio-Techniques: Anthropologie de Quelques Dispositifs Énergétiques, Thèse pour le doctorat Socio-Economie., Paris: École Nationale Supérieure des Mines de Paris.

[183] Some dimensions of the idea of "reality" will be discussed further in Chapter 3.

Overall, technologies come to be conceived as fluid objects that adapt to new networks, and can become active in a fundamentally different way from their creators' expectations – and their existence itself becomes co-dependent on this fluidity. This needs to be fully understood, for realities need to be portrayed throughout this multiplicity of objects and through the idea that technologies cannot be moved while fully maintaining their shape. One idea associated with this form of analysis is that "*there is no such thing as technology transfer"*[184]. As technologies are displaced from one network to another, they change, and the sets of relations established around technological objects are themselves modified.

However, the idea of "multiple realities" raised in the above paragraph runs deeper than the notion of transformation or transfer itself, and carries consequences essential to ANT. It emphasises the fact that any object, any actor-network, is fully reshaped by each network of which it is a part. (This does not necessarily imply any material displacement, but the contrast between networked space and Euclidian space will be discussed again below.) When looking at any object – and this was very clearly illustrated by Vicky Singleton and John Law when looking at diseases[185]– a number of its "stories" appear through each network of which it has become part and in which it is acting. Those distinct, sometimes superficially "contradictory" stories are all part of the reality of this particular object, of its inherent complexity, and each of these

[184] Law, J. (1997) "Traduction/Trahison: Notes on ANT", op. cit. http://www.comp.lancs.ac.uk/sociology/stslaw2.html, Department of Sociology, Lancaster University

[185] Law J. and Singleton V. (2000) "This is not an Object", op. cit.

stories and dimensions need to be understood if the aim is to provide a complete account of this object. This will be particularly important throughout this research.

SPACE AND ANT

The question of the relation between space and networks is a complex issue. It is however a key question to address when aiming to relate ANT based research to existing writings that have widely adopted the notion of globalisation, and when the aim is to apply ANT to the study of transnational law. One of the key elements characterising ANT is that networks appear as necessarily a-geographical, in the sense that they can never be defined in relation to a particular geographical unit. Through the example of the locality of a railway system, Latour highlighted how networks present this necessary characteristic of being indefinable in terms of geographical unit[186]. The understanding of space in ANT has thus become a debated issue, and the importance of place in these discourses remains unclear.

ANT emphasises that concepts of time and space as absolutes are neither useful nor realistic, and that those two phenomena depend on the constitution of specific networks. Consequently, traditional Euclidian geography becomes meaningless for ANT theorists[187] - and can even become a hindrance to the development of network based analysis. For example, while two things can be "close" in Euclidian terms, they could be complete strangers to each other. By

[186] Latour B, (1993) We Have Never Been Modern, op. cit.

[187] Latour B. (1993) We Have Never Been Modern, op. cit.

contrast, others "geographically" far apart could become strongly interconnected if embodied in a common network[188]. ANT thus requires a full revision of traditional visions of space as absolute reality, and implies the need for a new network based "topology". For ANT, space becomes relational, and is consequently a product of networks, as opposed to a pre-existing reality. While it is generally assumed that space pre-exists networks, and influences the constitution of networks to some extent, it is in fact necessary to accept that space is in itself fully relational, and that networks impact centrally on the constitution of space. They participate in connecting elements regardless of notions of distance.

"We want to suggest that making action and knowledge at a distance not only makes action, knowledge and global asymmetry – although it certainly does all these things. In addition we want, and somewhat counter-intuitively, to suggest that it also makes distance or space, performs these into being. Which means *that distance and space don't exist by themselves as part of the order of things. But rather that they are created."*[189]

[188] For comments, see Murdoch J (1998) "The Spaces of Actor-Network Theories", Geoforum 29(4) pp. 357-374.

[189] Law J. (1999) "Materialities, Spatialities, Globalities", op. cit; See also in Law J. (1999) "Objects, Spaces and Others", published by the Centre for Science Studies, Lancaster University, LA14YL, UK, at http://www.comp.lancs.ac.uk/sociology/papers/law-objects-spaces-others.pdf: "No doubt there are particular configurations which predate objects in that space. It is, however, also possible to make another argument; to say that the performance of an object-shape as stable and continuous in Cartesian terms also helps, at the same time, to perform a space, a world, that is Cartesian in form", on p.5.

A related question considers the way ANT proposes to respond to the notion of "globality", and how it offers an alternative approach to the study of transnational networks. It puts forward the idea that global events cannot be analysed only as a form of pure supranational element, but that one must consider how they relate to specific associations, and how specific networks translate into what appears to some as a "global network": "To address global concerns it is often best to be local, specific and material[190] ". The notion of "globality" loses any real substance, as the interaction of local happenings and complex networks is argued to be the only way to approach transnational networks. In practice, it becomes necessary to analyse the detail and local manifestation of what is inappropriately defined as "global phenomena", rather than aim for the development of an overarching framework that would be used to explain the whole.

"To talk of globalisation is at best a risky shortcut and at worst seriously misleading. It is a risky shortcut because it implies some kind of totality, some *kind of global system (...). A "global society", a "global order". Even a global disorder. But this missed out (...) both on the enacted materiality of that order* and also the compl*ex spatialities implied in that enactment."*[191]

Similarly, the notion of locality loses its traditional meaning and comes to be seen as the result of actions and connections in other places. The notions of

[190] Law J. (1999) "Materialities, Spatialities, Globalities", op. cit.

[191] Law J. (1999) "Materialities, Spatialities, Globalities", op. cit., on p. 12. see also Law J. (2003) "And if the Global were Small and Non-Coherent? Method, complexity and the Baroque", published by the Centre for Science Studies, Lancaster University, LA14YL, UK, at http/www.comp.lancs.ac.uk/sociology/papers/law-and-if-the-global-were-small.pdf

global and local are replaced by the idea of constant relations between connections in what might temporarily appear as "larger" or "smaller" but in fact remain either more or less connected[192].

Overall, ANT puts forward ideas of mobility and fragility of social networks and orderings, and emphasises the need to understand social life by analysing sets of heterogeneous and complex networks that create specific orderings. It is now necessary to reflect on what this means in practice for empirical research.

ANT AND EMPIRICAL RESEARCH

The practical impact of ANT on specific methods will be discussed in detail in Chapter 3. However, a few general points need to be made here, that will help understand how the key ideas and concepts put forward above relate to general issues raised by empirical research.

ANT has been developed essentially as a method, and has wide-ranging consequences for empirical research. One of its key components is its emphasis on description as a way to approach and narrate a particular story of social life. The aim of empirical work, when following an ANT framework, is to provide a story of an object or a situation as it appears for a researcher willing to understand its multiple dimensions. It is to provide a rich description of a

[192] See Latour B. (2005) Reassembling the Social: an Introduction to Actor-network Theory, op. cit. This obviously relates to what was said earlier in this chapter on the challenges brought by ANT to the structure/agency debate, although in terms more specifically relevant to this particular research.

system in its complexity, and in the different dimensions that appear to the researcher - dimensions that the researcher should aim observe without ever generating. Analysis needs to be done without attempting to rely on a heavy framework to understand the object under scrutiny, which would risk changing the meaning of the network as it is lived/created by those that make up the network.

This means, first, that empirical work and sociological analysis should be modest[193], and that researchers should follow informants through their connections, and trust that the system as they see it, present it, describe it, appear to make it, is the centre of the story to be told.

"Far from being a theory of the social or even worse an explanation of what makes society exert pressure on actors, [ANT] always was, and this from its very inception, a very crude method to learn from the actors without imposing on them an a priori definition of their world-building capacities."[194]

The idea of modest sociology, and ANT's emphasis on the need to avoid adding outside elements to the story has two further consequences. First, it implies that researchers should not attempt to simplify what appears as complex, and should accept this complexity as part of the realities of the network studied, and provide a faithful description of the network studied[195]. Second, it also implies that conclusions should not be stretched further than the

[193] Law J. (2000) Organizing Modernity, Oxford: Blackwells.

[194] Latour B. (1999) "On Recalling ANT", op. cit, on p.20.

[195] We will see in Chapter 3 the practical difficulties of this idea.

story told, and that each description should remain essentially useful for the story it tells, and the potential questions it raises[196]. One question that could be opposed to the essentially descriptive task encouraged by ANT is that of the role of critique. If the role of researchers is essentially to describe a situation, is there any space left in ANT for critical analysis? The position taken in this research is that a specific and faithful description, in which actors' voices are presented in detail, will result in controversies and discrepancies becoming apparent. By highlighting these various discrepancies between views, actions or outcomes, the potentiality for critique will remain intact.

Some of the ideas developed above can clearly be related to the practical implications of the principle of symmetry, and the idea that the role and function of each actor in a given network should not be assumed on the basis of their nature, but should be empirically observed. Once again, actors and networks cannot be deemed to have a certain type of function once and for all, or internal mechanics, but only take a certain shape because of the connections they establish with others. It is for researchers to understand the relevant set of

[196] See Latour. B (2005) Reassembling the Social: an Introduction to Actor-network Theory, op. cit**: "**So even if I do what you want, I will have one nice description of one state of affairs, and then what? Then, I still have to put it into a frame, find a typology, compare, explain, *generalise. That's why I'm starting to panic.*

- You should panic only if your actors were not doing that constantly as well, actively, reflexively, obsessively: they too compare, they too produce typologies, they too design standards, they too spread their machines as well as their organisations, their ideologies, their states of mind. Why would you be the one doing the intelligent stuff while they would act like a bunch of morons? What they do to expand, to relate, to compare, to organise is what you have *to describe as well. It's not another layer that you would have to add to the 'mere description'. Don't try to shift from description to explanation: simply go on w*ith the description. What your own ideas are about your company is of no interest whatsoever compared to how this bit of the *company itself has managed to spread", on p.149.*

connections and interactions that locate a specific object within a larger network. Only from this position can the role of the object be deduced. This is of clear practical impact, and means that researchers should consider and study each object within the system under scrutiny, without undue assumptions as to what the object is, what it does, or what it should do.

Finally, in addition to this, it is worth reemphasising the idea of actor-network itself, and the notion that the whole can only be studied by considering the parts and vice versa. Empirical research is conceived as necessarily dynamic in that researchers need to constantly move through the connections that appear in their study, and need to give attention to each actor-network that appears relevant, each part and dimension of this actor-network, and each larger actor-network of which it is part. This necessarily involves a practical emphasis on the dynamics of the research process more generally, to understand and question what appears to count as relevant connections, relevant actors, and where attention should be next directed – although, as will be commented upon in the conclusion, this can create practical difficulties when deciding where the process should stop.

We will see in the next chapter that these ideas, although they appear as perfectly linked to the concepts introduced earlier, raise complex issues when considering methods more specifically. First, however, the meaning of ANT for socio-legal research needs to be questioned.

SECTION 2: UNDERSTANDING TRIPS AND PHARMACEUTICAL PATENTS THROUGH ANT

As mentioned earlier, ANT was originally created by sociologists of Science and Technology. It has rarely been applied to within empirical socio-legal research[197], and several questions remain about its application to the study of legal tools – and in particular to the study of transnational objects. This section will review questions raised by the use of ANT used in this particular study to understand the mechanisms of socio-legal objects. The idea of complexity will be developed, by looking in particular at the contrast between the dominant story of TRIPS and pharmaceutical patents and the approach undertaken in this project.

Before entering this analysis, the relation between this research and existing analyses based on approaches other than ANT needs to be specified. It is understood that other theories could certainly have overlapped with some key questions and concepts of this research[198]. However, one of the strength of

[197] For exceptions see Latour B. (2002) La Fabrique du Droit, Paris: La Decouverte; or Strathern M. (1999) "What is Intellectual Property After?" In Law J. & J Hassard J. (eds) Actor- network Theory and After, Oxford: Blackwells, pp. 156-180.

[198] For example, Implementation Theory proposes a comparable approach to the study of the potential gap between the expected role of policy tools and their actual action in society (for examples showing the various approaches to implementation see: Pressman J. and Wildavsky A. (1973) Implementation, Berkeley, CA: University of California Press; Hogwood B. W. and Gunn L. A. (1984) Policy Analysis for the Real World, Oxford: Oxford University Press; Elmore R. (1980) "Backward mapping: implementation research and policy decisions", Political Science Quarterly, 26(2), pp. 185-228). Although implementation studies (in particular in the strands concentrating on individual action in order to understand the various effects of policies (Elmore R. (1980)) could have offered significant insights on the study

ANT for this particular project resides in fact in the origins of the approach in Science and Technology Studies. As this project is interested in the interaction between legal tools and sciences (medicine), it was felt that the symmetrical analysis provided by ANT would be particularly useful as a way to understand the complex interaction of this variety of objects. It was perceived as having the potential to provide a useful way to conceive of both socio-legal and scientific tools as they interacted. Throughout this research, and as will be demonstrated, it provided a highly relevant tool for the study, conceptualisation and description of each of the objects under scrutiny.

Transnational law, scientific objects and socio-legal tools - how to study TRIPS and patents in Djibouti?

At this stage it is useful to reflect on the application of ANT to an understanding of TRIPS and pharmaceutical patents in Djibouti, and to provide a brief introduction to the focus of analysis of this research. In particular, it is this section will present the way in which ANT has participated in making the mechanics of both objects – TRIPS and pharmaceutical patents - appear clearer. A full description of both objects as they appeared in Djibouti from this empirical research is given throughout the remainder of this thesis. However, this section will highlight why the dominant analysis of TRIPS and pharmaceutical patents put forward in most analyses mentioned in Chapter 1

undertaken here, ANT provided further tools for understanding the action of non-policy and non-legal objects that were relevant to this research. Its emphasis on the need to analyse symmetrically these various objects through their interaction was perceived as essential in this project.

needs to be revised in light of the key ideas put forward by ANT. For readers to follow the subsequent analysis, it is necessary to return to the objects of study chosen here and question why this analysis does not stop at the doctrinal legal definition of both objects. TRIPS and patents, although they might appear as simple objects, generating chains of causality – as the term "legal" often implies – are in fact highly complex and multi-dimensional actors. One of the aims of this analysis is, once again, to question the appropriateness of the legal/social dichotomy that is sometimes assumed. Before more specifically discussing how this was done in practice in Djibouti, it is necessary to reflect on the idea of complexity and fluidity of both TRIPS and pharmaceutical patents.

There are two elements discussed below. First, both TRIPS and pharmaceutical patents are multi-dimensional – not only are they "understood" differently in different networks, but each of these understandings forms part of their multiple reality. Second, TRIPS and pharmaceutical patents can only be understood by reference to other actors, and to the connections created between various sets of entities.

The first understanding of TRIPS which might be presented is what can be described as the "doctrinal" version of TRIPS. An initial view of TRIPS, and therefore one of the dimensions this analysis is aimed at understanding, is that TRIPS is a set of written rules – of prescriptive rules - a text of law open to analysis and criticism. In addition, TRIPS is also a set of rules carrying consequences and requiring a range of social mobilisations which are part of all

accounts (although some of their aspects might be simplified in ways that this analysis aims to solve).

In particular, the text of TRIPS and the prescriptions it carries are understood as generating a certain chain of reactions. As "prescription" is used throughout this project, in particular in Chapter 5, this term is briefly considered here. The term "prescription" has been used in ANT essentially in relation to technologies, when discussing the view that technologies are shaped and built in such a way that they tend to bind and determine the actions of others. Creators of technologies "build in" expectations and ensure through specific characteristics of the technology itself that those interacting with it will be directed towards acting in a certain way[199]:

"... the behaviour imposed back onto the human by nonhuman delegates prescription. Prescription is the moral and ethical dimension of mechanism*s"*[200]

Throughout this research, and as will be explained again in Chapter 5, the term "prescription" will be used to refer to the idea of rules and anticipated social regulation expected from the creators of TRIPS.

[199] Akrich M. and Latour B. (1992) "A Convenient Vocabulary for the Semiotics of Human and Non-human Actors", in Bijker W. and Law J. (eds) Shaping Technology, Building Society: Studies in Sociotechnological Change, Cambridge MA: MIT Press, pp. 205-224.

[200] Akrich M. and Latour B. (1992) op. cit. on p. 232.

From the understanding of TRIPS presented above, the main difference between the dimensions of TRIPS emphasised in most literature reviewed in Chapter 1, and the position adopted in the remaining chapters, is that in the former, the chain of reactions is sometimes summarized and framed as an almost automatic causal link. TRIPS is implemented, which generates pharmaceutical patents to act, which in turns might make drugs more expensive and less accessible[201]. This research tries to avoid such a causal account by focusing on complexity. Existing accounts that portray TRIPS mainly/only as an official set of binding rules obscure the range of connections which need to be understood in order to appreciate not only what TRIPS does, but also what TRIPS is. Throughout the remainder of this thesis, this expanded meaning of TRIPS will be discussed and clarified – while acknowledging that some of its dimensions might remain "othered" in spite of a constant attempt to understand the associations in which it is enrolled and enrolling[202]. At this stage, and in order to make the aim of the following chapters clearer, it should be observed

[201] The links between TRIPS, patents and access to drugs commonly drawn when dealing with TRIPS can be identified in the following quote: "The concern is that, when the patent provisions of the TRIPS agreement come fully into force in developing countries on 1 January 2005 and patent protection is extended to all pharmaceutical products, including many HIV/AIDS anti-retroviral drugs, the effect will be increased prices that will further reduce *access to essential medicines."* Matthews D. (2004) "Is History Repeating Itself? The Outcome of Negotiations on Access to Medicines, the HIV/AIDS Pandemic and Intellectual Property Rights in the World Trade Organisation", Law, Social Justice and Global Development Journal (1), available at http://www2.warwick.ac.uk/fac/soc/law/elj/lgd/2004_1/matthews/ (on p. 2)

[202] The notion of "othering" will be used throughout this research to refer to the process of exclusion of certain aspects of realities in accounts and research. The term is borrowed from Law J. (2003) "Making a Mess with Methods", published by the Centre for Science Studies, Lancaster University, LA14YL, UK, at http://www.comp.lancs.ac.uk/sociology/papers/law-making-a-mess-with-method.pdf

that the dominant version obscures some of the complexities that need to be better understood.

While TRIPS is certainly a text, it is also the result of actions within a particular organisation – the WTO – itself related to actions and connections happening largely outside of the WTO offices. Chapter 1 has explained the influence of the pharmaceutical industry in making TRIPS. TRIPS can therefore be understood as is the embodiment of a certain set of ideas, pressures and debates[203]. All of these might have materialised – partly – in a text, but it is essential to remember that their stabilisation in this material form should not result in these aspects being completely forgotten or ignored in analysing TRIPS. The text of TRIPS has also gained further complexity through its own subsequent relations with newly emerging networks, and through the reactions it generated in relation to public health, in particular. In a range of discourses, as explained once again in Chapter 1, TRIPS has therefore become an inherent part of public health networks, and needs to be understood in part by looking at its action in public health networks. It has mobilised actors linked to public health in various ways, and has reshaped both understandings of IPR and access to medicines (amongst others). This second dimension is particularly important in this project, and will be developed in more detail in Chapter 7.

The action of TRIPS, in addition, also needs to be understood in relation to its implementation in specific countries. In particular, the prescriptions created by

[203] Sell S. (2003) Private Power, Public Law, Cambridge University Press: Cambridge.

TRIPS, although they are "officially", "in writing", directed at "member states", are in fact dependent on the mobilisation of a complex range of actors in order to be realised. The complexity of TRIPS can be understood, in that respect, by emphasising the complex range of actor-networks with which it needs to connect and through which it needs to circulate in order to be transformed into national law – and the range of actors it needs to mobilise in order to maintain in national contexts its "public health" dimension. This is particularly interesting and necessary in this project in order to emphasise where TRIPS can be expected to leave traces, and what it means to investigate TRIPS "empirically". Potentially, it is when trying to understand this last chain of reactions, that the discrepancies between the causality of some existing accounts of TRIPS and its empirical investigation becomes most clear. While some accounts of TRIPS chose to assume the triggering of particular connections, this analysis aims at empirically observing some of them in Djibouti. In particular, it is considered as essential to question who/what TRIPS has been mobilising in Djibouti, and how its connections can be understood and undone. This study aims to understand how TRIPS circulates in Djibouti, through which specific offices, desks, actors. It is directed at analysing and questioning each trace left by TRIPS in Djibouti, and follow the threads of the journey made by TRIPS across networks in the country. This investigation will consider the places through which TRIPS has entered the country, the forms in which it has entered specific networks and the new connections it has triggered. It will also question the extent to which these different directions, connections and mobilisations might appear as a challenge to the causal chain of reaction drawn upon in some dominant trends of

literature highlighted in Chapter 1. However, before doing so, the need for empirical accounts of pharmaceutical patents has to be explained.

Once again, the complexity of patents is something that has been partly discussed in Chapter 1, where the dominant dimensions in the existing literature were explained. However, it is also important to explain some other aspects of the complexity of patents because those aspects have been investigated in more detail in this research, as will be presented throughout the next chapters. Once again, the prescriptive dimension of pharmaceutical patents has sometimes been translated into causal terms while some of their complex dimensions and modes of action were partly othered – partly excluded from understandings of reality. However, part of this complexity has also necessarily transpired from the number of perspectives from which patents have been discussed – and in particular, by the contrast between the dimensions of patents emphasised by "the industry" (once again, this term itself hides complexity that this particular project does not need to discuss at this stage, although some aspects will be questioned in Chapter 6) and actors working on access to medication or public health. Each of these perspectives has emphasised the links between patents and health (and their relation to TRIPS) in its own way. While these different perspectives have often conflicted, they need to be reconciled by understanding the complexity of patents, and the fact that each particular position on patents discussed in Chapter 1 reflects an inherent part of some dimensions of patents[204]. What also needs to be highlighted, however, is that once again the causality of some

[204] This relates to the idea of multiple realities in ANT writings put forward earlier.

accounts tends to other some elements of complexity that will need to be retraced throughout this particular research. In particular, when dealing with health, the range of elements that need to be taken into account when deciding whether and how patents are enrolled and enrolling in public health networks will be emphasised. In this research, the range of traces left by pharmaceutical patents in words, actions and drugs themselves will be considered in order to retrace some of their inherent complexity. The realities emphasised by discourses on patents will be considered as part of the story, although further dimensions will be explored.

Finally, the relation between pharmaceutical patents and written rules – including TRIPS – will be undone[205] and analysed throughout this project and cannot, once again, be assumed in a causal and pre-determined form at this stage.

The conclusions to be drawn from the above section in relation to TRIPS and pharmaceutical patents are at this stage essentially negative – the fact that they are not "simple" objects has been emphasised, but the nature of their complexity is still to be discussed in the subsequent chapters. Both TRIPS and pharmaceutical patents can be retraced through wide-ranging and numerous associations. As will be explained in the next chapters, they are neither global - since they are felt in the tiniest loci – nor local - since they are only and ever

[205] The term is used to refer to the process of describing networks with the aim to highlight each of the associations and nodes that make them in order to be able to understand how networks work as a whole – for discussions on the process of describing and re-assembling, see for example Latour B. (2005) Reassembling the Social: an Introduction to Actor-network Theory, op. cit.

the result of many more actions and many more associations spread in many more places – some of which will be identified, some of which might remain forgotten[206]. TRIPS and pharmaceutical patents are also multi-dimensional, and act in a number of networks, for a number of actors determine part of their reality. All that can be said at this stage is that the remainder of this thesis will be directed at questioning the meaning(s) and nature(s) of TRIPS and pharmaceutical patents as well as at criticising the othering nature of the causal chain often found in existing writings about TRIPS[207]. Overall, very little can be said about either instrument at this stage, since it is considered an empirical matter to be discussed throughout the following chapters.

CONCLUSION

As a whole, ANT offers many benefits for the analysis to be undertaken in this research. One key element that needs to be highlighted at this stage is the fact that the emphasis of ANT on flexibility and on the need to describe rather than assume is crucial for undertaking empirical work in a country such as Djibouti. It is particularly important to avoid trying to fit findings within pre-existing frameworks, given that very little has been written about this country. ANT allowed in particular for a way to approach the networks under scrutiny in Djibouti without undue assumptions as to the way TRIPS works – or should

[206] And once again, this relates to wider ideas explained in ANT and discussed above – see for example Law J. (1999) "Materialities, Spatialities, Globalities" op. cit; Law J. (2002) "And if the Global were small and incoherent" op. cit ; See also Latour (2005) Reassembling the Social: an Introduction to Actor-network Theory, op. cit. (especially in Part 2).

[207] Latour B. (2005) Re-Assembling the Social: an Introduction to Actor-network Theory, op. cit.

work – or as to what matters or not in the system. In addition to this, ANT allowed for a closer look at both pharmaceutical patents and TRIPS in Djibouti as socio-legal agents best understood through their hybridity, reshaping existing connections while being reshaped by new interactions. It offered a way of looking into and around both instruments; of questioning at the same time what the instruments are "doing" in Djibouti, what connections in and around Djibouti are "doing" to them, and what they are in Djibouti as compared to what they are generally assumed to be. This research will address some of the issues that could be raised when questioning what ANT can mean for socio-legal work. While doing so, it will also provide a particular story about ANT, explain what can be made of it and with it, and how the tool can be adapted to a new field. The next chapters will present the story of TRIPS and pharmaceutical patents in Djibouti. Before discussing the empirical findings of this research, the next chapter discusses the methodology adopted in this project.

CHAPTER 3 – METHODOLOGY

This chapter describes and explains how the analysis of TRIPS and pharmaceutical patents in Djibouti was carried out. Understanding and observing socio-legal objects is a task that can be both complex and frustrating – complex because the networks involved are never-ending and a specific focus needs to be chosen, and frustrating because the objects most central to the analysis are elusive and cover both very concrete and totally abstract sets of elements. This fluid character of the two objects under scrutiny meant that their presence often had to be studied through others – through words that were being said, through materials that were integrating them, through connections that made them real. This chapter will explain how this was done. It will consider how an analysis of TRIPS and pharmaceutical patents was carried out on the ground in Djibouti by analysing the range of connections and orderings of which they have become key actors – sometimes in their materiality, sometimes in a more unsettled and unclear way, through fragile and complex connections.

The relationship between ANT and methods can raise many issues, and if research methods as a whole have been denounced as necessarily performative by ANT authors[208], the necessity to maintain a rigorous and scientific approach to empirical research has also been emphasised. Overall, ethnography remains the discipline from which ANT research has the most obviously borrowed tools and strategies. This project is itself based on methods of data collection

[208] For example Law J. and Urry J. (2002) "Enacting the Social", published by the department of Sociology and the Centre for Science Studies, Lancaster University LA14YN, UK, at http://www.lancs.ac.uk/fss/sociology/papers/law-urry-enacting-the-social.pdf

inspired from ethnographic research. However, the definition and delimitation of ethnographic methods raises a number of questions that need to be addressed. Similarly, the use of ethnographic methods in practice has been questioned in many respects, and has evolved in recent years to suit better the new fields to which they have been applied. This project is based on a ten-week period of fieldwork – and a two-week pilot study. Data was collected mainly by using in-depth interviews with twenty-five actors from the public health and trade and industry fields. Additionally, it integrated some elements of observation stored through detailed fieldnotes, as well as complimentary document analysis. Both data collection and data analysis were carried out on the basis that research should remain fully grounded in data. It aimed to understand and describe the phenomena observed without enclosing them within tight frameworks or expectations.

This chapter presents the key elements of the methods used in this project. It begins by discussing the notion of validity in qualitative research, and whether ANT allows qualitative inquiry to be thought of as "scientific" (Section 1). It then explains the methodological choices made before fieldwork itself was started that narrowed down the focus of this research to an understanding of TRIPS and pharmaceutical patents in Djibouti (Section 2). The practical process of data collection is then considered (Section 3). Ethics are briefly addressed (Section 4). The approach to data-analysis is explained (Section 5). Finally, the practical steps taken to increase the validity of this research project are presented (Section 6).

SECTION 1: HOW TO BE A "CONSTRUCTIVIST" AND A "SCIENTIST"?

Before discussing the methods used in this research, and how they are aimed at increasing the validity of the claims put forward, it is essential to reflect on the way some aspects of ANT could recall challenges brought to the idea that qualitative research can be located within scientific practices. The "constructivist" perspective of ANT, in particular, and the emphasis of some ANT authors on the performativity of research methods, are two related elements that raise issues in relation to the potentiality for a scientific approach in empirical research. These issues are rooted in deeper debates about qualitative research, in which notions of truth and validity have been intensively discussed. This section will start by looking at these broader debates before returning to the specificities of ANT, the positions put forward by ANT authors, and how the potential conflict between constructivist perspectives and the notion of validity in empirical research have been addressed in this project.

Deciding whether the validity of empirical accounts is something that can be tested depends on the position adopted on the way "accounts" and "reality" are linked. This chapter considers later how validity can be tested; it first needs to discuss if it can. Whether qualitative research can claim to be scientific depends on whether one accepts that accounts can tend towards objectively presenting a world "out there", or whether the accounts will only result in the

description of a particular subjective artifact. Although the idea that accounts largely participate in generating realities has been widely accepted in qualitative research, researchers have disagreed on the consequences that should be drawn from this idea in relation to the potential links between qualitative research and validity. Some qualitative researchers ("relativists"), in particular, have argued that since all empirical research will produce subjective accounts, and since the world is only made through subjective accounts, these can only be understood as equally "true". The consequence of this position in terms of methods and validity of research processes can be easily deduced - if any story is equally valid, research cannot be ranked and no data can be considered as more scientific than other…[209] It is useful here to provide some explanation of this approach, in order to clarify how ANT could be thought of as related to some of its ideas. However, this first impression will be dismissed in the following discussion.

The idea that descriptions and social inquiry participate in shaping realities is not new[210]. In particular, it is the necessary consequence of the idea that society partly results from human understanding, and therefore is dependent on the observers' views and perspectives. The direct consequence is that subjectivity becomes central and unavoidable in empirical research – the story being told is fully framed by the interpretation given by each particular researcher, and is therefore no more – but no less either – than one particular social reality. In

[209] For a clear introduction to this relativist position, see Murphy E. and Dingwall R. (2003), Qualitative Methods and Health Policy, New York: Aldine de Gruyter.

[210] Its roots have been retraced to Dilthey and Weber – for details see Smith J. K. (1984) "The Problem of Criteria for Judging Interpretive Inquiry", Educational Evaluation and Policy Analysis 6(4) pp. 379-391.

terms of methods, however, the consequence of such a perspective can be radical. In particular, if accepting that sociological enquiry is the result of a subjective understanding of reality, and can never be anything else than a particular perspective, the positivist idea that social science can develop criteria for validity is challenged. Since any interpretation is equally true, there is no external, "superior" way of checking the validity of any specific finding. Some authors have tried to find a balance between relativist claims and a search for methodological rigour in arguing a relativist philosophy while seeking to establish some new and indirect methods of checking the validity of research projects[211]. However, when looking more closely into these arguments, it soon appears that there is no way to conciliate between radical claims on the subjective nature of the social and positivist-inspired strategies to establish an objective "validity"[212]. The only conclusion that can logically be drawn from relativist perceptions of the social as emerging from specific perspectives is that there can be no criteria to judge externally the validity of specific findings, because any finding can be justified as a subjective perception as equally truthful as any other[213].

[211] For example Guba E. (1981) "Criteria for Assessing the Trustworthiness of Naturalistic Inquiry in Educational Evaluation", Educational Communication and Technology Journal (29) 75-91.

[212] For further details, see Smith J. K. (1984) op. cit. or Schwandt T.A. (1994) "Constructivist, Interpretivist Approaches to Human Inquiry", in Denzin N. K. and Lincoln Y. S. (eds), Handbook of Qualitative Research, Thousand Oaks CA: Sage publications, pp. 118-137.

[213] With potentially the exception of informants' checks – see Guba E. and Lincoln Y. (1994) "Competing Paradigms in Qualitative Research", in Denzin and Lincoln (eds), Handbook of Qualitative Research, Thousand Oaks CA: Sage publications, pp. 105-118, although this does not go without its own difficulties (see Smith J. K. (1984)).

This form of radical thinking challenges the idea that sociological research can be carried out as "science", and has therefore been contested within the qualitative field[214]. Before seeing how this position and the dilemmas it raises have been answered in qualitative research, I discuss whether the positions put forward in ANT on the notions of truth and reality can relate it to some of the ideas presented above. This will be considered first by discussing the concept of "construction" in ANT, and emphasising why it can be misleading.

"Construction" of social facts

ANT is often presented as "constructionist". Although the term is put forward by ANT authors themselves, the meaning to be attached to the notion needs in this specific context to be fully understood. It is essential to avoid drawing premature conclusions on the implications of the use of this term in ANT for the understanding of "reality" it offers. In particular, the contrast between the notion of "construction" in ANT and its more general understandings in social sciences needs to be understood[215]. In ANT, the world is created – "constructed" – through the circulation of associations and the fluid movement of connections. Any object, any fact, any occurrence, is "generated" somewhere else, made through associations happening in some other place, at

[214] For further detail on the challenge brought by relativism to positivist approaches to sociology, see for example Altheide D. and Johnson J. (1994) "Criteria for Assessing Interpretive Validity in Qualitative Research", Denzin N. K. and Lincoln Y. S. (eds) Handbook of Qualitative Research, Thousand Oaks CA: Sage publications, pp. 485-499.

[215] For an example of the links drawn between relativism and the notion of "construction" in sociology, see for example Guba E. and Lincoln Y. (1994) op. cit, and Schwandt T.A. (1994) op. cit.

some other time. In this perspective, the role of a sociologist is to understand what has made their object of study. This understanding of construction does not imply that the world does not exist independently of accounts – it only implies that entities never exist independently from others – and the constructionist views of ANT should not be taken to represent a theory of truth. The contrast between the two competing meanings of the term in ANT and in other fields of sociology is put forward by Latour in these terms:

"… for other colleagues in the social as well as natural sciences the word construction meant something entirely different from what common sense had *thought until then. To say something was "constructed" in their minds meant* that something was not true. They seemed to operate with the strange idea that you had to submit to this rather unlikely choice: either something was real and not constructed, or it was constructed and artificial, contrived and invented, *made up and false. (…) When we say that a fact is constructed,* we simply mean that we account for the solid objective reality by mobilizing various entities whose assemblage could fail."[216]

Thus, the emphasis of ANT on the idea that any object of study is the result of something else, some other action, some other association, is fundamentally different from the idea that these same objects of study are not real. The constructivist views of ANT do not challenge the notion of truth but the notion of stability. It does not imply that there is no reality outside of accounts, and therefore does not require the "scientific project" to be dropped. However,

[216] Latour B. (2005) Reassembling the Social: an Introduction to Actor-network Theory, Oxford: Oxford University Press, on p. 90.

neither does it either reject the idea that accounts can play a part in shaping certain orderings.

Texts and representations of reality

In particular, although it accepts that there is something real out there, some connections that might be identified and reflect something that really is, ANT raises issues as to the extent to which this reality might be reflected faithfully – without transformation - in research and in texts. It emphasises the idea, in particular, that although a real world pre-exists/co-exists with research, any translation of an object of study will necessarily transform it. "Traduction is always trahison"[217], and any transfer of a phenomenon to paper will necessarily generate a particular version of this phenomenon. The consequences of this trahison are not neutral, because it results itself in a new version of reality – and the performance of a new reality: "Social inquiry and its methods are productive: they (help to) make social realities and social *worlds. They do not simply describe the world as it is, but also enact it"*[218] . The compatibility of this approach with the earlier discussion of constructivism can now be clarified . How can ANT claim that it wishes to steer away from social constructivism while stating that realities are re-constructed in the process of social research? The answer to this question has already been

[217] Law. J. (1997) "Traduction/Trahison: Notes on ANT", published by the Centre for Science Studies, Lancaster University, Lancaster LA14YN, UK http://www.comp.lancs.ac.uk/sociology/stslaw2.html

[218] Law J. and Urry J. (2002) "Enacting the Social", published by the department of Sociology and the Centre for Science Studies, Lancaster University LA14YN, UK, at http://www.lancs.ac.uk/fss/sociology/papers/law-urry-enacting-the-social.pdf , on p. 1

anticipated above - the idea of performativity of research does not imply that anything can be "made up", neither does it claim that facts do not exist independently from research – or objectively. What it implies is that some elements of the realities – of the many co-existing and multiple realities of the social – will be re-ordered in the process of telling any story, producing any data[219]. At the same time some concepts, even some facts, will only become real after social scientists have performed them.

But not everything can be performed by social research – indeed this is the main difference between relativist accounts and the approach adopted in ANT. As much as research is constrained by the researcher's situation, and as much as researchers are limited by what social science allows them to do, see and describe, social scientists are also limited in what they can perform by the "world out there", by facts that will oppose some form of resistance. This means that social scientists cannot perform any reality they choose, and that stories will not have the same validity[220]. ANT accepts that a world exists independently of social research – facts exist, although their stability is challenged more often than assumed. It is only by understanding how they are constructed (how they are created) by circulations and connections that they can be fully understood. However, the fact of telling a story itself, of providing one version of facts, necessarily limited and necessarily unfaithful, will produce a new form of reality – it will perform a new reality, within the

[219] John Law provides some examples of this in Law J. (2003) "Making a Mess with Method", published by the Centre for Science Studies, Lancaster University, at http://www.comp.lancs.ac.uk/sociology/papers/law-making-a-mess-with-methods.pdf

[220] And it is already possible to relate the ideas put forward in Murphy E.and Dingwall R. (2003) op. cit. when criticising relativism (p.12).

possibilities created by the social as circulation. The impact of the research process, and of the material creation of texts, should not, however, mean that qualitative research should drop its quest for scientific rigour:

"Since we are all aware that fabrication and artificiality are not the opposite of truth and objectivity, we have no hesitation in highlighting the text itself as a *mediator. But for this very same reason, we don't have to abandon the* traditional goal of reaching objectivity simply because we consider with great care the heavy textual machinery. Our texts, like those of our fellow scientists, *run the parallel course of being artificial and accurate."*[221]

Therefore, the search for truth does not need to be dropped. It should still remain an ultimate aim, although unavoidable constraints might always prevent us from representing a complete view of reality.

Before discussing how specific methods fit with these attempts to describe realities, one last element needs to be considered, as it emphasises more specifically the constraints within which academic projects need to remain located. When presenting the common aspects of realities performed by sociological research, and although the diversity of methods imposes limits to any generalisation, Law puts forward the idea that, in the current context of academic research, the inherent messiness of the social world, the result and expression of its complexity, tends to be othered by the reign of "order"[222].

[221] Latour B. (2005) Reassembling the Social: an Introduction to Actor-network Theory, op. cit. p. 124.

[222] Law J. (2003) "Making a Mess with Method", op. cit.

One of the most central "trahisons" committed by researchers, and one of the most difficult to avoid in the current context of academic research, is to try to fit the social world in categories, order and simplified stories. The necessity to "make" a story readable, within a limited amount of space and time, certainly limits the ways the social can be portrayed. This should be kept in mind as the approach chosen in this research is explained, and as the need to combine flexibility and rigour in empirical research is put forward.

Balancing flexibility and rigour

The position taken in this project is that there is nothing incompatible between the perception of the social put forward by ANT and the location of social research in scientific practice. Indeed, ANT not only argues for rigorous (although flexible) research methods but in fact implies their necessity. Constructed facts and objects – in the ANT common-sense inspired understanding of construction – exist, and limit researchers in what they can claim to be valid in observing the social world. The messiness of the social world might call for a limit to order and categorising in the writing process of academic research, but should in no case justify a lack of rigour in methods for data collection and analysis. In fact, the complexity of the social and its inherent instability, and the need to remain close to connections without adding unjustified and pre-determined ideas as to what directs the social (as already explained in Chapter 2) also mean that methods need to be adapted to this new version of sociology. The answer provided in ANT seems simple but calls for

precisions and explanations that will be offered throughout this chapter on what needs to be done in practice: "*follow the actors themselves!*"[223].

The position taken in this research is, once again, that this can only be done by adopting a scientific and carefully described process of data-collection. The difficulties of "following the actors" while undoing relevant networks will be emphasised throughout this project, and discussed critically in the conclusion. Some aspects of the potential difficulties raised, however, need to be discussed at this stage, relating to the difficulty of writing complete and faithful ANT accounts mentioned before. In that respect, it is essential to emphasise how far it is possible/feasible to follow the "ANT programme" as far as it goes without having to be restrained by the necessity of academic outputs. One of the claims of ANT is that objects are always and only the result of complex sets of associations and circulation. These make their stability constantly likely to be challenged. A direct consequence of this idea is that there is always more to a particular object than what can be directly perceived. However, the boundaries set by academic conventions involve limits to how far an analysis can be developed. Although each object considered throughout this analysis contains more than one could expect, emphasising in detail the associations that make it would require more space and time than is allowed by academic requirements. In addition to this, there will necessarily be some limits set by the need to make a narrative readable. Terms will need to be used, some of which might temporarily obscure the complexity of a particular object of study. ANT sets significant intellectual and theoretical challenges. Furthermore, it

[223] See Latour B. (2005) Reassembling the Social: an Introduction to Actor-network Theory, op. cit.

acknowledges the necessity to combine intellectual/theoretical debates with practical issues. In particular, as will become apparent, some limits must be set to the amount of detail and explanation that can be provided. Some terms will be used in a punctualised fashion before their full complexity is unravelled. This process does not need, however, to be totally arbitrary – and one solution for this is to follow once more the advice put forward by Bruno Latour that research should follow the actors.

At times throughout empirical research, some objects are understood as stable by actors themselves. Their complexity is left aside in the routines of those being studied. While the purpose of this particular research is to understand the complexity of TRIPS and pharmaceutical patents, other objects will necessarily be considered. They will be looked at in detail in relation to the connections that make them relevant to TRIPS. However, some of their dimensions will be left un-investigated. Essentially because they are taken as stable by those who deal with them and are being studied, and practically because the focus of this analysis needs to be maintained on what is relevant to understanding TRIPS and pharmaceutical patents.

This section has started by relating the issue of truth and validity to wider debates from qualitative research. It has then jumped into the specific, into the vision of reality put forward by ANT, and demonstrated that it should not be confused with the relativist argument that validity loses meaning in the face of "construction" – and this depended on diverging understandings of the notion of construction itself. It is interesting, however, to return now to qualitative

research more generally, and to observe how while moving away from relativism, the position on validity adopted in this research within the ideas of ANT can in fact be related to the same perspectives that responded to relativism:

*"Subtle realists accept that everything can be represented fro*m a range of *different perspectives, through different "cultural-biological lenses". Several* representations may coexist and be potentially true. Unlike the relativist, however, the subtle realist does not assume that all representations are equally valid. *(...) Science, in this view, is a procedural commitment."*[224]

Because of its emphasis on the complexity of the social and the need to provide a story as told by those living it, without undue simplification, and while limiting othering, ANT has traditionally been associated with ethnographic methods. The links between both have appeared clearly throughout Chapter 2, and will be re-emphasised in this chapter. This particular approach provides significant opportunities for integrating fluidity and complexity in telling a process as lived and expressed by the network under scrutiny. This chapter will explain how every significant methodological choice was made in this project, and how the data on which it is relying has been collected. Although this research does not claim to avoid the range of limitations that are associated with any attempt to present a part of the social world, this chapter aims to provide enough information and reflection on the choices made and their

[224] Murphy E. and Dingwall R. (2003), op. cit. on p.13.

consequences to offer readers the elements that need to be grasped in order to locate and understand this story.

SECTION 2: NARROWING DOWN THE FOCUS OF ANALYSIS

The first aspect of the methodology chosen in this project that needs to be explained relates to the way this research was narrowed down to the study of TRIPS and pharmaceutical patents in Djibouti. This section discusses the choice of using a case study for analysing both types of legal instruments, and explains how the example of Djibouti was chosen[225]. It emphasises in particular how this choice was linked to theoretical issues, and to some of the ideas put forward in ANT. It reinforces the fact that the definition of the specific focus of this research and the clarification of the approach chosen were shaped progressively and in parallel, rather than in a definite chronological order.

This research has been aimed from its start at providing a story of TRIPS and pharmaceutical patents and of their links to health in poor countries.

One of the first methodological choices to be made was therefore to decide which type of story should be told. When working in the area of IP and health, options are diverse. As explained in Chapter 2, the theoretical view adopted in

[225] For a definition of case studies, see Hammersley M. (1992) "So, what are case studies?", in Hammersley M. *What's* Wrong with Ethnography, Methodological Explorations, London: Routledge, pp. 183-200; Ragin C. and Becker H. (eds) (1992) What is a case? Exploring the Foundations of Social Inquiry, Cambridge: Cambridge University Press.

this project emphasises the need to study and understand transnational events by looking at their localized manifestations, before discussing how these relate to longer networked effects[226]. This explains why choosing a case study based analysis "worked" in relation to ANT.

However it is difficult to explain whether ANT participated in the original choice of working on a case study or not. It is of course a complex task to reflect back on how methods and perspective came into being, and in particular whether the approach or the methods came first – as far as the choice of a case study was made. In particular, while a case-study based project appeared as the best choice to analyse TRIPS and pharmaceutical patents from an ANT perspective, it can also be said that ANT appeared as the most appropriate method to study TRIPS and pharmaceutical patents on the ground in a particular networked system. It is fair to say that the choices and strategies developed below came into shape while the approach to be chosen was still being explored. In addition to this, it is also certain that ANT was "chosen" only as far as it best represented some of my own understandings of the aim of research, and formulated in an articulate way some elements that fit more broadly with my own perceptions. Overall, what needs to be demonstrated is

[226] See for example Law J. (1999) "Materialities, Spatialities, Globalities", published by the Centre for Science Studies, Lancaster University, LA14YN, UK, at http//www.comp.lancs.ac.uk/sociology/soc029jl.html, and Law J. (2003) "And if the Global were Small and Non-Coherent? Method, Complexity and the Baroque", published by the Centre for Science Studies, Lancaster University, LA14YL, UK, at http/www.comp.lancs.ac.uk/sociology/papers/law-and-if-the-global-were-small.pdf See also the discussion of this issue in Chapter 2 pp. 13-14.

that this particular approach appeared to fit the system under scrutiny particularly well.

Although they have at times been criticised for lack of generalisability, case studies are often valued and perceived as a necessary and useful way to study specific issues. The potential relevance of case studies can be based on several elements[227]. First, in many cases, the interest of case studies is essentially intrinsic – they are interesting because the story they tell is useful in their own right. They do not necessarily have to make a broader point to be pertinent. Without being symbolic of a particular issue, and without being a particular example of a widely spread situation, some case studies will therefore successfully provide an example of particularity, and will be relevant for their uniqueness[228]. Second, particular stories can be useful for what they tell about a broader phenomenon – their role runs further than the particular story told, and is a specific step in understanding a range of events or situations[229]. Finally, the relevance of case studies can come from what they tell about a particular theory or method.[230] In many cases, however, the relevance of a given case

[227] See for example the classifications provided by Stake R. (1994) "Case Studies", in Denzin N and Lincoln Y eds, The Handbook of Qualitative Research, Thousand Oaks: Sage Publications, pp. 236-247 and Hammersley M. (1992) "The Generalizability of Ethnography" in Hammersley M. *What's wrong with ethnography*, London: Routledge, pp. 85-95.

[228] "It is not undertaken primarily because the case represents other cases or because it illustrates a particular trait or problem, but because in all its particularities **and** ordariness, *this case itself is of interest."* Stake R. (1994) op. cit., on p. 237.

[229] "The case is of secondary interest, it plays a supportive role, and it facilitates our understanding of something else." Stake R. (1994) op. cit., on p. 237. See also the classification offered by Hammersley M. (1992) "So, What are Case Studies?", op. cit.

[230] On the generalisability of case studies, Hammersley states: "It may be claimed that the particular setting investigated is typical of some larger whole or aggregate" and "The second

study will borrow from several elements – and will often depend as much on what the reader is looking for as on what the researcher has wanted to emphasise.

The approach called for by ANT and adopted throughout this research emphasises the relevance – and necessity – of particular studies in their own rights. In fact, it emphasises the conceptual difficulties of studies that claim to be representative, and highlights the specificity and uniqueness of any particular network, any given story. The mobility and diversity of social orderings makes generalisability itself an elusive concept, and one that should not become unnecessarily central in empirical research[231]. The study presented in this research does not claim to be generalisable or representative – it is not a story about least developed countries and their relation to TRIPS, but a study about TRIPS and pharmaceutical patents in a specific least developed state. However, it is not an isolated study and finds some of its relevance by opposition to existing research. The value of this project is in fact partly to demonstrate why those existing studies that claim to talk about IP and health in developing countries are losing part of their own value by doing so, and put forward claims and generalisations that cannot be sustained by their findings. Therefore, in addition to being relevant for the story it tells about TRIPS and pharmaceutical patents in Djibouti, this case study can be perceived as a

---

and quite different way that ethnographers may seek to give their work general relevance is by drawing conclusions about one or more social scientific theories from the features of the local events they observe and describe", in Hammersley M. (1998) "The Generalisability of Ethnography" op. cit. p. 86 and p. 91.

[231] See for example Latour B. (2005) Reassembling the Social: an Introduction to Actor-network Theory op. cit in Chapter 2.

counter example to most existing research in the field. Finally, this research aims to provide an illustration of ANT as a tool for socio-legal research and some of the methods and concepts used in this project are believed to be of relevance for other projects. The justifications for choosing Djibouti as a particular case study now need to be discussed in order to understand how this aim to provide a "counter example" was filled.

Why Djibouti?

Selecting a basis from which to explore the story of TRIPS, pharmaceutical patents and health represented the second methodological step in organising this research. The choice of working on Djibouti as a particular case study was based on a number of elements, and essentially on the remaining gaps left by existing literature – and in particular by the lack of research on the smallest, poorest countries. The decision to look at a least developed state was essentially made as a way to look for difference, by looking at a network fundamentally different from what has been looked at in existing research, and observing the comparability of findings.

When choosing which state in particular to concentrate on, Djibouti appeared as a strong option for several reasons, both practical – it had to be feasible to collect data in the country chosen - and theoretical – as far as possible, the case study had to be chosen so that it added something new to existing research.

Practical elements considered were both specific to research in a small least developed state, and common to what is generally looked at when settling on a particular case study. The questions specific to the problems raised by collecting data in a least developed state could be related to the fact that the country chosen would by definition have poor infrastructures in terms of communications and transport. It was necessary to choose a country in which actors to be met could be centralised enough for these issues not to become a real hindrance to data collection. Safety issues also had to be considered, and in particular, the political situation of many least developed countries makes fieldwork locally unsafe or uncertain. Language was an issue that needed to be taken into account too, and it had to be certain that all relevant actors could be approached in a language that I could speak. Finally, if considering a country on which very little has been written – in terms of academic literature but also institutional reports etc, as is the case for most least developed states – it was absolutely crucial to ensure that opportunities for fieldwork would not turn out to be too limited, and a possibility to have reliable contacts at an early stage appeared essential.

In response to all of these elements, the situation of Djibouti appeared as highly positive and made it one of the few possible options considered. Djibouti is a French-speaking country. Although several official languages co-exist, almost every relevant actor could be approached in French, and most of those living in the capital city speak French fluently. Similarly, all policy and legal documents are produced in French (and Arabic). The country enjoys a relatively safe and

stable situation as compared to many other least developed countries[232], and carrying out fieldwork there did not present any particular risk. It is also a small country, in which the difficulties of using public transport are only an issue when travelling to the most remote areas. All relevant institutions and a large majority of the population are based in the capital city, where places are close enough to one another to travel without difficulty[233]. Contacts could be made in relevant fields at an early stage with key actors, and a pilot study followed by email contacts proved that they would be willing to participate in further research, and help me obtain access to other relevant people. In addition they proved willing to provide access to important documents. This will be developed below. Finally, Djibouti is a country in which I had spent time before undertaking this research, which I felt would be a strong advantage when trying to fit within local practices and culture.

However, in addition to these practical considerations, more theoretical elements came into play when choosing this case study, and were determinant. Once again, the idea behind investigating one small least developed country was essentially to provide a useful complement to what had been written so far, and to consider to what extent the generalizations made in existing literature could be challenged by a counter-example. In many respects, the situation of Djibouti soon appeared as a very good example of a country in a fundamentally different situation from that of the other states on which research has been

[232] At least this has been the case since the end of the civil war, as mentioned in Chapter 4.

[233] More information will be provided on Djibouti in Chapter 4, and the information given here is only that necessary to understanding how this case study was chosen.

carried out. The first, and potentially the most relevant, of these elements of difference relates to the IP situation of Djibouti. Djibouti is one of the few states that have never implemented any effective type of IP system, and never adopted any type of patent law. While in most of the countries studied so far it has been a rational policy choice to exclude pharmaceuticals from the patentability field, in the case of Djibouti patents are just legally non-existent. The implementation of TRIPS is thus likely to raise issues fundamentally different from those discussed so far. Djibouti faces a public health situation as critical as that of most Sub-Saharan African countries, as appeared from the first phase of empirical research described below. It has a very weak industrial base, and no pharmaceutical industry at this stage, which means that the role of pharmaceutical patents in the development process of the local industry is unlikely to be an immediate issue for policy makers. All these different elements made the example of Djibouti one of the most relevant that could be isolated from background research, and also one of the most feasible[234].

One issue that might be raised, however, is the idea that Djibouti as a state is taken as the central unit of analysis. In particular, as was explained in Chapter 2, if wanting to work within ANT, and accepting that the world is fully constituted of overlapping networks, territorial classifications appear highly irrelevant[235]. To that extent, it could be argued that a state-based case study is inappropriate in relation to the theoretical framework undertaken. It sounds artificial to suppose that the territorial borders of Djibouti could coincide with

[234] And once again, each of these elements will be introduced in more details in Chapter 4.

[235] See for example Law J. "Materialities, Spatialities, Globalities" op. cit. and the discussion provided in Chapter 2 on Space and ANT.

any kind of end to relevant networks and this assumption could present the risk of buying into one of the key performative aspects of research methods currently used[236]. However, the specific choice of a state based approach can be justified with regard to the area analysed in this research, and does not have to be understood as strictly limitative. This analysis is focused on the impact of TRIPS on the public health system of Djibouti. As the text will be implemented at national level, by national institutions, it is useful to use as a starting point the networks created by and including these institutions. However, the focus of this analysis will extend beyond and within state institutions, and will consider how the ramifications of TRIPS can be felt in Djibouti – including ramification and effects originating in other loci.

SECTION 3: METHODS FOR DATA COLLECTION

The data collected in this project was gathered essentially from in-depth interviews, although observation and document analysis were also used within the practical limits set by this case study. Although ethnography has traditionally adopted observation as its most symbolic and primary method of data collection – and although observation is essential to the claims of ANT – interviews appeared as the method that could be most systematically used in this project, and from which most data could be derived. This related both to the object of analysis itself and to the fact that one of the difficulties to be

[236] *"Thus the modern notion of "society" grew up within the sociologies which emerged in the* era of *European nationalism. The "natural" unit for sociology was, indeed, "society" and society itself "naturally" mapped onto the bounded region of the nation state*" in Law J. and Urry J. (2002) "Enacting the Social" op. cit. on p. 7.

solved was the "multi-sited" dimension of this project, and the fact that those to be considered were located in many different settings. The need to follow networks and connections through these different settings made it particularly crucial to adopt throughout this project methods that would be reflexive and flexible but rigorous.

1. Pilot study

The empirical part of this project started with a short pilot study carried out in Djibouti in April 2003. The aim of this pilot study was to determine whether or not field research would be feasible in Djibouti and, in particular, whether access could be negotiated with key actors. As the aim of the research was to observe the manifestations of TRIPS and pharmaceutical patents in relation to health as widely as possible, a flexible and extensive sample needed to be accessed. In addition to this, it was directed at evaluating whether the situation of Djibouti was likely to raise enough substantive issues to be used as a main case study.

This pilot study was carried out by interviewing some of the key actors working on health or on the import of pharmaceuticals in the country. Interview schedules were flexible enough to leave informants free to raise what they thought were the key issues in the country in relation to TRIPS and pharmaceutical patents. Broadly speaking, they brought interviewees to discuss their understanding of TRIPS (whether informants knew about TRIPS, and what they knew; how they thought it was likely to affect Djibouti) issues of

public health (what are the main public health issues facing Djibouti? Is access to medication an issue, and why?) and some more general questions on the political and economic situation of the country. At that stage, six key actors were met, and issues of access to other potential informants were also discussed in detail.

Two crucial points came out from this first contact with the network to be studied. First, it appeared clear that access would not cause difficulties. The informants met were all high ranking officials, who were happy to give me access to their institution and to assist me in identifying and meeting other relevant actors. Second, the issues raised during interviews were fundamentally different from what is often discussed in existing literature in relation to TRIPS, pharmaceutical patents and access to medicines. It became clearer that many elements, if studied and analysed in depth, would provide a highly relevant complement to existing research. In particular, the reaction of all informants to TRIPS was essentially one of indifference, and of doubts as to whether or not it would mean anything to Djibouti. The fact that the public health situation of the country was very different from that of larger and more industrialised developing countries was also raised by several informants. Similarly, the lack of meaning of patent policies for those involved in the industry was emphasised by all informants aware of the local situation in relation to the pharmaceutical industry – or rather in relation to the attempt to start a basic form of industry.

Broadly, informants emphasised that the situation in Djibouti was not what is often expected from "developing countries". This latter point was essential in convincing me that this was an interesting case study to undertake. It was likely to challenge many of the assumptions that are often constructed in relation to what "health" and "law" are about in Africa. This particular example, and the fact that it was probably "not representative" was considered useful to highlight a need for challenges in a field highly dominated by a few examples, and for the emphasis on diversity as part of understanding law – and health – in Africa[237].

2. Main period of data collection

The main period of data collection took place from January to May 2004. It mainly involved in-depth interviews, although detailed fieldnotes based on observation were taken during the course of this research and used widely in understanding the data collected. Documents were also used to support and complement some specific ideas. This section will explain the process of data collection adopted in this project, and emphasise in particular how the reflexive dimension of this fieldwork was essential to follow the key ideas of ANT. Although some aspects of in-depth interviews and observation are fundamentally different, the boundaries between both approaches are sometimes difficult to draw and both strategies can overlap in some of their aspects. This section addresses a number of issues common to all aspects of

[237] This can be related more generally to the limits of the existing field covered in academic research on law in Africa – and in particular the rarity of examples of French-speaking African countries in existing research.

data-collection – such as sampling and note-taking – it will also present elements specific to each strategy. The meaning of using multiple methods of data collection needs to be addressed. This will be done in section 6, when explaining why, although considered as essential to the completeness of the story provided, it was not used as a way to increase validity through what is often described as "triangulation".

Sampling and access

A first element to address in relation to both interviews and observation is the issue of sampling and access, and the associated question of the exact focus of data-collection. In this particular project, both elements were facilitated by the characteristics of the country. First, the issue of "representativity" that researchers often have to deal with was not a consideration in this project, since the small size of the country made it possible to meet virtually every actor directly concerned with pharmaceutical patents in one way or another, as the range of actors involved with the government or with health and industrial structures is very limited[238]. In addition to this, access was facilitated by the informal, "laid-back" atmosphere that dominated in most of the settings visited. This meant that actors were particularly helpful in introducing me to different people to whom I wanted to speak. It became was similarly easy to knock on a person's door at any time once I had become a "familiar" figure in the settings

[238] Although representativity is a more central issue in quantitative research, it arises in many qualitative projects involving a large number of potential informants.

considered[239]. Another consequence of this atmosphere was the fact that actors never seemed to be working to a tight schedule, and were very happy to take their time and talk for as long as necessary, as often as necessary. This allowed me to meet most actors several times, in different settings, and to discuss different issues in a different format. This allowed for the addition of an interactive dimension to the research. Issues that appeared throughout the course of data collection could be addressed with actors with whom they had not been discussed before.

In terms of identifying the actors that I wanted to interview, the process was progressive, and took place on the ground, by slowly mapping out the range of relevant institutions, and those in charge of particular issues in each institution. This was considered crucial in order to translate into practice the idea that "relevant actors" should not be pre-determined, and should be empirically considered. Actors involved in this project were identified both by finding out information on different people's role and by them contacting me spontaneously. In addition to this, many informants provided me with contact details of other actors they believed to be relevant to the focus of my research, and the "snowball" strategy often used in field research was important here. Overall, this project started by analysing as broadly as possible the different networks in which TRIPS and pharmaceutical patents have been enrolled in Djibouti – and the networks in which they could be expected to have been

[239] One actor thus told me by email before I started my fieldwork: "*There is nothing to worry about, Djibouti is not like France and we know each other very well. There are no formalities as such. I am in a position to introduce you with all these others you would like to meet.*"

enrolled on the basis of existing literature. Within each network, actors were interviewed or observed, and their respective role was then questioned on the basis of informants' understanding of the role of TRIPS and pharmaceutical patents, and of additional observations[240].

The key question in relation to sampling, however, was to determine the starting point – which networks should be considered as "relevant"? This had to depend on the specific aims of this research. Once again, this research aims to understand what TRIPS and pharmaceutical patents are in Djibouti. It explains throughout how both objects have become enrolled into different networks, and how their nature, modes of actions and mechanisms can be understood differently if looking at them from these different viewpoints. Following the pilot study described above, it became clear that the shape of public health, import, and trade and industry networks, as well as some local understandings of specific concepts were all elements that could impact on the role and mechanisms of both objects in the country, and needed further in-depth investigation. In relation to the specific sample chosen for interviews - and observational data - the focus of analysis can be divided into two main areas, for the purpose of this particular chapter.

First, the public health network and pharmaceutical import system of Djibouti have been looked at – and through them each of the different components and

[240] It is interesting here to refer to the strategy of "following the metaphor" presented by Maskus when dealing with ethnography in multiple settings, in Maskus G. (1998), "Ethnography in/of the World System", in Ethnography through Thick and Thin, Princeton University Press: Princeton.

relevant actor-networks that constitute the larger health network of which Djibouti is part. Throughout empirical research, the focus of analysis has shifted and refocused to integrate new and relevant connections. Informants from the public health area interviewed included doctors from each of the main hospital structures described in Chapter 4, pharmacists – private pharmacists, hospital pharmacists and those in charge of the new "Central d'Achats" - several actors from the Ministry of Health and representatives of the WHO. Those related to the attempts to build a local pharmaceutical industry were also met. In the course of the research, some international NGOs were approached, although none of their action was directly relevant to Djibouti and representatives were therefore not met in person. Second, the intellectual property and trade network of Djibouti, and in particular those elements that were expected to participate in the integration of TRIPS in Djibouti, was studied. Similarly, the identification of relevant actors was done in several steps, by following connections and new links that were highlighted throughout. It will be explained in Chapter 5 that the process of identification of relevant actors was made more difficult when working "across fields" – ie: when moving from the public health field to the trade networks. However, as this issue became in itself a central part of the data to be analysed, it was felt more appropriate to provide full explanation of this element when analysing the data collected. In the trade network, informants were met in the Ministry of Trade and Industry, the Chambre du Commerce et de l'Industrie, and included various actors who had been in the past involved in some decisions related to intellectual property issues.

Finally, in the course of this research a number of additional people asked to meet me and give me their opinion on issues that were not always related to my specific area of research – these were essentially lawyers, researchers and members or ex-members of the government. I met each of these actors, for several reasons. First, it would have been perceived as very inconsiderate to refuse a meeting with high-ranking individuals – especially because these meetings were offered both as a friendly favour and as a "social honour". Second, I considered these further meetings to be interesting additional data on the way politics and law work generally in Djibouti – something that could not be clarified on the basis of any type of background research and was highly relevant to some aspects of my research[241]. Data from each of these meetings was transcribed and kept exactly in the same way as meetings I had organised, as will be developed below.

In-depth interviews as ethnographic data

This section will explain how interviews were used in this project. Although interviews have been criticised as a method of data collection for several reasons, as will be explained later, it appeared to be the most feasible approach

[241] It is crucial for researchers to be aware of the potential bias introduced by involving many "spontaneous" informants, as these are likely to represent a specific and defined set of examples from a wider social group. However, this data was mainly complementary in this research, and the sample from which findings were derived was determined by the strategies described above, apart from one informant from whom on quote was borrowed. To that extent, the potential bias has been kept to a minimum. For comments on this issue, see Hammersley M. and Atkinson P. (1996) "Insider Account: Listening and Asking Questions", in Hammersley M. and Atkinson P., Ethnography: Principles in Practice, London: Routledge, pp.124- 156 (in particular p. 134-135).

to empirical research in this project. This was essentially linked to the fact that data needed to be gathered from a range of settings, and could not therefore be observed from a single location. In addition to this, the type of data to be collected itself could sometimes be accessed only through informants' perspectives – largely because a wide part of this data was about informants' perspectives and understandings of TRIPS and pharmaceutical patents. However, once again, the distinction between interviews and observation cannot be clearcut. Observational data was collected during interviews, and that actors' perspectives were discussed outside of strictly defined "interview sessions".

"Interviews in ethnographic research range from spontaneous, informal conversations in places that are being used for other purposes to formally arranged meetings in bounded settings out of earshot of other people."[242]

This citation summarises the range of situations that should be included and considered when discussing the way interviews were carried out in this research. Interviews have traditionally been regarded as taking a range of formats, from structured lists of questions to broadly guided discussions on a particular topic[243]. In this research, the approach taken was aimed at balancing

[242] Hammersley M. and Atkison P. (1996) "Insider account: listening and asking questions"., op. cit. on p.139.

[243] Kvale S. (1996) Interviews, London: Sage; Fontana A. and Frey J. H. (1998) "Interviewing: The art of science", in Denzin and Lincoln, (eds) Collecting and Interpreting Qualitative Materials, Thousand Oaks: Sage publication, pp. 47-78.; Gorden R. L.(1980) Interviewing: Strategy, techniques and tactics, Doresey: Homewood; Maccoby E. E. and Maccoby N. (1954) "The Interview: a Tool of Social Sciences", in Lindzey G. (ed) Handbook of Social

the requirements to remain focused around a particular theme against the need to allow actors to discuss their own story without being limited by a pre-defined list of questions. Overall, interviews were mainly carried out in a "conversational way". This was based both on the theoretical views put forward in this research that researchers should avoid "adding" to the setting as much as feasible, and on the need to provide opportunities for reflexive questioning, as well as on the social environment in which I was working. Although a broad interview schedule was created for each particular meeting, it was used more as general guidance than as a strict list of questions to be asked. Other than this common characteristic, interviews carried out in this project involved varied circumstances, ranging from brief conversations in informal settings to lengthy discussions in informants' offices. In addition, and as mentioned, most informants were in fact met several times[244], and themes were discussed in a range of settings and environments. Overall, the interview process in this project involved the main characteristics that often illustrate ethnographic interviewing.

"Ethnographers do not usually decide beforehand the exact questions they want to ask, and do not ask each interviewee exactly the same questions, though they will usually enter the interviews with a list of issues to be covered. Nor do they seek to establish a fixed sequence in which relevant topics are

---

Psychology: vol 1, Theory and Method, Reading: Addison Wesley, pp. 449-487; Spradley J. P. (1979) The Ethnographic Interview, New York: Holt, Rinehart and Winston; Rubin H. J. and Rubin I. S. (1995) Qualitative Interviewing, Thousand Oaks: Sage; Seidman I. E. (1991) Interviewing as Qualitative Research, New York: Teachers College Press.

[244] Of the list provided in appendix, 8 were met only once, while others were met between 2 and 5 times.

covered; they adopt a more flexible approach, allowing the discussion to flow in a way that seems natural. Nor need ethnographers restrict themselves to a single mode of questioning. On different occasions, or at different points in the same interview, the approach may be non-directive or directive, depending on the function that the questioning is intended to serve; this will usually be *decided as the interview progresses."*[245]

The range of questions discussed with interviewees varied depending on the background of informants, and was once again kept flexible in every case. However, some key themes were discussed with all informants. Questions asked to public health actors were directed at understanding both the health situation and needs of Djibouti, as well as informants' understandings of intellectual property issues. After a first set of interviews was carried out, further more specific elements were discussed such as particular projects, diseases or the links and relations between specific actors. Themes discussed with informants in the trade and industry area were directed more specifically at the implementation of TRIPS, the view of informants in relation to the role patents could play in Djibouti, past experience in terms of implementing international law and creating new legal structures. Finally, additional informants provided information related more broadly to local politics, culture and tradition.

A key question that needs to be addressed in relation to interviews is that of recording. It is generally considered in social research that tape-recording is the

[245] Hammersley and Atkinson, "Insider account: listening and asking questions", op. cit. on p.152.

most complete way to record interviews. It guarantees that a faithful transcript of what was said by informants is kept and avoids the potential disruptions that note-taking can create. However, recording is not always possible, and thorough note-taking can in fact prove to be less disruptive in particular social settings than recording interviews. In this research, it was decided at an early stage that tape-recording could not be used and needed to be replaced by detailed note-taking during and after interviews. There were several reasons for this choice. First, it was felt early in this research that most of the interviews would be best carried out by maintaining the informal aspect of most local social relations. In addition, people familiar with local traditions, and aware of local events, reminded me that it was necessary to understand that local actors were often wary of being recorded, saying things that could be critical of governmental policies. While local actors are allowed freedom in most of their actions, it is often in their interest to ensure that they keep good relations with one another, and in particular with governmental actors. To that extent, people often tend to be more careful to what they will say if they think they might be recorded – and it would probably be even more the case if they knew they were being recorded. Finally, some interviews were conducted in noisy settings where tape-recording would have been unclear, and thus could have left some aspects of the interview un-saved. Each of these elements made it both impractical and potentially obstructive to use a tape-recorder during interviews, and notes were used as a way to record data. As note-taking is again one of the issues on which interviews and observations overlapped, the process of note taking will be discussed below to include both research strategies.

The use of interviews as a central method for data collection has been criticised, however, and these criticisms need to be examined briefly in order to discuss how they have been addressed in this project. The main set of criticisms is that by relying fully on the interviewee's narratives, researchers will obtain only their description of their own or others' actions. Informants can adapt their narratives to what they think they "should" be saying. They can for example try to project an image of themselves closer to what they think should be expected from someone in their situation. They can also genuinely give an account that is different from what really happened, because their memories are confused for any specific reason[246]. Overall, it is necessary for interviewers to keep in mind that what they are obtaining are narratives, as opposed to real events that could have been directly observed. While this needs to be understood and acknowledged, it is not necessary, however, to see it as an inherent and unavoidable weakness, and can be considered as a characteristic that needs to be addressed in order to guarantee the relevance of the method[247]. This is particularly so if it is believed that the world is constituted of multiple realities, since the aim of social researchers then becomes to understand specific "subjectivities". It is only by understanding these multiple

[246]On this set of issues, see also for example: Miller J. and Glassner B. (1997) "The "Inside" and the "Outside": Finding Realities in Interviews", in Silverman D. (ed) Qualitative Research: Theory, Method and Practice, Thousand Oaks: Sage Publications, pp. 98-111; Dean J. P. and Whyte W. F. (1958) "How do we Know if the Informant is Telling the Truth?", Human Organization 17(2) pp. 34-38; Kvale S., op. cit; Gudmundstottir S. (1996), "The Teller, the Tale, and the One being Told: the Narrative Nature of the Research Interview", Curriculum Inquiry 26(3) pp. 293-306; Mischler E. G. (1986) Research Interviewing – Context and Narrative, Cambridge: Harvard University Press.

[247] *"Research cannot provide the mirror description that positivists strive for, but it may* provide access to the meaning people attribute t*o their experiences and social world",* Miller J. and Glassner B. (1997) op. cit. on p.100.

subjectivities that the social world can be explained. It is in this perspective that interviews were perceived in this research, understanding informants' narratives as an inherent part of the reality to be studied in this project. The potential gap between what was being said by interviewees and what would be observed on the ground was accepted in the research process, and the different sets of data collected were used as complementary sources presenting different viewpoints all relevant to this project. This point will be developed again in Section 6, when discussing how the aim for scientific validity has been sought through the use of multiple methods of data collection. At this stage, the way observation was used in this project needs to be presented.

Observational data

Although interviews were originally thought of as a main method for data collection, and most data used in this project was indeed obtained through interviews, observation was used to collect further data and adopt additional viewpoints on the action of TRIPS and pharmaceutical patents. Overall, about twelve weeks were spent in Djibouti during this research – two weeks on conducting a pilot research and ten weeks for the main period of data collection. Although a lot of this time spent in the field was used to carry out interviews, the period spent there was also sufficiently long to spend significant periods of time in the settings that were under scrutiny. This was particularly important because this research was carried out in a socio-cultural environment that has been little studied. It was therefore necessary to include data complementing what was being said during interviews and helping to

understand interview-data. Observation and interviews acted as fully complementary methods[248]. While some data could only be obtained from speaking with actors, other elements, in particular some human/non-human associations needed to be observed. In addition to this, observational fieldnotes were used as a way to complement the narrative provided by informants, in order to provide further knowledge of local politics and traditions that could help frame what was being said in interviews. Once again, observation in this research should not be understood as a different process from that of interviewing – in many cases, observational data was in fact collected during interviews. In addition to this, the boundary between interview and observation data is difficult to set when considering fieldnotes on informal conversations in unofficial settings, for example. Overall, throughout the period of fieldwork carried out in this research, detailed fieldnotes were kept on what was seen and heard in a range of settings[249] – in particular those in which interviews per se were carried out. Additional data could therefore be collected on primary observation of actor's behaviour, institutional setting, or day-to-day conversation with actors less directly involved in the key elements of this research

Note taking

The process of taking fieldnotes needs to be briefly discussed, in order to emphasise how the need for thorough notes had to be balanced against

[248] Hammersley M. and Atkinson P. (1996) "Insider account: listening and asking questions", op. cit.

[249] Ministries, hospitals, pharmacies, for example.

practicalities on the ground[250]. This is something that has been widely discussed in the literature, and researchers have often highlighted that the behaviour of informants can be affected by them noticing that researchers are scribbling down in front of them[251]. This is particularly the case in settings in which those observed might not be totally familiar with the research process, and not used to seeing people writing down what they are doing or saying. Once again, this was particularly the case in Djibouti, where information is traditionally transmitted orally, and where people are often uncomfortable with the need for others to keep a written record of what they are doing or saying.

In this research, although it was agreed from the start that informants had no objection to me taking notes on what they were saying, doing, or of what I was seeing more generally, I felt that in many cases it would be disruptive to make this note-taking activity too obvious. This was not as much the case when meeting people formally in their office as when meeting them in more informal settings such as restaurants. Similarly, a number of informants came to talk to me in unexpected situations such as on the street, at evening parties or even on

[250] For comments on the practice of fieldnotes, and issues of validity and reliability, see for example: Emerson, R, Fretz R., Shaw L. (1995) Writing Ethnographic Fieldnotes, Chicago: University Press of Chicago; Lareau A. and Shutlz J. (eds) (1996) Journeys through Ethnography: Realistic accounts of Fieldwork, Boulder CO: Westview Press; Van Maanen J. (1988) Tales of the Field: On Writing Ethnography, Chicago: University of Chicago Press.

[251] For comments on the interference between the process of note-taking and informants' behaviour, see for example Hammersley M. and Atkinson P. (1996) "Recording and Organizing Data", Hammersley M. and Atkinson P. (1995) Ethnography: Principles and Practice, London: Routledge, pp. 175-204: "The conduct of note-taking must be broadly congruen*t with the social setting under scrutiny. In some contexts, however "well-socialised"* the hosts, open and continuous note-taking will be perceived as inappropriate or threatening, and will prove disruptive. In other contexts, fairly extensive notes can be recorded without *undue disruption"* on p.177.

the beach. Although I kept a notebook with me at all times, I did not feel it was appropriate or convenient to pull it out from my bag when having an informal chat with someone in these circumstances. When researchers cannot for some reason take notes while observing a particular element, or during a conversation, it is essential that they do it as soon as possible after the observation took place, in order to keep a record as faithful as possible to what was observed or said[252]. This can be easy when it is quick and convenient to get away from the setting or informant observed, and was in particular not difficult in the many cases where I just "bumped into someone" in public places and had a brief conversation. It was more difficult when having a lengthy conversation with someone – planned or not – and I had to use the many strategies with which researchers have become familiar over the years. The "researcher's disease" referred to by Hammersley[253] is something I might have been accused of by many informants. Overall I ensured as much as possible that notes were taken as frequently as possible during long conversations and as soon as possible after relevant observations, and used any thinkable strategy to isolate myself when possible to do so – which was not always a pleasant experience.

[252] Hammersley M. and Atkinson P. (1996) "Recording and Organizing Data", op. cit., p.176-177.

[253] "A common joke about ethnographers relates to their frequent trips to the lavatory where such hasty notes can be scribbled in private" in Hammersley M. and Atkinson P. (1996) "Recording and Organizing Data", op. cit. on p.178.

Document analysis

In addition to interviews and observation, document analysis played an important part in this research. Documents were crucial both as a source of data complementing perspectives obtained from interviews and observations and essential in allowing for the wide ramifications of the network under scrutiny to be encompassed in this project. Documentary analysis was an important starting point in this research, prior to carrying out fieldwork in Djibouti, in understanding the framing of TRIPS and patents in relation to health internationally. This was based on analysing legal documents from different countries – policy documents and laws – as well as the range of pre-existing analyses of this type of documents. Academic writings were most centrally used, but media reports and the documents produced by different lobby groups were also taken into consideration. The difficulty of documentary analysis is in part common to those of interviews mentioned above, in that documents represent only a particular narrative, and cannot always be taken as facts[254], as will be explained in more detail below. However, these narratives were in fact what needed to be understood as a starting point to this research – the simplification and extensive generalisations provided throughout writings in the field needed to be understood in order to respond to it through this project.

In addition to this, documentary analysis played a central role in this research both in complementing some of the findings made in Djibouti itself and in

[254] On the use of documents in ethnographic research, see for example Atkinson P. and Coffey A. (1997), "Analysing Documentary Realities", in Silverman D. (ed) Qualitative Research: Theory, Method and Practice, London: Sage Publications, pp. 45-62.

extending the data collected to the ramifications of the network analysed outside the country. Two types of institutional documents were used. First, documents from local institutions were accessed, in relation to health projects, IP and trade issues. These were essentially used for complementing findings from interviews and observation, by showing the "official" and "material" version of particular stories, and illustrating the perspectives with which informants were faced in their own activities. In addition, documents from international organisations (WTO, WHO, WIPO and the World Bank) were used in order to understand the localized manifestations of international relations and happenings.

The need to adapt ethnographic methods to the newly extended forms of international networks now under scrutiny in many fields has been highlighted by Maskus in particular when discussing how ethnography could be applied in the "world system"[255]. In this research, the networks followed throughout involved sites and objects that could not be physically observed. Using documents, in association with the analysis in Djibouti of the impact of these different parts of the network allowed the integration of key elements in the data collected.

[255] "Although multi-sited ethnography is an exercise in mapping terrain, its goal is not holistic representation, an ethnographic portrayal of the world system as a totality. Rather, it claims that any ethnography of cultural formation in the world system is also an ethnography of the system, and therefore cannot be understood only in terms of the conventional single-site mise-en-scene of ethnographic research, assuming indeed it is the cultural formation, produced in several different locales, rather than the conditions of a particular set of subjects that is the object of study", Maskus G. (1998) op. cit. on p.83.

The difficulty of using documents as data is essentially that they can only be taken as facts in that they exist and they become actors in the system (through their own shape and narrative). Their narrative, however, cannot be taken as a necessarily faithful reflection of other realities. The perspective adopted in this research meant that this was not as much of an issue as it might have been in other projects. In particular, it is accepted in ANT that what needs to be collected are sets of subjectivities, elements of perspectives, and that the social world is purely constituted of such elements. This can be illustrated particularly clearly if reflecting on the role that documents from international organisations played in this project. The aim of analysing such documents was, in particular, to understand how activities from international organisations were portrayed in Djibouti, and by opposition how events and networks in Djibouti were described in documents emanating from international organisations. In addition, documents were used in relation to local informants' narratives of their relations with actors based outside the country, and were designed at understanding the connections established between actors in Djibouti and wider international networks. Overall, it was understood in this project that: *"…rather than being viewed as more or less biased sources of data, official* documents and enumerations should be treated as social products: they must be examined, not relied on uncri*tically as a research resource."*[256]

[256] Hammersley M. and Atkison P. (1995) "Documents", in Hammersley M. and Atkinson P. Ethnography: Principles and Practice, London: Routledge, pp. 157-174 on p.168. Although this statement is essentially directed at official statistic in this particular book chapter, the idea holds true for other type of official data.

SECTION 4: ETHICS

Ethical issues were considered at various points of this research, and I followed appropriate ethical guidelines – such as those provided by the ESRC[257]. Some characteristics of the fieldwork made particular elements rather complex in this research. Anonymity and confidentiality were made particularly crucial because of the political situation of Djibouti, and the fact that any form of criticism of the government is still very widely avoided. In addition to this, the "informality" of a large part of the research process, raised some specific issues in relation to informed consent.

Informants were made aware of the aims of this research from the start. They were informed that I was interested in evaluating the role of pharmaceutical patents in Djibouti and the potential impact of the TRIPS agreement on the

[257] The ESRC guidelines propose six key principles: *"Research should be designed, reviewed* and undertaken to ensure integrity and quality; research staff and subjects must be informed fully about the purpose, methods and intended possible uses of the research, what their participation in the research entails and what risks, if any, are involved. Some variation is *allowed in very specific and exceptional research context (…); the confidentiality of* information supplied by research subjects and the anonymity of respondents must be respected; research participants must participate in a voluntary way, free from any coercion; harm to research participants must be avoided; the independence of research must be clear, and any conflicts of interests *or partiality must be explicit."*[257] ESRC Research Ethics Framework, available at: http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/Images/ESRC_Re_Ethics_Frame_tcm6-11291.pdf?data=XgFbyby6cC%2feX0vvCbUzElpmty2597nOiZBNzMdyp1%2bYbb26zfuNeA7JM%2bo6bv2pAtBPo5e%2foUUPE2EoXLiXeRvo%2bsUEx1oC1XzlQzW%2bvgvi6lWaURvkIfIn6B1sqq14C0lIzE42k7brIGiWRdQXayvCbl44yh9m&xu=&isAwardHolder=&isProfiled=&AwardHolderID=&Sector=, on p. 1.

country. They were also made aware that in order to do so I needed to understand the public health system of the country as a whole, and in particular the mechanisms of the pharmaceutical market. Informants were also informed that this research was for academic purposes, and that the final findings made would appear in a thesis, that would therefore be in the public domain. They all provided their verbal consent to the use I was intending to make of the data provided[258]. The queries they had were addressed, although they were generally related to the content of my research and my personal aims rather than issues of diffusion of information. Informants were made aware that I would be taking notes of what I would "hear or see" during our meetings, and that these notes would later be used in my research. When appropriate I asked informants whether they believed anyone else in their institution (such as Ministers or actors hierarchically "above" them) should be made aware of the existence of my research. By doing so, I made sure that adequate people in each of the institutions visited had appropriate information on my work. As mentioned earlier, some of the data collected was provided by informants during "informal conversations". It should be clarified that this data was essentially complimentary to what had been said in formal meetings, and was also presented by informants in relation to our earlier conversations. Although discussions were conducted on a more "informal" tone in these circumstances, the relation researcher/informant was still framed as such. None of the information on which this research was done can be considered as having been

[258] Although according to ESRC standards consent is "typically" given in a written form (ESRC Research Ethics Framework, op. cit on p. 24), it is not a compulsory condition, and was once again something highly unfamiliar in this setting, in which verbal and fully informed consent was judged to satisfy the "*the primary objective (…) to conduct research openly and* without deception" (ESRC Research Ethics Framework, op. cit on p. 24)

obtained without the acknowledgement of informants that what they were telling me was directed at informing my research.

In relation to anonymity and confidentiality, one of the difficulties is the fact that the country is so small that it is very hard to provide the basic and necessary information on who the interviewees were in this research – necessary to prove the validity of this project – while ensuring that they cannot be recognized. A direct consequence of this difficulty can be found in the presentation of the data collected made throughout this research, for which a balance had to be found between what could and could not be disclosed. While this thesis provides a list of informants stating their professional occupation and status (see Appendix), specifying which informants are quoted in the thesis, citations had to be kept anonymous throughout this research. While this presents some limits, it was the only way to ensure that what a particular informant said could not be retraced. This was essential to address the key concerns of my informants. In particular, while all of them were happy to be "officially interviewed" for my project, many mentioned once in a while things such as "*of course, I haven't said this but…*" In such cases, I asked them whether they had any objection in me using the information provided in my thesis as long as it remained anonymous, and they made it clear that this was not an issue as long as the statement could not be identified as emanating from them. As every quote provided in this thesis has been anonymous, and as limited information is provided throughout on the specific origin of a particular idea, no such statement can be attributed to specific informants. In this way, the

emphasis of informants on their expectation to such specific statements remaining anonymous was respected.

Further elements had to be addressed. It was important to make sure that the data stored was fully anonymous, and stored in a safe location. In addition, although it was necessary to keep the data until the PhD process was completed, it will then be destroyed[259]. Confidentiality was also crucial on the ground, and it was essential to ensure that information provided by informants would not be divulged for any purpose outside those specific to the research. In a context where interactions, formal and informal, were frequent, it was central to make sure that trust would not be broken by communicating information in an inappropriate fashion, and that professional and ethical behaviour would be maintained throughout the research period.

Finally, if working within an ANT framework, it is particularly crucial to acknowledge the thesis itself as a potential "actor", and to evaluate its potential effects on the network studied. As will be explained in more detail in Chapter 4, a fairly limited amount of research has been carried out on Djibouti, and it is likely that an internet search of the country could, in the future, provide information on my thesis. To that extent, it was essential to ensure in the redaction of this thesis that none of its content would risk creating difficulties for my informants. This could potentially have obscured some elements of the research if highly controversial data had appeared. Nevertheless, the key issues

[259] In accordance with the Data Protection Act 1998, and reminded by the ESRC Research Ethics Framework, op. cit. on p. 18.

to be discussed in this research were not specifically controversial, and it was felt that if anonymity was respected no particular risks would be created for any of the informants.

SECTION 5: APPROACH TO DATA ANALYSIS

"In ethnography, the analysis of data is not a distinct stage of the research. In many ways, it begins in the pre-fieldwork phase, in the formulation and clarification of research problems, and continues through to the process of writing reports, articles and books. Formally, it starts to take shape in analytic notes and memoranda; informally, it is embodied in the ethnographer's ideas and hunches."[260]

This quotation illustrates some of the difficulties faced when aiming to describe how data was analysed in this research. The main characteristics of what will be defined as the data-analysis process[261] were that it was reflexive

[260] Hammersley M. and Atkinson P. (1995) "The Process of Analysis", In Ethnography: Principles and Practice, London: Routledge, p. 205-238 on p. 205.

[261] For general discussions of data analysis processes, see Miles M. B. and Huberman A. M. (1993) Qualitative Data Analysis: a Sourcebook of New Methods, Newbury Park: Sage; Miles M. B. and Huberman A. M. (1994) Qualitative Data Analysis, an Expanded Sourcebook, London: Sage; Silverman D (1993), Chapter 5 "Interview Data", in Interpreting Qualitative Data: Methods for Analysing Talk, Text and Interaction, London: Sage Publication; Huberman M and Miles M. (1998) "Data Management and Analysis Methods", in Denzin N and Lincoln Y eds, Collecting and Interpreting Qualitative Material, Thousand Oaks: Sage publications, pp. 137-157[261] Hammersley M. and Atkinson P. (1995), "The Process of Analysis", op. cit.

and on-going. It included elements and strategies that can only be broadly explained[262].

The first element to reinforce in that respect is that the way data was approached in this project followed closely the key ideas of ANT - in particular its emphasis on the need to avoid simplification as far as possible, and to remain as close as possible to the data collected[263]. In this research, it was considered essential to ensure that data remained at the centre of the analysis offered, and was not limited or directed in its interpretation by heavy frameworks for analysis. One of the strengths of ANT is to allow an approach encouraging researchers to return to their data, and to follow their data without relying on pre-existing concepts. It emphasises the need to understand any object of analysis - presented as always subject to change and highly flexible - in a dynamic way. It also requires researchers to provide thick descriptions fully based on fieldwork data, and to add as little as possible to the elements collected. In this research, this was followed closely, and the aim of data analysis was more centrally to present and explain it than to draw unwarranted general conclusions.

A central element in doing so was to proceed to frequent thinking and analysis of what had been collected, and to maintain a high degree of reflexivity in the

[262] It is useful at this stage to specify that it was decided in this research that no use of data-analysis software would be made. The main reason for this was that it was thought that it might limit some of the potential reflexivity on which data-analysis can be based, and that is crucial to ANT understandings.

[263] See for example Latour B. (2005) Reassembling the Social: an Introduction to Actor-network Theory, op. cit.

research process. In particular, as sets of data were collected they were also used to determine the direction to be taken by further data-collection, and the research process evolved in this way. This research started with minimal assumptions as to what TRIPS and pharmaceutical patents should look like in Djibouti. This was partly due to the fact that early assumptions that might have existed up to the pilot study carried out in 2004 were understood as inappropriate and fully left aside before the main period of data collection started. From then, data was collected and partly analysed throughout fieldwork. Research diaries were kept to register new ideas and comments that were developing throughout the research process. This allowed for a large part of the analysis to be done while in Djibouti and for the focus of analysis to be narrowed down according to informants' emphasis and early findings[264].

In analysing data, and in particular large sets of data collected through several weeks of fieldwork, coding is often presented as a useful way to proceed. It involves attributing particular sets of data to categories that are created as data is being analysed. Sets of interview scripts and pages of fieldnotes are divided – physically or not – in thematic categories and each part can then be compared across interviews and observations. The process is ongoing, as each step of

[264] On the way ethnographers develop concepts and ideas during and after the data collection process, see for example Hammersley M. and Atkinson P. (1995) "The Process of Analysis", op. cit; see also Sanjek R. (1990) "On Ethnographic Validity" in Sanjek R. (ed) The Making of Anthropology, London: Cornwell University Press, pp. 345-418.

coding, interpretation and analysis will combine to highligh new categories to consider when analysing the overall data collected[265].

The process of data analysis used in this research was partly inspired by coding strategies. These were used while going through notes and interview scripts many times, in order to compare how different informants had been approaching similar issues and themes. However, it is now difficult to assess fully the part that formal coding played in analysing and understanding the data collected and, in particular, it is now uncertain what part it played as compared to the overall process of familiarisation with this data that I went through over the course of this fieldwork. Emphasising that formal techniques and more informal processes that allow researchers to understand their data go hand in hand is certainly not an original element in sociological or ethnographic research. In this research, it is fair to say that by the end of this fieldwork and the few weeks that followed it I had read most of my fieldnotes and interview scripts so many times that I could have quoted full sections of the most crucial interviews or observations made. In addition to this, the many sets of comments and scribbles produced throughout this fieldwork were crucial in making key-concepts emerge allowing the links between ideas and observations to take shape in a clearer way. Overall, the process of data analysis in this research essentially involved defining concepts, ideas and categories by both formal and informal strategies, and using data to provide a

[265] On "coding", see for example Esterberg K. G. (2002) Qualitative Methods in Social Research, London: Mc Graw-Hill, in Chapter 8; similarly, on processes used by ethnographers for indexing, see Sanjek R. (1990) "On Ethnographic Validity" op. cit.

thick description of the key ideas that emerged in relation to TRIPS and pharmaceutical patents as understood by informants.

SECTION 6: ASSESSING THE VALIDITY OF RESEARCH METHODS AND FINDINGS

This chapter began by explaining that empirical research should remain driven by scientific rigour and aimed at validity. On this aspect, ANT could be related to broader debates in qualitative research – and in particular to "subtle realism". However, it is now important to reflect on the way in which the validity of this project can be evaluated, and on how the methods used in this research aimed at increasing this validity. Once again, the specificities of ANT will give way to more general questions raised by ethnographic research – and by the answers given by ethnographers. This section discusses two sets of issues. First, the solutions put forward by ethnographers to evaluate the validity of qualitative research are presented – and illustrate the means researchers should deploy to increase the validity of their research, as well as how they were used in this project. Second, the role of multiple methods in increasing the validity of research will be discussed – as a whole and in this project.

Discussing the validity of ethnographic research is a complex issue, because the flexibility of the research process itself makes it difficult to evaluate the methods undertaken[266]. Some authors have in fact rejected the idea that criteria

[266] For comments on the validity and reliability of qualitative research, see for example Altheide D. L. and Johnson J. M. (1994) op. cit.; House E. R. (1980) Evaluating with Validity, Beverly Hills: Sage Publications; Kirk J. and Miller M. L. (1986) Reliability and Validity in

can be identified to judge ethnographic research – and the notion of "validity" itself, as has been explained early in this chapter. However, the idea that there could be such thing as "validity" in empirical research – including in ANT research – has been defended in Chapter 1. This does not need to be redeveloped here. What is more relevant at this stage is to look at the way most ethnographers have emphasised the possibility and necessity to judge the validity of qualitative research, and have offered specific criteria and ideas that can be used in that respect. Once again, Hammersley's "subtle realism" can be drawn upon:

"From my point of view, then, the assessment of validity involves identifying the main claims made by a study, noting the types of claim they represent, and then comparing the evidence provided for each claim with what is judged to be *necessary, given the claim's plausibility and credibility. Some claims may be* beyond reasonable doubt in themselves, in which case they will be judged not to need evidence. In other cases, evidence will be required, evidence whose nature will depend in part on the type of claims involved. This evidence will, in *turn, need to be assessed in terms of its plausibility and credibility."*[267]

Qualitative Research, Beverly Hills: Sage Publications; Mishler E. G. (1991) "Validation in Enquiry-guided Research: The role of Exemplars in Narrative Studies", Harvard Educational Review, 60, pp. 415-442; Schofield J. W. (1990) "Increasing the Generalizability of Qualitative Research", in E. W. Eisner and Peshkin A. (eds), Qualitative Inquiry in Education, New York: Teachers College Press, pp. 201-232.

[267] Hammersley M. (1992) "By What Criteria should Research be Judged?", in Hammersley M. *What's Wrong with Ethnography*, Methodological Explorations, London: Routledge, pp. 57-84, on p. 72.

Evidence becomes central at each level of analysis in order to sustain ethnographic claims. Similarly, Sanjek provides three different types of elements that can be used to increase the validity of ethnographic research: "theoretical candor", description of the "ethnographer's path" and "fieldnote evidence"[268]. By these, he emphasises the fact that the validity of ethnographic research depends on the amount of information provided by researchers on why they chose to collect and emphasise particular data, how they went about collecting it, and what this particular data was about. The need to provide detailed evidence is therefore central to this approach too.

The position adopted in this project follows closely these perspectives; it was felt essential throughout to explain the path chosen to both theoretical exploration and methodological choices. This was done respectively through Chapter 2 and this chapter, and aimed to provide readers with enough information to understand the choices made in this research, the reasons for these choices, and the origin and content of the data collected. Throughout the remainder of this study, citations from interviews will be used to illustrate the ideas put forward, and will offer extracts of raw data that readers can therefore directly access. Although questions might remain open as in most research, it is hoped that this will answer most issues that could be raised in relation to the validity of the data collected.

In addition to the way methods and strategies were discussed, and to the way evidence was used to sustain the validity of this project, it is essential to come

[268] See Sanjek R. (1990) "On Ethnographic Validity" op. cit.

back to the validity of the specific methods chosen and used in this project. A large part of the questions to be addressed have been discussed above, in the section dedicated to the three methods used – interviews, observation and document analysis. One issue that has not been addressed yet, however, and needs to be looked at now, relates to the way these different methods fitted together, as a whole in this project, and how this is believed to have participated in increasing the validity and the comprehensiveness of this research.

However, before discussing what have been the benefits of using multiple methods, it is essential to emphasise first why the term "triangulation" has been left aside throughout this chapter. Triangulation has been referred to in many projects as a way to check one method against the other, and compare findings collected through each method in order to determine whether they confirm each other or not. The term has become so commonly used that when putting forward the fact that several methods of data collections were used in a particular project, it is more than tempting to state that findings were "triangulated" and hope that most readers will then assume that they must be valid. The temptation has become easier to resist, however, thanks to the powerful critiques of the "strategy". Two of these – and certainly two essential ones – are articulated in a clear way by Bloor[269]. The first critique made is partly "practical" – although conceptual issues underlie it. In most research projects using several methods of data collection, one is generally privileged,

[269] Bloor M. (1997) "Techniques of Validation in Qualitative Research: a Critical Commentary", in Miller G. and Dingwall R. (eds) Context and Method in Qualitative Research, Sage Publications: London, pp. 37-50.

considered as most appropriate to the aims of the research, and therefore somehow "superior" to other methods used in the project. If wanting to "triangulate", the findings made through this "superior" method will be compared to those of the "not quite as good" approach. But what if they disagree? Should one set of data prevail over the other because it is "better"? Should the other one just be ignored? And if not, is it right to challenge findings made through the most appropriate methods with those obtained through a somehow "inferior" strategy? As long as no answer can be found to these questions, the pertinence of "triangulation" remains questionable. Although this critique is already quite powerful, and probably enough to generate a certain wariness, a deeper conceptual issue is also suggested by Bloor. Different methods generate inherently different types of information, and can therefore never be fully compared. The specificities of each type of interaction, the focus of particular methods or exercises, all produce particular results that cannot be expected to "superpose", neither do they necessarily aim at collecting the same set of answers[270]. If this is the case, how can the validity of one be judged on the basis of the other? This second argument, once again, highlights the weakness of the notion of triangulation. The challenges brought to the concept of triangulation should not, however, result in casting doubts on the separate advantages remaining in the use of multiple methods for data collection.

[270] "All research findings are shaped by the circumstances of their production, so findings collected by different methods will differ in their form and specificity to a degree that will make their direct comparison problematic." Bloor M. (1997) op. cit. on p.39.

These benefits can be stated generally, before illustrating them more specifically in relation to this project. The first of these advantages is that although they do not provide fully comparable data, different methods of data collection generate complementary sets of information. In addition to this, multiple methods have been presented as providing the researcher with better opportunities to understand their data – although data from observation cannot be "the same" as data from interviews, what has been observed can certainly help understand better what has been said in interviews by highlighting the circumstances or environment to which they relate.[271] These two elements were central in this research. First, observation and document analysis were aimed at obtaining data that could not be gathered through interviews – material interactions, and the manifestation of TRIPS and pharmaceutical patents in particular documentary forms in Djibouti, for example, as mentioned before. In addition to this, each of the methods of data collected presented specific stories, generated particular findings. Although these were never considered as comparable, they each provided sets of concepts, narratives, and ideas that helped to understand better the meaning of others. By offering wider perspectives on what constituted the networks under scrutiny, and on the agency of TRIPS and pharmaceutical patents in these different networks, the combination of the methods presented above aimed at ensuring that the story told would be based not only on valid sets of information, but also on a valid understanding of their meaning by always locating them within other sets of associations.

[271] Hammersley M. and Atkinson P. (1996) "Insider account: listening and asking questions", op. cit. on p. 131.

CONCLUSION

The methods used throughout this research were those that balanced most effectively the practical imperatives of empirical work, the feasibility of the project undertaken, and an awareness of the weaknesses of rigid methods of data collection. In-depth interviews were chosen as the main method of data collection partly because they were the most feasible way of accessing the wide range of data needed in this project. However, they remained understood as a set of perspectives that this research aims to describe. In addition to this, observations were produced and used throughout this project, in order to include elements and data that would have been inevitably excluded from interviews. They participated in providing complementary data that added to the substance of interviews, as well as to the understanding made throughout of what had been said and done. However, this project remains understood as a particular story, and although it necessarily embeds some of the inevitable limitations of any textual translation and provides only some elements of a complex and multiple reality, it aims to describe in as much detail as possible the elements that make up TRIPS and pharmaceutical patents in Djibouti. By concentrating on a rather small set of objects to consider, it offers a way to include as much as possible in the story of these few objects – although it also presents the inevitable difficulty of excluding others. The way it hopes to increase its validity and limit the potential weaknesses of any research process is by making its focus and limits as explicit as possible, hoping that in the process what has been included will be defined thoroughly if not perfectly fully. It has set itself a limited focus and provides a story on the subject chosen

as close as possible to the reality as portrayed by informants' narratives and by my own observations as a researcher, and aims to provide throughout the following chapters enough information for readers to be able to perceive the potential role of further complexities that could not be fully detailed. Before entering the core of this analysis, and following the approach detailed in this chapter to analyse TRIPS and pharmaceutical patents as they appeared in Djibouti, the next chapter will provide some further elements of introduction on this case study. It will explain some elements of the networks in which this case study has been carried out, by presenting some of their dimensions that need to be known before following how TRIPS and pharmaceutical patents are acting and circulating in what is understood as "Djibouti" in this research.

CHAPTER 4 - FINDING TRIPS AND PATENTS: AN INTRODUCTION TO THE VIEWPOINTS CHOSEN

The aim of this research, and of the specific case study undertaken, is to understand the action of pharmaceutical patents and the TRIPS agreement in a least developed country in an extreme economic situation, and with a public health system on which empirical data still has to be produced. The example chosen also provided a good opportunity to test the relevance of actor-network theory to the study of transnational socio-legal objects. Throughout this research, it became clear that TRIPS and pharmaceutical patents in Djibouti could not be understood as single instruments, with a clear and unified role in the country as a whole. Understanding their role and mechanisms in a complete way could only be done by analysing how they acted and interacted in the different overlapping networks in which they have become enrolled and are enrolling. This will be developed in the next three chapters, by considering the empirical data collected during this research.

This chapter is a preamble to the main analysis of data provided in the next three chapters. Its double aim is to narrow down once again the focus of this project by introducing some elements – some aspects of networks - that are crucial to understand the analysis that will follow. This will be done by introducing Djibouti and some aspects of the main networks under scrutiny in this research. Three networks will be presented – following a brief introduction to Djibouti itself (Section 1). The "intellectual property system" of Djibouti will be introduced (Section 2). The public health system will then be presented

(Section 3). Finally, a few words will be given on the pharmaceutical industry of Djibouti (Section 4). These three areas have been chosen to reflect what appear as both relevant and somehow "punctualised" fields in a wide set of writings about TRIPS. They also represent networks that appeared as largely independent in many respects in this thesis, and could therefore be isolated in this chapter for the purpose of introductory clarification without being overly arbitrary.

The limits to the theoretical benefits of this chapter need to be acknowledged by highlighting its transitory role and illustrating the difficulties of "writing an ANT account" discussed in Chapter 3. This chapter is intellectually – as well as materially – located between two largely different - if interdependent - tasks. While Chapter 1 to 3 have been dealing with "contexts", debates and approaches in which this empirical research is located, Chapters 5 to 7 will fully bring together the ideas from ANT explained earlier and the empirical findings made in this project. The present chapter is transitory position because it is still "introductory", still "background" from many perspectives, though it narrows down the case study clearly. However, because it is still partly introductory, it does not yet fully engage with particular debates that will only be progressively addressed. It acts as a "starting point", by using for the first time in this empirical context some terms that are still not fully defined – and that this research as a whole will ultimately clarify. It presents points in the network studied that are also enrolled in many other overlapping networks – not all of which are relevant for this particular project. This means that the approach and narrative undertaken in this chapter will inevitably present some

boundaries and limits that are necessary to any academic exercise, although not fully engaging with the theoretical perspective. Even so, the complexity and dynamics of each node analysed here will be rendered more visible by following the connections and associations that link them to/in TRIPS and pharmaceutical patents as they appeared in Djibouti, in the course of this fieldwork.

SECTION 1: INTRODUCING DJIBOUTI

More than many other countries, the Republic of Djibouti needs introducing – this was, at least, the impression that came out from many people's first reaction to the focus of my research. Although this section needs to be short and this introduction will therefore only be partial, it is hoped to give a "feel of the country" to readers unfamiliar with the place. The pictures provided throughout this chapter aim to participate in providing readers with a clearer understanding of the country. Although they mainly offer views of Djibouti that are relevant to this whole chapter rather than specific pages, some of them will be referred to more specifically throughout the text.

Although its history – in particular up to the few years following its independence in 1977[272] – has gathered interest from a number of writers, and

[272] For a detailed History of Djibouti until its independence, see Hugo P. and Oberle P. (1996) Histoire de Djibouti, des Origines a la Republique, Paris : Presence Africaine. See also for example Dubois C. (1997) Djibouti 1888-1967, Heritage ou Frustration, Paris: L'Harmattan.

in spite of the presence of many famous writers in the country in the past[273] – Djibouti has somehow fallen into disregard and become one of these countries that many people would dismiss as irrelevant. This is partly understandable. After all, it is very small, the local population is smaller than that of many European medium-sized cities[274]. It is essentially covered with rocks. The "made in Djibouti" label does not reach any of our shops. To that extent, the choice of this particular case study could be questioned for its relevance. However, this relevance itself needs to be understood, in addition to the many academic reasons that I presented in Chapter 3, partly because there is much more to Djibouti than what common knowledge anticipates. Because in spite of what is often implied[275], it is a country with its own history, identity, culture,

[273] For literature on Djibouti see Monfreid H. (ed. 1994) Secrets de la Mer Rouge, Paris: Grasset, or more recently: Waberi A. (2002) Balbala, Paris: Gallimard; Waberi A. (2003) Transit, Paris: Gallimard.

[274] Although estimates are difficult to establish due to the fact that a part of the population is nomadic (and there are not as many updates as for many other countries), one estimate from the World Bank considered that in 2000 the population would be around 700000, with an annual natural rate of population growth of about 2.8%– although this could not take into consideration the illegal influx of refugees, mainly underreported; World Bank (2001) Memorandum of the President of the International Development Association to the Executive Directors on a Country Assistance Strategy for the Republic of Djibouti. 21414 DJI, available at: http://www-wds.worldbank.org/servlet/WDSContentServer/WDSP/IB/2000/12/19/000094946_00120105303 66/Rendered/PDF/multi0page.pdf) Overall, about 80% of people are thought to live in the Capital, while most of the others are spread between the main towns of Tadjoura, Ali Sabieh, Dikhil and Obock.

[275] On the assumption that Djibouti should/could maybe "merge" with one of its larger neighbours see for example de Waal A. (2003) "The perverse logic that divides impoverished Africa", The Guardian 16th June 2003: "Take Djibouti in north-east Africa. It has about half a million people and almost no domestic economy. It depends wholly on three things: a port and railway link that serve the much larger economy of landlocked Ethiopia, a French military base (recently augmented by a US command centre, used for keeping watch on Yemen and monitoring al-Qaida's attempts to infiltrate the Horn of Africa), and lastly the fact that tiny

that deserves to be known – and more importantly for the purpose of this thesis, that needs to be understood. This section aims to provide a very basic but necessary introduction to a country more complex than these few paragraphs can explain, and which in part of those complexities will appear throughout the remainder of this research.

Once again, part of the reputation of Djibouti – or its "non-reputation" - can be explained, and for many foreigners stepping into the country, the first wave of heat and a first look around will often create an immediate urge to leave. When listening to the constant complaints of some of the French soldiers and their families based in the country, there could not be a worse place to live – and these complaints soon become as irritating as unjustified. Local people are keen to reemphasise that life is rather good in Djibouti compared to neighbouring Somalia, nearby Sudan, and other countries of the region from which stories of war and starvation constantly arrive. Djibouti is certainly a "country of extremes"[276] but this is partly what makes it most interesting to get to know – including for sociological inquiry. The weather can certainly be a deterrent, in a country where temperatures can reach 50C in the summer, where rain falls only a few times a year – which does not eradicate the risks of

---

Djibouti, by virtue of its sovereign independence, has a seat at the United Nations, the African Union and the Arab League, and therefore also has representation at the World Bank, UN *specialised agencies and bilateral donors (...)Five years ago, there was some discussion that* Djibouti might merge with its neighbour Ethiopia."

[276] Sellen J. (ed)(2003) Djibouti, Terre des Extremes, Milan: Graphic International Publishers – the picture of Ali Sabieh provided on the next page is an illustration of the most dry of its dimensions.

flooding[277] - and where the sun is always highly "threatening"[278]. The economic situation is also certainly highly concerning[279]. Agriculture is almost unknown[280] – how could it be different considering the weather conditions and the fact than less than 0.3% of the land is cultivable[281]? Industry has been very limited so far, and most of the country's economy is based on services[282]. Djibouti's location on the Red Sea and its international port have been the main assets of its development, and it represents a central point of passage for goods travelling between Arabic countries and Africa – in particular land-locked Ethiopia[283]. Most striking, however, is the human side of this economic crisis. About 50% of the population is believed to live below the poverty line[284], and the same proportion is officially unemployed – although estimates need to be looked at carefully, since the situation of refugees is often overlooked and difficult to establish. According to the World Bank, it could be the case that

[277] A few hours of rain while I was carrying out the last stages of my fieldwork created extensive damage and several deaths– for details and pictures of the damages caused, see http://www.who.int/disasters/repo/13002.pdf#search='photos%20hospital%20djibouti' (see also the picture provided in this chapter.)

[278] A particularly fair-skinned friend of mine is still remembered by some in the country several years after visiting it for managing to get a nasty sunburn sitting in shed, with a long-sleeved top and in spite of having used a fair amount of sunscreen.

[279] World Bank (2001)op. cit: "*Over the past two decades Djibouti's situation has become* increasingly precarious, with stark declines in per capita income, structural problems and *declining external assistance. The country's regional economic importance (…) has declined* in recent years as neighbouring countries have adopted market oriented policy reforms and *Djibouti's own economic* situation has deteriorated", on p. 3.

[280] A few fruits and vegetables are grown in the limited fertile zones of the country, near Ambouli.

[281] World Bank (2001) op.cit.

[282] 70 % of GDP (World Bank (2001) op. cit)

[283] The country's strategic situation has also played a part in attracting interest from France that led to its colonization – see Dubois C. (1997) op. cit.

[284] and 10% of the population is considered as extremely poor (World Bank (2001) op. cit.)

unemployment rates amongst certain groups are much higher when disaggregated, and certain age categories are particularly vulnerable – 80% of those between fifteen and twenty years old are believed to be unemployed[285]. The familial and social ties that unify the relatively small and compact population are essential in limiting the potential disaster that this could create. When people are in a critical situation, family and community networks are considered crucial, and it is common to have a few people on which a whole family is almost fully dependent[286].

Djibouti is culturally and politically at the crossroads between East and West, Africa and Middle East. It has been an important centre of immigration for many years from neighbouring countries facing civil wars or food crisis, in particular since the state has enjoyed relative stability compared to others in the region and the diversity of the population has continued to increase. Its population is largely mixed, with two main ethnic groups – Afars and Issas – that have been in rivalry for many years[287]. The majority of the population are thought to be Issas - although most of the Afars maintain that the data is biased by the high number of Afar nomads, and that the proportions of Afars and Issas are almost identical[288]. Other ethnic groups established in the country for several generations include Yemenites, Indians, and Greeks. In addition to this, since the country became independent, a strong French presence has remained,

[285] World Bank (2001) op. cit.

[286] An informant explained: "Everything works through the family here. If someone cant get *something they will rely on the family to get it for them".*

[287] That has been partly at the root of the civil war that shook the country in the 1990's

[288] In addition, official estimates in Djibouti are often considered as biased by the Afar because the government is essentially Issas and might not release objective data, in their view.

and in particular Djibouti is still nowadays the biggest permanent military base abroad for France. An important number of cooperants are still provided in each Ministry, and French advisors still play an important role in the country's policies. In addition to the French presence, an important American base has opened in the country following the start of the so-called "war on terrorism", and the country is used as a base from which to contain terrorist networks in the region. Similarly, German soldiers are based in the country, and a number of foreign boats – Spanish in particular – use the port as their main base in the region. Finally, and as mentioned before, crises in neighbouring countries have generated a large flux of refugees moving to Djibouti – although their number is impossible to evaluate[289].

Djibouti is therefore a state in which a great mix of cultures and origins relate[290]. It is also a state that has been relatively close to a number of powers with possibly divergent interests. In particular, it is constantly trying to fit between the influence of Europe and the US, hoping to see the place becoming central in the development of a modern form of Islam, and between that of stronger Islamic powers such as Saudi Arabia or Yemen, hoping to see the place turn more clearly towards the Middle East. It is in Africa without feeling

[289] As an indication of the extent of illegal immigration from neighbouring countries, as compared to the size of the population, it is interesting to mention that in 2003, the government of Djibouti announced that it would expel 100 000 illegal immigrants – for press report, see for example: The Guardian, "Djibouti throws out its immigrants", 17th September 2003. It should be noted, however, that the common understanding in Djibouti is that many of those expelled have since then manage to re-enter the country (legally or not).

[290] The next three pictures of Djibouti-town project some images of the "feeling" of the town, partly resulting from this cultural richness.

fully African[291], and quickly gives the impression of being characterised by a great mix in many respects. Finally, it is also a country where things work fundamentally differently from what a European might expect, where notions of time are as flexible as possible, where the difference between what will happen and what should happen is stronger than in most places, and where the national reliance on God's will quickly becomes contagious. Nothing is ever sure, what is written on paper and planned might or might not happen, no-one can ever be sure and especially not a foreigner trying to understand how some international law far from everyday concerns will be implemented. However, regardless of all the difficulties that the country faces, its natural beauty and cultural diversity make it a captivating country, rich in many respects.

In spite of what might all seem unique to a particularly small, particularly poor and somehow different country, one might wonder if Djibouti is more "unique" than any other place. That observation might lead to questioning whether or not what we expect to find in "developing" states, or in any state for that matter, might be anything else than "unique"[292]. The need to reconsider some

[291] Local people generally refer to people from other African countries as « the Africans », and often raise the fact that maybe they should actually see themselves as African too.

[292] This reminds of the following comment made by Latour: *"The great divide between Us* – Occidentals – and Them – everyone else, from the China seas to the Yucatan, from the Inuit to the Tasmanian aborigines – has not ceased to obsess us. Whatever they do, Westerners bring history along with them in the hulls of their caravels and their gunboats, in the cylinders of *their telescopes and the pistons of their immunizing syringes. They bear this white man's* burden sometimes as a tragedy, but always as a destiny. They do not claim merely that they differ from others as the Sioux differ from the Algonquins, or the Baoules from the Lapps, but that they differ radically, absolutely, to the extent that Westerners can be lined up on one side and all the cultures on the other, since the latter all have in common that they are precisely *cultures amongst others. In Westerners' eyes, the West, and the West alone, is not a culture,*

assumptions one might have on social life when hoping to understand how law will affect people's behaviour becomes pressing when considering how much some "developing" states might in fact have in common. This case study is thus based on a country that many would dismiss as lost and irrelevant, maybe not worth the trouble of social inquiry, but that is also important to many and probably no more unique than any other. By looking at this small state in detail, many questions will be raised about the assumptions of a literature too quick in judging what developing countries have in common, rather than wondering what makes every social network unique. Before looking in more detail at the specific fields with which this research is mainly concerned, a few other aspects should be highlighted, as they will be central when considering how Djibouti might respond to the implementation of TRIPS. The first element to be described will be the current IPR system. I will then present the public health situation of the country, before introducing the status of the two attempts to develop a local pharmaceutical industry.

SECTION 2: DJIBOUTI AND IPR LAW – PRE-TRIPS "IPR SYSTEM"

As emphasised in ANT, change is one of the most central catalysts for waking the sleeping connections so that they become visible to social researchers[293]. The implementation of TRIPS in the political networks of Djibouti is calling for new changes. It is expected to reshape the links between the many actors

---

not merely a culture Latour B. (1993). We Have Never Been Modern, Brighton: Harvester Wheatsheaf on p. 97.

[293] See Latour B. (2005) Reassembling the Social: An Introduction to Actor-network Theory, Oxford: Oxford University Press.

that make up what is often summarized as “the intellectual property system” of the country. The next chapter will detail the changes taking place because of TRIPS, and will highlight the range of connections that generate action in relation to IPR in Djibouti. Before doing so, however, it is useful to introduce the previous events in the IPR area in Djibouti. This will be essential in order to understand where the changes required by TRIPS are happening.

Creating IP laws

In terms of competence, the Ministry of Trade is in charge of industrial property issues. It is thus responsible for the creation of patent laws and the implementation of patent-related dispositions of TRIPS. The Ministry of Culture is in charge of other forms of IPR, and deals in particular with the issue of creative and artistic rights. The next chapter will show that this is a partly inappropriate and unspecific presentation, and that, when looking inside the Ministry of Trade more detail needs to be given as to what is hidden behind these terms.

The history of Djibouti in relation to IPR will not detain us for long. In relation to patents, and concentrating on the legal system of Djibouti per se, no patent law has been adopted since the country became independent. However, one aspect of the intellectual property regime of Djibouti is worth detailing. This is not as such for what it demonstrates in relation to its specific content, but mainly for the example it sets in relation to the practical application and the social situation of one intellectual property instrument in Djibouti. This part of

history relates to the protection of artistic and creative rights. In 1996, the Ministry of Culture put forward a law to protect artistic and literary creations. This law was adopted by the Parliament[294]. This was felt as appropriate in order to promote intellectual and creative activities in the country. For the first time, intellectual property became an active part of political debates, and materialised in a text of law expected to generate further mobilisations. The text of the law itself seems to offer a rather strong protection for authors[295], and refers in particular to a new structure within the Ministry that would study applications and grant authors the named protection[296]. The structure is to be created by decision of the Council of Ministers. Since 1996, however, the structure has never been created – and consequently the law has never been applied. The brief social role of this intellectual property concept in generating discourses disappeared very quickly, and the text became a set of materials put aside, isolated, and followed by no further impact. Lawyers questioned on this issue seemed to see it as rather normal in the country:

"This kind of things happens all the time – there are so many laws that have been adopted because of pressure, lobbying, or on the basis of external advice

[294] Loi no114/AN/96/3e L relative a la protection du droit d'auteur.

[295] Article 1(1): "*L'auteur d'une oeuvre jouit sur cette oeuvre, du seul fait de sa creation, d'un droit de propriete incorporelle exclusive et opposable a tous" Article 2* : « Les dispositions de *la presente loi protege les droits des auteurs sur toutes les œuvres litteraires, scientifiques, ou artistiques originales quelqu'en soient le genre, la forme d'expression, le merite ou la* destination, et sans que cette protection ne soit assujettie a une quelconque formalite. »

[296] Article 66: "La gestion des droits ainsi que la defense des interets moraux et materiels des auteurs et compositeurs seront *confies a un organisme d'auteurs et compositeurs denomme Bureau Djibouti du droit d'auteur (BDDA) dont les attributions et le fonctionnement seront fixes par decret pris en Conseil des Ministres".*

from organisations for example. The Parliament passes the law, but then when it comes to applying it, no one knows what to do with it, and nobody is *interested in it any more, or they realise we just don't have the means to apply it!"*

However, the introduction of TRIPS is now calling for this law to be revised – and applied – and it is therefore now becoming once again a policy actor – and potentially a mobilising force in future change.

Djibouti and "IP organisations"

A second set of connections that appeared in the past few years in Djibouti in relation to IPR linked actors in Djibouti to particular "international organisations" – although, once again, this terminology hides much of the complex connections gathered in these systems. Until recently, Djibouti was not a member of any IPR organisation. However, in particular since signing the TRIPS agreement, it has started accessing several key treaties. First, Djibouti started the process to become member of the Organisation Africaine de la Propriete Intellectuelle (OAPI)[297]. However, policy-makers quickly felt that this was not the right choice with regards to Djibouti's economy and relation to other states:

[297] Loi no63/AN/94/3eL Portant Adhesion de la Republique de Djibouti a l'Accord de Bangui instituant l'Organisation Africaine de la propriete Intellectuelle (OAPI) 26/11/1994. For information on the OAPI iself and the Bangui agreement, see http://www.oapi.wipo.net/fr/OAPI/index.htm

"The Organisation covers in practice a very clearly defined geographical area – it mainly covers West Africa. Djibouti is located in a very different economical space, namely the Gulf. And in this area, countries have developed their laws completely independently, so we thought it would be more appropriate for us to work on an independent model, like our economic *partners…*"[298] Consequently, Djibouti left the OAPI and accessed WIPO in 2002[299]. In order to fulfil the conditions for joining set by WIPO's treaty, Djibouti had to ratify the Paris Convention, and the Berne Convention in the same year[300].

Overall, whether there was such thing as an "IPR system" in Djibouti until TRIPS became part of the story is open to questioning. A number of connections were made and unmade, demonstrating the difficulties for any actor-network to remain stable in the area. The following chapters will show how the mechanisms of TRIPS in Djibouti can be understood if following the set of existing or failing connections built around the new instrument, and how the uncertain situation which preceded TRIPS is being modified.

[298] This example is also revealing in what it says about the complex situation of Djibouti that could be described as "geographically in Africa", socially in the Middle East…

[299] Loi no150/AN/02/4eme L Portant Adhesion de la Republique de Djibouti aux Conventions Internationales Relatives a la Propriete Intellectuelle, le 31/01/2004.

[300] Loi no150/AN/02/4eme op. cit.

SECTION 3: PUBLIC HEALTH IN DJIBOUTI: DEFINING SOME TERMS AND NETWORKS

The particular focus of this research has called for an in-depth scrutiny of the role and action of both TRIPS and pharmaceutical patents in relation to health. The observation of both objects has therefore taken place largely in the public health field, and it is necessary to introduce briefly what is understood as "public health system" in this project. This will be done in more detail throughout the next few chapters, but in order to provide an idea of the type of issues and situation with which we will be concerned, this section needs to introduce some aspects of this field.

The field of public health is characterised by numerous ruptures and uncertainties in Djibouti. This makes the harmony of the narrative provided slightly broken at times, as, rather than the coherent and stable image that the notion of "public health system" tends to project, this section will deal with a range of networks acting fairly independently from one another. If the question to be answered here relates to the nature and structure of what can fall within the term "public health" in Djibouti, at least three different elements need to be considered at this stage. This section will review in turn the main diseases/health concerns with which the country has to deal – the hospital structures which have been developed to deal with these concerns; and finally where and how drugs to fight these concerns can be obtained.

Health concerns

When wanting to discuss how TRIPS and pharmaceutical patents might be impacting on health in Djibouti, an important starting point is to explain what diseases are currently considered as forming part of the health concerns of the country. The relation between the treatment of these diseases and pharmaceutical patents will be discussed in more detail in Chapter 7, as will be the changes currently operating in the classification of health priorities in Djibouti. However, a few introductory words are needed on the type of issues faced by the country. As might be anticipated from the economic situation of Djibouti[301], it is facing a serious health crisis. The specific nature and extent of this crisis is particularly difficult to describe because, in addition to the fact that little official data exist about this, it is defined in different ways by different sources. The data provided here aims to emphasise both common and diverging information which appeared in this field. Chapter 7 will return to the meaning of these discrepancies and their potential consequences.

When looking at the diseases discussed in Djibouti – and by those looking at Djibouti – three such diseases most traditionally thought as health crises in Africa appear straightaway. TB is the disease most commonly put forward by actors met in Djibouti on the ground – World Bank reports also put forward the high TB prevalence in the country, stating that "with 588 case of TB per 100000 inhabitants, Djibouti has the second highest rate of TB in the

[301] And the picture of the centre of Tadjoura, second city of the country, provided before can offer an illustration of these difficulties

world"[302]. The extent of the TB crisis was not contested by any actor met in the course of this research, and it is fair to say that it was framed as one of the most central concerns for health professionals during the fieldwork period. It was also a unique example of a disease portrayed as crucial both by actors in and outside Djibouti. Once again, few reports exist in relation to the health situation of Djibouti. The World Bank has produced several reports prior to funding some projects that will be described in Chapter 7, and the government of Djibouti has also produced official information – although the most recent dates back from 2000. If looking at the World Bank reports, malaria is an important concern in Djibouti: "since 1988, malaria is steadily increasing and reaching areas where it was unknown before"[303]. This contrasts with statements from doctors in Djibouti, one of them stating for example that "th*ere was lots of malaria 20 years ago, but in the last couple of years that I've been here I have only seen very few cases. It's not really a problem at the* moment." The same discrepancies appear when considering the HIV/AIDS prevalence in the country. The World Bank states that "nation-wide HIV/AIDS sero-prevalence rate is estimated at 3.0% of the whole population"[304]. In the same report, it also mentions that its research did not offer results as high as the 1999 UNAIDS estimate amongst Djiboutian adults 15-49 (11.9%). For actors interviewed in Djibouti, however, AIDS should not be the main health priority yet. This will be discussed in detail in Chapter 7. Next to these three diseases, several cholera outbreaks have been recorded in the country in recent years,

[302] World Bank (2003) Report No AB7, Updated Project Information Document, HIV, Malaria and Tuberculosis Control Project, March 2003 on p.1.

[303] World Bank (2003) Report No AB7, op. cit. on p.1.

[304]World Bank (2003) Report No AB7, op. cit. on p.1.

catching the attention of both national actors – recording that the most serious one in 1993 had touched 4415 people, while the latest one in 2000 concerned 1920 patients[305] – and the WHO[306].

In addition, the health situation of the country needs to be understood within the broader difficulties that the country is facing, and in particular its economic situation[307]. The most characteristic concern linked to this environment is that of malnutrition[308]. The extent of respiratory and diarrhoeal diseases of the population, especially young children, is also a reflection of the broader problems faced by the country[309]. The high rate of maternal death in the country can similarly be read in the context of poverty and poor sanitation. Finally, heart problems were commonly put forward by actors interviewed, and related in particular to behavioural causes[310].

---

[305] Sante publique a Djibouti – internal document, Ministry of Health, 2003.

[306] http://www.who.int/csr/don/1997_11_26b/en/index.html

[307] "Approximately 33 percent of the population lacks access to potable water and sanitary conditions, and many are very poor" World Bank Group (2003) Report No AB7, op. cit. on p.1. In addition, the following photograph offers a view of Djibouti after the floods of April 2004 mentioned earlier in this chapter – this picture illustrates some of the factors that can quickly participate in the spread of epidemics in the country.

[308] Estimates from 1995 made on a sample population of children less than five years old, consider that 14% of them suffer from serious malnutrition, and 31.1% from chronic malnutrition. These results presented a strong increase as compared to those of a study realised in 1990. Although the results from 1995 are not recent, and new estimates would be useful, they illustrate the extent of this concern

[309] If looking at young children and the reasons why they are taken to hospital, the three key factors are respiratory diseases (36.6%), diarrhoea (21.2%) and malnutrition (11.6%)[309] - Sante publique a Djibouti – internal document, Ministry of health, 2003.

[310] More commonly than the diets of rich minorities, the consumption of Khat (a drug grown in Ethiopia and Yemen, chewed by most men and some women, during most of the afternoon) was put forward to explain the high rate of heart conditions.

The data presented above might not be particularly unusual, except maybe in the contrast and discrepancy concerning specific and well-known diseases, such as malaria and AIDS. To that extent, when looking at this list of health concerns, it might be assumed that the situation of Djibouti does not present anything truly contrasting with common understandings of health difficulties in Africa. Analysing the meaning of the impact of TRIPS in this system might not, therefore, be any stranger than studying its impact in many other countries. However, as this thesis progresses it will demonstrate how, when looking more closely at some of the discrepancies highlighted and at the role of TRIPS and patents in this system, this case study will participate in generating new questions in relation to this same common understanding of what makes health such a difficult issue in poor countries.

Hospital system(s) and access to treatment

The second step in understanding what will be referred to when talking about "public health" in Djibouti is to introduce the hospital system – or rather the different co-existing systems – through which diseases and poor health are addressed in Djibouti. This is partly peripheral to the core of the research questions, and is not something that needs, therefore, to be explained in full detail. However, it is also something that needs to be introduced, as it is an essential part of the overall "public health system" that will be referred to throughout this project. It is also in many respects symbolic of some of the difficulties that will be highlighted in this field. In addition to this, and most importantly, understanding the distribution of patients in specific structures as

well as the overall medical system of the country will be central when discussing both import systems and changes in the pharmaceutical markets in Chapters 6 and 7. Finally, as the following chapters will often refer to the names of particular structures, it is essential to provide a more precise picture of what these names cover.

The importance of the hospital system in the country is better understood by emphasising the fact that they are the first place where patients can hope to get access to treatment. By opposition to what is the case in many countries, private doctors are the exception rather than the rule, and patients will visit hospitals for most consultations. Highly varied standards appear in the hospital system of the country, making clear the difficulties of guaranteeing "health for all" in the country. Although much more time could be spent discussing this particular range of difficulties, this section can only remain basic, essentially serving the aims mentioned above. When looking at hospitals in the country, the largest health related structures can be divided between the public hospital (Hopital Peltier), the semi-public structure for local workers (Organisme de Protection Sociale (OPS)), and the French military hospital (Hopital Bouffard). In addition, a number of smaller dispensaries are spread around the country.

"*Patients will basically first try to get into Bouffard. If they can't, they'll try to get into the OPS. And if they can't be accepted in either, their o*nly option will be to go into Peltier."

This quote is a particularly clear illustration of the relative situation of the three main health structures of the country. The negative reputation of the Hopital Peltier is a crucial element. At the time of fieldwork, it was the very last option for everyone, and brief consideration quickly shows many reasons for this. Although until thirty years ago Peltier was considered a very good hospital, "a reference in the region", its situation has since then slowly degraded. The hospital is believed to be weak on many aspects, from the qualifications of staff to the number of beds available, the availability of drugs, or even the salubriousness of most of the wards. In terms of medical staff, the hospital has thirty five doctors, including two Djiboutians, and cooperants from several countries[311]. Several problems arise from this mix. First, the system of cooperation raises issues of communication and harmony[312].

"*There is very little coordination between anyone's action or* approach here – donations come from here and there, different countries send a bit of money, a *few staff, but nothing seems coherent."*

Second, the inadequacy of the staff in terms of speciality is often mentioned as a key problem of the hospital – some specialities are not represented at all, while other key fields are under-represented[313].

[311] It should be noted that changes in the hospital happen frequently, and that the situation described here is as it was described in 2004.

[312] China has in particular provided medical staff most recently, although none of them speaks French or any other local language, which makes consultations rather chaotic. Egypt was also providing four doctors, who have all left recently after a conflict with the local staff ended up in a general fight leading to a wide diplomatic incident.

[313] Only two surgeons are available, which is insufficient to deal with the population referred to them, especially in cases of emergency.

In terms of facilities, the hospital also has poor reputation, both amongst medical professionals and amongst local people as a whole. "Trust me, you *don't want to ste*p in there! Nobody wants to anyways – *it's so dirty and so* disgusting…"[314] Facilities are getting old, inadequate, badly maintained and often not up to any cleanness standards. The government makes some forms of investment in the hospital, and a brand new building has, for example, been constructed recently. It contains amongst other things a new X-ray machine, of very high standard even on "European" criteria, according to several doctors. However, without any radiologist in the hospital at the moment, it is very likely that no-one will be able to use or maintain this machine, and many wonder why so much money went into something that will be of very little use. "What are they going to do with it now? It all looks great, and we can say that we have a highly modern device – but then how to use it? How to maintain it? In a year it *will probably be completely out of order…*"

The second hospital that will be referred to throughout this project is the semi-public OPS (Office de Protection Sociale), which provides free health services to private employees in Djibouti. It is based on a health insurance system where employers have to pay a certain monthly amount towards the structure[315] and where employees may then benefit from the services. Most of the people treated there have low incomes – many employed as maids or private guards for example - and would not be able otherwise to access health treatments. "We mainly treat people with little resources, people employed privately as maids

[314] This comment was made by a local patient shortly after I arrived, when I stated that I had not had visited Hospital Peltier yet.

[315] 7.2% of salaries, according to informants from the hospital.

for French people here, and their families." The standard of services is believed to be rather high, according to informants from the medical field, or from patients of the structure. Doctors are French and local doctors. Overall, and although the structure lacks a few specialists, it is considered an efficient hospital, and is now much favoured above the public hospital.

The last of the main hospital structures in Djibouti is the French military hospital – CHA Bouffard. The hospital is a fully French-run structure, administered by the central health administration of the Army, with fifteen French doctors, and both French and local staff. Access to the hospital is run both by formal and informal rules. Officially, the hospital is open to French military staff and their families, as well as members of the Djiboutian army and their families, and a number of contractors – such as German soldiers based in the region, or most other employees from military boats using the port. In addition, local people can access the hospital according to rules which seem more based on customs or habits than on written regulation – although written rules do, of course, exist. While I was carrying out fieldwork, the hospital had just been put under new management, and rules of access seemed to have become more restrictive[316].

[316] This has been criticised both by a number of the French doctors employed in the hospital, and by local people and members of the Djiboutian government. Ministers have thus been refused access by the soldier in charge of letting people in, and had to call doctors they knew personally to enable them to access to facility. The issue became more controversial recently, when the President of the Republic of Djibouti was refused access by a soldier because he did not have his ID on him.

The basic rule for accessing the hospital was that patients needed to have an appointment with a doctor to be able to enter the premises of the hospital. In practice, people who were not officially on the main list of those who are allowed to enter the hospital needed to know one of the doctors or staff, in order to obtain a certificate of appointment signed by a doctor. Apart from particular controversies in determining who should be eligible as patients, the hospital is a well-run structure, of high quality even by European standards, and with most medical specialities represented. Many patients who can access the hospital can be exempted from payments although most medication is to be bought from private pharmacies once the patient gets out of hospital. In terms of facilities, tests or drugs available within the hospital, the structure also follows French standards, and does not encounter any specific difficulties.

In addition to these main medical structures, a few others are worth mentioning. First, a few private doctors are established in Djibouti-town, as well as a private clinic – access is generally, however, limited to patients with enough money to pay for consultation. In addition to this, smaller public hospitals are run – technically, every district has its own hospital, although their state is as can be expected by comparison to what is considered as the "main" public hospital of the country, and although staff are often largely unqualified. Cooperation programs have been run to try to improve the situation, but it remains rather catastrophic[317]. Finally, some specialised

[317] The issue of geographical access to health has thus become a great concern. It is estimated that about 80% of the population lives in the capital. For the remaining part, getting into Djibouti town for treatment is a very serious issue. Means of transportation are limited from smaller towns, with very few people having private cars, and the conditions of transportation in

structures exist, such as the Centre for Tuberculosis, the pediatric hospital of Balbala, the Maternity Hospital de Dar el Hanan[318] and the Centre Yonis Toussaint (which deals with STIs and AIDS). Each of these structures are public and complement the treatment available in Hopital Peltier – in each of these fields, however, the two other main hospitals – Bouffard and OPS - provide their own treatment. Once again, comments on these structures are rather frightening. The hygiene and facilities of the places are deemed to be fully inappropriate to the needs of the population.

Overall, the standard of hospitals in Djibouti varies largely according to each specific infrastructure. For many patients, however, the opportunities to access good treatment remain limited. The size of the structures and number of staff might seem relatively satisfying at first sight. However, they cannot hide the extent of the crisis:

"When you lo*ok at the "number of beds per inhabitants", which is one thing* the WHO for example always looks at when estimating the state of public health services in a country, it all seems quite good. But then when you get there and ask to actually look at the beds, *its another issue… some of them are simply not there. And many are there, but hardly look like a bed anymore!"*

---

public buses raising serious issues of safety for people with a fragile health. A number of people thus have to rely almost exclusively on family help for bringing over drugs if needed, and talk to a doctor in their place, or have to rely on traditional medicine if they fall ill. The following picture of the countryside of Djibouti illustrates the difficulties of circulating in the country. The ferry from Tadjoura to Djibouti is an important mode of transportation.

[318] As an indication of the problems faced by smaller structure, the maternity unit del Hanan - see previous picture - was provided with its first phone line in June 2002, see La Nation, 02/06/2002.

To conclude, in spite of having two well-functioning hospitals – Bouffard and the OPS – the country cannot fully ensure that its population gets access to decent medical structures.

Access to medication

The last element that needs to be considered in order to understand f the expression "public health" relates to access to medicines. This chapter addresses issues of "surface" – what can be gathered from a first look at the country, without raising problematic issues. It will not run yet deeper into the most complex aspects of the networks, as these will be addressed in the following chapters. What will be considered here is essentially the perspective of patients – where do they find drugs? How likely are they to afford them? What do they do when they cannot afford them? Chapter 6 will then look deeper into issues of import, and look further into the origin and nature of the different drugs used.

The first question to consider here is from where patients buy their drugs. Private pharmacies are the most central points of passage[319] through which patients access medication – they import their own supply of drugs, which carries consequences that will be explained again in Chapter 6. Three private pharmacies have been created in town – two in the centre and one in the

[319] Not full "obligatory points of passage" for the population as a whole, but certainly so for most patients – for an early use of the term, see Callon M. (1986) "Some Elements of a Sociology of Translation: Domestication of the Scallops and the Fishermen of Saint-Brieuc Bay" in Law J. (ed) Power, Action and Belief: a New Sociology of Knowledge? Sociological Review Monograph 32, London: Routledge and Kegan Paul, pp. 196-233.

suburbs[320]. The laws on opening pharmacies and regulating their management are officially based on French legislation – although a degree of flexibility is allowed[321]. Next to private pharmacies, the OPS is the second source from which drugs may be obtained – but only for some, since the structure is only opened to private employees. Drugs are provided to patients free of charge, which is an essential element in facilitating access to long term treatment. Bouffard provides appropriate medication while patients are treated there, but external patients have to buy their medication from private pharmacies. The same is true for patients from public hospitals. At the time of fieldwork, however, a further source was being created, and public community pharmacies (see picture) were being opened to try to provide new sources of access for medicines (considered in detail below) and for the moment a very small part of what most patients encounter daily. The need for new sources of medicines is particularly crucial because the price of drugs in private pharmacies is high, compared to European prices. The result is that most drugs in private pharmacies are unaffordable for a considerable part of the population, and only a minority of the population are regular customers in private pharmacies. French patients and wealthy locals are largely represented in the queues of private pharmacies, while others are likely to remain only

[320] Two of them are owned by the same pharmacist.

[321] While French law forbids a pharmacist to open more than one pharmacy on his own account, two of the pharmacies in Djibouti town belong to the same pharmacist – by putting it under another pharmacist's name, it became tolerated. "Everyone knows its mine, the *government knows its mine. Its not legal, but it doesn't bother anyone, so its fine!"* Interesting approach to law, where although every person concerned seems to consider the law as useless a "legal trick" is paradoxically considered as necessary – one could wonder why not just openly ignoring the law if the government accepts it.

occasional visitors. As will be explained in Chapter 6, this relates to the quasi-absence of generics from the pharmaceutical market of Djibouti, and the remaining role played by pharmaceutical patents in spite of their absence of legal existence.

Surprisingly, the price of medicines legally available has not caused the parallel market for drugs that might have been expected. While the spread of counterfeit medicines, in particular in poor countries, is emphasised in many reports[322], most informants in Djibouti said that the black market for drugs was very limited, and not a real concern for the state. Some also mentioned, however, that the real control of drugs within pharmacies was very limited. There was little means to know if drugs illegally imported are not occasionally sold in stores[323]. Apart from this, no drug was observed to be sold on the street during the fieldwork, and it is very likely that pharmacies remain the main place where people try to buy drugs. Consequently, the main impact of the cost of drugs is a non-existing access for many local people, or often a "temporary access" – people buy some drugs but cannot afford to follow their treatment as prescribed for lack of funds.

Traditional medicine is often considered an important element in countries where access to "modern" drugs is limited. This is an area in which official

[322]see for example the WHO website: "Counterfeit Medicines: factsheet", available at: http://www.who.int/medicines/organization/qsm/activities/qualityassurance/cft/counterfeit_factsheet.htm

[323] Frightening stories of "boutres" (wooden boats – see picture) illegally bringing counterfeit drugs into the country from Yemen were mentioned, although no-one was quite sure where these drugs were meant to end up.

reports do not really exist, and apart from one research report on the pharmacy sector[324] produced for the Ministry of Finances, the main data available for this research was collected during interviews. Actors interviewed emphasised that traditional medicine was rather limited in the country, and that most people living in town would spontaneously seek access to modern medicines. They attributed this in part to the fact that there were only restricted "natural resources" in the country, and in part to the fact that people in town had been used to relying on modern drugs, even if the degradation of the public hospital had now changed this. It was also said that outside town, traditional medicine remained used for many basic diseases, and the report written for the Ministry of Finances provided some examples of the remedies used[325].

Overall, at the moment, it is fair to say that access to medicines remains limited to the richest part of the population in Djibouti. Chapters 6 and 7 will address two key questions that will complement this analysis: first, what role do pharmaceutical patents play in this system? Second, how can the changes currently being implemented following an input from the World Bank be described?

[324] Institut Superieur des Affaires de Djibouti, Collection "Etudes de Metiers", Pharmacie, available at www.ministere-finances.dj/publications/PHARMACI.HTM

[325] TB patients are for example looked after by feeding them camel meat and goat meat; hepatitis is treated by making patients drink and bath with water in which local plants are boiled (Wabialia and Mahina Faro), while some plants remain known only by the "guerisseur".

SECTION 4: DEVELOPMENT OF A LOCAL PHARMACEUTICAL INDUSTRY IN DJIBOUTI – IS IT A TRIPS ISSUE?

As explained before, studying patents in society is almost always understood as involving a study of how patents impact on industrial development. However, in this research, it became clear early on that, although studying the pharmaceutical industry in Djibouti raised highly interesting questions, it was not truly part of the answer to questions drafted in relation to the impact of TRIPS and pharmaceutical patents on health in the country. This section, rather than introduce the links between patents and industrial development in the country, will explain how it became clear that this link was at the time of fieldwork unclear at best and should not become the centre of this analysis.

Finding information on the emergence of a local industry in Djibouti was an interesting part of the fieldwork. The lack of awareness of many actors of what was happening in relation to this, or what had happened over the past few years, made data-gathering particularly difficult. In 1996, a first attempt was made to create a local pharmaceutical industry in Djibouti – La Societe Djiboutienne d'Industrie Pharmaceutique. It involved local investors, one of the local pharmacists from the OPS, and later on some pharmacists from other countries, plus several employees – around twenty people are said to have been employed originally. A French laboratory was somehow associated to this initiative, although informants did not seem very clear on this issue, and were

in particular unable to give a name to this lab[326]. The structure produced four basic drugs - paracetamol and aspirin, chloroquine and metronidazole – "because that is what we need the most around here". They were all out-of-patent drugs. The structure has now collapsed[327], for various reasons that will be explained below.

At the time of fieldwork, a second attempt to create a local industry was in process – one might have expected it to be located within the premises created in 1996, but this was not actually the case. A new building was being built next to the original factory. Once again, the project involves local and foreign pharmacists, and is led in association with a French lab. The project aims at producing basic drugs, as well as some pharmaceutical solutions. As in the first case, the drugs to be produced are out-of-patent, and the project as it is currently framed does not involve research in any way. The practical realisation of the industry was limited, at the time of fieldwork, to a building only a few centimetres from the ground.

The impact that TRIPS might have on the emergence of a local industry in Djibouti is obviously an issue that was considered closely in this project. The impact of TRIPS on emerging industries has been questioned centrally in the literature, as explained in Chapter 1, and, in particular, the impact of TRIPS in limiting possibilities for an emerging generic industry to grow stronger has

[326] The report from the Institut Superieur des Affaires de Djibouti (op. cit.) mentions Panpharma, although this could not be verified.

[327] A short visit to the site, built in zone franche, showed me a building still apparently guarded by a few men, although it is currently officially out of use.

been highly controversial[328]. The positive effects of a legal regime in which pharmaceutical products are not patentable on the development of a local industry has been demonstrated by the experience of many countries[329]. The impact that TRIPS could have on countries which have not started developing a local industry can therefore be questioned in that respect. What needs to be considered at this stage is whether the empirical evidence collected in this case study on the difficulties met by the pharmaceutical industry can demonstrate a link between pharmaceutical patents and industrial development – if pharmaceutical patents can be framed as an actor in the network developing around the local industry, and how this relates to health.

When looking at the example of the pharmaceutical industry in Djibouti, several elements need to be highlighted. First, the industry considered here is aimed exclusively at producing some of the most common drugs with structures clearly known, widely available, and out-of-patent – such as paracetamol and aspirin. The local industry is very far from aiming at

[328] See for example Seeratan N. N. (2001) "The negative Impact of Intellectual Patent Rights on Developing Countries: an Examination of the Indian Pharmaceutical Industry", *St Mary's* Law Review on Minority Issues (3) Spring 2001 pp.339-412; Koshy S. (1995) "The Effect of TRIPS on Indian Patent Law: A Pharmaceutical Industry Perspective", Boston University Journal of Science and Technology Law (4) pp. 1-56.

[329] See for example: Henderson E. (1997) "TRIPS and the Third World: The Example of Pharmaceutical Patents in India", European Intellectual Property Review 19(11) pp.651-663; Keayla B.K. (1999) Pharmaceutical Industry and Patent System in India: A Case Study, in TRIPS Agreement on Patent Law: Impact on Pharmaceuticals and Health for All, New Delhi: Centre for the Study of Global Trade Systems and Development; Kirim A.S. (1985) "Reconsidering Patents and Economic Development: a Case Study of the Turkish Pharmaceutical Industry", World Development 13: 219-36; LaCroix Sumner J. and Kawaura A. (1996) "Product Patent Reform and its Impact on Korea's Pharmaceutical Industry", International Economic Journal, 10(1), Spring 1996, pp. 109-124.

producing modern drugs which are still under patents - essentially because those in charge believe that what the local market needs most is these few basic drugs, as quoted above and as will be explained again in Chapter 7. It is even further from considering any form of research activity, both because of a lack of material and financial means, and because of a lack of available expertise of this type. Some questions might be considered. In particular, both the development of expertise and the determination of the needs of the population could themselves be read in the light of patents – and of the affordability of patented drugs. Some of this second idea, in particular, will be discussed in more detail in the coming chapters. However, it should be noted that, as far as the pharmaceutical industry is concerned, there was no empirical evidence that could be read as highlighting the embedment of patents in any of the decisions taken[330]. To that extent, this hypothesis will be left aside at this stage, although some of its dimensions will be discussed again when looking more specifically at the shaping of health issues.

The second element to emphasise is the complexity of the issues raised when looking at the emergence of this industry. It is essential to consider the place that TRIPS can have in these questions. These can be understood more clearly by using the example of the first attempt to build an industry. Some of the reasons for the failure of this industry seemed to contrast with the complex issues raised by the long term effects of TRIPS. Speculation on the potential long term impact therefore seemed unnecessary. The problems mentioned by

[330] "*In ANT, it is not possible to say: "No one mentions it. I have no proof but I* know there is some hidden actor at work here behind the scene"", Latour B. (2005) Reasembling the Social: an Introduction to Actor-network Theory, op. cit. on p. 53.

informants concerned the lack of local expertise, personal conflicts that emerged around the industry, and conflicts around what could appear as basic manufacturing techniques – the quality of paracetamol was thus questioned by potential investors. The lack of information that most actors, including in the Ministry of Health, have on the industry is also striking in a country of such small size and where industrial projects remain very small in number.

The difficulties now faced by the second attempt to build an industry already appear to be similar to those experienced before. They also include practical concerns and issues of expertise. The difficulties expressed by informants working on this new project were essentially basic practical issues. The actual authorisation to build a laboratory was apparently difficult to obtain, and was finally obtained directly from the president – as some investors are close to him. In addition, the question of local expertise is an issue investors are currently struggling with, since they would like it to remain a Djiboutian project, but are finding it difficult to identify people with adequate expertise to work in the laboratory. Finally, it is worth re-emphasising that this research is ultimately concerned with the relation between TRIPS, pharmaceutical patents and health. The dimension of the project being planned is not of such an extent that it is at the moment likely to become a key public health actor in any case, and its place in the research questions appeared, in this respect as well, to be rather limited. Overall, it was decided in this thesis that patents in their relation with the industry in Djibouti were not at this stage relevant enough to be part of the story to be told on public health. Although it was necessary to spare some

time explaining this choice, we will now concentrate on IP and public health systems.

CONCLUSION

This chapter has presented the final elements of background necessary to understand the focus of this research. The notions of "IP" and "public health" in what they cover in this project should appear clearer. The views of TRIPS and pharmaceutical patents undertaken here should also be more precise. In the course of this project, when discussing how pharmaceutical patents and TRIPS have become public health actors in Djibouti, and when questioning how "intellectual property" and "public health" can be perceived as interdependent but overlapping in Djibouti – at least in some of their actors – what appeared was a multiplicity of relevant networks, relevant connections, in which TRIPS and pharmaceutical patents seemed to become inherently fluid and difficult to define. Throughout the empirical part of this research, the complexity of TRIPS and pharmaceutical patents appeared progressively clearer, and the extent of the associations through which they exist had to be seized before the objects in their relation to "health" could be fully understood. The next three chapters will present three dimensions of the story of TRIPS and pharmaceutical patents in Djibouti, and explain why these objects can be understood totally differently if looking at them through their many expressions and sometimes contradictory effects. From different viewpoints, TRIPS and pharmaceutical patents appeared as playing a particular role, as different objects or sets of prescriptions, as well as acted through different

mechanisms and in different directions. The following chapters will present in turn what TRIPS was if following the Ministry of Trade network; the political connections of which TRIPS as a set of written prescriptions is dependent; the role of pharmaceutical patents in the import system of Djibouti; and finally the role of TRIPS in its networked effects in the health networks of Djibouti. One of the difficulties of this task is that, as these networks sometimes overlap, the presentation and definition of their own limits can be difficult. However, it will be explained throughout why, in this particular case study, these appeared essentially as distinct spheres, and we will discuss in conclusion how the gaps between these spheres can explain the originality of some of the findings made in this research.

CHAPTER 5 - TRIPS AND "LEGAL" ASSOCIATIONS - UNDERSTANDING THE ROLE OF TRIPS AS PRESCRIPTION

This particular chapter follows the traces left by TRIPS as a set of prescriptions – as a set of official rules carried on paper, expected to have a pre-defined impact – in Djibouti[331]. Although the pre-definition and delimitation of the particular dimension of TRIPS under investigation here is complex and will partly become clearer throughout this chapter, "TRIPS as prescription" refers to TRIPS as a material punctualised on paper, carrying a set of supposedly prescriptive, official and written rules. It is understood that there are further relevant dimensions to TRIPS, and that the set of written rules that are often punctualised as "TRIPS", and are under scrutiny here, obscure a large body of complex connections, some of which will be undone[332] throughout the remainder of this project. However, the idea of TRIPS as prescription also translates a relevant and specific dimension of TRIPS – a point of entry and a particular shape through which the arrival of TRIPS in Djibouti can be traced, and a set of expectations. It is also the most commonly studied dimension of TRIPS and a necessary starting point for questioning the relevance of a large

[331] The term prescription, as explained in Chapter 2, is used in ANT to reflect the idea of expected mobilisation and regulation of action – see Akrich M. and Latour B. (1992) "A Convenient Vocabulary for the Semiotics of Human and Non-human Actors", in Bijker W. and Law J. (eds) Shaping Technology, Building Society: Studies in Sociotechnological Change, Cambridge MA: MIT Press, pp. 205-224. It will be used here to refer to the idea that TRIPS is expected to carry effects anticipated to mobilise actors in a certain pre-defined way by its creators.

[332] As explained in Chapter 2, the term is used here to refer to the process through which the hidden connections that make up what appears temporarily as a punctualised network can be highlighted through explanations, in order to make the mechanisms of the networks understandable.

set of literature in this area– although the terminology used here is often borrowed more strongly from ANT than from other texts discussing TRIPS. This chapter therefore follows the set of connections and mobilisation generated by the arrival into Djibouti of TRIPS as a new, written set of rules, officially binding and prescriptive. It investigates the links created by and around the introduction of TRIPS as a set of written rules in Djibouti, and explores how far it appears to have mobilised actors directly concerned – and where it stopped. It emphasises how, when investigating the role of TRIPS as a set of prescriptions in the different networks in which it needs to be enrolled to maintain its social action in its prescriptive pharmaceutical patents dimension, the limits to the translations and mobilisations generated by the text appeared as tighter than is often expected in some legal writings.

This chapter is based on an investigation of the way different actors have modified their behaviour – or anticipate future modifications of their actions – following the integration of TRIPS as written prescription in the country. The question to be answered here is whether TRIPS as prescription is generating new associations and translations in Djibouti. This will be addressed by presenting the traces left by TRIPS in different loci, and by questioning its action and circulation.

This chapter starts by presenting TRIPS as prescription in its dimension as a social mediator – as an agent able to act and make others act[333]. It discusses the

[333] The term is borrowed from the distinction between mediators and intermediaries offered by Latour B. (2005) Reassembling the Social: An Introduction to Actor-network Theory, Oxford: Oxford University Press: "An intermediary, in my vocabulary, is what transports meaning or

marks it is leaving in one particular office and questions what this means in terms of its social action (Section 1). It then questions whether traces of TRIPS as a set of official rules can be found when moving out of this particular office, by extending the range of connections to be considered (Section 2). Finally, this chapter discusses how the action of TRIPS as prescription needs to be read within the policitical networks of Djibouti and how this wider context can participate in understanding the issues raised throughout[334] (Section 3).

SECTION 1: TRIPS IS CHANGING WRITTEN, NATIONAL LAW…

This particular section looks at what can be described as the official story of TRIPS in Djibouti, by explaining the changes generated by TRIPS through its integration as written prescription in the Ministry in charge of its implementation. It explains the extent of the re-orderings it generated within the Ministry of Trade – although this term is partly misleading, and the

---

force without transformation: defining its input is enough to define its output. For all practical purposes, an intermediary can be taken not only as a black box, but also as a black box counted for one, even if it is internally made of many parts. Mediators, on the other hand, cannot be counted just as one; they might count for one, for nothing, for several or for infinity. Their input is never a good predictor of their output, their specificity has to be taken into account every time. Mediators transform, translate, distort and modify the meaning of the *elements they are supposed to carry"* on p.39.

[334] The notion of context can of course provide some conceptual contradictions with ANT if understanding the term as referring to a stable, preestablished "frame". However, the term becomes less problematic by understanding the relation between "parts" and "whole" explained in Chapter 2; the fact that every action and association can be relocated within more complex and other associations and relations. "Since they are pinpointed inside the many *oligoptica and panoramas, there is nothing wrong anymore with using the word "contexts*", Latour B. (2005), Reassembling the Social: An Introduction to Actor-network Theory op. cit., p191.

networks followed will only travel through one particular office, in which one person officially works and others occasionally visit[335]. It is the story of TRIPS in this particular office and through the connections that make up both TRIPS as written law in Djibouti and this office as a mediator in this translation that needs to be given here.

To begin understanding the story of TRIPS in this office, what it is doing and where it is, the traces left by TRIPS as written prescription need to examined[336] – its (limited) material presence as a set of rules laid on paper, the traces of the WTO and others left in these materials, the words, thoughts and new concepts it left behind (predominantly expressed by the member of staff officially in charge of TRIPS). There is no need here to remind the reader again of the extent of the changes that TRIPS should be generating in the legal system of Djibouti for the country to be considered as "TRIPS-compliant". These new obligations, as well as the time limit for this to happen, have been detailed in Chapter 1. All that needs to be said here is that, for this research, TRIPS needs to (or needs to make others) generate pharmaceutical patents as an active tool, produce written rules that should circulate back to the WTO, create new structures that will ensure that all those that relate to TRIPS comply with its dispositions, and most importantly, generate some form of social mobilisation

[335] As far as is materially feasible, this study will keep "looking down" and analysing how circulation can be narrowed down before being deployed again – see Law J. (2002) "Method, Complexity and the Baroque" published by the Centre for Science Studies, Lancaster University, LA14YL, UK, at http://www.compa.lancs.ac.uk/sociology/papers/law-and-if-the-global-were-small.pdf

[336] Following Latour's emphasis on the need to understand the social through the traces its circulation leaves – Latour (2005) Reassembling the Social: An Introduction to Actor-network Theory op. cit.

– "legal compliance". When visiting the office where TRIPS as a set of written rules is being translated from an international law text into national prescription that actors in Djibouti itself are expected to follow, I tried to understand what had been done in that respect so far. This meant following the road already paved by research in this field of looking at the "legal impact of TRIPS" - in the office implementing TRIPS, the logical starting point was to find out what had been done in terms of "legal implementation".

TRIPS and legal changes

The answer given was itself straightforward, and did not at this stage contrast with my expectations: "We are now working on implementing patent law – because we have signed the TRIPS agreement. WIPO is offering us some advice when creating the law". The fact that TRIPS as prescription should trigger a set of reactions was not challenged at this stage: TRIPS had been signed, someone knew about it and was "working on it". There was no material outcome of this "work" yet, no documents produced through it, but it did not appear as truly "worrying" as there was still a bit of time for Djibouti to implement TRIPS. In addition, WIPO was providing some assistance, as it is expected to do[337]. The general feeling that this story would conform to existing

[337] « WIPO has been providing a wide range of technical and legal assistance for developing countries and least-developed countries for the last three decades. This includes assistance for the establishment, modernization and automation of intellectual property offices, human resources development programs, the provision of legal advice on compatibility of legislation with relevant international treaties, and assistance in strengthening capacities to enforce intellectual property rules." Available on: http//:www.wipo.int/about-ip/en/studies/publications/health_care.htm

understandings and expectations remained while the official story of TRIPS was being unfolded by the man in charge. Details of the "work" carried out did not bring any more unexpected findings. Although a number of things were being discussed, little was established in any definitive form at this stage. Pharmaceutical patents were one of these "things":

"We will also deal with questions of licences for making drugs, and the questions raised by generic medicines will also be in there. But for the moment, we are only at a discussion stage – nothing is on paper yet."

Pharmaceutical patents had entered the office – at least in words. It was not there in a material form yet, as once again nothing was ready "on paper". But it was there as a concept – if someone could talk about it, it "existed" at some level at least.

At this stage, it is useful to step back briefly and reflect on what all this means about the set of transformations that TRIPS as prescription has been generating in this office of the Ministry of Trade at the time when this fieldwork was carried out. The first thing it has changed, of course, resides in the new role given to this member of staff to implement the text, and hold meetings with advisors from WIPO to decide on the way to implement TRIPS. It has also participated in generating new issues, new concerns, that all made in turn "intellectual property" appear as a policy element in the limited part of networks that we have so far studied. Next to the specific case of pharmaceutical patents, issues of structures and expertise were mentioned

many times by the actors in charge of implementing TRIPS. They were all elements that had briefly emerged as social questions in 1996, when the law on artistic rights was adopted, before slowly disappearing. However, these issues somehow remained in the background, hidden behind what was centrally presented as the key priority of the "government" - the transposition of a set of rules visible on paper which would satisfy TRIPS requirements[338]. This sense of priority is of course understandable from the logic of TRIPS itself, and the common idea that its impact will be causal and ordered in a certain way – as well as by the fact that the main element to be circulated back to the WTO – and other interested parties - would be this written set of rules[339]. TRIPS was therefore creating work directed at writing a new law, transferring the set of rules created by the WTO into something made in Djibouti, for Djibouti. But what else was TRIPS anticipated to do? How much further was it likely to reshape orderings in Djibouti?

Potential impact of TRIPS – if it "works" as expected

This was the second step needed in this analysis, and this still related largely to parts of the wider debate of the "impact of TRIPS". In this chapter, the maybe more modest – although possibly more cryptic – terminology used will remain that of the "direct impact of TRIPS as prescription" (as we will see in Chapter 7 that the question of the impact of TRIPS as a political actor runs much further than what is often understood). The question of the impact of the new

[338] The efforts were repeatedly presented by the official as directed towards legal compliance – *"le respect des dispositions".*

[339] See TRIPS Article 63.

set of official prescriptions carried by TRIPS – and of the new set of rules created in Djibouti following TRIPS – was first addressed with the representative of the Ministry of Trade in charge of its implementation, and those working closely with him. Once again, the first stage of answer given was not very different from what is often officially stated in relation to TRIPS. The answers provided balanced the potential benefits[340] of creating an IPR system with the relative weaknesses of TRIPS[341]. With a few industries starting up in Djibouti, the introduction of patents was presented as something that could potentially benefit the country:

"Until recently there was absolutely no industry in Djibouti, so we really did not see how patents could be useful for us. Things are changing though, and we are trying to develop some industries here, as well as attracting new foreign *investors."*

[340] And related to this extent to comments made in a large range of literature on the impact of TRIPS on industrial development or foreign direct investment – for example, see Mansfield E (1994) "Intellectual Protection, Foreign Direct Investment and Technology Transfer", Journal of International Economics 16: 205-226; Maskus K. E. (1998) "The Role of Intellectual Property in Encouraging Foreign Direct Investment and Technology Transfer", Duke Journal of Comparative and International Law (9) pp. 109-161; Primo B., Fink C. and Sepulveda C. (2000) "Intellectual Property Rights and Economic Development", World Bank Discussion Paper no. 412, available at http://www.bvindecopi.gob.pe/colec/cbraga.pdf; Sherwood R. (1990) Intellectual Property and Economic Development, Boulder: Westview Press.

[341] Once again related to wider comments on the problems generated by the agreement – see for example Abbott F.M (2005) "Managing the Hydra: The Herculean Task of Ensuring Access to Essential Medicines", in Maskus K. E. and Reichman J. H. (eds) International Public Goods and Transfer of Technology under a Globalized Intellectual Property System, Cambridge: Cambridge University Press, pp. 393-425. See also the discussion provided in Chapter 1.

However, TRIPS itself was criticised as not being the most appropriate instrument for poorest countries, and the "classic" story of TRIPS thus appeared, once again, to be repeating itself in this office:

"After Doha, there were some recommendations, but since then nothing was done in practice. So far nothing has changed, the text is still the same. In a context where all we have are industries just starting to emerge, some aspects of the text seem inadapted. TRIPS is not flexible enough for developing states, and especially for least developed countries with a very small *recent industry."*

But this was also still only expectation, anticipation, based on theoretical discussions on whether active patent laws would benefit the country or not, and whether the written content of TRIPS was close to the ideal of the poorest countries. This was essential to consider, but when comparing this particular set of data to what is to follow, it started losing some of its immediate relevance. Although TRIPS was producing effects, opinions, work, meetings and new concepts amongst a few, although its effective implementation would potentially be loaded with effects, key questions were still not answered: was TRIPS actually likely to be followed by any actor? Would it actually ever deploy its effects and mobilise any other actor? And was it in any respects yet the considerable public health issue it is framed to be? This now needs to be discussed.

SECTION 2: … BUT DOES IT REALLY MATTER?

The role of TRIPS in the Ministry of Trade, and the anticipation of the potential effects of a set of written rules if it was to be obeyed, is only a small aspect of what needs to be looked at in order to understand what TRIPS as a set of prescriptions is currently doing – and can be expected to do – in Djibouti. The issue that also needs to be addressed is that of the re-orderings operated by TRIPS not only within the Ministry of Trade, but also around it. In particular, for TRIPS in its pharmaceutical patents dispositions to be active, drugs in breach of international standards of patents need to remain excluded from the territory. And this implies that those importing drugs are aware of the rules and made to obey them. In order to understand how TRIPS in its pharmaceutical patents dispositions is currently starting to act in Djibouti, it was thus central to move out of the office of the Ministry of Trade itself, and talk more broadly to actors in the public health field, the Chambre du Commerce, to other actors in the Ministry of Trade itself, all those that can somehow influence what goes in and out of the country in relation to pharmaceuticals. This is particularly crucial not only because this research is interested in what TRIPS is doing as a whole, but more specifically in what it is doing to health – and whether it is yet shaped as a public health matter in Djibouti. When looking outside the "TRIPS office" however, only "negative" traces of TRIPS appeared, in statements that emphasised the irrelevance of TRIPS, and shaped it as only one more rule that no one would take interest in.

Prescriptive value of international trade rules and mobilisation in Djibouti

This section investigates the role and action of TRIPS as written prescription outside of the particular office where it is being implemented. Part of the difficulty of this section, as will appear throughout, is that it aims to some extent to demonstrate "absence", something which, by definition, leaves little traces for empirical research. However, it appeared in this research through actors' perceptions and views, and through travelling empirically through associations that TRIPS would need to follow to move from the Ministry of Trade into further connections. Mainly, this section is a brief story of absence and weakness of TRIPS as a set of official prescriptions – and we will see that there is more to TRIPS than that - and is offered as a reply to the common expectation that TRIPS as written law is a public health issue, as explained in Chapter 1. It is also offered as a reply to the limitations of the notion of "IP system" or "pharmaceutical patent system" as a stable social network, and demonstrates that instead of a network, several sets of sub-connections were identified in an unrelated fashion. This will be done in two steps, first by explaining how the limits to the social role of TRIPS as prescription appeared within the trade area, and second by moving outside this field, and watching what remains of TRIPS within the public health network of the country.

When questions about the role of the official implementation of TRIPS were extended within the trade field, but outside of this particular office, the action of TRIPS as prescription became more doubtful, and its limits clearer. Interviews with actors outside the particular Ministry of Trade office – in other

offices of the Ministry or in the Chambre du Commerce for example – emphasised the idea that TRIPS was unlikely to modify actors' relations and behaviour outside that particular ministry. This was explained partly on the basis of their informed knowledge about WTO mechanisms more generally:

"*the way it works is that it doesn't change anything unless someone complains about what you are doing… we are so small that hopefully they won't complain!"*

Next to the written/official changes actually made, and on which actors such as WIPO representatives can have easy access to information[342], they seemed convinced that it would indeed change nothing to local practice. However, this might not need to be seen as an essential point – although probably a symbolic one. Indeed, TRIPS in its pharmaceutical patents dimension might still be highly socialised and active in political networks if extending only from the office where it is being implemented to public health actors. It might not strictly need to connect to any other actor within the trade and industry field if one office is aware of it and those who import and market drugs are made to follow new procedures closely. However, once starting to question what is TRIPS as prescription within the public health network of Djibouti, its relation to social actors becomes maybe even more doubtful. One can begin wondering whether TRIPS in this particular dimension has any agency in this network.

[342] Although looking through the WIPO website can raise some questions about this "access" or the interest of international institutions. The diverging information provided on the WIPO website was introduced in Chapter 1 and can be found at http://www.wipo.int/about-ip/en/ipworldwide/pdf/dj.pdf and http://www.wipo.int/eds/en/ccs/pdf/dj.pdf

We will see in Chapter 7 that TRIPS is certainly leaving traces within the public health network, including in some governmental offices. However, this section will start by explaining how TRIPS as written prescription appeared to struggle to move from one office in the Ministry of Trade to wider political networks.

TRIPS in public health policy networks – an uncertain presence

When actors in the public health area were asked about the official implementation of TRIPS, their answer was less moderate than the quotation provided above. When discussing the potential role and impact of TRIPS through its implementation in Djibouti, most informants stated that TRIPS would not have any form of impact - some of them adopted a tone particularly strong and convinced when making statements such as those illustrated below, or openly laughing at the idea that anyone could actually think it might work. Every informant met was convinced that the agreement would not impact at all on actors' behaviour at national level, and simply would not change anything to the way they work – it would not raise any issue in relation to health and access to drugs. For example:

"This will not affect us in any way. For at least one good reason: international *law doesn't mean anything here, and nobody will change the way they work* because of it. It is utopic to think it will have any effect, no one will be interested here."

"As far as my job here is concerned, TRIPS is not gonna change anything. I can't see anyone being interested here, and I really can't imagine it changing anything."

In terms of research and expectations, this was a bit of a stepback, as the mobilisation of public health actors in reaction to TRIPS is widely observed in other places[343]. The more I talked about TRIPS with all these people who buy drugs, choose drugs, distribute drugs, the more it appeared that they were truly not interested in the issue. Many of the comments made by informants related to further issues of the meaning of international law for Djiboutian networks. However, the aim of this research remains to investigate particularity rather than the whole, and what is at stake here is what this particular example of international law might be showing us about its own difficulty to stabilise in social relations[344]. Maybe further investigation on other international laws in the country would allow future research to draw wider conclusions, but this is beyond the scope of this project. What is central to understand here are some of

[343] The mobilisation of MSF and other organisations against TRIPS is widely known (see for example Ford N. (2003) "Patents, Access to Medicines and the Role of Non-governmental Organisations", Journal of Generic Medicines, Vol.1 (2) pp.137-145). The WHO has produced several reports in the field (see for example : WTO/WHO (2002) WTO agreements and public health, available at http://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf#search='WTO%20agreements%20and%20public%20health') . Policies aiming at limiting the impact of pharmaceutical patents have emerged partly from Ministries of Health – the South African Medical Act is one of the most symbolic cases of the clash between pharmaceutical patents and health concerns (for information see for example Halbert D. (2002) "Moralized Discourses: South Africa's Intellectual Property Fight for Access to AIDS Drugs", Seattle Journal for Social Justice (1) Fall/Winter 2002 pp. 257-288.

[344] Sociological inquiry needs to remain "modest" to remain fully empirical – see Law J. (1994) Organizing Modernity, Oxford: Blackwells.

the reasons why this particular written set of rules did not seem to mobilise any actor – at least through its official implementation. This is particularly essential in order to reinforce the distance and potential discrepancy between the translation of TRIPS in a material set of written rules in the country and its enrolment as a fully social actor in political networks. For most human actors interviewed in this case study, and in particular in the public health field, TRIPS and patents were thus a non-social issue. They did not see how it could affect the country; they believed that it would not become any more than a set of rules excluded from active networks.

In order to understand better these reactions, as well as the contrasts between this case study and other examples used by researchers, it is essential to consider the issue of expertise. All actors in the public health field interviewed stated at least at one point that they did not consider themselves as having any true expertise in relation to TRIPS. The lack of expertise is something I had been warned about early in my research, when asking someone working for the Ministry of Trade what was the IP situation of Djibouti: "Well, our IP situation *is "very little, very bad"! There are very few people aware of it, and hardly* anything is done about it". When observing the health sector, this was particularly obvious. On several occasions, informants acknowledged TRIPS as something they knew about, but when asked further questions about it they seemed unsure what it was precisely about[345]. Most of them acknowledged having a rough idea on the issue mainly from what they had read in the press, and knowing essentially that it was about international law:

[345] This was particularly obvious from one interview transcript "Of course I know what TRIPS *is!"* and a bit further "*So can you remind me again, what does it exactly say?"*

"*I don't know much about this whole issue* – only what I have read in the *press"*.

"The problem here is that no one has any kind of expertise here. There are a *few pharmacists, but they won't understa*nd what it is about. TRIPS, everyone *talks about it but no one knows what it is about, so it just won't change* anything!"

Most informants also mentioned having received only very little official information about IPR, or surprisingly sometimes about other aspects of IPR than pharmaceutical patents:

"I am not interested in patent law, and I know hardly anything about it – I have followed some training a while ago, but it had to do with software and issues *like that, not with drugs…*"

However, none of the sources that are sometimes expected to provide all relevant actors with information[346] about TRIPS were mentioned as having provided appropriate detail about the text to anyone in this particular field (the circulation of information is something that will be discussed further below). TRIPS was discussed essentially as a media issue, but not as a set of rules binding on the country. Next to the statements of lack of relevance presented above, all actors emphasised was the fact that they did not know about the

[346] Such as the Ministry of Trade itself, thematic workshops, international organisations, NGOs.

"legal side"[347] of TRIPS – that TRIPS as a set of official rules had not reached them. TRIPS in its written/official dimension was there though at least in one form – it was in the Ministry of Health, in a report published by the WTO and the WHO on TRIPS and public health[348]. But that was passive material, sitting at the corner of a desk, and not discussed by the official sitting at this same desk until I mentioned it and it was brushed aside as something that "was sent to us". This example will be discussed again in the next section when discussing the role of international organisations as intermediary/mediators in Djibouti[349].

Overall, the agency of TRIPS as a set of prescriptions outside the particular office where it is being implemented appeared largely doubtful. The impact of this lack of mobilisation is double – on the one hand, if TRIPS only mobilises actors in one particular office, it is unlikely to be followed with practical effects. On the other hand, if TRIPS has not been integrated within the health sector, it might mean that there will not be any coordinated action in response to the impact of TRIPS on public health. To discuss this further, the relation between TRIPS and health will first have to have been fully investigated, and

[347] Although the notion of "legal" as an independent set of characteristics and specific field is contested throughout this project, it is used here to reflect actors' terminology when referring to TRIPS as a written set of rules.

[348] WTO/WHO (2002) "WTO agreements and public health", available at http://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf#search='WTO%20agreements%20and%20public%20health

[349] The distinction between intermediary and mediators was introduced earlier to present the contrast between networks which transport others without modifications (intermediary) and those who participate directly to change and movement (mediators) – the definition given by Latour (2005) Reassembling the Social: An Introduction to Actor-network Theory op. cit is given above.

these issues will be revisited in the following chapters. The main elements that this section demonstrated is that TRIPS, through its official written implementation, did not generate the reactions and mobilisations it is generally portrayed as creating. The striking contrasts between what TRIPS as prescription is "expected to be" in relation to health in particular, and what it was in this case study, are worth investigating at this stage before drawing wider conclusions on the overall impact of TRIPS and pharmaceutical patents on health.

However, one hypothesis needs to be raised at this stage - perhaps this situation is only due to the fact that Djibouti could decide to wait for another ten years before implementing pharmaceutical product patents? This is of course something that I considered during the course of this fieldwork – and that I in fact discussed with a few informants – but it is also a hypothesis which never appeared truly satisfying, although I could of course not definitely rule it out either. First, because this does not fully explain the contrasts between this example and others – the mobilisation of public health actors is not necessarily expected to occur after national implementation[350].

There were further elements that also made this hypothesis somehow unsatisfactory. First, although pharmaceutical product patents are not fully binding yet, the implementation of other measures – including patents for pharmaceutical processes – is imminent. More crucially maybe, it is not clear

[350] Once again, if referring to the examples of public health actors' mobilisation quoted above, these have occurred largely before the deadline for implementation for most developing countries was reached.

yet whether the official in charge of implementing TRIPS has decided to exclude pharmaceutical product patents from the law to be adopted, and, as it currently stands, these could be introduced at any time. In addition, the range of developments that need to be done if TRIPS is to be implemented in practice, such as the development of appropriate structures, the information of relevant actors, the development of local expertise, will all need a large amount of time to be tackled. None of these were taking place at the time of fieldwork. International organisations are also already supposed to be working with developing countries, including least developed countries, to solve some of these issues – although the next section will raise some questions in that respect. Overall, although there is no official urgency for any of the actors concerned to be made fully aware of the expectations of TRIPS, the findings presented below should not appear less surprising nor less contrasting with existing literature for this reason. Finally, it is crucial to reemphasise that actors' position was not at any point that TRIPS would take long to be implemented, or was still too far away to think about it; but that the concept of pharmaceutical patents itself would never be practically relevant to their activities, and that the respect of TRIPS or other international texts of this type was simply irrelevant to anyone in the country. For all these reasons I do not think we should be satisfied with the speculation that things might change, nor happy with the assumption that the limited time left for Djibouti to be fully TRIPS-compliant can on its own explain the lack of mobilisation generated by TRIPS as official prescription.

Overall, the conclusions from this section need to remain balanced in what they are able to claim about the future role of TRIPS, and what they emphasise in relation to the limits of current research. Chapter 1 has explained how TRIPS has largely become framed in certain discourses as a public health issue. The mobilisation of public health actors is not only a reaction to TRIPS and its impact, but also something that is necessary for TRIPS to produce effects. Obviously, the situation in Djibouti might change, and actors might change their views about TRIPS. However, at the moment, the situation that appeared in this case study is not one in which TRIPS – at least in its official/written prescriptive dimension - is a key public health actor – it is one of indifference. Can the relative non-action of TRIPS as prescription be explained? This is a difficult question, since explaining absence can easily turn into speculating on "what could have been different", which is not a matter for empirical research. However, if doubts will have to remain as to the full reasons behind the loss of agency of TRIPS as prescription outside the office where it is being implemented, some empirical elements can at least participate in bringing light onto the question of expertise and information. The next section will discuss some elements that can help in understanding the difficulties for entities to circulate across "policy-networks" in Djibouti.

SECTION 3: ACTION AND CIRCULATION IN DJIBOUTI

On governments as "punctualised" units

As reflected in more detail in Chapter 1, most literature on the impact of TRIPS on "developing countries" tends to discuss how "countries", "states" and "governments" react to the text. The notion of stability behind the term government is one that is often "felt" rather than told – and in some cases, indeed, the coherent action of governments and the stable connections that holds them can justify their terminological punctualisation.

"If we consider complexity as an index of irreducibility, then one of the intended and imagined effects of governments has been to reduce complexity and to produce a unified and economic order, an order that can be summed up. *The very popularity of the idea of "the state", conceived as a functional and indivisible unit, attests of the prevalence of this view."*[351]

When literature on TRIPS talks about the action of "states" or "governments", feelings of coherent and "smooth" action spread to mind. States are portrayed as acting as one. However, through this case study, the idea of stability through political networks crumbled away rather quickly, and it is now useful to

[351] Barry A. (2002) "In the Middle of the Network", in J. Law and A. Mol (Eds.) Complexities: Social Studies of Knowledge and Practice, Durham, N. Ca.: Duke University Press, pp. 142-165, on p.142.

explain how this happened and what this might mean for TRIPS and its circulation.

This section presents some elements that can help in understanding why TRIPS as prescription is not constructed as having effects outside of the specific office where it is being implemented. In particular, it discusses some elements that clarify how TRIPS in this particular dimension remains excluded from public health networks as a relevant social actor. It questions whether a coherent governmental network could be identified in this case study, and how the shape of institutional connections can participate in understanding the action – or absence of action – of TRIPS as prescription in Djibouti. This section highlights how, when looking at pharmaceutical patents in Djibouti, it appeared that a number of people who could be expected to work together on this issue were in fact in complete isolation from one another. As mentioned earlier, the action of TRIPS is the result of associations involving not only the trade and industry area, but also, as far as pharmaceutical patents are concerned, a wide range of public health actors[352]. The mobilisation of public health actors – even if in the form of open opposition and resistance – is also often assumed when talking about "TRIPS and developing countries"[353]. If TRIPS is such a big issue for public health in "developing countries", as is framed in academic

[352] As explained in particular in Chapter 2.

[353] For an analysis of the opposition to TRIPS that followed its implementation, see for example Sell S. (2002) "TRIPS and the access to medicines campaign", Wisconsin International Law Journal Summer 20(2) 481-522.

writings and the media[354], the "health sector" of developing countries should certainly be aware of it! And for them to be aware of it, TRIPS has to have become a social actor for them too, something that they expect to have the potential to act. Unless of course this is not true of all developing countries, and, unless in some countries TRIPS as prescription has not entered public health as a social actor yet, maybe because it has not reached this network at all yet in its prescriptive dimension. The above section has demonstrated that this was the case in Djibouti. This section resets this element within questions raised by the punctualisation of policy-networks in Djibouti – and contrasts the findings made on the ground with the widespread use of notions such as "governments" or "international organisations" to represent what appeared here as uncertain and largely unstable sets of fragile connections. It highlights how the difficulties found when trying to circulate between actors from different "fields" for the purpose of this research soon illustrated the lack of connections between different networks, and provided elements essential when trying to understand why TRIPS was deprived of agency outside its "official" implementation setting. Because the ideas discussed in this section emerged essentially from practical issues arising during fieldwork, this section will follow closely the course of this research to emphasise how weak or missing connections appeared. It will then question how the lack of punctualisation of the networks studied could be related to the circulation and action of TRIPS as written prescription.

[354] For media coverage of this issue, see for example Maniere de Voir (2004) Apartheid Medicale, No.73; see also Riviere P. (2001) "Apres Pretoria, quelle politique contre le SIDA?", Le Monde Diplomatique, 20th April 2001.

Moving across policy networks: how hard can it be?

Chronologically, this empirical research started with interviewing actors in the public health field. Connections were made very quickly, and informants knew each other enough to introduce me to whomever they thought might be a relevant contact. Although actors from different institutions – hospitals, ministry, WHO – were not always sure of what each other's job exactly was, they were generally able to name some people they thought were informed about specific questions, and to explain roughly where they worked and what their responsibilities were vaguely about[355]. As mentioned before, actors in the public health sector were mainly unaware of the current steps of implementation of TRIPS, or of what TRIPS might mean for them – or rather they all agreed that TRIPS would mean nothing to them, when discussing its official implementation. Although this was a rather surprising start compared to the findings I was expecting to make, and the background information I had collected on "public health actors" reactions to TRIPS[356], their lack of information would become more understandable when looking at the way in which they relate to those officially in charge of implementing TRIPS, in the Ministry of Trade. When following the course of this fieldwork, it became an increasingly clear element that maybe TRIPS as official written prescription

[355] The familiarity of actors from each institution with the setting of other buildings was demonstrated by the facility with which they walked me from one place to the other, without hesitating on which door to knock on to find relevant interlocutors.

[356] Next to the South African case, examples can be found in Brazil (Nogueira J. (2002) "Intellectual Property Rights, the World Trade Organisation and Public Health: The Brazilian Perspective", Connecticut Journal of International law (17) p. 311-318) or Malaysia (Third World Network, Tackling AIDS with cheap generic drugs, Monday 6th December 2004, available at www.twnside.org.sg/title2/gtrends35.htm)

was not entering the public health network because there was no channel for it to circulate from the Ministry of Trade, where it has arrived in its written form, to the health sector.

After having met most of the actors I wanted to talk to in the public health sector, the next logical step was to try to meet "their contacts" in the trade and industry field. The ease with which each informant had been able to introduce me to relevant colleagues made me - wrongly – assume that meeting someone in the trade related field would be as simple. I truly expected that people creating rules on pharmaceutical imports for the Ministry of Health could introduce me to someone they knew working on import rules more generally. Considering the current president of the Chambre du Commerce is also a pharmacist, the relations between the two sectors must be somehow facilitated? At least he would certainly know who works on trade and industry issues? It was probably all going to be straightforward. Surprisingly, it was not the case. When asked to what extent they worked with other Ministries, or actors from different fields, informants in the public health sector were all rather unsure. "I think the Minister here sometimes works with the Ministry of Finance to try to *get some tax limitations for pharmaceuticals…. But it is really punctual action…*" Overall, it was impossible to find anyone in the Ministry of Health who could name anyone in the Ministry of Trade or the Chambre du Commerce – after a few days of search, "anyone" would have been good enough! It was finally through personal relations only, by asking different people until someone mentioned a name that I could find a way to meet someone from the Ministry of Trade. As had been the case with the health

sector, once one person was met things progressed quickly again, and that person was able to put me in touch with a number of other relevant informants.

Although this does not call for as much attention, since it does not touch as closely the issue of pharmaceutical patents, it is worth mentioning that this difficulty to circulate from one field to another, from one building to another in some cases, was also felt in other circumstances. The emergent pharmaceutical industry could only be accessed by almost randomly meeting someone who was directly involved in it, while the Ministry of Trade and Industry, the Chambre du Commerce et de l'Industrie and the Ministry of Health had all been ruled out as potential sources of information and contact. No one truly seemed to know what was happening to this industry or who was involved in the project. The National Research Institute of Djibouti was also visited, to find out that none of the researchers had received information on IP from anyone, in spite of their interest in the issue, and did not know anyone in any other governmental agency that could provide them with information.

From the very first stages of this research, it therefore appeared that the issue of the limited action of TRIPS as prescription could not be isolated from understanding the lack of stability of policy-related networks in the country. It was not only TRIPS that was not circulating or mobilising, it was much more than this – it was most actors. The question of networking and punctualisation in governmental action has been raised elsewhere, including within developed states[357], and appears clearly in this particular case study. It is crucial in an area

[357] See the example of Barry's research (Barry A. (2002) op. cit.).

where coordinated action from different fields is necessary not only to create a specific regulation, but also to build a specific tool as a policy issue. These overall findings on the weakness of relations across fields in Djibouti can seem even more surprising given the size of the country[358], and the small number of actors actually involved in any form of governmental institution[359]. It is also most surprising since actors who would not relate in any ways at work, although their interests could find a common ground, would often know each other on a personal level – they just did not have any work-related information on each other. For example, many actors went to the same school, studied in France in the same town where a strong Djiboutian community is established, and are often relatives or family friends[360]. Personal networks seem never ending, but professional ones much weaker. The lack of interaction between actors did not stop them from manifesting some curiosity and interest as to what each other was doing, or where expertise and information was located. It was thus often the case that when discussing patent issues with actors from either public health or trade and industry, informants seemed truly interested in

[358] The contrasts between topological closeness and relations in a networked space interestingly illustrate some of the difficulties with geography when dealing with networks and relational theory – see Law J. (1999) "Objects, Spaces and Others", published by the Centre for Science Studies, Lancaster University, LA14YL, UK, at http://www.comp.lancs.ac.uk/sociology/papers/law-objects-spaces-others.pdf and Law J. (1999) "Materialities, Spatialities, Globalities", published by the Centre for Science Studies, Lancaster University, LA14YN, UK, at http//www.comp.lancs.ac.uk/sociology/soc029jl.html, for examples.

[359] It is interesting to relate this lack of connection between actors to Rogers' approach to the diffusion of innovation, and the difficulties for innovations to travel across heterogeneous groupings, while this is in fact the most efficient way for innovations to spread across society – See Rogers E. (1995) The Diffusion of Innovations, New York: Free Press.

[360] "I *studied in Reims because I knew some people there, friends, relatives etc… A lot of Djiboutiens live there, I don't know why*."

working with the other sets of actors, but completely unsure about how to go about it[361]. Informants from each field thus asked me if I could let them know who would be an approachable actor in the other field, and explained that they wanted to get information or raise awareness – depending on whether health or trade was concerned – but did not know where to start from nor who would be receptive. The difficulties of remaining an outside observer in this kind of situation of course needed to be tackled, in order to ensure that the research process itself would not impact on the existing situation – this was particularly important if wanting to carry out further interviewing at a later stage to follow the evolution of the situation.

Several key questions need to be addressed here: how does this lack of connections between actors and fields relate to the difficulties for TRIPS as prescription to move beyond the associations generated in the Ministry of Trade? Is it because actors do not relate that TRIPS does not generate action? Or should TRIPS itself generate this new set of connections? Does this mean that TRIPS is failing, since its action appears as more limited than its creators have been expecting? First, this issue of failure can be pushed aside, and for several reasons. Some reasons are practical – the next chapter will explain that even before TRIPS arrived in Djibouti, pharmaceutical patents were playing their own commercial role. Some slightly more theoretical, relating to the idea of co-existing realities and dimensions – if TRIPS in its prescriptive dimension limited to its emergence in Djibouti appears to be mobilising fewer actors than we might expect, it is certainly doing many other things in Djibouti, and

[361] This was also true of researchers who wanted to find out how their work could be protected, but did not know who they could turn to.

making many others do things. These effects might not be as some lawyers would expect, but why limit ourselves to evaluate the failure/success of TRIPS as an actor on the basis of pre-determined expectations? Before answering the other questions set here, a few more elements need to be put forward to illustrate the difficulties of circulation and connection in the networks studied here.

International organisations and the circulation of TRIPS

When investigating the integration of TRIPS as a set of rules in the health system of Djibouti, the question of the role of international organisations was raised. In particular, they are often presented and understood as creating some kind of link between TRIPS and actors across "governments" – and this was assumed to include public health actors when starting this research. While TRIPS originated from the WTO – at least the finalised, "printed and stamped" version of TRIPS - WIPO is expected to offer advice and guidance to states when implementing it[362]. The WHO has also participated in the debate on the impact of TRIPS[363]. However, in spite of general statements and assumptions as to what international organisations do in developing countries, specific details on the impact of their action are not always given. In this case study,

[362] See the aims of WIPO as quoted above, and available at: http//:www.wipo.int/about-ip/en/studies/publications/health_care.htm

[363]For example: WTO/WHO (2002) "WTO agreements and public health", Geneva available at http://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf#search='WTO%20agreements%20and%20public%20health; WHO (2001) "Globalization, TRIPS and Access to Pharmaceuticals", available at http://www.who.int/3by5/amds/en/regulations1.pdf

this appeared as part of the story to be told on the circulation of TRIPS, and it needs to be discussed briefly.

Few international organisations have a local office in Djibouti. Most carry information to relevant people locally through visiting advisors or posted documents. The WHO is the only relevant structure to have a local office. It involves mainly five people. They mentioned being frequently in touch with their regional office, and many documents produced by the central office were also available in the small library of the WHO office. Whether this should be understood as an appropriate diffusion of information from the central office to representatives in Djibouti is of course contingent on them reading these documents. However, it is important to ask whether the WHO plays any role in making TRIPS an issue for public health actors: "We are in charge of organising meetings on TRIPS and other issues, and we work with WIPO on this for example", replied a representative of the WHO. But for actors in the Ministry of Health: "The WHO has never talked to me about anything like that. *We sometimes work with them on specific projects, but we don't see them very much…*" So the office of the WHO based in Djibouti might have organised meetings on TRIPS, but other public health actors in Djibouti were not involved. Nevertheless, the WHO still had some links to the Ministry of Health, at least through this unread report sitting on a desk. The contrast between intermediaries and mediators put forward by Latour could not be more striking than when thinking back about this particular trace of TRIPS.

The second organisation that is often perceived as central in developing IP as a policy issue, and in integrating TRIPS in national systems is the WIPO. It is important to reflect on its role in Djibouti. We have seen that it was quoted by the official in charge of implementing TRIPS as a source of advice. Its presence was also confirmed by other actors: "The TRIPS agreement was a great opportunity for WIPO! Before, noone had ever heard of them in developing countries, now they are everywhere. They come and give *presentations everywhere they can!"* However, later comments by other actors working with WIPO seemed to question whether this advice was of any true relevance to the country. In fact, the "WIPO" does not have any office in Djibouti, and is only temporarily part of the country when it sends representatives over. Their actual role and action, however, was questioned by many actors in Djibouti. When discussing their role, informants presented rather strong and passionate views on the role of "visiting advisors", and insisted that they could not be perceived as "appropriate sources of information". None of the advice provided could be considered as tailored to the needs of the country, and that it was therefore of no use to anyone in Djibouti. Examples of this were widely quoted:

"Recently, in the Ministry of Finance, an international advisor came to help them change the tax system. You have to know that in the Ministry of Finance, in particular, people are all very qualified! They all have at least 4 years of university in France behind them! Well, this advisor came, and tried to explain *to them that we should introduce VAT in Djibouti… If you know even a bit the system in Djibouti, it is obvious that it's impossible to introduce VAT here* at

the moment! Businessmen don't even have an accountant, and don't actually hold anything like a real accountancy book! Everybody tried telling him, and *they are all qualified, and they all know the place, but he didn't listen to anyone… Instead of giving* us appropriate advice on what we could actually do, he held onto his idea that we should introduce VAT, and wrote a very *complete report, but perfectly useless for us!"*

This idea that international advisors, not only had little knowledge of the local needs, but also very little respect for the opinion of local actors, or for the local specificities of the country was presented many times, by people from different backgrounds and working in different institutions:

"International advisors are really funny*... they come here, stay here for a while, come to lots of cocktails, and meetings… the rest of the day, you hardly see them. We don't actually know what they do… and then after a few days or* a few weeks, they go back home, and they send a report which is meant to be *adapted to the specificities of the country… that's why they come, after all, to* look around, talk to people, find out what our needs are, and then give us *advice on this basis… well, you just can't imagine how many times I received a* report with *in its introduction: 'Djibouti* – Capitale: Dakar or Nouakchott or *something else'… They just take a report they had prepared for another country, and put "Djibouti" in there… but what worked in Cambodia might not work here… It's a bit discouraging!"*

These quotes are most interesting when reflecting on the circulation of information – in particular that of TRIPS as prescription. Once again, their immediate impact can only be suggested – but some questions need to be asked: can WIPO truly be considered as a mediator if those receiving its information believe that this is inappropriate? Can it extend far enough to act beyond its temporary presence and generate through its advice new relevant associations?

The last organisation to look at is obviously the WTO. It is through the WTO that TRIPS as written law officially originated and it is also the WTO that should ultimately evaluate behavioural compliance with TRIPS as prescription. It is an integral part of TRIPS, as much as TRIPS itself only exists through the WTO. Djibouti has a representative in the WTO central offices in Geneva. However, he does not deal with TRIPS. The only way in which the WTO communicates about TRIPS with actors in Djibouti is through the reports it sends and through occasional contacts it makes in the country. When asking someone in the Ministry of Trade if they were made aware of changes "regularly" by the WTO, they replied with a laugh: "*Regularly…no! but* sometimes! Once in a while! But things change so quickly that by the time we ha*ve been informed and decided to react others have already moved on!"* When looking at the WTO it therefore also appeared that connections were weak or missing.

As a whole, when observing more closely the role of international organisations in Djibouti, the image of a highly coordinated network appeared

as weaker than suggested by academic writings and the media. While the involvement of the WTO, WIPO and WHO can be found through the many reports they have published linking TRIPS and public health[364], and while "governments" and "countries" are widely described as being influenced by the new set of rules created by TRIPS, the connections followed here all appeared to be coming to a complete stop at some point, and the circulation of TRIPS as written prescription, the necessary movement that makes social associations remain active could not be retraced further than a range of punctual and limited associations.

However, if wanting to look for further explanations, to the weak circulation of materials and information in Djibouti, a few other elements could be put forward. It appears that TRIPS entered the Ministry of Trade, but did not truly move out of it. It is also in the WHO, in the form of many reports travelling from the central office, and through the awareness of the main representative. And it is in the Ministry of Health – on a desk. But why did it not move from this desk? Certainly partly because it did not mobilise the interest of the owner of the desk. According to a number of other actors in the field, there was no need to look too deep into this issue – the problems Djibouti is facing in terms of expertise mean that some of the officials given a specific job do not necessarily have the training and qualification that will make them fully

[364] See for example: WHO/WTO (2002) "Implications of the TRIPS agreements and the Doha declaration and public health" op. cit; WHO (2001) "Globalization, TRIPS and Access to Pharmaceuticals", available at http://www.who.int/3by5/amds/en/regulations1.pdf ; See also the WIPO website, on pages such as "Striking a balance: patents and access to drugs and healthcare, available at: http://www.wipo.int/about-ip/en/studies/publications/health_care.htm

involved. The structure of some ministries is particularly complex in that respect, and while cooperants are employed by the government to make up for the lack of local trained personnel, the main posts in each ministry are held by a national of Djibouti. While this works perfectly well in some cases, since many Djiboutians are qualified in some areas – and increasingly so – it still creates tensions in others, where communication and cooperation are both consequently affected. In the example of this office, in which the TRIPS-related document was observed, this was clearly the case. It was clear that if the actor to whom it was addressed had not been willing to read and process it, it was unlikely that it would be moved – except of course maybe to clear the desk.

A fair question to ask, at this stage, is whether any of the above ruptures and disconnections described above can fully explain why TRIPS is not mobilising more actors outside of "its" office. To put it differently, if all of the actors mentioned above had been connected in a stable way, if international organisations had efficiently transmitted messages and participated in generating the prescriptive aspect of TRIPS in Djibouti, if the reports sent to a few people had travelled to more, would anyone have felt differently about TRIPS? The answer to be given to this question will appear as obvious from the positions argued from the start. I cannot claim to know and it would be inappropriate from the standpoint of ANT to speculate. Maybe even if connections had been more stable, noone would have cared about TRIPS outside this one office. However, in these circumstances, within this particular set of weak and unstable associations, the circulation of TRIPS within Djibouti

faced many obstacles that are often absent from existing writings, but appeared as crucial in this project. Maybe TRIPS as prescription would not have acted any more if it had circulated better, but without circulating and without being known, its agency disappeared without being given an opportunity to come into being. While it would be purely speculative to discuss what would have happened under other circumstances, or to claim that the circulation of TRIPS as written rules is the only element that stopped it from deploying full agency, it seems safe and relevant enough to claim that the difficult and limited connections in the fields concerned with TRIPS played a large part in preventing it from acting fully.

CONCLUSION

The conclusions to be drawn in this chapter need to be as modest as ANT calls for. They cannot overstep the limits of what was said and observed in the course of this research, and I do not wish to discuss too sweepingly the meaning of "law" as a whole in the policy networks of Djibouti. What this chapter has explained relates only to TRIPS – and only for the moment to TRIPS in its prescriptive, written dimension, although the next chapters will explain that there might be more to TRIPS than this – and only to the networks that can relate to TRIPS, and that were in this respect studied in the course of this research. It has explained that, in contrast with its international framing as a public health issue, TRIPS as prescription has not become part of networks concerned with public health – or at least not in its official dimension investigated so far. If TRIPS as written rules is modifying some orderings in

one particular office of the Ministry of Trade, its action in Djibouti as a new set of rules appears as limited to this particular localised set of connections – localised in this office, in this particular action and circulation, although it involves associations that run from Geneva to Djibouti via the many places in which TRIPS was discussed before it reached Djibouti. Once moving out of this office, TRIPS does not leave many traces, and does not reshape many orderings. It is there in words, in thoughts – and essentially in words and thoughts emphasising its irrelevance. It is also occasionally there in its materiality, but as a clear example of passive intermediary more than anything else. This of course relates more broadly to questionings known in the socio-legal field of the contrasts between "law on paper" and "law in action"[365]. However, these terms have been left aside here both for the specificity of their original use, and because Chapter 7 will explain that TRIPS might be limited in its action as a set of official/written prescriptions (although even then, it is certainly acting), but that it remains a social actor in other ways, through what it has generated, and in a fashion that will become understandable once opening the door of the effects of TRIPS in other fora.

Although the absence of TRIPS as rules could not be explained with certainty by attempting to borrow from causal mechanisms, the links between the limited circulation of TRIPS as written prescription and the structures of other associations in policy-networks in Djibouti was also discussed. By looking

[365] Or approaching conceptual ideas – see for example: Nelkin D. (1987) "Law in Action or Living Law? Back to the Beginning in Sociology of Law", Legal Studies (4) pp.157-174; Pound R. (1910) "Law in Books and Law in Action", American Law Review (44) pp. 12-18.

more in detail at these "networks", what appeared were in fact sets of ruptures and the instability of connections that are often assumed to be stable in terms such as "systems", "government", or "organisation". By looking more closely into particular connections, their weakness and the avoidance of their performance by many actors appeared as essential elements in understanding how TRIPS in its written/official pharmaceutical patent dimension stopped its circulation and social integration. The idea that the story of TRIPS and pharmaceutical patents in Djibouti might end just there was something that was briefly considered in this project – it seemed at a time that TRIPS and pharmaceutical patents might just be largely irrelevant objects in Djibouti. However, things became both more complex and more interesting as data accumulated. It became clear that the questions asked in this chapter only covered one particular dimension of TRIPS and only considered pharmaceutical patents as far as they related to their official creation in Djibouti. Although these might be the most widely acknowledged roles and dimensions of both objects that have been looked at, they remain only a limited part of what makes the story of both instruments in Djibouti. The next two chapters will demonstrate why, in spite of the official situation of TRIPS and pharmaceutical patents in Djibouti, both instruments remain to be understood as social agencies – and as social agencies in the public health field more specifically. Although defining them as actors in "a legal way"[366] in the country remains too broad and therefore uncertain, their social action through

[366] "*It's not only that law, for instance, is unexplainable by the influence social forces exert over it; it's not even that law has to explain in turn what society is, since there is no society to* be explained. Law has much better things to do: one of them is to circulate throughout the landscape to associate entities in a legal way", Latour B. (2005) Reassembling the Social: an Introduction to Actor-network Theory, Oxford: Oxford University Press, on p. 239.

living and dynamic connections needs to be fully understood in order to explain what both tools mean for society in Djibouti.

CHAPTER 6 – EMBEDMENT OF PHARMACEUTICAL PATENTS IN THE DRUGS USED IN DJIBOUTI

Throughout the empirical part of this research and when investigating the traces left by TRIPS and pharmaceutical patents in Djibouti, other aspects than the prescriptive dimension of TRIPS appeared crucial to understanding the links between TRIPS, pharmaceutical patents and health in Djibouti. This chapter presents one of these aspects, and explains where pharmaceutical patents were found when investigating the pharmaceutical market. It discusses what this means in relation to the mechanisms of pharmaceutical patents, and speaks to the limits of some assumptions about what socio-legal objects do or how they work. This chapter questions the link between the existence (or absence) of pharmaceutical patents in written national law and the socio-legal role of pharmaceutical patents.

I started this research with the assumption that, because pharmaceutical patents had never been created in the national law of Djibouti, they were irrelevant to current social networks in the country. The indifference of local political actors to TRIPS presented in Chapter 5 seemed to sustain this idea, by demonstrating that the official introduction of patents did not appear to generate change or mobilise any relevant actor. However, the original impression that patents were non-existent and irrelevant in Djibouti started being questioned as the pharmaceutical system of the country was being

studied. In particular, the potential embedment[367] of pharmaceutical patents in the drugs used in Djibouti was considered. This chapter explains how this was done, and reflects on the potential role of patents in the pharmaceutical market of Djibouti. By doing so, it offers a way to understand further why the divide between "legal" and "social" needs to be rethought and replaced by a clearer empirical understanding of the specific mechanisms of particular socio-legal objects[368].

This chapter is a central step in discussing how patents operate in relation to health in Djibouti. However, it also constitutes only one step in a reasoning that will be continued in the following chapter. Some elements will only be fully explained in the next chapter, such as the specific meaning of the role of patents in the pharmaceutical market of Djibouti in relation to health and diseases. This chapter is divided into two sections. First, the pharmaceutical market of Djibouti is described, and some characteristics of the specific medicines found in the country are presented. The embedment of pharmaceutical patents in the pharmaceutical market of Djibouti is introduced in this section (Section 1). Second, the set of connections that have participated

[367] As explained in Chapter 2, the term can be found in many ANT texts – for example: Law J. (1999) "Materialities, Spatialities, Globalities", published by the Centre for Science Studies, Lancaster University, LA14YN, UK, at http//www.comp.lancs.ac.uk/sociology/soc029jl.html or Law J. (1997) "Topology and the Naming of Complexity", published by the Centre for Science Studies, Lancaster University, LA14YL, UK, at http://www.comp.lancs.ac.uk/sociology/papers/law-topology-and-complexity-pdf.

[368] The position taken by Latour (in Latour B. (2005) Reassembling the Social: an Introduction to Actor-network Theory, Oxford: Oxford University Press) and mentioned earlier that law acts in a "legal way" is by definition not untrue – however this case study aims to explain why many uncertainties still exist as to the full meaning of "law" as far as social action is concerned.

in stabilising patents as socio-legal actors, while excluding the most controversial generics from the Djiboutian market, are introduced (Section 2).

SECTION 1: PHARMACEUTICAL PATENTS AS DETERMINANT TO THE LOCAL PHARMACEUTICAL MARKET

When looking at the issue of access to medicines in Djibouti in Chapter 4, it was made clear that only one main aspect was considered – that of the availability of drugs for patients. This section needs to consider in more detail the pharmaceutical market of Djibouti. This will illustrate another aspect of the implications of ANT to the empirical study of pharmaceutical patents. When discussing the role of pharmaceutical patents, their complexity has been briefly introduced in Chapter 2. However, what has been left partly to one side is their actual relation with "pharmaceuticals". Once again, it is important at this stage to emphasise the full interconnection between actors often presented as independent, but who fully merge into one in many cases. In particular, when considering more closely both patents and drugs from a public health perspective, it becomes clear that the object of study is often a unique but complex hybrid[369]. Once a patent has been granted, a new hybrid is created, made both of the complexity of pharmaceutical patents and of drugs. The complexity of the drug/patent hybrid cannot be fully undone here, although some of its dimensions will be discussed. What is more important, at this stage,

[369] The notion has been introduced in Chapter 2 – see also Latour B. (1993) We Have Never Been Modern, Brighton: Harvester Wheatsheaf. Although the term was originally used to break the human/non-human divide, it presents an interesting metaphor that could more broadly be applied to contest dichotomies, such as those here between law/technology.

is to understand that the social presence of pharmaceutical patents can be read within these hybrids, and that when looking for traces left by pharmaceutical patents, it is essential to look within the drugs found in the system studied.

In Djibouti, all actors interviewed, as explained before, dismissed pharmaceutical patents as something that was of no social relevance to them. They stated many times that they were not part of any action in the country and were almost invisible apart from reports emanating from institutions external to the country and from the basic expertise of a few officials. When explaining this, one of my informants vehemently stated his own lack of interest in the concept of patents in these terms: *"Patents, no patents….all the same here!"* Although at the time I understood this statement only as an indifference towards the content of written law, based on the perception that introducing patents would not change anything – and this statement was indeed made during discussions of the official introduction of patents – for me it became symbolic of other elements that were progressively taking shape in the data collected. In particular, while introducing patents would potentially not change anything to social orderings in Djibouti, the fact that patents did not exist in Djibouti in written law did not seem to shape the pharmaceutical market any differently from countries in which pharmaceutical patents officially existed. In particular, the official absence of patents from written law in Djibouti did not make patents/drugs any less present in the pharmaceutical market of the country.

When investigating the pharmaceutical market of Djibouti, the inherent presence of patents became a clear characteristic of the network. Although patents were not present in words or opinions, as explained before, they were embedded in the range of medicines that were selected on medical prescriptions, within doctors' and pharmacists' strategies and patients requirements. If pharmaceutical patents are understood as more than their written/official dimension, if the hybrids that patented medicines represent are understood as keeping patents alive, patents were certainly a crucial part of the pharmaceutical network of Djibouti. A brief description of this system can explain the extent of their presence and action.

When describing the pharmaceutical system, two elements need to be addressed – the rule and a minor exception. As a whole, generic medicines are not sold in Djibouti, or are sold only in very limited amounts:

"In Djibouti we don't like or the doctors don't prescribe generic products yet so in the Republic of Djibouti we essentially don't use generics."

"I own two pharmacies. One has about 90% of foreign customers, the other 100% locals. But the drugs are the same in both – no generics."

Although every actor in charge of importing drugs affirmed that patents did not play a role in their decision-making about which drug to import and from

where, there were hardly any generic drugs in the country[370]. In the largest of the pharmacies, a drawer marked "generics" contained a few boxes. In the time spent in the pharmacy, either as a pure observer or as a patient, I never saw this drawer accessed – I only observed what was inside when I asked one of the staff members specifically to open it[371]. Outside of this particular drawer, and with the very few exceptions of some "branded generics"[372], most drugs sold were the originally patented version of a given product. The same was true in the different hospitals – with the exception of the OPS, as will be explained below. Most pharmacists and doctors interviewed similarly confirmed that they

[370] A methodological note is necessary at this stage – in order to find out whether the drugs observed were branded generics or the "original" version of a patented drug, different registers were used. Mainly, the lists provided by the Agence Francaise de securite sanitaire des produits de sante (AFSSAPS) were used. For access to the latest updated version of these lists, see http://agmed.sante.gouv.fr/pdf/5/alpha.pdf. The British National Formulary was used to compare whether generic versions of the drugs studied also existed in the UK.

[371] This particular drawer contained "pure generics" only, as opposed to "branded generics" – generics named under their scientific name, as opposed to a specific brand chosen by their producer.

[372] National law regulate the rules relevant to the commercialisation of generic medicines, including their denomination – this can be either the scientific name of the compound concerned, or a "brand" chosen by the producer. However, it is necessary that the generic version makes it clear that it is a generic. In France, the relevant article is Art. 5000 Code de la Sante Publique. For comments on these issues, see for example Larrieu J. and Houin G. (2001) "Medicament Generique et Propriete Intellectuelle", Revue Internationale de Droit Economique (1). Numero Special: Brevets Pharmaceutiques, Innovation et Santé Publique pp.173-185. In particular, it should be noted that, although the impact of brands on the price of medication will be discussed again in Chapter 7, that branded generics remain more expensive than "pure generics"- see Dumoulin J. (2000) "Les Brevets et le Prix des Medicaments", Revue Internationale de Droit Economique, 2000/1, Numero Special: Brevets Pharmaceutiques, Innovation et Sante Publique pp. 45-69. In Djibouti, the exceptional generics found on pharmacies' shelves – as opposed to those found in the unaccessed drawer – were, in addition, products of large pharmaceutical companies. One of these exceptions, for example, was that of doxycycline – the version found in private pharmacies was not the Vibramycine but the branded generic Tolexine produced by Biorga.

did not deal with generics – we will see below how this can be explained. Finally, doctors' prescriptions processed at private pharmacies equally contained lists of branded medications only[373]. Although patents were officially "non-existent" and "irrelevant" for policy-makers, it is particularly difficult, outside of the exception that will be presented below, to find any drug in the country that is not a patented drug or the branded version of a drug which was originally its patented version – that is not one of those hybrids mentioned above. On the basis of this observation, should it be assumed that patents are inoperative tools in Djibouti because they do not exist in written law? Or are there ways of acting outside and independently of their official written creation. Before questioning this element, it is necessary to look briefly at the limited exception to this rule – in order, in particular, to explain why it remains a limited exception.

The only current exception to the absence of generics in Djibouti – in addition to the rarely-accessed drawer mentioned before - can be found in the pharmacy of the OPS. Doctors and pharmacists in this hospital, all affirmed that "we use almost exclusively generic medicines." Indeed, their lists of medication and a brief look at their stocks demonstrated that generics seemed largely predominant in the hospital. The two pharmacists estimated that about 75% of the drugs used in the hospital were generics. However, a closer look at the range of generics imported in the OPS highlighted once again more similarities than discrepancies with what could be found in Europe, for example. In order to understand this point, it is useful to reflect back on the different meanings

[373] Those observed contained only the originally patented versions.

attached to the word "generics". As we have seen before, the term generic refers to two fundamentally different situations – one in which these are new versions of a drug still under patent, the other where they are a new version of a drug whose patent has officially expired[374] (and this second type of generics are those that can be found even in countries where patents are part of the written legal landscape). In this respect, the generic drugs found in the OPS are not any different from what one would expect to find in a country where patents are officially part of written national law. All the generic drugs used in the hospital were also commercialised in generic version in France or the UK. In other words, none of the drugs used in the OPS and found on the lists of generic imports would have been infringing patents in Europe[375]. This could be checked fairly easily as the drugs provided by the pharmacy of the OPS are rather limited in number, and I was given full lists of what the pharmacists buy

[374] This distinction was introduced in Chapter 1.

[375] From a patent perspective, the fact that generic versions exist in France (and in the UK) mean that the patent has expired in these specific countries. The European Patent system has been introduced in Chapter 1, and it explains why it could be fairly reasonably assumed that the patent situation is likely to be the same in the rest of the EPC members. This is not definitely and necessarily the case, however – patents could theoretically have been applied for in France and the UK only (this is highly unlikely considering the way the patent system works in the EPO); patents could have been challenged at the national level in France or the UK. Similarly, the fact that generic versions exist in France or the UK does not necessarily mean that they exist in other countries yet – marketing authorisations might take longer in other states for example (although even at this level EU law has partly harmonised the procedures – see Poillot Peruzetto S. (2001) "L'apport du Droit Communautaire aux Problemes Poses par le Medicament Generique", Revue Internationale de Droit Economique (1). Numero Special: Brevets Pharmaceutiques, Innovation et Santé Publique pp.187-196). Once again, however, the structure of the European system justifies the possibility to extend findings made on the basis of the French listings, compared to the British National Formulary information, to "Europe". For further comments on the EPC system, see for example Stinger M. and Stauder D. (2003) European Patent Convention: a Commentary, London: Sweet & Maxwell.

and with which they provide their patients[376]. The drugs network created in the supposed (official) "absence" of pharmaceutical patents was not looking any different from the situation in states in which patents officially exist. One hypothesis, however, could be that this is simply the case because of the nature of pharmaceutical needs in the OPS, as opposed to any determinant role played by patents[377]. However, this hypothesis does not seem convincing. Mainly, it can be challenged because the exceptions to generic medications found in the OPS corresponded partly to emergencies, and partly to drugs that pharmacists "did not find" in a generic version. A key example of this second exception found during this fieldwork was that of HIV/AIDS medication. It was given immediately by pharmacists, and demonstrated that in this case where patented drugs are needed, the versions imported were not generics – this example will be discussed again towards the end of this chapter. Finally, when looking at the origin of the generics imported by the OPS, the role of patents in shaping health priorities will need to be questioned, and the potential impact of this role on the imports of the OPS will be discussed. Once again, causal conclusions to be drawn from this example, at this stage, can only be limited, as it is not so much a matter of what patents cause, as a matter of where patents are, that

[376] Once again, this could be checked against the lists of existing generics produced by the AFSSAPS.

[377] What is meant by this is that this could be understood as resulting from diseases rather than from the action of patents on decisions as to what medication to import – however, even this statement requires the addition of a mark of caution. In particular, the example of the questions raised by the potential role of patents in the creation of the Essential Medicines List in the WTO has shown that health priorities, diseases and patents might not be fully independent from one another - this is something that will be addressed again below and in Chapter 7, and has been discussed for example in Laing R., Waning B., Gray A., Ford N. and Hoen E. (2003) "25 years of the WHO Essential Medicines Lists: Progress and Challenges", The Lancet (361) pp. 1723-1729.

needs to be investigated. The main conclusion that can be drawn from this example is that, even in the exceptional case where generic medicines are imported, they remain limited to those that are "patent-compatible". Drugs in which patents are embedded are still chosen over other versions in cases where patents are still officially valid in other countries. The presence of patents can be identified through the absence of any drug that would be incompatible with their legal/official standard in countries other than Djibouti. In addition to the first limit of this exception, it should be emphasised that the OPS represents only a small part of the pharmaceutical market of the country, available only to those allowed to access this particular hospital, and only when physically visiting the hospital.

The situation in Djibouti, in terms of medication and the limits of a "generics market", might appear surprising in light of assumptions about the role of generics in the pharmaceutical markets of developing countries[378], as will be

[378] To contrast the findings made here and the focus of other analyses on the situation of developing countries that rely on generic medicines – and the potential subsequent confusion that this might be representative of "developing countries" as a whole - see for example :
"… for nations such as India, Brazil and Argentina, which before 1995 granted no drug product patents and hosted thriving generic drug industries, the ability to supply generic versions of new drugs will be curbed. And for other developing nations that relied upon such nations for generic drugs, the ability to import the newest medicines could be limited", Scherer F.M and Watal J. (2002) "Post-TRIPS Options for Access to Patented Medicines in Developing Nations", Journal of International Economic Law 5(4) pp. 313-319, on p.314. The generalisation sometimes made is particularly obvious in some NGO or policy reports. See for example "These longer patent periods will delay the availability of the low-cost generic equivalents that traditionally supply developing-country needs; only the expensive, patented version of a new medicine will be available" in Oxfam International (2001) "Priced out of Reach: How WTO patent policies will reduce access to medicines in the developing world", p.6 available at www.oxfaminternational.org

discussed again in Chapter 7 in relation to public health. However, it does not contrast as strongly with research done, for example, in Chad. In particular, a report was published on this issue by the Ministry of Health in Chad[379], and the lack of availability of generic medicines, in particular in private pharmacies, is largely emphasised. Once again, this might be an example which makes the issues raised in Djibouti not appear as so unique to this country.

Overall, in the current market situation of Djibouti, the only generic drugs sold are those provided by the OPS. These are limited to out-of-patents medication, and represent a small part of the overall market. What might this reveal about the role of patents in Djibouti, and about the links between the written/official existence of patents and their action in Djibouti? The first observation that should be made is that, in Djibouti, at the time of fieldwork, there was no drug – or at least no drug which I came across during my research – that would infringe patents if they were sold for example in Europe. Even drugs for which generic versions were legally sold in Europe only appeared as "generics" in the OPS. And in the OPS, only drugs that were out-of-patents in Europe appeared as generics. One meaning is that patents are inherently embedded in most of the drugs sold in Djibouti. This is interesting given that written laws in Djibouti have never officially created patents – they do not exist on paper at the moment, and even if they did, policy-makers explain that this would not mean that they will consider them prescriptive. The discrepancy between the written

[379]Direction de la Pharmacie et des Laboratoires, Ministere de la Sante Publique, Republique du Tchad "Enquete sur le Prix des Medicaments au Tchad", Mai 2004, available at http://www.haiweb.org/medicineprices/surveys/200405TD/survey_report.pdf#search='enquete%20sur%20le%20prix%20des%20medicaments%20au%20tchad'

existence of law and its action "in society" has been widely discussed before[380]– through varied theoretical approaches. In addition, in this case the discrepancy between the written and official existence of legal rules and the action of socio-legal objects adopted an unexpected shape– a particular set of socio-legal objects appeared to have agency without being rooted in written rules. Somehow, through means and connections that we will study below, patents have become part of the system, which are never truly bypassed by importers, patients or doctors.

This does not mean, however, that the pharmaceutical market in Djibouti is similar to that of Europe. However, the difference is not located where it was assumed when starting this research. In fact, in Europe some drugs at least, once their patent has "officially" run out, start appearing in new generic versions in most pharmacies– new drugs without patents. But in Djibouti, outside the OPS, patents socially exist independently from any written rule and any official, written temporal limit. Patents are not only what gives a drug market exclusivity for several years, but they determine which drug will or will not enter the territory with no pre-established time limit. One should bear this in mind when rethinking the links between patents and pharmaceutical markets. In particular, it suggests that patents cannot only be understood in their socio-legal action on the basis of their official, written existence and of the temporal limit supposedly attached to it. The case of the OPS in relation to this needs to be clarified. In this particular example, the only aspect of patents that appears to have been limited is this "extra-legal" (in a temporal sense)

[380] A traditional example is found in Pound R. (1910) "Law in Books and Law in Action" American Law Review (44) pp.12 – 18 .

dimension – the fact that they generally act in Djibouti far beyond the temporal/legal boundaries of specific patents. In the OPS, the temporal limit of patents in Europe has somehow overlapped with their social existence.

The consequences of this analysis in relation to public health are important for this research. In particular, the meaning that this might have in relation to access to medication will need to be explored. This is essential in order to answer the questions asked in the field of intellectual property on the links between pharmaceutical patents and access to medication. However, this is most interesting if discussed in relation to the effects of TRIPS, and in relation to the impact of TRIPS on the pre-existing situation Djibouti. For this reason, the issue of the meaning of pharmaceutical patents for health and treatment in Djibouti will be studied in detail in Chapter 7.

In addition, at the time of fieldwork, some reforms were being made to the import system, so that the import of generic medication was being encouraged. As these changes are also most interesting if discussed in relation to TRIPS, and as they were only at an early stage of development at the time of fieldwork, therefore of limited impact on the pharmaceutical market studied during this fieldwork, it is more appropriate to discuss them in chapter 7.

Overall, what needs to be noted in this section is that, although a purely doctrinal analysis of the situation of pharmaceutical patents in Djibouti would portray them as "non-existent", analysing the local pharmaceutical market seems to highlight their role and centrality. Through a series of connections

and relations, these drugs of which patents are an integral part are almost the only ones to enter the country. Reciprocally, no drugs that would infringe patents if they were to officially exist on the model set in other countries enter Djibouti. This is important because it forces us to reconsider the meaning of the "official" status of pharmaceutical patents, the modes of actions of patents, and as will be detailed in the next chapter, the links between pharmaceutical patents and health. In order to provide a clear understanding of the way in which patents become a relevant element in the pharmaceutical networks of Djibouti, it is useful to discuss in more detail the connections through which patents enter the country. This will be done by looking at some key aspects of the import system of Djibouti, before explaining in detail how connections between patents and the import network were stabilised.

SECTION 2: ENROLMENT AND ACTION OF PATENTS IN THE PHARMACEUTICAL MARKET OF DJIBOUTI – HOW DO THEY GET THERE?

We have seen in the first section of this chapter that the pharmaceutical market of Djibouti appears to incorporate patents within its network. This section presents some of the key connections that explain how patents find a way of acting in Djibouti, although they have not been officially created by written law in the country. It focuses on some specific connections within the import system, and within the medical field more generally, that help to explain why a country with no official system of pharmaceutical patents has a pharmaceutical market almost exclusively based on branded medication, fully in compliance

with the strongest patent systems worldwide and in which patents are in fact more extensively embedded than in many countries where they are an official legal instrument. This will highlight the discrepancies between the idea that patents are somewhat dependent on their official written creation and the fact that, in this case study, patents appeared in most drugs used in the country, in spite of not being an official instrument.

In order to describe the range of connections through which patents become embedded in drugs in Djibouti, it is essential to explain in more detail the origins of the drugs observed in the market of the country.

Pharmaceutical imports

When describing the routes followed by drugs in Djibouti, four directions need to be followed: first, the central role played by private pharmacists in the import system; second, the system of the OPS; and finally, two limited complementary sources – the origin of drugs found in the Hopital Bouffard and the donations collected in the Pharmappro. Once again, the important changes that are in action will be most extensively discussed in the next chapter.

At the time of fieldwork, imports in Djibouti were essentially carried out by private pharmacists. As mentioned in Chapter 4, private pharmacists are the key source from which patients can obtain their medication. In addition to this, drugs found in public hospitals are bought directly from private pharmacists (with the now limited exception of those originating from donations, as will be

explained below). This was confirmed by health professionals: *"At the* moment, public hospitals get a bit from the Pharmappro and a lot from private *pharmacists."* (Pharmappro is discussed below.) The lack of official data in the country makes it difficult to evaluate the actual share of imports for which these pharmacists are responsible, but informants all stated that it was a significant one. Indeed, apart from the OPS, "almost every drug" found in the country came from private pharmacists.

"At the moment, the import and distribution system in Djibouti is almost exclusively private – and almost exclusively based on branded medication. Private pharmacists buy very few generics, and sell their drugs for a very high price."

Overall, informants presented pharmacists as the main source of import of drugs in Djibouti. When talking about private pharmacists with any governmental actor interviewed, one of the key elements they emphasised was the complete lack of power the government had over what pharmacists chose to import. We have seen in Chapter 4 that this meant that controls made by the governmental inspectors on the quality of drugs were very limited. However, even these minimal controls do not extend to any type of advice or influence on issues such as prices of drugs, cost efficiency, or whether generics could be used, for example. This can result in some inconsistency between the aim of government policies and the reality of pharmaceutical imports in the country. In particular, informants in the Ministry of Health emphasised that this

sometimes meant that the private interests of pharmacists were privileged over the public interest pursued by official government policies:

"The private pharmacists have a lot of power here – and especially one of them. He was clearly not happy with the changes we are trying to make, and *blocked any attempt to move forward we have made so far. And it's no surprise that things were held for so long by the Chambre du Commerce…*"

This informant implied that the fact that the Director of the Chambre du Commerce is one of the two private pharmacists meant that it was even more unlikely that any regulations on imports in the pharmaceutical field that would limit pharmacists' independence could ever be implemented[381]. Private pharmacists act mainly independently from the government, with limited control, and limited interactions with national health policies. Private pharmacists essentially act commercially, and remain motivated by what will be most convenient, practical, or financially rewarding, rather than by governmental policies.

The second important source of imports that needs to be mentioned here is that of the OPS. As mentioned before, the OPS has its own pharmacy, in which generics have become fully integrated. The OPS has developed its own policy in relation to both import and distribution of medication to patients. It is once again a structure largely independent from the health policy network. This was presented as potentially damaging by one key actor in the Ministry of Health:

[381] This was the case in particular in relation to the changes to the import system that will be presented in Chapter 7.

"We have some issues of coordination with the OPS in relation to *pharmaceuticals"*[382]. The OPS imported drugs fully independently from private pharmacists. All generics were provided by the Dutch organisation, IDA[383], with additional supplies provided by a French wholesaler:

"About 75% of our drugs are generics, and all of these come from IDA – we send them two orders a year, and drugs come either by plane or by boat, which is of course cheaper but much slower. And then we have about 25% of branded *medication, when these particular drugs don't exist as generics on IDA's list.* In this case we buy from the CERP in Rouen."

Further details on this system will be provided below, when analysing the range of connections that make patents enter the networks of Djibouti.

In addition to these two main sources of imports, two minor complementary sources need to be mentioned. First the Hospital Bouffard offers an additional point of entry for drugs in the country, although this only represents a very small part of the overall market of the country. The limited amount of drugs found in Bouffard itself, being a French military hospital, are supplied by the same centralised providers as other army bodies[384]. However, as explained in

[382] This was in particular said to be the case in relation to anti-HIV/AIDS policies and the development of resistance.

[383] For information, see www.idafoundation.org

[384] "Drugs here come from the army supplier anyways, so it is a completely independent system." For information on the supply system used by French Military Hospitals, see for example Faure J. (1999) "Le Service de Sante des Armees: les defis de la professionalisation", *Rapport d'Information au Senat fait* au nom de la commission des Affaires étrangères, de la

Chapter 4, this source of medicines is limited to the treatment of patients in hospital, and their cost does not impact directly on patients. To that extent, this particular source will not need to be discussed in more detail.

In addition to this, until recently, international donors participated in providing public hospitals with some medications, through a specific structure - the Pharmappro[385](although this was done occasionally rather than as a coherent long-term programme):

"Until recently, the only public system of imports was the Pharmappro. But it had a very very limited budget, and it was almost exclusively living from *donations. But it was kind of 'DIY'* – bits and pieces brought together."

This system has now largely crumbled – excluding the building itself, some exceptional donations and remaining stocks. The relevance of this example lies maybe more firmly in its progressive disappearance than in what was its temporary stabilisation. The Pharmappro was created as a structure through which international donations – from France essentially, but also Yemen, Egypt or India for example – could be received, managed and distributed in

---

défense et des forces armées, available at http://www.senat.fr/rap/r98-458/r98-458.html . Five suppliers are named in Annexe 3: « la pharmacie centrale des armées et l'établissement central des matériels à Orléans, les établissements centraux de ravitaillement de Chartres, Marseille et Vitry-le-François, la pharmacie-magasin du port de Brest, l'établissement central de matériels de mobilisation de Caen-Mondeville ».

[385] For a more general discussion of international pharmaceutical donations, see for example Scherer F. M and Watal J. (2002) "op. cit; see also Grabowski H. (2002) "Patents, Innovation and Access to New Pharmaceuticals", Journal of International Economic Law 5(4) pp. 849-860.

public hospitals. The system was considered beneficial for a while, until France started limiting its donations. The remaining "gifts" from countries then became rather criticised by people in charge of dealing with the stocks. One of the reasons for this was that doubts started emerging on the quality of the drugs given – no test could be carried out locally as Djibouti does not have any laboratory in which this could be done, and there was not always any guarantee from donor governments that tests had been carried out at home. The main reason, however, was that the donations were very often completely inappropriate to the needs and facilities of the country. For example, when visiting the buildings of the Pharmappro, the pharmacist in charge showed me a number of ophthalmologic materials that could not be used in any of the public hospitals since none of them had an ophthalmologist, or anyone qualified to use these materials. In addition, a donation from India had just been obtained by the President, and was being distributed to representatives of different public hospitals – most of the drugs were unsuitable to the needs of the country, for example because they targeted diseases almost non-existent in Djibouti, or because they needed to be used in combination with products or materials unavailable in the country, or given by a specialised doctor that the country did not have. Overall, most of the people present seemed reluctant to take any of the boxes with them, but had to in order to make sure that political sensibilities would not be hurt by refusing a donation obtained by the President himself. As a whole, the Pharmappro's efficiency diminished over the years, with changes in the flows of medication, themselves entangled in wider political and practical changes that cannot be fully developed here. Its lack of

coherence and harmony made it a weak network and its independent parts are now becoming more clearly characterised as such.

Finally, and as has been mentioned several times in the course of this research, next to the existing systems of imports, and partly replacing the Pharmappro system, a new centralised network was being set up for imports, at the time of fieldwork. It is directly aimed at importing more generics, and is in that respect an essential step in relation to the role of patents in the country. However, it is something that will be described and discussed in full detail in Chapter 7. What this section focuses on is the system as it stands at the moment.

Embedment of patents/drugs in the import system of Djibouti

Following this brief introduction to the import system of Djibouti, it is now essential to question and understand the set of connections through which patented drugs have become omnipresent in the country, and to emphasise how these connections have become stable enough for the import network of Djibouti to appear to exclude any generic version of patented drugs – and exclude any generic in a predominant part of the market. The enrolment of patents within the pharmaceutical system of Djibouti - without facing the temporal limit existing when patents are created in written law as far as the private market is concerned - is the result of complex sets of relationships and connections, shaped by a range of personal, practical and commercial relationships, some of which are embedded into habits and routines linking France and Djibouti in a somewhat "postcolonial" way. It is necessary to

present and discuss these different connections in a way that illustrates best the complexity of the links while maintaining a clear narrative that highlights the key mechanisms that have stabilised some of the networks described above. The importance of understanding dislocated[386] actions, and the effect of multiple connections on a particular network will be emphasised[387].

Private pharmacists and patents

The first set of connections that needs to be detailed links private pharmacists to patents/drugs. This link is stabilised by a range of practical and commercial connections that have to do with information and advertising, shipping conditions, importers' habits and trust. They also have to do with doctors' habits and patients' expectations. This range of connections will now be studied, before questioning further how the limited market of generic drugs of the OPS is regulated, and why it is limited to out-of-patent medications – thereby restraining the potential exception set by generic medicines to the role of patents in Djibouti.

[386] Understood as actions taking place in loci other than the direct object of analysis and "making others act" – see Latour B. (2005) Reassembling the Social: an Introduction to Actor-network Theory op. cit.

[387] To that extent, part of this analysis will integrate some ideas put forward by ANT when discussing the impossibility of notions of "globalities" or "localities" – see for example Law J. (2003) "And if the Global were Small and Non-Coherent? Method, complexity and the Baroque", published by the Centre for Science Studies, Lancaster University, LA14YL, UK, at http/www.comp.lancs.ac.uk/sociology/papers/law-and-if-the-global-were-small.pdf

Advertising and information

When discussing with private pharmacists why they only imported branded medication, a number of suggestions were made by them. The first was that private pharmacists in fact "worked" only with a few companies, mainly large multinational companies, and bought their drugs essentially from branches based in France. Smaller generic producers were not generally used as sources of medication, and a large set of drugs were therefore already excluded by the strong links between large multinational companies and Djibouti. When asking for explanations as to why the range of exporters was so limited, and why private pharmacists were so close to large multinational companies, several elements were presented. A key element to highlight related to the circulation of information between drug producers and pharmacists based in Djibouti. To put things simply, pharmacists in Djibouti imported and distributed drugs they knew about. Only drugs that had been brought to their knowledge will enter the country – and the quasi-monopoly of the two private pharmacists might have made it rather unnecessary for them to go out of their way to find out about new products. Therefore, questions to address here are the following: how do importers in Djibouti hear about specific drugs? How do they find out what is available, reliable, and worth buying? To answer these questions, it is useful to have a look at the way multinational companies make their products known in Djibouti[388] - or rather at the way importers in Djibouti

[388] This is not fundamentally different from strategies deployed in other countries, although the impact might be even stronger in Djibouti were private pharmacists hold a particularly central place. See for comparison on advertising strategies (although essentially directed at doctors in France) Kapferer J.N. (1997) « Marque et Medicaments : le Poids de la Marque dans la

receive the information provided by companies. When asked how they found out about particular drugs, or how they chose which drugs to import, private pharmacists listed spontaneously the range of strategies used by large pharmaceutical producers to advertise their products. They talked first about the range of leaflets that large companies were sending them from France. They also mentioned that representatives from large pharmaceutical companies were regularly visiting Djibouti, and that Sanofi even had a permanent local representative in charge of organising monthly meetings with health professionals where specific products would be displayed – not necessarily new products, but from what was observed during the meetings I attended, some of their well-known products and original brands. In addition to this, one of the two private pharmacists explained that he attends the Pharmagora meetings held in Paris every year[389]. For him, this was the best way of developing contact with companies that had been in touch through the profusion of leaflets, posters, advertising pens and writing pads that are sent over by pharmaceutical companies mostly from France. Each of these strategies is summarized in the following quotation:

"There are two important ways to find out about drugs – the first one is to attend those big meetings held in France once, sometimes twice, a year. The other is through the permanent or non-permanent representatives of companies *who come to Djibouti."*

Prescription Medicale », Revue Francaise du Marketing (165) pp. 43-51; see also Belot L (1998) « Une etude met en evidence les « facteurs psychologiques » qui influencent les prescriptions medicales » Le Monde 17th July 1998.

[389] For information and lists of companies represented, see www.pharmagora.com

This enrolment of pharmacists in strong connections with large French-based companies runs even further in one case. One of the private pharmacists in Djibouti mentioned that he owned an advertising company through which he promoted the medication of some of these French-based companies:

"I own an advertising company for pharmaceuticals… basically I hire people to go and introduce new drugs to doctors."

The information he provided was rather vague, and the conversation we had about this could not move into more detail than the information he was willing to disclose. However, it is an interesting and highly symbolic element which illustrates how this particular actor remains entangled with large companies.

Routes and Shipping

Although the strong links between private pharmacists and multinationals in terms of advertising do not necessarily mean that generic companies could not find a way to reach Djibouti[390], importers explained that they chose to import drugs from large companies based in France for several additional reasons. These had to do with the practicalities of importing drugs in Djibouti. One element that was mentioned many times was that shipping drugs to Djibouti can be particularly lengthy, and that once importers can be convinced that the

[390] Although the fact that Djibouti is a small market means that generic companies with limited advertising budgets might not find it worth investing in getting their products advertised in this particular country.

medication they ordered will reach them as planned, they tend to remain with the same provider. Informants thus emphasised several times that they tend to keep the same providers because "*At least we know it works!"* This is an interesting example of the way some general economic and practical difficulties faced by Djibouti impact on the creation of particular sets of relationships, and on the stability of these same connections. This point provides a good opportunity to reflect on one issue that has only been discussed in Chapter 1, and left to one side when presenting data on Djibouti. One of the latest evolutions of the post-TRIPS debates related to compulsory licences, and to the doubts left by TRIPS and the Doha declaration as to whether the poorest countries with no pharmaceutical industry could take advantage of compulsory licences[391]. In August 2003, as explained in Chapter 1, the TRIPS council agreed that in cases of emergency, countries with no industry – under certain conditions – could grant producers in another country an authorisation to produce a patented drug[392]. Doubts were expressed about this move, as it was unclear whether the proposed system could in fact work, for many practical reasons as detailed in Chapter 1[393]. The comments of

[391] For details and comments on the role and limits of compulsory licences, and the questions raised in and following Doha, see Abbott F.M. (2002) "The Doha Declaration on the TRIPS agreements and Public Health: Lighting a Dark Corner at the WTO", Journal of International Economic Law, 469-505; Abbott F.M (2002) "Compulsory Licensing for Public Health Needs: the TRIPS Agenda at the WTO after the Doha Declaration on Public Health", Quaker UN Office, Occasional Paper 9 available at http://www.accessmed-msf.org/upload/ReportsandPublications/25620021018167/fred%20abbott.pdf

[392] WTO document IP/C/W/405, available at http://www.wto.int/english/tratop_e/trips_e/imple_para6_e.htm

[393] And highlighted by NGOs: Oxfam International (2003) "WTO patent rules will still deny medicines to the poor", 27th August 2003, available at: http://www.oxfam.org/eng/pr030827_wto_patents.htm

importers in Djibouti on the difficulties they encounter when dealing with any "new" provider, for practical reasons, and on the fact that shipping any product without delay through new routes is particularly difficult, can be related to this issue. One questions whether in the current situation Djibouti would be likely to adopt a compulsory licence and expect supply from generic producers with which they have never had any contact before. In addition to this, what we have seen in Chapter 5 and in this chapter, of the difficulties for different actors to connect and create a coherent network, adds substance to the argument that the system created by the WTO is unlikely to be of relevance to Djibouti – at least in the near future. As it is hoped that this issue has become clearer, we can return to discussing imports and their connections.

The importance of advertising and shipping issues explain why large companies are privileged over smaller generic producers by pharmacists in Djibouti. However, in order to understand the omnipresence of branded medication on pharmacy shelves, further connections need to be explained. The fact that even "branded generics" are very rarely found in Djibouti is not explained by this link between private importers and a few large companies – as companies such as Merck for example produce their own branded generics. In order to understand what shapes the embedment of patents in Djibouti, it is

---

and MSF, 27th August 2003, "Chairman's text brings new difficulties to WTO paragraph 6", available at: MSF (2003) "Chairman's text brings new difficulties to WTO paragraph 6", 27th August 2003 http://www.msf.org/msfinternational/invoke.cfm?component=article&objectid=77830ACA-8EC5-419A-82AB7D7ED6A2E1ED&method=full_html

now important to reflect on the role of doctors in stabilising key connections between patients, diseases and patented drugs.

Doctors, patients and patented drugs

When looking back at the presentation of the health system given in Chapter 4, it is clear that French doctors represent an important part of the public health network, through their exclusive role in Bouffard and partial role in Peltier, and in fact determine largely the direction of the prescribing system. Although they are by no means the only doctors in the territory, their share in the prescribing system is significant enough for their behaviour to influence the actions of pharmacists. In addition to this, Djiboutian doctors working at the time of fielwork had also been trained in French universities. As mentioned earlier in this chapter, prescriptions written in Djibouti generally refer to a branded drug, and not to its generic version. This finding compares to research carried out in France on doctors' behaviour that highlighted how they tend to prefer prescribing branded medication[394]. In Djibouti, the training and habit of French doctors are two of the factors that impact on what doctors will write on prescriptions, and several doctors have thus explained why they generally prescribe branded drugs:

"*That's what we've been taught at uni, and maybe for younger doctors it is* different, but if I need to prescribe Prozac *or Primperan I can't tell you the* g*eneric name, and I don't have time to go and look it up*."

[394] See Larrieu J. and Houin G. (2001) op. cit ; Kapferer J.N. (1997) op. cit.

Patents were therefore fully embedded in prescriptions themselves, in the same way as they have appeared to be an inherent part of drugs materially found in the country. However, their embedment in prescriptions should not necessarily mean that they are unavoidably and causally embedded in drugs. If we compare once again one aspect of the situation in Djibouti with that of France, from which laws in the pharmaceutical field in Djibouti are largely inspired, the right of substitution of the pharmacist established by French law means that the specific content of a medical prescription will not be the only determinant to the final version of drug officially dispensed[395]. In Djibouti, officially, pharmacists require the consent of doctors before they can change a particular medication[396]. Pharmacists interviewed, however, emphasised that this was not their main concern, and in particular that they would not consider themselves as "legally" unable to replace a branded version of a drug by its generic version – and emphasised once again the flexibility of legal rules in their field of activity. However, they also suggested other factors that stopped them from doing so. One of the main elements of this was that, according to the pharmacists I met, patients would not accept generics – or replacement of drugs by any equivalent medicine, for that matter. Patients who are offered a competitor's product in the pharmacy would often refuse anything else than what was written on the prescription:

[395] Article L.512-3 Code de la Sante Publique: "Le pharmacien ne peut delivrer un medicament ou produit autre que celui qui a ete p*rescript qu'avec l'accord expres et prealable du prescripteur, sauf en cas d'urgence et dans l'interet du patient. Toutefois, il peut delivrer par substitution a la specialite prescrite une specialite generique…*"

[396] Article 24: Loi n°145/AN/91 /2ème L relative aux conditions d'exercice de la pharmacie

"Patients don't want generics. They want what's written on the paper."[397]

This was explained in various ways by different doctors or pharmacists, and a range of factors can be considered as important to keep in mind. According to pharmacists, as far as French patients are concerned, most of them would not be interested in buying cheaper versions since they would be fully refunded by the Securite Sociale on their health expenses[398]. As far as Djiboutians are concerned, one idea often put forward emphasised that Djiboutians who had managed to access a doctor they trusted, in the difficult situation presented in Chapter 4, would be unwilling to see their prescription "overruled" by pharmacists or pharmacy staff, and would not want anything other than the specific drug that had been prescribed. Overall, it appeared clearly that the relations between doctors, patients and drugs were set in such a way, and stabilised in such a fashion, that generic medicines were almost necessarily excluded from the network in which private pharmacists were involved.

As a whole, it is difficult to explain fully the causality between the shape of the private pharmaceutical imports system of Djibouti and the quasi-omnipresence of patent/drugs actor-networks in the country. However, the range of relations and connections highlighted above has provided what appeared in this research

[397] It should be noted, however, that whether generics had in fact ever been proposed by private pharmacists to their patients may be doubtful, since they did not actually import generics at any stage – and since the example of the OPS shows that this specific structure managed to start providing some generics – the exact weight of this particular factor therefore needs to be balanced and might not be as significant as other factors.

[398] For information on the mechanisms of the Securite Sociale in relation to medical expenses, see Code de la Securite Sociale, Titre 6 – Dispositions relatives aux prestations et aux soins – Controle medical – Tutelle aux prestations sociale.

as the key elements explaining the embedment of patents in drugs, prescriptions and private import networks. These emphasise and explain why some of the assumptions held about the consequences of the absence of "written legal" patent systems on pharmaceutical markets had to be rethought. In particular, this research highlighted how the tight links between some agents in Djibouti and others in France resulted in connections between actions in the import system of Djibouti and patents as official agents in France being established. In particular, the central and independent role of private pharmacists, the connections between medicine in Djibouti and training in France, drugs in Djibouti and multinational companies based in France – themselves resulting from multiple enrolments and exclusions - all resulted in sets of associations through which routines that can be understood as emerging from pharmaceutical patents, as official tools in France were repeated and embedded in habits of actors in Djibouti. Overall, although officially pharmaceutical patents are non-existent in Djibouti, these connections and associations resulted in them being fully embedded in drugs, prescriptions, routines and actions relevant to the pharmaceutical network of Djibouti. Before concluding this chapter, however, I shall consider the elements that can explain why the system of imports offered by the OPS does not enrol any generic versions of drugs still under patent in other countries.

Import network of the OPS – how have connections stabilised around one European generics-provider?

We have seen above that the OPS essentially works with generic medicines. However, this is not exclusively so, and in particular it only concerns drugs which are out-of-patent in Europe. To that extent, although pharmaceutical patents might not appear as a central actor for most of the imports carried out in this network, they remain embedded in at least some of the drugs bought and distributed by the OPS. The OPS is a small system of distribution, and it is thus not necessary here to give it as much attention as has been given to private pharmacists. However, it is also important to consider why, in spite of the attempts made in the OPS to keep the price of drugs as low as possible through generic medicines, it in fact only imports generic versions of drugs that are out-of-patent in other countries. The main reason for this appears to relate to the fact that imports realised by the OPS, as far as generics are concerned, are made through IDA, a Dutch non-profit organisation that provides cheap drugs to poor countries[399]. The main list of medication, at the time of fieldwork, provided by IDA[400], showed exclusively out-of-patent medication[401]. The lists created by IDA were based on the WHO Essential Medicines List[402]. The

[399] For full information on IDA and listings of the drugs and prices they offer see www.idafoundation.org

[400] This does not include the additional but separate system dedicated to AIDS that will be discussed below.

[401] Once again, information on the products sold by IDA can be found on their website, at www.idafoundation.org; in this research, the primary source of information used, however, was the lists sent by IDA to the OPS itself (to which are attached further information documents such as the Bulletin IDA.)

[402] http://www.idafoundation.org/en-us/content.aspx?cid=71

WHO list of essential medicines is itself considered as made up of around ninety percent of out-of-patent medicines[403].

The link between this list and patents could be understood in two different ways. First, it could be read to mean that patents play a minor role in access to medication, since essential drugs are almost all out-of-patent. Second, and in the alternative, it could be understood as resulting from patents and their impact on the price of drugs, in the sense that the list is partly established as a result of a balance between a range of concerns, including cost and affordability[404]. Therefore, the main list of drugs provided by IDA – with the recent exception that will be explained below – might itself have been established so that it excludes patented drugs. What is most relevant is the fact that, whichever explanation is correct, the OPS buys generic drugs from a list from which patented drugs are mainly excluded. This partly explains why generic versions of drugs patented elsewhere have not entered the OPS.

Two further points can be made at this stage. First, it is important to question why the OPS has not sought routes of generic imports outside this particular list. The reasons why the OPS exclusively deals with are essentially practical, and relate to a large extent to practical issues raised above. For example, longevity was a relevant factor:

[403] See Laing R., Waning B., Gray A., Ford N. and Hoen E. (2003) op. cit.

[404] This result in particular from the fact that cost and affordability are some of the factors that the WHO takes into account when creating its EML. For comments, see Laing R., Waning B., Gray A., Ford N. and Hoen E. (2003) op. cit.

"We have worked with IDA for six years, we know them. We have had so many problems before that, now that at least we know it works, we decided to stay *with them."*

In a similar way to private pharmacists, they then explained that practical transport issues were essential for them to consider, as it could be complicated to import drugs in a reliable way in Djibouti.

Second, the range of medication offered by IDA was being extended while this fieldwork was carried out to include some HIV/AIDS medication which are still under patent in some countries. These new drugs were dependent on a particular system, and not integrated into the main list of medication on which actors in the OPS were working – although this parallel system was part of IDA. While this fieldwork was carried out, this was still at an early stage and not fully organised yet. However, even this new source of medication, although officially part of the broader IDA system, was not considered as relevant and immediately useful by the pharmacists of the OPS. In particular, although this was underway and already advertised in different countries, the pharmacists of the OPS emphasised that they still regarded this as speculative and not something they would consider straightaway as they had only been given limited information on the matter. Moreover, they had not received lists of price or specific explanation on steps to take to participate in this new system yet[405]:

[405] for details on these administrative steps, see http://www.idafoundation.org/fr-fr/content.aspx?cid=134

"It is all very new, and therefore very complicated, so at the moment we are buying branded anti-retroviral and we will probably do that for a while still."

The difficulties of adapting import systems to changing situations in Djibouti can be understood through this example, and although IDA is now starting to by-pass the limits set by pharmaceutical patents, these changes are not yet integrated in Djibouti. Overall, the only generic drugs that the OPS currently buys are those offered by IDA on its most traditional list of imports, and through the means that they have used for six years. The OPS does not consider sources of imports of generics apart from this particular system, which results in the fact that patents remain embedded in the drugs found in the OPS that are still "under patent" in other countries. Overall, because of this exclusive relation to the main list of medicines offered by IDA, the exception to generic medicines offered by the OPS remains limited to some medicines only – all out-of-patent worldwide.

CONCLUSION

The relation between the absence of national written law on pharmaceutical patents and the embedment of pharmaceutical patents in the market of Djibouti raised important issues about the role and modes of action of patents as socio-legal objects. Some more general issues will be discussed in the conclusion of this project, although some elements can be summarised already at this stage. In particular, it is important to reflect on the contrast between the original idea that could have been derived from the absence of written law on

pharmaceutical patents in Djibouti and the traces left by patents within the pharmaceutical networks of Djibouti. Overall, patents appeared in this example as a complex set of connections, as the result of social circulation that made patents social actors in many ways, gaining agencies in a number of fashions not necessarily related to their written/official status in the country. The artificiality of the potential divide between "social" and "legal" appear through the investigation of these connections that emerged as as blurred, uncertain, and never dichotomic. While Latour stated that legal objects act in a "legal way"[406], it appeared here that the definition of the modes of action of so-called "legal" objects could not be pre-defined and certainly not perceived as acting in an inherently different, independent or unique way that could be isolated from other social connections. The "legal" way needs to be understood here as a socio-legal range of connections fully embedded in various types of practices and networks.

As a whole, the embedment of patents in drugs sold in Djibouti, in each dimension of its "pharmaceutical market", and in the routine action of importers – to take only a few examples of the locations where patents could be "found" - appeared as fully co-dependent on a range of connections. The weakness of shipping networks, of material connections between Djibouti and other places where drugs are being produced, the unreliability of many systems of transport, the crumbling system of international donations, are all examples of some of these connections, and more specifically of limited networks, less extended and less stable than found in other locations. Next to these somewhat

[406] Latour B. (2005) Reassembling the Social: an Introduction to Actor-network Theory, op. cit.

restrained networks, several stable systems have developed. The first one is built around two private pharmacists and their shops, obligatory points of passage[407] for most drugs entering Djibouti, which are entangled in sets of strong and well run connections that they expect to remain stable and foresee as unlikely to crumble. This set of stable connections has involved actor-networks of which patents are an inherent part, and have been reshaped in such a way that patents have become materialised and present through most drugs in the country. Bypassing their non-existence in written national law in Djibouti, this tool that officially emerged on paper in other countries, supposedly for other countries, has become centrally realised through the connections lived and relived by private importers in Djibouti[408]. Patents have not even been fully by-passed by the OPS, although they have created their own stable network, of which generics are an official part, and in which a different set of actors is therefore present that could be expected to exclude pharmaceutical patents. In particular, when dealing with drugs under patent, the OPS uses the patented version. This is circumstantial, however, and might be modified if the new network created by IDA around some anti-HIV/AIDS drugs reaches Djibouti. But this was not the case when fieldwork was carried out. In addition to this, other aspects of the import system of drugs and pharmaceutical policies

[407] Callon M. (1986) "Some Elements of a Sociology of Translation: Domestication of the Scallops and the Fishermen of Saint-Brieuc Bay" in Law J. (ed) Power, Action and Belief: a New Sociology of Knowledge? Sociological Review Monograph (32) London: Routledge and Kegan Paul, pp. 196-233.

[408] This in fact relates to comments made elsewhere: "While technically it is true that patent laws in Africa have had little to do with access to medication, patent laws elsewhere in the world have made all the difference", Halbert D. (2002) "Moralized Discourses: South Africa's Intellectual Property Fight for Access to AIDS Drugs", Seattle Journal for Social Justice (1) Fall/Winter 2002 pp. 257-288.

of Djibouti are currently being changed. These changes will aim, in particular, at introducing generics in Djibouti for a wider range of pharmaceuticals. Their result will be to create a new network from which patents are actively excluded, and in which generics are given a central and stable role. Although this change might appear in isolation, resulting from changes linked to health rather than patents, and seemingly taking the country in the "wrong direction" when it is supposed to be officially implementing pharmaceutical patents to become TRIPS compliant, these changes can be particularly interesting if thought of in the light of TRIPS, as will be discussed. The next chapter will aim to question further the changes brought in by TRIPS in Djibouti, and will determine how, when reading TRIPS as a complex and fluid actor-network, rather than as a set of prescriptions to be followed by specific consequences, a different aspect of its links to public health might appear. This research is concerned with the potential links between TRIPS, pharmaceutical patents and public health, and the following chapter will explain how, after having understood the complexity of the role of TRIPS and pharmaceutical patents in both political and trade networks of Djibouti, it is now possible to go further in discussing what TRIPS is and does in the public health network of Djibouti.

CHAPTER 7 - TRIPS, PHARMACEUTICAL PATENTS AND HEALTH IN DJIBOUTI - UNDERSTANDING TRIPS IN ITS NETWORKED EFFECTS

The key question that this project aims to address relates to the links between TRIPS, pharmaceutical patents and health in Djibouti. The two previous chapters have presented sets of connections that are essential to understand before discussing what TRIPS and pharmaceutical patents might mean in relation to public health in the country. This chapter builds on the descriptions presented above, and explains how the links between patents, TRIPS and health in Djibouti need to be understood. It argues that these links are not necessarily where they might be expected to be found. While on the one hand the links between diseases and patents in Djibouti can only be understood in relation to the current social action of patents in Djibouti – partly independent from their written creation, as explained in Chapter 6 - TRIPS appeared to have left some additional traces in the public health network, as manifestation of its action in many other places. By following these traces, further complexity appears in the TRIPS-network, and in the task of understanding its impact. The role of TRIPS in Djibouti in relation to health can only be understood by recognising that TRIPS remains a complex network in spite of its apparently punctualised aspect. The description of TRIPS as a "global" actor is not appropriate to the frame of this research, and the gaps left by the idea of globality have been discussed before[409]. However, TRIPS is also something

[409] See for example for comments on the notion: Law J. (1999) "Materialities, Spatialities, Globalities", published by the Centre for Science Studies, Lancaster University, LA14YN, UK, at http//www.comp.lancs.ac.uk/sociology/soc029jl.html.

that happens in many places, that generates changes in many networks, that is embedded in multiple actions and networks, and in order to understand what it does in Djibouti, it is essential to have a clearer idea of the effects it has in these many other places.

This chapter is divided in two main sections. The first section brings together findings made in Chapters 5 and 6 and the links between modern drugs and disease in Djibouti. It looks at the current links between health and patents in Djibouti on the basis of the pastiche we have drawn, in particular, of the import network of the country. It will emphasise the difficulties in establishing clearly the relation between TRIPS, patents and health, and will discuss how they can only be understood by considering the role of patent/drugs hybrids in Djibouti (Section 1). The second section questions whether the embedment of TRIPS in a range of policies and lobbying can impact on Djibouti. It considers whether TRIPS can be found as embedded in Djibouti itself through complex relations happening in other places. This is done by questioning the dislocated effects of TRIPS, and by considering whether two specific health projects implemented in Djibouti at the time of fieldwork can be read in the light of these effects (Section 2). This chapter provides an important aspect of the socio-legal role of both TRIPS and pharmaceutical patents in public health networks in Djibouti, and will bring us to question how this understanding of both instruments calls for a wider vision of the mechanics of socio-legal objects.

SECTION 1: UNDERSTANDING THE LINKS BETWEEN TRIPS, PATENTS AND HEALTH

Chapter 5 has explained the role of TRIPS as prescription– and its limits – in the public health policy networks of Djibouti. It emphasised why it appeared that TRIPS and pharmaceutical patents had limited effects in shaping actions in public health related offices, discourses, and reports. However, it has also been emphasised that this was only one aspect of the picture to be drawn, and that the connections linking pharmaceutical patents to public health should be followed wherever they may lead. Chapter 6 has therefore explained how following drugs in Djibouti could take us back to patents, through complex set of hybrid connections. One question that now needs to be addressed, and can only be addressed by following the connections highlighted in the previous chapters a little further, is that of the links between pharmaceutical patents and diseases.

The task of analysing the links between patents and health in Djibouti is made particularly difficult by the fast-changing dimension of the area, and the range of complex and overlapping connections that need to be highlighted. These are all highly co-dependent and circumstantial, which makes their narrative particularly difficult. All the connections presented in this section are also dependent on the enrolment of each relevant actor in further networks and relationships. In order to understand the overall meaning of each of these instruments for Djibouti, it is necessary to understand the intersection of several networks in which patents and TRIPS have different meanings and

dimensions. Finally, it should be re-emphasised that all the links presented here are likely to change or disappear at any time. We will see below how some new connections are already appearing and reshaping public health networks, and the role of patents within them.

The theoretical links that are drawn between patents and health in existing comments and literature have been discussed in the previous chapters, and only need to be briefly mentioned here. First, a common expectation is that patents relate to access to health. The basic reasoning behind this assumption is that since patents impact on the price of drugs, they impact on access to medicines, and therefore on access to treatment – which in turn limits opportunities to eradicate diseases[410]. When TRIPS creates patents, it is therefore expected to generate a causal chain that will end in disease being unavoidable. The key question to be answered here is whether or not this chain can be followed in

[410] The links between TRIPS, patents and access to drugs commonly drawn when dealing with TRIPS have been discussed in Chapter 1, and their apparent immediate causality in some academic writings has been illustrated in Chapter 2 by a quote from Matthews D. (2004) "Is History Repeating Itself? The Outcome of Negotiations on Access to Medicines, the HIV/AIDS Pandemic and Intellectual Property Rights in the World Trade Organisation", Law, Social Justice and Global Development Journal (1), available at http://www2.warwick.ac.uk/fac/soc/law/elj/lgd/2004_1/matthews/. It can similarly be read in some NGOs documents. For example: "With the implementation of TRIPS in nearly all countries in 2005, pharmaceutical products will be given patent protection for 20 years, and developing countries will have far more difficulty in accessing affordable generic versions of patented drugs", in Ford N. (2003) "Patents, Access to Medicines and the Role of Non-governmental Organisations", Journal of Generic Medicines, Vol.1 (2) pp.137-145, on p. 140; for a general discussion of the links between patents and health, see for example Velasquez G. (2000) « Medicaments Essentiels et Mondialisation », Revue Internationale de Droit Economique, 2000/1. Numero Special: Brevets Pharmaceutiques, Innovation et Sante Publique pp.38-44; Rozek R. and Berkowitz R. (1998) "The Effects of Patent Protection on the Prices of Pharmaceutical Products: is Intellectual Property Raising the Drug Bill in Developing Countries", Journal of World Intellectual property (1) pp. 179-244.

Djibouti. The approach adopted here is to analyse in detail elements and connections that explain the action and mechanisms of pharmaceutical patents in Djibouti, rather than assuming the causality and simplicity of their links. Next to this first perspective of patents as allowing diseases to spread, a diverging understanding presented before makes patents a condition for treatment – without patents, there would not be any new drugs, and without new drugs, there would certainly be more diseases[411]. Once again, this first section needs to consider if this causal relation holds any truth in relation to the links between health and patents in Djibouti.

This section tests the assumption that the links between patents and health can be established in either of these simplified and causal ways. Once again, it attempts to avoid drawing definite and causal links between networks that are more complex than any account can fully reflect. To that extent, it emphasises its own limits as ideas are developed. The roots of this section in empirical data need to be re-emphasised. In order to follow the links between health and

[411] See in particular the position of the pharmaceutical industry – for example: "The commercial sector discovers and develops nearly all new drugs and vaccines, and the dependence of pharmaceutical and vaccine discovery and development on adequate and enforceable intellectual property rights is the highest amongst various industry sectors", International Federation of Pharmaceutical Manufacturers (2001) "TRIPS, Pharmaceutical Patents and Developing Countries: Implications for Healthcare Access, Drug Quality and Drug Development", available at http://www.ifpma.org/documents/NR86/TRIPS.pdf, on p.2; see also Mansfield E., Schwartz M. and Wagner S. (1981) "Imitation Cost and Patent: an Empirical Study", Economic Journal (91) pp. 907-918; Scherer F. M. (2000) « Le systeme des brevets et l'innovation dans le domaine pharmaceutique », Revue Internationale de Droit Economique, 2000/1, Numero Special: Brevets pharmaceutiques, Innovation et Sante Publique pp.109-124; Dimasi J. A., Hansen R and Grabowski H. (2003) "The Price of Innovation: New estimates of Drug Development Cost", Journal of Health Economics, 22:151-185.

patents, it is important to return to actors' perspectives when discussing specifically how they perceived the links between patents and health:

"*The drugs we need are very basic medication, they're not under patents* anymore."

"If you look at the health situation here, most problems could be solved without *access to "modern drugs". What we really need is paracet*amol, aspirin, a few antibiotics, some antiseptic and some anti-diarrheic. All of these are in the *public domain anyways, and don't cost anything! Our real concern is first:* how to get those to the population? We are really far from there, so modern drugs *will probably not be a concern for a very long time…."* [412]

Thus we should consider whether health priorities themselves need to be considered as determined by patents – this issue, as mentioned briefly in Chapter 6, has been raised in relation to the international definition of "essential medicines". In particular, the WHO list was established by keeping in mind the cost of medication. That has raised the issue that the absence of patented drugs from the list might be due to their price rather than to the fact

[412] This similar to comments made by the industry when pleading that patents are not the cause of limited access to medicines in poor countries – although this argument can be criticised when coming from the industry which also argues, as explained above, that patents are important for R&D that could matter to developing countries. Although as we will see below the argument does not hold fully in the case of Djibouti: "Patents do not, in fact, have a significant impact on access to the drugs which most of the population in developing countries actually consumes, which are primarily off-patents drugs", International Federation of Pharmaceutical Manufacturers (2001) op. cit. on p.15.

that they would be "less important" than others[413]. Although this issue has been considered, it did not seem to be significant in Djibouti itself. When discussing with doctors what their main concerns were, they constantly stated that what most people need are the range of medications quoted above. They emphasised the impact that untreated diarrhoeas or fevers had on the overall health crisis. To that extent, the empirical findings made in this research did not at any point seem to suggest that this opinion was based on a concern for the cost of particular drugs rather than for the actual medical needs of a large part of the population[414]. If returning to the quotations given above, the two sets of causal chains presented early in this chapter are fully challenged, because the basic assumption that treatment depends on modern drugs itself is contested.

Since modern drugs are not necessary to treat diseases in Djibouti, access to modern drugs is not crucial for health, and therefore patents should not be an issue in relation to the predominant diseases of the country. Similarly, if Djibouti does not need new drugs to treat diseases, the argument that patents are important for research and development, and are consequently essential to tackle diseases with much needed new drugs, does not hold true in Djibouti itself. The diseases that need to be addressed in Djibouti have treatment that has been available in the public domain for several years. The role that might be played by patents in relation to health in Djibouti would therefore appear to be necessarily limited. But this is itself based on an assumption – very

[413] See for example for comments on the structure and evolution of the WHO Essential Medicines List: Laing R., Waning B., Gray A., Ford N. and Hoen E. (2003) "25 Years of the WHO Essential Medicines Lists: Progress and Challenges", The Lancet (361) pp. 1723-1729.

[414] The only potentially debatable case was that of AIDS, which will be discussed again below.

reasonable, nevertheless, from a common sense perspective and found in a range of texts quoted in Chapter 6[415] – that appeared to be wrong in the case of Djibouti. The above statement therefore assumes that, since new drugs are not an issue when trying to address the diseases that Djibouti has to face, patents do not relate to drugs needed in the country, and therefore do not relate to diseases. In other words, it assumes that, if patents are not embedded in the diseases present in Djibouti, they cannot be embedded in the drugs used for treating them. Consequently, since they cannot be embedded in drugs needed in Djibouti, they cannot participate in determining their price nor access to them. However, once again, some elements need to be added to this reasoning. In particular, it is important to ask whether the fact that new drugs are not needed to address most illness in Djibouti should imply that patents do not relate to these illnesses in any way. To answer this question, it is essential to reflect on what was demonstrated in Chapter 6 on the role of patents in the pharmaceutical market of Djibouti.

As explained in that chapter, the impact of pharmaceutical patents on the largest part of the current market of Djibouti – if excluding so far the limited exception of the OPS - is such that, once a patent has been granted on a drug, it will in fact remain determinant of this drug being the version imported in Djibouti, even after it has officially "expired" in other countries – and after the

[415] For example: Scherer F.M and Watal J. (2002) "Post-TRIPS Options for Access to Patented Medicines in Developing Nations", Journal of International Economic Law 5(4): 313-319; Oxfam International (2001) "Priced out of Reach: How WTO patent policies will reduce access to medicines in the developing world", available at http://www.oxfam.org.uk/what_we_do/issues/health/downloads/priced.rtf, as quoted in Chapter 6.

drug is considered as "off-patent". Patents are therefore critical in determining which version of "out-of-patent" drugs will enter the country [416]. To that extent, in spite of the fact that there is no essential link between modern drugs and disease in Djibouti at the moment, this should not rule out a potential link between disease and patents.

Patents are inherently embedded into most of the drugs entering the country, apart from the exceptional source of generics that we have seen before. The consequences of this in terms of access to medication need to be drawn in order to understand the links between patents and health in Djibouti. In order to do so, it is central to reflect on the role of patents in terms of price not only during the official term of a patent, but also once generic versions start appearing. Indeed, branded versions of drugs remain more expensive than new generic versions entering the market. This has been attributed to the value attached by patients to drugs they already know by name[417]. Even once the official term of a patent has run out, the original producer of a drug will maintain a market advantage that will allow them to charge higher prices than its less widely

[416] Athough the term "out-of-patents" is becoming highly confusing, it is essential to use it at times in order to locate the findings from this case study by comparison to statements made elsewhere.

[417] See Dumoulin J. (2001) "Les Brevets et le Prix des Medicaments", op. cit; See also Caves R. E., Whinston M. D., Hurwitz M. A. (1991) Patent expiration, entry and competition in the US pharmaceutical industry, Brookings Papers on Economic Activity, Microeconomics, pp. 1-48; Grabowski H.G. and Vernon J.M. (1992) "Brand Loyalty, Entry, and Price Competition after the 1984 Drug Act", Journal of Law and Economics (35) pp.331-350.

known competitors – although prices of branded medication generally drop once the market opens to competitors[418].

The meaning of this for Djibouti is particularly important. Crucially, it means that patents play a role in the high price of drugs in the country. They are certainly not the only factor explaining the fact that drugs are expensive in the country, but they are clearly part of the story[419]. Branded drugs are bought by importers at a higher price than generics would be, and are therefore also sold at a higher price. This in turns means that, although modern drugs are not needed to exclude diseases from Djibouti, patents participate in the obstacles that currently exist in access to medication in the country. However, caution needs to be maintained. One must avoid the pitfalls of generalisation that are criticised in this research. Patents are certainly not the only obstacle to access to medication: the weakness of hospital structures, the extent of environmental concerns, the choices of sources made by pharmacists when importing their drugs are all very important factors, and partly interdependent[420]. However, patents certainly should not be perceived as fully excluded from health and

[418] See Dumoulin J. (2001) "Les Brevets et le Prix des Medicaments", op. cit; Larrieu J. and Houin G. (2001) "Medicament generique et propriete intellectuelle", Revue Internationale de Droit Economique (1). Numero Special: Brevets pharmaceutiques, Innovation et Sante Publique pp.173-185.

[419] Such as the cost of various taxes, the margin of profit made by the pharmacist, potential wholesalers etc… To see an example of how this might quantitatively materialise in another least developed country, see "Direction de la Pharmacie et des Laboratoires, Ministere de la Sante Publique, Republique du Tchad, (2004) "Enquete sur le Prix des Medicaments au Tchad", Mai 2004, , available at http://www.haiweb.org/medicineprices/surveys/200405TD/survey_report.pdf#search='enquete%20sur%20le%20prix%20des%20medicaments%20au%20tchad'

[420] These factors are now increasingly presented as important to treat, although this is sometimes not stated clearly by critics of TRIPS.

disease, since they make drugs a bit more expensive, and therefore make disease at least a bit harder to treat.

The contingence of these links is particularly clear. If importers started buying more generic drugs, the links between patents and drugs sold in the country would disappear; patents would be embedded in a more limited range of drugs, and would be by-passed more easily when providing treatment– and the links between patents and health would therefore be even less obvious. We will see in the next section how the reforms being implemented in Djibouti at the time of fieldwork were already beginning to reshape part of these links. In addition to this, the arrival of new diseases, the reshaping of health priorities or the re-emergence of forgotten microbes are all elements that can change the current links and networks.

The complexity of the links between patents and health in Djibouti therefore needs to be fully understood before attempting to discuss how TRIPS is likely to re-order the existing connections. As patents do not exist officially, on paper and in national law in Djibouti, it could have been assumed that there were no connections between patents and diseases in the country. This assumption could have been reinforced by two elements – first, the lack of enrolment of TRIPS as prescription in public health policy networks in Djibouti, and second the weakness of connections between modern drugs and diseases in Djibouti. However, the import and distribution systems of Djibouti currently enrol patents in a way that needs to be fully understood, and that results in patents having an impact in spite of their lack of official existence – and an impact

running further than temporal limits that standard written patent laws would have set. The complexity of these links is of course co-dependent on their mobility, and on the fact that each of these connections is likely to be challenged at any time by new actors, new associations and the emergence of stability in new sets of relations. These re-orderings might be generated by the emergence of new diseases, the introduction of new drugs in the market or new governmental links and policies, for example. However, some of them might embed TRIPS or some effects of TRIPS, not only because of its official legal implementation, as this was proven to be of limited immediate impact, but following its impact on shaping health priorities and "Third World issues" in places other than Djibouti. The next section will be devoted to questioning how and why the dislocated impact of TRIPS as a complex network with multiple effects should be taken into account when assessing the role of TRIPS in specific health networks.

SECTION 2: RE-ORDERING OF HEALTH NETWORKS AND DISLOCATED EFFECTS OF TRIPS

ANT reminds us of the need to relate what are generally perceived as "global" and "local" events in a more subtle and integrated way, that emphasises the artificiality of both terms. It calls for the understanding of networks through their manifestation and existence in specific connections, while emphasising that no specific connection can be understood in total isolation from wider

networked space[421]. Any actor, any happening, is the result of other actors, other happenings and other connections, all embedded into what might temporarily appear as one. This section questions the potential embedment of TRIPS in public health in Djibouti, through actions and projects that can appear to relate to some aspects of TRIPS as a complex network. Once again, it necessarily has to be limited in the claims it makes for causality, and it has to limit itself more often to narrow questions than wide-ranging answers. It analyses how the effects TRIPS has had on shaping health priorities worldwide are felt in Djibouti, and relates local re-orderings to changes generated elsewhere by the enrolment of TRIPS in particular networks – and the enrolment of issues or diseases as part of TRIPS. The method is essentially illustration - by looking at two key health projects that are currently being set up in Djibouti, and which highlight particularly well some of the reordering that health networks are currently undertaking. This section explains how these can be read in the light of TRIPS, and how this can be used to rethink our understanding of what TRIPS is or does, and how it should be studied. The approach accepted here is that "TRIPS in Djibouti" can only be understood as the gathering of the many effects of TRIPS in other places, and their embedment in other associations. Throughout this research, it appeared clearest that the punctualised and unified vision of TRIPS as one clear set of prescriptions in a chain of reactions – one intermediary that would just carry

[421] This relates to ideas put forward in ANT when dealing with the notions of "globalities/localities" explained in Chapter 2 and developed for example in Law J. (1999) "Materialities, Spatialities, Globalities", op. cit. and Law J. (2002) "And if the Global were small and incoherent" published by the Centre for Science Studies, Lancaster University, LA14YL, UK, at http://www.compa.lancs.ac.uk/sociology/papers/law-and-if-the-global-were-small.pdf.

patents as a pre-defined entity - could not be sustained once its wide ranging effects start being undone and observed.

The following discussion considers how the delocalised effects of TRIPS can be related to re-orderings currently taking place in Djibouti. This involves once again moving beyond the purely doctrinal analysis of TRIPS and understanding its multiple and complex dimensions, while accepting their mobility and dynamics. What will be questioned in this section is the role of TRIPS within what can be – imperfectly – defined as "the international health system" (once again, a network more complex than can be fully explained here, although this section will only concentrate on those aspects which are important to understand for this specific case study), and how TRIPS might have become embedded in Djibouti through "international projects". It considers whether some of the programmes set up currently in Djibouti can be perceived as bringing TRIPS in some of its dimensions to Djibouti, as suggested by other research in the field[422]. The overall meaning of this broader role and enrolment of TRIPS for its analysis will therefore be questioned.

Two programmes will be examined. The first programme aims specifically at introducing generic drugs on a more institutionalised basis in Djibouti, and is therefore likely to re-order, at least in part, the current links between patents, drugs and health in Djibouti – although it is at an early stage. The second

[422] Sell S. (2003) Private Power, Public Law, Cambridge: Cambridge University Press; Sell S. (2002) "TRIPS and the Access to Medicines Campaign", Wisconsin International Law Journal Summer 20(2) pp. 481-522.

project studied relates to the treatment of AIDS in Djibouti. In addition to raising questions related to the embedment of TRIPS in Djibouti, it raises more practical and political questions on the adequacy of some particular policies and discourses to the needs of Djibouti, and is useful to consider in order to illustrate more clearly the potential inadequacies between international changes generated by TRIPS and the local reception of these reorderings.

Introducing generic drugs in Djibouti – what does this mean for TRIPS?

I have already mentioned some changes to the health system of Djibouti – and in particular its pharmaceutical system – that were being implemented as the fieldwork for this project was undertaken. These now need to be reviewed. In particular, the import system for drugs in Djibouti is currently being partly reshaped. This is the result of a new project financed by the World Bank directed at the reform of several aspects of health services[423].

The World Bank project has several dimensions, and aims to "improve the quality of basic services"[424]. It has various components, but what has been presented by actors throughout this project as the most central – and the aspect most relevant to this research - relates to the creation of the Centrale d'Achats des Medicaments et Materiels Essentiels (CAMME)[425]. The first aim of this

[423] See for detailed information on the project World Bank (2002) Report No PID10697, Djibouti- Health Sector Development.

[424] World Bank (2002) Report No PID10697, op. cit. p.2.

[425] The centrality of this aspect can be seen both through the spreading of the financing proposed by the World Bank and – mainly – through actors understandings and actions in the course of this fieldwork.

new structure is to build a point of entry for cheaper drugs in the country. This is to be achieved by introducing a new centralised system of import of medicines, in which policies to procure cheaper drugs for patients could be implemented in a harmonised way[426]. In addition to this, the CAMME was to participate in developing new points of distribution for this cheaper medication, by creating new community pharmacies in and outside Djibouti town[427]:

"The aim of this programme is to start facilitating access to medicines in the whole country. This will be achieved by introducing generics – which would be very cheap, and therefore accessible. We also need to create a new system of distribution – basically we have been given money by the World Bank to *develop these structures and finance the first order of medication."*

In order to understand the importance of the CAMME in terms of the pharmaceutical market, two questions need to be asked: first, where will these cheaper drugs come from? Second, where will they go? This will set the ground for further discussion on the meaning of these changes in relation to patents.

When discussing the origin of the drugs entering the CAMME, it is important to emphasise that when this fieldwork was carried out, the CAMME was just

[426] "CAMME will buy drugs from the cheapest quality sources and sell them to public and non-profit health establishments with a small mark-up to finance its operating cost", World Bank (2002) Report No PID10697, op. cit. p.4.

[427] World Bank (2002) Report No PID10697 op. cit. on p.4.

starting up: the first batch of drugs had been ordered, and was expected to arrive in the summer. This means that it is difficult to draw long term conclusions on the preferred routes followed by drugs. However, looking at what happened in the first order and how those in charge foresaw the future raises interesting questions. When deciding which drugs to buy, the pharmacist in charge of the CAMME explained that she would consider two types of options: international bid or restricted bid. The first procedure will consist of advertising internationally the future order, and comparing the prices of companies all around the world. The company offering the cheapest version of the drug – often a generic version[428] – will then be assigned the contract. As Djibouti does not yet have any structure through which drug quality can be tested, the company will be given its contract only if they are authorised to sell the drug concerned in their own country – and only if this country has the structures necessary to carry out drug testing[429]. Under the second procedure, the CAMME will send details of what they are looking for only to a few

[428] The fact that patented drugs are more expensive than generic versions has been discussed in Chapter 1 – for comments on this aspect, see Velasquez G. (2000) op. cit.; Dumoulin J. (2000) "Les Brevets et le Prix des Medicaments", Revue Internationale de Droit Economique, 2000/1, Numero Special: Brevets Pharmaceutiques, Innovation et Sante Publique pp. 45-69.; Abbott F. M. (2002) "The Doha declaration on the TRIPS Agreement and Public Health: lighting a dark corner at the WTO" Journal of International Economic Law 5(2) pp. 469-505. It has also been explained above that even after a drug has run out of patents, the originally patented version will remain more expensive than generics – for detail, see Dumoulin J. (2000) op. cit; See also Caves R. E., Whinston M. D., Hurwitz M. A. (1991) op. cit. ; Grabowski H.G. and Vernon J.M. (1992) op. cit.

[429] This is not an unfamiliar approach in developing countries – see Abbott F.M (2005) "Managing the Hydra: The Herculean Task of Ensuring Access to Essential Medicines", in Maskus K. E. and Reichman J. H. (eds) International Public Goods and Transfer of Technology under a Globalized Intellectual Property System, Cambridge: Cambridge University Press, pp. 393-425.

companies – companies they have worked with before – and compare their prices. This will not necessarily give the cheapest results, but would be a much quicker option, and more realistic in the long term, with regards to the size of the structure[430]. Of course, in the context of Djibouti and of the many difficulties of shipment that have been explained in Chapter 6, it is highly plausible to imagine that, in the long term, the range of companies considered as "potential providers" might be progressively restricted. At the time of fieldwork, the first procedure has been used for drugs ordered in largest quantities, or most expensive drugs. For others, the pharmacist in charge has applied the second procedure. So, at least at this stage, at least in theory, drugs can come to the CAMME from anywhere, from any company, and from any network in which drugs of "satisfactory quality" can be produced.

Now that the origin of drugs has been briefly explained, we can look at where these drugs will be brought locally. This relates to the second role of the CAMME, to create community pharmacies in which the drugs will be distributed at very limited cost, in parallel with the existing system based essentially on the private pharmacies of Djibouti town[431]. Eight community pharmacies will be built overall, in each of the districts of Djibouti. A pilot study has been started on four of them, built in January 2004. The results will be used when opening the other pharmacies. The community pharmacies will need to maintain very low costs, and patients will be asked to pay a purely

[430] The structure employs only one full-time pharmacist in charge of selecting, ordering and distributing internally every drug.

[431] "The public health establishments will sell the drugs through a community pharmacy or directly (in case they are legally autonomous) and the proceeds of the sales will be used to restock", World Bank (2002) Report No PID10697 op. cit. on p.4.

symbolic price for the drugs they buy. Although the stocks will be limited to a few essential drugs – mainly paracetamol, aspirin, a few antibiotics and anti-diarrhoeal - those in charge hope that once fully implemented, community pharmacies might make a difference to access to medication across the country. Others remain sceptical. Those who are doubtful as to the viability of the project emphasise the range of problems that are still to be solved[432] - amongst those are for example, issues of expertise[433], and, in spite of the original aim to keep costs as low as possible, the high level of "complementary costs"[434]. However, community pharmacies should not be, in the long term, the only place where the drugs bought by the CAMME are expected to be distributed. In fact, all "public structures" should, in the longer term, become supplied by the CAMME. As the project is still in its earliest stages, it is currently more an aspiration than a reality. However, it may lead to changes in the future and might affect current expectations.

Overall, the project set up by the World Bank aims to improve access to medication, by offering cheaper sources of imports through the CAMME and easier and more accessible points of distribution through community pharmacies. The impact of this new project on import networks and on the links between patents, drugs, and disease in Djibouti is highly relevant to this

[432] "*It has just started, and already we don't really know where the money is going…*"

[433] As very few people in the country have expertise in the field of pharmaceuticals, it was not possible to put a qualified pharmacist in any of the new pharmacies. "We had a training session for the new staff –but it was a one day course!" People in the Ministry have been very critical of this situation, and would like to see further training implemented.

[434] Such as the always increasing cost of fuelling up the car of the four "inspectors" going around the pharmacies every day.

discussion. Following the presentation of this impact, the role of TRIPS in public health networks in this reordering of drugs networks in the country will be discussed – as well as what this reveals in relation to the nature of TRIPS.

TRIPS and the re-ordering of health networks

What can be read into this new project is that it is likely to limit the current role of pharmaceutical patents in the import system of the country, and therefore to limit the links between patents and health. By introducing new sources of drugs, including generics, the programme is therefore potentially limiting the enrolment of branded/patented drugs in the country. When observing the list of sources that those in charge of the CAMME are investigating, it is very clear that those include both multinational research-based companies and smaller scale generic producers. Once again, the list might narrow down once a particular network has stabilised, but this is not the case yet. As explained above, the inscription of patents within import networks in Djibouti at the moment is central in linking patents to health, and if this inscription disappears fully, the links between patents and disease in Djibouti would lose most of their substance. If drugs coming into Djibouti are not anymore quasi-exclusively linked to patents, then patents will not find much of a way to relate to health, as explained above – the making of patents as a health actor is indeed currently fully dependent on their embedment in drugs used/needed in Djibouti. However, this would only be the case if patents were to be fully excluded from drugs imported in Djibouti – and it is essential in that respect to understand the limits of the changes created by the new project. The main limit that needs to

be emphasised is that the new source of import that the CAMME is creating is not at the moment perceived as a replacement for the private system of independent pharmacists. The drugs to be imported by the CAMME will therefore exclusively be sold in community pharmacies and public structures. As far as community pharmacies are concerned, as explained above, only some drugs will be sold[435]. Other drugs will have to be purchased from private pharmacies, and it is expected that most patients who can afford it will remain dependent on the imports of private pharmacists:

"Private pharmacists expressed some concerns at first, but when you look into *it, we really won't deal with the same share of the population. Our aim is mainly to supply those who don't buy anything at the moment. Those who buy from private pharmacies now will certainly keep doing the same."*

The possibility that the CAMME might supply the whole pharmaceutical market of Djibouti, including the private market, was considered and had to be abandoned because of the pressure applied by private pharmacists:

" The original plan was that it would supply every drug in the country, like it is the case in other countries. But obviously, private pharmacists did not agree to that."

[435] This needs to be understood in particular in relation to the lack of trained personnel, as was explained above.

This is an interesting illustration of the limits of the CAMME as well as of the influential role played by private pharmacists in the country, and commented upon in Chapter 6.

Although the new project is therefore unlikely to challenge the social role that patents play in Djibouti, it is y interesting to reflect further on its meaning in the context of TRIPS – in terms of its impact on social reordering, while its emergence will be discussed below. Two questions need to be asked in this respect: first, could the activities of the CAMME create legal conflicts in relation to TRIPS? Second, what is the meaning of the CAMME if reflecting more broadly on the spirit of TRIPS and the apparent direction taken (for the moment, although it is necessarily open to change) by re-orderings in Djibouti?

First, while TRIPS is being implemented, one might ask whether the imports of generic drugs from other developing countries that are considered by the CAMME might bring drugs that would not be compliant with TRIPS standards into Djibouti. In particular, since those in charge of the CAMME are amongst those who stated that they were not interested in TRIPS, it is therefore likely that compliance with TRIPS will not be an issue in their decisions. They also reinforced that the CAMME *"does not have any regulation about patents. All we are concerned with is quality."* But the practical risks of the CAMME actually "meeting" TRIPS are limited. The drugs to be imported by the CAMME, as shown on their current listings, are for the moment all out-of-patent, and the risk of Djibouti not being TRIPS compliant in terms of enforcement is therefore minimal so far. This is in harmony with the current

needs of the population for basic medication. The only potential exception to the exclusive export of out-of-patent drugs that was mentioned was once again that of anti-retroviral drugs. Although they had not been bought by the CAMME yet, the pharmacists in charge mentioned that they were expecting to buy "access price" medication rather than generics – as the overall cost of getting them into Djibouti was expected to be lower. Although this is itself potentially subject to change and reordering, it is at the moment unlikely that the CAMME will import drugs which contradict the standards of TRIPS. In addition to this, as TRIPS is implemented in all developing countries with a producing capacity, the range of controversial generic drugs will slowly disappear.

The project is most interesting, however, if reflecting on the spirit of TRIPS as well as on its specific dispositions. When considering the aim of the proponents of TRIPS and its creators, what transpires is the fact that TRIPS was mainly directed at "reinforcing" pharmaceutical patents - at making them available in more places, for longer, on a wider range of inventions. This is very clear when looking at the role of the pharmaceutical industry in the pre-TRIPS era[436], and it can be interpreted as meaning that patents should and will

[436] See Sell. S. (2003) Private Power, Public Law, op. cit; Sell, S. (2002) "Industry Strategies for Intellectual Property and Trade: The Quest for TRIPS and Post-TRIPS Strategies", Cardozo Journal of International and Comparative Law. 10(1) pp. 79-108; Sell S. (2002) "TRIPS and the Access to Medicines Campaign", op. cit.; Drahos P. (2002) "Negotiating Intellectual Property Rights, Between Coercion and Dialogue", in Drahos P and Mayne R (eds), Global Intellectual Property Rights: Knowledge, Access and Development. London: Palgrave, pp. 161-182.

probably be more active, more important, more relevant after TRIPS becomes active in specific networks than before.

Nevertheless, surprisingly, the current changes that are taking place in Djibouti following this new international project, seem to be having the opposite effect. While so far pharmaceutical patents were de facto inherently part of most drugs imported in the country, their share in the market is now becoming more limited. While pharmaceutical patents were central to all imports apart from those of the OPS, the CAMME is now creating a parallel system of imports from which patents are for the moment largely excluded as potential determinants. Their action in other connections of the pharmaceutical chain remains determinant. Investigation within the networks of each producer would probably reveal traces of pharmaceutical patents[437], but these do not determine which drug will or will not enter the CAMME and Djibouti, or at least not at this early stage of its creation, when this fieldwork was carried out. The impact of patents on the country is therefore socially becoming more restricted, at the same time as they are being officially introduced in written law, as explained in Chapter 5.

While TRIPS is making pharmaceutical patents part of the official landscape of Djibouti, the CAMME appears to be creating a new concurrent network from

[437] To some extent, it becomes almost impossible to consider any part of the pharmaceutical chain without at some stage coming back to the role of patents – in the development of drugs to be produced by others than their official "inventor", for example. However, it is important here to remain focused on the impact of patents that can directly be felt as active in Djibouti, and can be seen as shaping patents as a determinant to the action and ordering of networks in Djibouti.

which they are newly excluded. When analysing the meaning of this, two explanations can be given. The first one follows the idea of coincidence: the fact that patents are losing part of their social role in Djibouti at the time when TRIPS is being implemented is only a coincidence, an example of two independent and contradictory events happening at the same time. However, a wider reflection on the delocalised impact of TRIPS within an international health network can raise many questions as to whether this is coincidental or whether this reveals the need to understand both the text of TRIPS and the opposition and actions it has participated in generating as part of the same network.

Social re-ordering and delocalised effects of TRIPS

This second hypothesis now needs to be tested. We need to understand whether TRIPS can be perceived as linked to the World Bank project and the creation of the CAMME. In order to present the emergence of this hypothesis and the elements that participate in defending it, it is important to explain two further sets of ideas. First, the fact that the World Bank project was presented as truly originating outside Djibouti, and second the inherent embedment of TRIPS in the many health-related debates and policies that have emerged in the last few years. Once again, this section cannot impose causality on any links or projects, and can only suggest some correlations and embedments that made it difficult to conceive of the project described above without relating it to TRIPS in a number of ways.

The origins of the CAMME project can be found outside of Djiboutian networks. Rather than being funded by the request of the Djiboutian government, the project appeared to originate in the World Bank itself:

*"The way it works here is generally that the World Bank whispers an idea and asks us to officially apply for this particular fund. That's wha*t basically *happened in this case."*

The CAMME was also described as the result of *"the World Bank policies in the pharmaceutical field."*

It is therefore important to understand this particular project as resulting from international policies, and the need to question more broadly the context in which "access to generic medicines" is currently being discussed. The embedment of TRIPS within international debates and discussions about access to medicines, and access to generics, forms the background. It is essential to reflect on what has been portrayed as the relation between TRIPS and the development of the access to medicines campaign[438]. The adoption of TRIPS followed a long history of pressure for stronger protection of inventions, including those in the pharmaceutical field. For many authors, as explained in Chapter 1, the adoption of TRIPS revealed the lobbying power of the pharmaceutical industry, especially in the US. The years following TRIPS,

[438] The impact that TRIPS might have had in triggering the access to medication campaign is not a new issue, and has already been discussed and investigated – "Without TRIPS there *would be no access to medicines campaign"* see S. Sell (2002) "TRIPS and the Access to Medicines Campaign" op. cit.; See also Sell. S. (2003) Private Power, Public Law, op. cit.

however, are less often analysed in terms of lobbying. Nevertheless, some research has focused on this period. Chapter 1 has explained how TRIPS has changed after its adoption as a public health issue, and has been moved from trade networks to public health debates. New actors in the public health field joined around TRIPS, and connected in new ways. The mobilisation of those opposed to TRIPS resulted in turn in emphasis being put on new problems, including that of access to medicines. By triggering a new set of critics, TRIPS has also generated a new set of pressures on governments and international organisations to deal with the issues raised in poor countries, and to deal more specifically with the issue of access to medication[439].

TRIPS clearly has created not only technical debates and analyses amongst lawyers but also –sometimes in an overlapping way - large networks of opposition[440]. Actors in NGOs and in a number of governments have drawn to the attention of others, including the general public and the media, the potential risk that introducing TRIPS in developing countries could represent. These critics have in turn had input in generating new policies, and in particular a new approach of industries and policy-makers to health solutions for poor

[439] The overall impact of TRIPS on generating new policies within international organisations runs beyond the purpose of this particular research; however, the triggering of access to medicines campaign by TRIPS has been largely proven, and the development of policies in recent year in this field has also been documented – see S. Sell (2002) "TRIPS and the Access to Medicines Campaign" op. cit; Sell. S. (2003) Private power, Public Law, op. cit.

[440] "While industry was spectacularly successful in its quest to institutionalise the link between intellectual property and trade, in the wake of TRIPS a number of challenges have emerged. *Two of the most important challenges are the "no patents on life" and the "access to essential medicines" campaigns*" in Sell S. (2002) "Industry strategies for intellectual property and trade: the quest for TRIPS and post-TRIPS strategies" op. cit. on p.105.

countries[441]. From the industry's side, projects involving research on tropical diseases[442], restraint from enforcing some high-profile lawsuits and the negotiation of "access prices" on specific drugs[443], have been increasingly appearing since the mid-1990's. In addition to these, the impact of the access to medicines campaign on national or international policies has been crucial[444]. TRIPS can be seen as playing a part in this evolution, and in putting at the forefront of international issues the problem of the conflicts of interest between commercial pressures in developed states and access to health in poorer countries. Although it cannot be stated with certainty that TRIPS is a determinant actor in each of these policies, there seems to be enough evidence

[441] "Arguing that intellectual property rights should be construed as a public health issue, rather than a trade issue, this civil society campaign has scored some victories in challenging the corporate perspective. This group seeks to limit the expansion of intellectual property rights and reduce such rights for essential medicines in an effort to contain costs and increase access.", Sell S. (2004) "The Quest for Global Governance in Intellectual Property and Public Health: Structural, Discursive and Institutional Dimensions", Temple Law Review (77) Summer 2004 pp.363-399 on p. 366.

[442] Some of these based on public/private partnership initiative, such as the Novartis Institute for tropical diseases – for information, see http://www.novartis.ch/special/FR/nitd.shtml

[443] The withdrawal of the lawsuit against the South African government by the group of thirty-nine pharmaceutical companies was presented as one of the main early victories of the campaign; the cuts offered on prices on the industry can also be read in the light of this campaign. For further detail, see Sell. S. (2002) "TRIPS and the Access to Medicines Campaign", op. cit, p.512-514.

[444] For details of US policies in the area, see Sell S. (2002) "TRIPS and the Access to Medicines Campaign" op. cit. and Sell. S. (2003) Private power, public law, op. cit; at international level, specific agencies have addressed this issue, such as UNAIDS, created in 1996, addresses issues specific to HIV/AIDS – for information, see http://www.unaids.org/NetTools/Misc/DocInfo.aspx?LANG=en&href=http://gva-doc-owl/WEBcontent/Documents/pub/Publications/IRC-pub05/JC1117-ExceptionalResponse_en.pdf; the involvement of the WHO, including in relation to the Doha Declaration, has been discussed earlier – for detail of relevant activities, see for example Abbott F. M. (2002) op. cit.

to state that it has now become at least a part – potentially minor but nevertheless unavoidable – of policies relating to access to medication. TRIPS cannot nowadays be described, thought of or looked at without considering the access to medicines campaign. Similarly, the issue of access to medication, and access to generics in particular, is largely related to TRIPS and its subsequent action.

We can now return to what this might mean in relation to the links between the World Bank project introducing generic drugs in Djibouti[445] and TRIPS. Whether causal and direct links can be found between the adoption of TRIPS and this particular project is contentious, and stating that this project is "the result of TRIPS" would be unduly simplistic. The World Bank project is made of a wide range of other actors, all interconnected as well as linked to further networks – and once again, the practical limitations of both empirical research and written accounts makes it impossible to look at each of these actors in detail. TRIPS is certainly part of these, as it is now embedded in any project or discourse linked to access to medications. It is necessary to maintain modest claims in the causality of this presence. Arguing that TRIPS "generated" this project would hide the fact that the World Bank considered health issues before TRIPS came into place, considered the role of generics before TRIPS was adopted and thought of access to medication in the past[446]. However, there is also evidence that the World Bank's action is now increasingly relating to

[445] In addition to the few found in the OPS.

[446] For an example of early project referring to generic medicines – although not making it the centre of analysis – see Foster S.D (1990) Improving the Supply and Use of Essential Drugs to Sub-Saharan Africa, World Bank Policy Research Working Paper WPS 456.

issues raised by TRIPS, and that TRIPS has therefore become fully embedded in the Bank's policies[447].

Thus, the conclusions to be drawn from this section and example can only be modest and balanced. On the one hand, this particular project of the World Bank needs to be understood as the complex gathering of multiple connections, some happening in Djibouti, some in the World Bank offices, and many more in other places. On the other hand, the increasing attention brought to access to medicines and to generics in particular has been largely facilitated and generated by TRIPS, to such an extent that it becomes difficult to conceive of one without thinking of its other. To that extent, the World Bank project being set up in Djibouti at least partly embeds some of the discourses that have so largely proliferated since TRIPS. Reflecting on Djibouti itself in the light of this specific project, the impact of TRIPS can only be fully understood by considering the multiple effects it has been having, and highlighting its embedment in the notion of generics, and in access to medication.

[447] See for example: "In the early 2000, the Bank did not have an explicit and consistence practice with regard to the procurement of generic versions of ARVs that were on-patent in *most developed countries. (…) More recently, the World Bank produced a Technical Guide to* offer guidance to improve the performance of the agencies involved in the procurement of *HIV/AIDS products. In the Guide's chapter on IPRs, the Bank offers ex*plicit guidance to developing countries on how to use the flexibilities of the TRIPS and of their own legislation in order to obtain the lowest possible prices while ensuring a standard quality of the supply of *pharmaceuticals and other medical products."* In Rovira J. (2004) "Trade Agreements, Intellectual Property, and the Role of the World Bank in Improving Access to Medicines in Developing Countries", Yale Journal of Health Policy, Law and Ethics 4(2) pp. 401-413, on p. 410.

Two different understandings of TRIPS – at least – emerge from the above idea. While on the one hand TRIPS is a set of written rules that Djibouti needs to implement, it is also a crucial actor in stabilising newly emerged connections in the access to medicines network. It is an essential part of these networks, and this role is itself an integral aspect of TRIPS, a dimension that cannot be put aside. When understanding what TRIPS is *"doing"* to health in Djibouti, what needs to be appreciated is that TRIPS is more than only a written set of prescriptions with no further effects than what the causality of doctrinal analysis could foresee. It is more than a set of written rules, and covers networked effects that have different sets of impacts, direct or not, in Djibouti. Its written legal implementation and direct consequences are one crucial element to understand, but they remain only one element, one aspect of an instrument that is fully reshaping what patents are and do – and as we will now see an instrument that has also the potential of reshaping what diseases are or should be.

Patents, TRIPS, disease and access to "modern drugs": an example of AIDS in Djibouti

The hypothesis put forward in the above section also has to be understood in relation to its political meaning. In particular, it seems to suggest that the dominant story told about TRIPS and its impact on poor countries in terms of access to medication might have created new opportunities in this field – and in a sense performed the reality of TRIPS as a public health actor in Djibouti. If the above project can be read in this light, the post-TRIPS developments could

appear as having unexpectedly participated in improving access to generics in Djibouti. However, the performativity of the dominant story of TRIPS can also be read as having had further, more specific effects, some of which might raise more difficulties. Although the enrolment of TRIPS in the access to medicines campaign, and the reciprocal embedment of part of this campaign within TRIPS, appear to have brought opportunities as illustrated by the example given above, they have also participated in performing a particular understanding of specific health issues and particular diseases in developing countries.

This section illustrates the complex relation between pharmaceutical patents, TRIPS and health by questioning the role of both objects in shaping health priorities and diseases. This will be done by presenting the current reshaping of AIDS as a health priority in Djibouti, and how this is perceived by local actors. The aim of this section is to build on the hypothesis developed above by showinh how one of the key fields that has been presented worldwide as threatened by TRIPS might have impacted on the shaping of health priorities in Djibouti. It follows the idea presented above that the effects of TRIPS – and consequently "TRIPS" itself - need to be understood in relation to the networked nature of TRIPS, by emphasising how it can be perceived as a central actor in reshaping understandings of AIDS as central to public health priorities, and of anti-retrovirals as essential elements in access to health. This is an important illustration of the complexity of understanding the links between TRIPS and health borrowed from the most usual example used to explain why TRIPS is a threat to access to medication.

AIDS in Djibouti

When fieldwork was carried out in Djibouti from January to April 2004, a second project financed by the World Bank was being put into place by the government. It was directed at financing treatment for AIDS, malaria and TB (essentially tackled as "risk co-factors")[448]. Once again, the project itself is complex, and although AIDS is officially only one of the diseases to be tackled with this financing, it appeared to be its most central aspect– and the project is referred to in Djibouti as "the AIDS project". The centrality of AIDS can be read in the stated aims of the project: *"(i) preventing the spread of HIV/AIDS* by reducing transmission, in particular among high risk groups, (ii) expanding access to treatment of opportunistic illnesses and malaria, and to care, support and treatment to People Living with HIV/AIDS (PLWHA) in Djibouti (iii) supporting multi-sectoral, civil society and community initiatives for HIV/AIDS prevention and care and malaria prevention."[449] The particular emphasis of the project on AIDS can also be read if looking at the specific financing offered for this disease[450].

[448] For details on the project, see World Bank (2003) Report No AB7, Updated Project Information Document (PID), Djibouti – HIV/AIDS, Malaria and Tuberculosis Control Project, March 2003.

[449] World Bank (2003) Report No AB7, op. cit. p.5.

[450] On the 12 million dollars that the project is investing in Djibouti, 5.2 million dollars are specifically directed at treating AIDS, 2.3 millions to "AIDS, TB and STI management" (TB as "opportunistic disease), and the remaining 4.5 millions are common capacity building investment.

The project is summarised by local actors as being essentially designed in practice to offer "free HIV treatment to 250 patients in Djibouti". The funds officially, however, also aim to develop the infrastructure necessary to deal with the disease – although "many questions remain unanswered – and in particular that of social structures. It is crucial that patients get the *appropriate social support that is needed, and for the moment we don't have* the means to give them that."

Most public health actors appeared rather sceptical as to the appropriateness of the project to the needs of patients in Djibouti, and it was challenged by informants several times. In particular, the high priority of AIDS as a public health concern and of anti-retroviral drugs as a public health solution, in Djibouti has been widely questioned and challenged by actors met in the course of this study. Although AIDS is becoming a concern in the country and progressively spreading, it was not presented by any of the actors interviewed as one of the most urgent concerns to which the government should try to respond. In particular, and although prevention was presented as crucial as a long term policy, treatment of patients with AIDS was not generally presented as a priority as compared to other types of diseases – or at least not a realistic priority.

One of the reasons for this is that treatment is expensive. This clearly raises once more the questions raised above in relation to the potential role of patents and the price of medication in the shaping of health priorities. However, this idea needs to be balanced by the empirical findings made here. The cost of

medication was only one of the elements put forward when explaining why AIDS was not yet one of the highest priorities of the government. Several social elements were presented by informants when explaining why public health actors did not believe they should be concentrating too strongly on AIDS. The first element is that, based on the current evaluations presented in Chapter 4, and on what informants from the public health field stated "seeing" in Djibouti, other diseases are currently creating more damage in Djibouti. In addition to this, and very importantly, AIDS still also carries a cultural taboo, and many health actors interviewed emphasised that many patients would refuse to come forward and face the fact that they had AIDS, because of the social stigma still attached to the disease: *"There is a bit of AIDS, but we are* mainly concerned with TB. And to be fair, we have very few patients coming forward and willing to talk about AIDS, it is *still a real taboo."* Finally, the range of social support and infrastructures that needed to be developed to offer treatment to patients with AIDS, and ensure that they would follow a long term treatment, are not yet available in Djibouti. The financial issues raised by AIDS were therefore not only linked to the price of medication itself, but to wider elements that need to be considered when dealing with AIDS. Overall, considering the current impact of AIDS as compared to other diseases in Djibouti, and considering the cost and difficulties of developing adequate strategies to treat AIDS in the country, most actors in the public health field believe that it should not be the highest priority at the moment .Other concerns have been placed above AIDS until now.

It is in this context that the AIDS project of the World Bank has been set up in Djibouti. The shaping of AIDS brought through the project is one of health priority[451], and requires public health networks to enrol AIDS in a new, unfamiliar way. AIDS and its new embedment in the World Bank project have both been generated by and generating new connections, new links, new drugs, stabilised in what is known as the "AIDS project". Nevertheless, this remains criticised, and perceived by health professionals in Djibouti as the result of the embedment of AIDS in its external shaping rather than as the appropriate response to what had been until recently perceived as "AIDS in Djibouti":

"From a public health point of view, it is complete nonsense. With all that money, we are going to cure 250 people, while it could have been used to solve all the problems of maternity death, which is a key problem here. It could also have been directed at basic treatment for childhood diseases that we cannot cure at the moment. *But at the moment, internationally, AIDS is the question… so we have to "do" AIDS* – it looks good."

As introduced in Chapter 4, the contrast between local framings of AIDS and the focus put by international policies on the disease appear essential. However, the increasing emphasis put on AIDS in discourses on "health in developing countries", explains this discrepancy. In addition, applying the framework developed above, the potential links between TRIPS, this shaping of AIDS and the project set up in Djibouti can be questioned. Indeed, for the purpose of this research, what is most interesting is to question, once again,

[451] In terms of financial mobilisation, at least.

whether TRIPS itself might be embedded in this particular project, and to what extent its role in generating new resources for AIDS and a large international focus on the treatment of AIDS, might need to be read when questioning what it does in a specific developing country. Once again, the need to understand TRIPS in its networked effects can be emphasised, and it is interesting to question whether TRIPS as a network can be perceived as partly embedded in this particular project.

Since TRIPS has been adopted, access to anti-HIV/AIDS medication has become one of the most intensively discussed issues both in the media and academic literature when dealing with TRIPS or access to treatment[452]. It has also become one central element of the access to medicines campaign, and projects supporting access to anti-HIV/AIDS drugs have spread around the

[452] The relation between access to anti-retroviral, access to medicines as a whole and TRIPS can be illustrated by the following quotation: "In many respects, the debate about how best to ensure access to essential medicines to combat the HIV/AIDS virus has come to typify anxieties about the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property (the TRIPS agreement) and its potential to have adverse socio-economic *impacts on developing countries"*, see Matthews D. (2004) op. cit., p.2; the links between the specific example of AIDS and the wider issues raised by TRIPS can be found in many other texts – for example: Shoell S. (2002) "Why can't the Poor Access Lifesaving Medicines? An Exploration of Solving the Patent Issue*" Minnesota Intellectual Property Review* (4) pp. 151-182; Joni J. (2002) "Access to Treatment for HIV/AIDS: a Human Right Issue in the Developing World", Connecticut Journal of International Law (17) pp.273-280; Bass N. (2002) "Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century", George Washington University International Law Review (34) pp. 191-222; Nerozzi M. (2002)"The Battle over Life-saving Drugs: are Developing Countries being TRIped by Developed Countries?" Villanova Law Review (47) pp. 605-641.

world[453]. It is not my intention to undermine the importance of AIDS in many countries. In any case, TRIPS can only be one – possibly minor - element that has made AIDS emerge as a key health issue for many countries, in particular in Africa. Similarly, the uniformity with which "developing countries" are discussed runs further than this particular example, although it has become a central characteristic of TRIPS-related literature as explained earlier. Overall, the worsening AIDS crisis that has spread in many large African countries is clearly the main element that has triggered concerns about this fast-growing disease. The high price of medication has also been important in increasing concern for access to treatment. In addition to this, the "Pretoria" trial and similarly emotional and intense cases have revolved around AIDS, and increased awareness of the devastation created by this disease[454]. However, the links between TRIPS and AIDS remain important. The reason why both actors have become so strongly enrolled into each other explains why this example is

[453] See in particular the decision by the UN general assembly to create a Global Fund to Fight AIDS, Tuberculosis and Malaria – originally providing 31 countries with a total of $378 millions in aids. For media coverage, see Benkimoun P. (2002), "Le Fond Global Contre le SIDA accorde ses premiers financements", Le Monde, 27 Avril 2002; see also for further details on specific projects financed in recent years by international organisations: Fleet J. (2003) "U.N. Approach to Access to Essential AIDS Medications, Intellectual Property Law and the WTO TRIPS Agreement", Emory International Law Review (17) Summer 2003 pp. 451-466.

[454] See for comments on the Pretoria trial Halbert D. (2002) "Moralized Discourses: South Africa's Intellectual Property Fight for Access to AIDS Drugs", Seattle Journal for Social Justice (1) Fall/Winter 2002 pp. 257-288 and Sell. S. (2002) "TRIPS and the Access to Medicines Campaign", op. cit. See also for the links between this trial and access to medicines: Mercurio B. C. (2004) "TRIPS, Patents and Access to Life-saving Drugs in the Developing World", Marquette Intellectual Property Law Review 8(2) Summer 2004 pp. 211-250: "The issue of access to patented medicines gained worldwide attention in 2000, when several drug companies challenged the legality of the South African Medical and Related Substances Control Act of 1997, which allowed for compulsory licences of patented pharmaceuticals", on p. 224.

highly relevant to the wider aim of this research. The most central connection between TRIPS and AIDS revolves around pharmaceutical patents, and the fact that many anti-HIV/AIDS drugs are still under patent. This has made the links between patents and access to medication particularly strong in this field. AIDS is also a disease that is quickly evolving and mutating, and for which new drugs are likely to be constantly needed. For these main reasons, the debate on patents and access to medication has often been dominated by the more specific debate on access to anti-HIV/AIDS drugs.[455] Because of the strong links between patents and AIDS, TRIPS has quickly become perceived as a central issue in relation to access to anti-HIV/AIDS drugs, not only in academic writings, but also in various policy programmes[456]. As the campaign on access to medicines started growing, one of its main impacts was the emphasis put on the necessity to improve access to anti-HIV/AIDS drugs worldwide. The role of TRIPS in the access to medicines campaign therefore needs to be understood as particularly relevant to the unanimous emphasis on AIDS as a key disease for which drugs are urgently needed in "developing countries" – in a way that appeared in this particular country as potentially contradictory with the actual health needs of the population concerned. Once again, the point made here is not that AIDS is not a relevant issue in many poor countries, but that its shaping as an immediate priority and of access to anti-

[455] "In this case, consumer and health group on the front lines of the HIV/AIDS pandemic mobilized to protest the high cost of HIV/AIDS drugs, the subsequent lack of access to drugs and the danger of overly strong intellectual property protection as embodied in TRIPS", Sell S. (2002) "TRIPS and the Access to Medicines Campaign", op. cit. on p.497.

[456] For details on the way TRIPS and AIDS have become officially embedded into each other in international policies, see Fleet J. (2003) op. cit.

HIV/AIDS drugs as a central part of health development, was contested by several health actors in this particular research, as far as Djibouti is concerned.

Causality needs to be kept as a minimum, while the co-generation of fully embedded and dependent actors is put forward. AIDS is itself a complex network, understood and lived differently by all those that it affects. As is the case for any disease, and as has been demonstrated in other examples, there is not one story or one reality about AIDS, but multiple and co-existing stories that all merge together[457]. AIDS in TRIPS and TRIPS in discourses on AIDS are only part of these realities, but one that becomes difficult to by-pass in the current context. As appears to have become the case with access to medication, AIDS cannot be thought of, nowadays, without considering patenting issues and the impact of TRIPS. The World Bank itself, as was explained in the previous section, has emphasised that TRIPS as a set of rules should not prevent countries from treating AIDS. Although TRIPS cannot be perceived as having "generated" the World Bank project per se, it has certainly played a role in every aspect of the HIV/AIDS related lobbying, and of the increasingly unanimous agreement that AIDS is a key disease to address in order to solve health issues in poor countries, and that access to anti-HIV/AIDS medication is therefore a priority. TRIPS has become embedded in new policies and actions concerning AIDS, and when looking for its presence in Djibouti, its embedment in international framings of AIDS cannot be fully ignored. The

[457] This can be related to ANT writing on other diseases, highlighting the variety of realities that can be identified when investigating the nature of a particular disease. See for example Law J. and Singleton V. (2000) "This is not an Object", published by the Centre for Science Studies, Lancaster University, LA14YL, UK, at http://www.comp.lancs.ac.uk/sociology/papers/law-singleton-this-is-not-an-object.pdf

links to be drawn might be indirect, limited, but TRIPS needs, nevertheless, to be understood and questioned in each of its ramifications, and access to medication, in particular anti-HIV/AIDS medication, is certainly one of these. In this particular example, the performance of AIDS as a key disease to be tackled in the "developing world", however, did not go without opposition for those who considered that the specificities of their environment were let down by the generality of this particular story.

Complexity of TRIPS network and pharmaceutical patents as "public health issues": interdependence and re-ordering.

The conclusions to be drawn from this chapter are complex and need to be balanced. The co-dependency and complexity of the links between TRIPS, patents and health in Djibouti is striking. Health might not appear to be affected by the written implementation of TRIPS, and seems largely independent of official legislation in the country. However, health is also fully dependent at the moment on the socio-legal action of pharmaceutical patents through the complex connections described in Chapter 6. Currently, however, some re-orderings are taking place in the public health field in Djibouti, reshaping both the role of patents themselves and the prioritising of diseases in health policies. Whether these re-orderings can be read as direct consequences of TRIPS or not is something that is difficult to state empirically with certainty, since every particular change and connection taking place in the field is the result of other moves and changes that are tightly interrelated and indissociable. Nevertheless, it is crucial to emphasise that the embedment of

TRIPS within recent policies directed at what have been widely defined – and performed – as "developing countries" is something that needs to be considered when questioning what TRIPS does and where it is in a given network. The limits that ANT sets itself forbid conclusions to go further than a certain stage, and it is therefore essential to remain cautious in discussing whether this is "the result" of TRIPS or not. However, what has been emphasised in this chapter is that determining the role, impact, action or presence of TRIPS could only be done if accepting and understanding that TRIPS is embedded in more than the material form through which it travels to a given country. It has the potential, as pharmaceutical patents proved they had, to travel through other connections, and these need to be considered when discussing the role of TRIPS in any particular network. Now that the different pictures and dimensions of TRIPS and pharmaceutical patents as empirically illustrated in this project have been analysed, it is possible to reflect more broadly on the meaning of this project as a whole. This reflection concerns what the project illustrated both in its own field of enquiry and in relation to socio-legal research and the roles that ANT can play in it.

CHAPTER 8 - CONCLUSION

This chapter brings together the findings and ideas laid out in this research, and aims to provide answers to the research questions set in this project. This research aimed to discuss the "role and impact of TRIPS and pharmaceutical patents in health networks in Djibouti". While doing so, it also aimed to assess specifically the role of TRIPS and pharmaceutical patents through from different perspectives – the role of TRIPS as an official/written text of law; the role of pharmaceutical patents in relation to the pharmaceutical market of Djibouti; and the role of TRIPS as an "international health" actor. Overall, the central research question was addressed by emphasising the nature of TRIPS and pharmaceutical patents as multi-dimensional actor-networks. The empirical data analysed in the preceding chapters has dealt with most of the above issues, and therefore largely answered the questions raised in the introduction. This chapter returns to each of the essential elements of the research questions, and, while doing so, explicitly discusses what this project revealed of the nature of TRIPS and pharmaceutical patents.

This chapter entails a degree of summarisation of the project, and in this respect, the process of producing conclusions whilst remaining faithful to the ideas put forward by ANT, and in particular to ANT's wariness of

simplification and shortcuts[458], becomes a difficult task. It is to some extent impossible to "summarise" what has been said throughout this project by simplifying it, while hoping to provide a shortened but faithful version of what has been said throughout. However, it is also necessary to bring together some key ideas and specific findings that can help us understand the overall meaning and potential consequences of this research. This conclusion will therefore aim to re-emphasise some of the main points put forward in this project, acknowledging that other elements are best left as presented throughout, and that the stories told and networks followed cannot be shortened in a number of their dimensions. It seeks to find a fair balance between the need to remind the reader of the key points of this research, against the risk of hiding complexity and therefore reality by simplifying to an undue extent a story in its entirety. I will also discuss the prospects for the further use of ANT in other projects looking at socio-legal objects.

This conclusion comprises two sections. The first section emphasises some key findings from the case study undertaken, and explains how TRIPS and pharmaceutical patents have been analysed throughout and how their relation to health has been framed. The second section discusses the potential relevance of the methods and concepts used in this project for future research, and evaluates some aspects of ANT.

[458] This difficulty might be particularly accurate in the context of a PhD where a conclusion is expected to return to what has been discussed throughout.

SECTION 1: EXPECTATIONS AND DISRUPTIONS: TRIPS AND PHARMACEUTICAL PATENTS IN ACTION IN DJIBOUTI

This section will return to the analysis made of TRIPS and pharmaceutical patents as socio-legal objects, and will emphasise the complexity and fluidity of their nature as they appeared throughout this project. Before looking at both objects, however, this section will reflect briefly on the research process itself, and on the progressive evolution of this research.

Process and changes of the research

This case study has analysed and interpreted the effects of the implementation of TRIPS in Djibouti, and the role of pharmaceutical patents in the country before and after TRIPS was created. The process of this research has incorporated many changes in expectations and direction. These have been of sufficient impact in the overall approach undertaken to merit further elaboration.

This research was started by considering a wide range of literature that discusses the links between TRIPS, patents and health in "developing countries". Most of these texts adopted a common dimension, although their final conclusions and positions on the potential impact of TRIPS and pharmaceutical patents on "developing countries" were often divergent. Some texts argued that if implemented in an appropriate way, TRIPS could be a positive development for poor countries, since pharmaceutical patents were a

beneficial tool both for the development of needed modern drugs[459], and for the development of a local industry[460]. Many others, however, emphasised the potential risks of implementing or creating rigid standards for pharmaceutical patents across the world, in particular for developing states. The latter set of literature emphasised that pharmaceutical patents were only useful for industrial development when countries already had a strong generic local industry[461], and that extending patent rights worldwide would have negative consequences on the price of medication, and therefore on access to medication in poor countries[462]. In the media, the debate has been greatly simplified, and

[459] See for example: Bale H.E. (1997) "Patent Protection and Pharmaceutical Innovation", New York University Journal of International Law and Politics, 29(1/2) pp. 95-107; Scherer F. M. (2000) « Le Systeme des Brevets et l'Innovation dans le Domaine Pharmaceutique », Revue Internationale de Droit Economique, 2000/1, Numero Special: Brevets Pharmaceutiques, Innovation et Sante Publique pp.109-124.

[460] For examples of literature emphasising the potential role of patents in economic development, see Barro R. J. and Lee J.H. (1994) "Sources of Economic Growth", Carnegie Rochester Conference Series on Public Policy (40) pp. 1-46; Kondo E. (1995) "The Effect of Patent Protection on Foreign Direct Investment", Journal of World Trade (29) 97-122; Lee Lee J.Y and Mansfield E. (1996) "Intellectual Property and US Foreign Direct Investment", Review of Economics and Statistics (78) 783-820; Maskus K. E. (1998) "The Role of Intellectual Property in Encouraging Foreign Direct Investment and Technology Transfer", Duke journal of comparative and international law (9) pp. 109-161; Primo B. and Castern F. (1998) "The Relationship between Intellectual Property Rights and Foreign Direct Investment, Duke Journal of Comparative and International law (9) 163-188.

[461] Seeratan N. N. (2001) "The Negative Impact of Intellectual Patent Rights on Developing Countries: an Examination of the Indian Pharmaceutical Industry", *St Mary's Law Review on* Minority Issues (3) Spring 2001 pp.339-412; Koshy S. (1995) "The Effect of TRIPS on Indian Patent Law: A Pharmaceutical Industry Perspective", Boston University Journal of Science and Technology Law (4) pp. 1-56; Henderson E. (1997) "TRIPS and the Third World: The Example of Pharmaceutical Patents in India", European Intellectual Property Review 19(11) pp.651-663.

[462] For example: Velasquez G. (2000) « Medicaments Essentiels et Mondialisation », Revue Internationale de Droit Economique, 2000/1. Numero Special: Brevets Pharmaceutiques, Innovation et Sante Publique pp.38-44; Dumoulin J. (2000) "Les Brevets et le Prix des

some reports have emphasised the idea that "pirates" in the developing world were "free-riding" on the inventions of industries in the West, while others have taken the view that the "pharmaceutical industry" in the West was largely contributing to difficulties in the health situation in "developing countries".

When looking more closely into the broad range of texts analysed early in this project, (detailed in Chapter 1) it became clear that they were grossly simplifying the issues at stake. First, most research aiming to look at "developing countries" only concentrated on a few states – such as India, South Africa, Brazil. The situation of many other states remained overlooked. In addition to this, most research in this field provided an understanding of TRIPS and pharmaceutical patents that assumes that prescriptive regulations determine individual behaviour. It was based on the analysis of "articles" or "dispositions", and deduced the impact of TRIPS essentially from these written and official prescriptions, therefore often leaving unquestioned potential discrepancies between expectations and realities.

The focus of this research was originally chosen as a way to address the first limitation of existing literature – it aimed to extend the questions raised by TRIPS and pharmaceutical patents to a country fully "overlooked" by existing

---

Medicaments", Revue Internationale de Droit Economique, 2000/1, Numero Special: Brevets Pharmaceutiques, Innovation et Sante Publique pp. 45-69; Nogues J. (1993) "Social Costs and Benefits of Introducing Patent Protection for Pharmaceutical Drugs in Developing Countries", The Developing Economies, 31(1) pp. 24-53; Rozek R. and Berkowitz R. (1998) "The Effects of Patent Protection on the Prices of Pharmaceutical Products: is Intellectual Property Raising the Drug Bill in Developing Countries", Journal of World Intellectual property (1) pp. 179-244.

literature. In particular, this was directed at questioning whether the homogeneity of "developing countries" that appears when reading many texts was sustainable. Thus, one of the smallest, least developed countries in Africa was chosen – Djibouti - in order to see how "TRIPS" was felt in this largely undocumented part of the world.

While analysing TRIPS in Djibouti, and from the pilot study carried out in the first year of this research, the second limit of existing literature became clearer, however. One of the main elements that appeared inappropriate was the simplification drawn by a certain type of writings of the relations between TRIPS, patents, drugs and health, which has broadly defined TRIPS and pharmaceutical patents as entities that act according to certain pre-determined rules. In particular, in the case study chosen, the potential discrepancies between the prescriptive dimension of TRIPS and its actual impact in terms of social mobilisation became clear. Similarly, possible roles of pharmaceutical patents appeared as potentially differing from the official status of the tool in a given country. Consequently, the need to understand TRIPS and pharmaceutical patents in Djibouti as independent actors, in spite of the fact that TRIPS would officially "create" pharmaceutical patents in Djibouti, was emphasised. Finally, the need to understand the effects of TRIPS not only through its prescriptive dimension, but also as a consequence of effects it has generated in terms of opposition and discourses was raised.

As the complexity of TRIPS and pharmaceutical patents appeared, ANT presented itself as an invaluable tool to analyse and frame the nature and

modes of action of both objects. The remainder of this conclusion will explain in detail how the questions set in the introduction were answered throughout this project. It will discuss the understanding of TRIPS and pharmaceutical patents produced during this research, before explicitly discussing their meaning for health in Djibouti.

Understanding TRIPS and its complex, networked effects

The understandings of TRIPS and pharmaceutical patents provided in this research needs to be explained in two steps, as the two objects appeared partly independent in this project. First, the contrasts between this research and the story of TRIPS as told by the dominant set of literature that has considered its relation to health in poor countries will be discussed. In this research, the role of TRIPS appeared as distinct from its only official/prescriptive dimension, and while TRIPS as prescription in Djibouti did not mobilise actors in a convincing way, its impact on the country could be retraced through its action in other places.

This case study highlighted the fact that the implementation of TRIPS as a set of prescriptions in Djibouti did not generate the mobilisation that might have been expected by its creators. Although TRIPS was in the process of being implemented "on paper" in Djibouti, and transferred from its original form as international rules into national regulations, the integration of these rules into actors' daily practices was described as unachievable by all informants. The action of TRIPS was presented as necessarily limited or inexistent. One of the

elements seen as explaining this lack of mobilization of actors was the strong limitations on communication and the restricted circulation of information about TRIPS throughout the country. Although information about TRIPS is expected to circulate across a set of pre-determined actors within and around governments, the structure of political networks identified in this research was set up in such a way that many key actors had surprisingly little information about TRIPS. The absence of mobilisation generated by TRIPS was at least partly explainable through this absence of connections and communication between key-actors. This may not be the only explanation to be provided. The poor circulation of TRIPS might not have been the only reason for its lack of prescriptive action. However, in the current context it appeared as a central element to understand the meaning of TRIPS and its role and effects on the country.

However, as was explained in Chapter 7, this lack of mobilization around TRIPS in its written/prescriptive dimension should not be understood as a total inaction of TRIPS as a network. In particular, the effects of TRIPS appeared in this case study as acting through routes other than its official implementation "on paper". The actual enrolment of TRIPS in networks, and its subsequent action in enrolling new actors into these same networks in Djibouti was dependent not only on TRIPS as a set of written prescriptions but also on the set of discourses and actions generated by TRIPS elsewhere – and outside of TRIPS. This related clearly to ANT's approach to "global" events, and its emphasis on the need to consider the range of actions and connections that

appear to gather in a given locus[463]. This approach is distanced from what the more "doctrinal" approaches to TRIPS, produced in the dominant set of literature on the text, appeared to claim. In particular, it resulted in TRIPS needing to be understood not only through its written dispositions, but also beyond its complex origins. It became necessary to understand TRIPS as series of connections and associations gathered under a simplified and widely used term, materialised originally in sets of paper and ultimately in multiple actions. These actions involved opposition and critics, and resulted in TRIPS taking directions and having impacts that its creators had potentially not foreseen, which reading its text alone could not highlight or explain. TRIPS came to be perceived as a complex network of unexpected connections, occurring in many loci that ultimately reached Djibouti not only in the one official way it was supposed to take – through the text of TRIPS – but also indirectly, through actions which are – or are not - connected to TRIPS elsewhere.

The contrast between creators' expectations and the action of technologies has been discussed and emphasised in ANT[464]. It recalls the concern of ANT writers for the potential gaps and discrepancies between the ideal network envisaged by creators of technologies and the actual set of interrelations

[463] As expressed most clearly in Law J. (2003) "And if the Global were Small and Non-Coherent? Method, complexity and the Baroque", published by the Centre for Science Studies, Lancaster University, LA14YL, UK, at http/www.comp.lancs.ac.uk/sociology/papers/law-and-if-the-global-were-small.pdf; Law J. (1999) "Materialities, Spatialities, Globalities", published by the Centre for Science Studies, Lancaster University, LA14YN, UK, at http//www.comp.lancs.ac.uk/sociology/soc029jl.html.

[464] In theoretical ways that are more relevant to this particular research that writings on "law in action" that were briefly mentioned in Chapter 5 and 6 – as will become clearer throughout the remainder of this chapter.

technological objects will become enrolled into when taken out of their "laboratory"[465]. ANT assumes the complexity and multiplicity of objects as part of their nature, and calls for an understanding of the potential gaps between expectations and multiple realities based on the idea of circulation and constant re-orderings, some of which the creators of technology might not have foreseen or expected. When emphasising the nature of TRIPS as a socio-legal object – a hybrid made of complex and varied sets of connections - the need to understand its action through its empirical traces rather than by comparison to its creators' expectations becomes clearest. This is because TRIPS is not a neutral addition to a given and stable "social context", but one element within a circulating network. It generates power through associations with a number of actors that were potentially not part of what the creators of TRIPS had expected or hoped. This therefore results in power circulating further than might have been foreseen. TRIPS as a system comes to be perceived as the gathering of interactions between beliefs, expectations, discourses, and actors including pharmaceutical companies, governmental actors, drugs, patents, generic producers, pharmaceutical labs and others. This gathering itself generates new links and connections between this network and actors that were previously largely unrelated to it, or in a way that differed fundamentally from the new connections TRIPS was establishing. These new connections between

[465] For example in de Laet, M. and A. Mol (2000) "The Zimbabwe Bush Pump: Mechanics of a Fluid Technology", Social Studies of Science (30) pp.225-263; Akrich M. and Latour B. (1992) "A Convenient Vocabulary for the Semiotics of Human and Non-human Actors", in Bijker W. and Law J. (eds) Shaping Technology, Building Society: Studies in Sociotechnological Change, Cambridge MA: MIT Press, pp. 205-224; Law J. (2000) "Ladbroke Grove, or How to Think about Failing Systems", published by the Centre for Science Studies, Lancaster University, UK, at http//www.comp.lancs.ac.uk/sociology/papers/law-ladbroke-grove-failing-systems.pdf

activists and patents, patents and the media, or labs and members of the public, for example, have in turn generated the stabilisation of new systems as networks, and resulted in power circulation producing new effects and translations in particular systems. This can be seen in the example of the development of generic medicines and AIDS as central to the understanding that the general public and the media have of health crises in "developing countries". In turn, this new awareness has enforced a new type of action onto international organisations, so that these have become enrolled into a new type of public health network in which AIDS and generic medicines are key drivers.

Pharmaceutical patents: action, translation and social networks.

During the course of this research, the second story, concerning pharmaceutical patents, unexpectedly diverged from that of TRIPS. Although the mechanics of pharmaceutical patents are often understood, as in the case of TRIPS, as derived from their written/official existence, the example of their action in Djibouti demonstrated that understanding their role as socio-legal objects could only be done by moving away from this particular origin. The action of pharmaceutical patents was strongly separated from their written existence in national law in Djibouti. Therefore, while on the one hand their official implementation was not likely to modify actors' behaviour, their official existence as written national law did not appear as necessary to their action. In fact, the official introduction of written law creating – in theory - pharmaceutical patents in the country was taking place in a context where the influence of patents seemed to diminish.

Elements of the expected mechanisms of pharmaceuticals patents have been discussed in Chapter 1. However, the example of Djibouti has shown how the "limits" of pharmaceutical patents networks could be expanded, and how unexpected actors could be brought into playing a crucial role within the network it has illustrated. It highlighted how unexpected translations could take place, that would make pharmaceutical patents influential and active even while national texts of patent law were not in theory part of a system. In order to understand the unexpected and largely unofficial connections that make patents active in Djibouti, it was necessary to understand the complexity and heterogeneity of the networks that make both the import system of Djibouti and the pharmaceutical patent network of France complex systems. The heterogeneity of the pharmaceutical patent network in which importers in Djibouti are enrolled was one of its central characteristics. It is through the connections established between drugs, importers, producers, leaflets, planes and boats that the action of patents could transcend official boundaries, and reach actors that were not all directly linked to their textual existence. However, this role and action itself is open to challenges and modifications through other associations – in this case study, through a new understanding of pharmaceutical needs in other instances, through the creation of new national policies emphasising the need for generics, and through the development of new structures for the import and distribution of pharmaceutical patents. The direct causality of various actions in different places on the role and action of patents in Djibouti is impossible to establish with certainty, and chains of events can only be described and questioned. Despite this, it emerged in this

case study that a variety of understandings of pharmaceutical patents – and a variety of definitions and actions of pharmaceutical patents – in different networks, in and outside Djibouti, were co-existing. Patents were written rules, part of drugs, determinant to health policies, and elements of pricing, amongst other things. A singular and uniform description of what pharmaceutical patents are or do became impossible to establish, as they are best characterised by their mobility and fluidity.

Overall, studying pharmaceutical patents in this case study emphasised the artificial dimension of the largely accepted "social/legal" dichotomy. It demonstrated why it was impossible to isolate any dimension of pharmaceutical patents – or of TRIPS – from varied connections and associations that make up the social as circulation. It became both limitative and inappropriate to try to define or understand socio-legal objects on the basis of pre-conceived assumptions stabilising their action as pre-determined, or stating the origin of their potential "power" as a stable and pre-defined element. As ANT claims, power, objects and associations all need to be understood as fluid, mobile, and have to be empirically described rather than theoretically conceived. This proved particularly important in this case study through the examples of both TRIPS and pharmaceutical patents, although these findings raise questions broader than this case study.

TRIPS, pharmaceutical patents and health

The story of TRIPS, pharmaceutical patents and health that arose from this case study is clearly different from that introduced in Chapter 1. The dominant story found in existing literature frames TRIPS as prescription as a highly relevant actor in relation to access to medication in "developing countries" and was challenged in several respects, as pre-existing assumptions were questioned. The lack of mobilisation that "TRIPS as prescription" generated in public health networks appeared fundamentally different from what was predicted in the early stages of this research, on the basis of existing literature. However, this lack of mobilisation itself can be considered as having two potential meanings in relation to health. First (as highlighted in Chapter 5), if actors from the public health field are not informed of or mobilised by TRIPS or pharmaceutical patents, issues of compliance with international IP standards could emerge. Secondly, without a common acknowledgment of TRIPS by public health actors and of health issues by those in charge of implementing TRIPS, it is likely that a suitable framing of pharmaceutical patents dispositions, in a way appropriately addressing health issues, will be difficult. This in itself is an important element to consider when offering developing states solutions to implement "health-friendly" patent dispositions[466]. Nevertheless, in order to understand fully whether this itself is of any relevance, the second discrepancy between initial expectations and the

[466] As has been widely done in existing literature – for example Correa C.M. (1998) "Implementing the TRIPS Agreement in the Patent Field: Options for Developing Countries", the Journal of World Intellectual Property, 1(1), pp. 75-100; Scherer F.M and Watal J. (2002) "Post-TRIPS Options for Access to Patented Medicines in Developing Nations", Journal of International Economic Law 5(4): 313-319.

empirical findings needs to be highlighted. In particular, the potential impact that the changes brought by TRIPS to developing countries could have on their public health system needs to be understood in contrast to pre-existing situations. As emphasised above, in Djibouti, and in spite of the absence of law on pharmaceutical patents prior to TRIPS, pharmaceutical patents were in effect regulating the flow of drugs entering the country. This influence ran further than the standards of TRIPS, as patents had the virtual effect of granting a monopoly to originally patented versions of drugs without temporal limits – therefore influencing the price of medication in the country. Indeed, it appeared that the overall reshaping of health concerns that TRIPS has been generating might be changing the situation of Djibouti, and opening its market to generic medicines in a newly increased way.

The fact that TRIPS, pharmaceutical patents and health were related in unexpected ways, different from what most existing analysis or media coverage have emphasised, could appear to be neutral and no more than an anecdotal example of the contrasts between a given set of literature and a specific, different case study. However, as was emphasised in Chapter 7, some of the effects of TRIPS in Djibouti can be read as the result of the performative understanding of TRIPS in dominant discourses about the text in recent years. Looking at this impact from a political perspective, the conclusions to be drawn need to be balanced. On the one hand, the framing of TRIPS as a "negative" development for health in developing countries, explained in Chapter 1, and the opposition to TRIPS that appeared in that respect, can be considered as having participated in the introduction of generic medicines

being brought back onto international priorities, including in Djibouti. In that respect, some positive outcomes might have appeared from TRIPS, in spite of its controversial origins – and of its potentially negative impact in countries other than this, or even maybe in the longer term in this particular country. On the other hand, the example of AIDS as it is now being reframed in Djibouti illustrates one issue that will need to be addressed in the future. While the access to medicines campaign has emphasised the need to provide anti-HIV/AIDS medication to poor countries, this might have resulted in the health priorities of some countries being left aside. Although the specific role of TRIPS in this case remains indirect, it can certainly be read as one of the elements that have shaped specific issues, as priorities in "poor countries" as a whole, including access to anti-HIV/AIDS medication. The fact that issues other than access to medication, and diseases other than AIDS, need to be given more interest is now beginning to be discussed more widely. It is likely that the need for diversification in health policies and answers to health crises will be emphasised increasingly. Whether countries of the size and international status of Djibouti attract specific international interest is likely, however, to remain an issue.

As a whole, what appeared in this case study were different stories about both TRIPS and pharmaceutical patents, resulting in them being understood, perceived, but (mainly) active in different ways in specific networks. The impact of this dislocation and lack of punctualisation and unity on the action of both socio-legal objects, and on their role in public health policies are complex. In particular, as explained above, some undesirable political effects can be

discerned in the current relation between TRIPS, pharmaceutical patents and health in Djibouti. If comparing this example to what has been written on other countries, one key issue that appears is the lack of coherence and harmony between policies and actions in the public health field in which TRIPS or pharmaceutical patents are embedded. In fact, it could be thought that this coherence will only be achieved if a common story of TRIPS and pharmaceutical patents manages to reintegrate each of the networks considered. If TRIPS and pharmaceutical patents in Djibouti become perceived in similar ways in each of the networks considered, and act in convergent ways within each of them, a coherent policy in which drug prices, health and patents can all be considered jointly and harmoniously might begin to develop.

Throughout the analysis carried out in this research, ANT provided a relevant and useful tool to understand and describe the connections relevant to TRIPS, pharmaceutical patents and health in Djibouti. It is now necessary to return to what ANT specifically brought to this research, and what it could bring more generally to socio-legal studies. Its emphasis on empirical research, the fragility of orderings and artificiality of classifications needs to be understood more broadly in relation to socio-legal research.

SECTION 2: UNDERSTANDING SOCIO-LEGAL OBJECTS THROUGH ANT – STRENGTHS AND LIMITS OF THE APPROACH

This study has raised many questions in relation to the role and modes of action of "socio-legal" objects, and in that respect goes beyond the specific example of TRIPS and pharmaceutical patents it has analysed. However, once again, the ideas of ANT itself, and the position taken in this project, stress the need to avoid undue generalisation. At times, ANT will appear as a "negative approach", by emphasising what cannot be said rather than what can be clearly and definitely stated[467]. Nevertheless, there are important issues to be discussed, about the empirical study of socio-legal objects, and about the relevance of ANT as a theoretical and methodological framework for analysing such objects. This section will return to questioning the potential benefits of ANT in empirically examining socio-legal objects, before discussing the potential limits of the method.

Understanding socio-legal objects empirically

The example chosen in this research and the emphasis placed throughout on the need for empirical work to remain the basis of research calls for some final comments on the impact of ANT on practical issues in empirical methods.

[467] *"…ANT is first of all a negative argument. It does not say anything positive about any state of affairs"*, in Latour B. (2005) Reassembling the Social: an Introduction to Actor-network Theory, Oxford: Oxford University Press, on p.141.

On the basis of what has been said so far, it is important to ask how the approach undertaken in this particular project can be empirically useful for future research on other socio-legal objects – including transnational objects. The role of socio-legal objects needs to be evaluated and understood on the basis of the traces they leave of particular actions and connections, which can empirically be observed. This is made particularly complex by the fact that, once again, neither the socio-legal objects under scrutiny nor pre-existing connections can be assumed to remain stable over time. The creation and action of new socio-legal objects will generate re-orderings in any pre-existing set of connections. At the same time, the socio-legal object under scrutiny will change from being that which its creators have designed it to be in an idealised network, to being a new object reshaped by the network in which has become enrolled.

Although this constant movement and total interdependency appears to generate a particular form of complexity, and one that cannot be fully escaped, focusing on description of connections and relations is a useful way to draft and draw this complexity, in order to understand how things happen – rather than try to frame what things are or will be. The role of socio-legal analysis in this view becomes to determine how the range of associations that bring agency to socio-legal objects can be described, to discuss how these associations themselves need to be related to other connections in a circulating network; and how socio-legal objects are shaped in each of the loci where these connections occur. Empirical analysis comes to be about understanding how links are made and unmade; how the multiple nature of socio-legal objects

comes to be expressed within the different networks and connections into which they have become enrolled.

The overall consequence of applying ANT to the analysis of specific socio-legal objects is to study their mechanisms within orderings, while assuming neither the consequences of their supposed nature, nor the existence of an overarching "social" encompassing other disciplines and fields. Boundaries between objects become blurred, and to some extent irrelevant to empirical analysis, for which what becomes essential is to work from objects to their mechanisms, rather than deduce mechanisms from the supposed nature of given objects or systems.

Understanding "transnational" socio-legal objects

One aspect of ANT that was particularly relevant in this research, and can be expected to remain so in the case of other empirical research on transnational socio-legal objects, relates to the challenges it brings to the idea of "globality". The mechanisms of international law have often been incorporated into the general discussion triggered by the "globalisation" paradigm in recent years. In this research, however, the view was that "globalisation" was not a helpful notion for empirical research. The notion of space as being network-based, adopted by ANT were integrated in the theoretical background. The consequences for the understanding of transnational socio-legal objects are wide-ranging, and call for the reintegration of local complexity within explanations and descriptions. The need to understand the dislocated effects of

transnational socio-legal objects becomes crucial, as the action of these objects in a number of different places could impact on any given loci under scrutiny. Similarly, the shaping of objects as "global" and the potential performativity of this understanding need to be understood – and potentially linked to these same dislocated effects. However, the range of effects and links that can be drawn by seeking to analyse such widely spread objects enables certain empirical concerns to emerge. This will now be addressed by questioning more generally how the emphasis of ANT on complexity and the inherent fragility of any network can be reconciled with the practical limits of research, and with the need to avoid silencing or obscuring elements that cannot necessarily be empirically evaluated.

Reflecting on ANT in empirical research – balancing theoretical ideals and empirical issues

The questions raised by the empirical analysis of transnational socio-legal objects are a particularly relevant example of the difficulties that some of the claims of ANT raise in practice more generally – and could in fact highlight some of its internal issues and potential contradictions. This issue has been partly addressed in Chapter 3, but needs to be briefly discussed again here, as it has consequences that extend beyond this particular project.

If the intent is to remain faithful to the most central claim of ANT, it is essential to avoid taking any actor-network as stabilised, without investigating how it is constructed – in the sense defined in Chapter 3. It is crucial to explore

the complexity of any object that may appear, at first, as simple and stabilised, as what has made it needs to be grasped in order to understand its action. In this particular project, this was illustrated by a need to constantly look beyond the punctualised image that some objects seemed to reflect – the "government" of Djibouti was defined in its complexity. Drugs were characterised as complex hybrids in which patents were playing a key role. Patents were defined as multiple and complex, originated in connections happening in a range of settings including in France; TRIPS was portrayed as made up of complex interactions and creating new connections, themselves resulting in wide ranging effects. However, a number of times throughout this project, the fact that some aspects could not be detailed, that some connections could not be analysed, was also emphasised. Some objects were taken for granted, were not undone, not always questioned, and their complexity could not always be highlighted in as much detail as some aspects of ANT would have required. Similarly, the effects of some entities – such as some aspects of strategies of pharmaceutical industries towards developing countries – could not be empirically evaluated within the course of this research. One of the consequences of ANT was to prevent their full integration in the research findings, since statements need to remain empirically based. This opens questions about the potential limits of ANT itself, and about the fact that it might result in providing only a partial story in which some elements remain othered – and this has been acknowledged in Chapter 2. However, it is a limit that almost necessarily follows the strengths of the method – its inherent grounding in empirical data. On the one hand, some entities not studied in detail empirically might remain partly obscured by the method. On the other

hand, researchers are in practice prevented by making claims that cannot be empirically sustained. What are presented throughout are phenomena as expressed in the specific networks studied, and external influences are analysed through their local manifestations.

One of the difficulties with using the key-concepts of ANT to analyse transnational socio-legal objects is that their dislocated effects, as well as the associations that make and reshape them continuously, are likely to be so numerous that it becomes impossible in practice to analyse in detail each relevant connection or mention at every step of the analysis where more complexity might be hidden. Part of the decision in determining which network to study in more detail, or which connections to take as punctualised for the purpose of a particular research might remain partly arbitrary. To some extent, with some particular objects, researchers might be faced with a choice of either making the research empirically feasible while accepting its potential imperfections, or aiming for perfect completude while taking the risk of ending with an unfeasible project. However, several strategies can be found to reconcile the potential difficulties raised here with the practicalities of empirical research.

The first element, of strategy (put forward in Chapter 3), consists of making the potential limitations of the research and the choices to accept particular objects as punctualised as clear as possible. The reason why these choices were made is also an important element to facilitate understanding the potential impact this choice might have had. The second element needs to be found in ANT itself,

and consists of "following the actors themselves". Therefore, when actors consider a particular network as punctualised and take it as one stable whole, it sometimes becomes justified to accept this in the research itself as one object. This in fact highlights what might at times appear as a potential contradiction within ANT itself – while "following the actors themselves" is constantly put forward by Latour as essential to the strategy[468], the emphasis of ANT on always questioning what might appear as stable[469] can sometimes lead to challenging some of the punctualisations that actor themselves perform. Nevertheless, by recognising that some punctualisations performed by actors can become accepted in the research process – although the fact that they might hide part of other realities needs to be acknowledged – it becomes feasible to understand the mechanics of transnational socio-legal objects while avoiding some of the potential practical limits of ANT. Once again, this can only be done by making potential limitations explicit, and stating clearly why some objects can be taken for granted, the nature of these objects, and why it does not impact on the actual focus of the analysis whether they are fully undone or not. In studying a transnational socio-legal object through the associations that make it in a particular network, following the actors will result in highlighting the multiple realities of this object in the networks chosen as examples – although other dimensions, other actions and other realities of this particular

[468] The emphasis is particularly explicit in Latour (2005), Reassembling the Social: an Introduction to Actor-network Theory, op. cit..

[469] The necessity to question constantly the many connections that make up any actor-network can be found in most ANT literature referenced in Chapter 2, and is particularly explicit for example in Law J. (2003) "And if the Global were Small and Non-Coherent? Method, Complexity and the Baroque", published by the Centre for Science Studies, Lancaster University, LA14YL, UK, at http/www.comp.lancs.ac.uk/sociology/papers/law-and-if-the-global-were-small.pdf

object might still exist. This translated in this case study into emphasising that what was under scrutiny here was what TRIPS and pharmaceutical patents are in Djibouti, and stressing that this should not be generalised to understandings applicable per se in other places or countries.

Overall, this research has highlighted the complexity and fluidity of the mechanisms of socio-legal objects. By looking at the way TRIPS and pharmaceutical patents act in Djibouti, it has participated in challenging some expectations built in a field where broad generalisations have been often accepted. The need to complete the investigation of the links between TRIPS, pharmaceutical patents and health in a wider range of places has been detailed. In addition, the need to challenge the assumption that some categories, groupings or dichotomies can be accepted when studying the action of socio-legal objects was emphasised. As a whole, this research raised many questions in relation to the specific field of research under scrutiny, as well as in relation to socio-legal research and the potential role of ANT in this discipline. It called for a reintegration of fluidity and complexity in socio-legal analysis, and for the emphasis to be brought on assumption-free empirical research – within the limits unavoidably set by the format of academic research.

BIBLIOGRAPHY

Abbott F.M. (1998) "First Report to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation", Journal of International Economic Law (1) pp.607-636

Abbott F.M. (2002) "Compulsory licensing for Public Health Needs: the TRIPS Agenda at the WTO after the Doha Declaration on Public Health", Quaker UN Office, Occasional Paper 9, available at http://www.accessmed-msf.org/upload/ReportsandPublications/25620021018167/fred%20abbott.pdf

Abbott F.M. (2002) "The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO", Journal of International Economic Law 5(2) pp. 469-505

Abbott F.M (2005) "Managing the Hydra: The Herculean Task of Ensuring Access to Essential Medicines", in Maskus K. E. and Reichman J. H. (eds) International Public Goods and Transfer of Technology under a Globalized Intellectual Property System, Cambridge: Cambridge University Press, pp. 393-425

Adam B. (2000) "The Temporal Gaze: the Challenge of Social Theory in the Context of GM Food", British Journal of Sociology, 51(1), pp.125-143

Adler P. A. and Adler P. (1998) “Observational Techniques”, In Denzin and Lincoln (eds) 1998, Collecting and Interpreting Qualitative Materials, Thousand Oaks CA: Sage Publications, pp. 79-109

Akrich M. (1993) Inscription et Coordination Socio-Techniques: Anthropologie de Quelques Dispositifs Énergétiques, Thèse pour le doctorat Socio-Economie., Paris: École Nationale Supérieure des Mines de Paris.

Akrich M. and Latour B. (1992) “A Convenient Vocabulary for the Semiotics of Human and Non-human Actors”, in Bijker W. and Law J. (eds) Shaping Technology, Building Society: Studies in Sociotechnological Change, Cambridge MA: MIT Press, pp. 205-224

Al-Ali N. (2003) “The Egyptian Pharmaceutical Industry After TRIPS – a practitioner’s view”, Fordham International Law Journal, 26(2) pp. 274-314

Altheide D. and Johnson J. (1994) “Criteria for Assessing Interpretive Validity in Qualitative Research”, Denzin N. K. and Lincoln Y. S. (eds), Handbook of Qualitative Research, Thousand Oaks CA: Sage publications, pp. 485-499

Amsterdamska, O. (1990). "Surely, You Must be Joking, Monsieur Latour!" Science, Technology and Human Values (15) 495-504

Anand S. and Sen A. (2000) “Human Development and Economic Sustainability”, World Development 28(12) pp. 2029-2049

Atkinson P. and Coffey A. (1997), “Analysing Documentary Realities”, in Silverman D. (ed) Qualitative Research: Theory, Method and Practice, London: Sage Publications, pp. 45-62

Attaran A. (eds) (2003) Delivering Essential Medicines: the Way Forward, The Brookings Institution Press

Bala K and Sagoo K. (2000) “Patents and Prices”, HAI news, April/May, pp. 1-9

Bala K., Lanza O., Kaur SR. (1998) “Retail Drug Prices: the Law of the Jungle”, HAI news, April, pp. 1-16

Balasubramaniam K (2002) “Patents, Prices and Public Policy”, in Drahos P and Mayne R (eds), Global Intellectual Property Rights: Knowledge, Access and Development, London: Palgrave MacMillan, pp. 90-107

Bale H.E. (1997) “Patent Protection and Pharmaceutical Innovation”, New York University Journal of International Law and Politics, 29(1/2) pp. 95-107

Bale H.E. (1998) “The Conflicts between Parallel Trade and Product Access and Innovation: the Case of Pharmaceuticals”, Journal of International Economic Law, 4(1) pp. 637-653

Barnes J. A. (1954) “Class and Committees in a Norwegian Island Parish”, Human Relations, 7, pp.307-312

Barro R. J. and Lee J.H. (1994) “Sources of Economic Growth”, Carnegie Rochester Conference Series on Public Policy (40) pp. 1-46

Barry A. (2002) “In the Middle of the Network”, in J. Law and A. Mol (Eds.) Complexities: Social Studies of Knowledge and Practice, Durham, N. Ca.: Duke University Press, pp. 142-165

Bass N. (2002) “Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century”, George Washington University International Law Review (34) pp. 191-222

Beaverstock J.V., Smith R.G. and Taylor P.J. (2000) “World City Network: a new metageography?”, Millenial Issue of the Annals of the Association of American Geographers (90) March 2000, pp. 123-134

Belot L. (1998) « Une étude met en évidence les « facteurs psychologiques » qui influencent les prescriptions médicales », Le Monde, 17th July 1998

Benkimoun P., “Le Fond Global Contre le SIDA accorde ses premiers financements”, Le Monde, 27 Avril 2002

Bentham J. (1839) A Manual of Political Economy, New-York: Putnam

Beshers J. M. and Laumann E. O. (1967) "Social Distance: A Network Approach", American Sociological Review (32) pp. 225-236

Bijker, W. and J. Law (Eds.) (1992) Shaping Technology, Building Society: Studies in Sociotechnical Change. Cambridge, Mass, MIT Press

Bloche G. (2002) "WTO Deference to National Health Policy: Towards an Interpretive principle", Journal of International Economic Law, 5(4) pp. 825-848

Bloor M. (1997) "Techniques of Validation in Qualitative Research: a Critical Commentary", in Miller G. and Dingwall R. (eds) Context and Method in Qualitative Research, Sage Publications: London, pp. 37-50

Bodgan R. and Taylor S. J. (1984) Introduction to Qualitative Research Methods: a phenomenological approach to the social sciences, New York: John Wiley

Bond P. (1999) "Globalization, Pharmaceutical Pricing and South African Health Policy: Managing confrontation with US Firms and Politicians", International Journal of Health Services, 29(4) pp. 765-792

Bott E. (1957) Family and Social Networks, London: Tavistock Publications

Boyle J. (1996) Shamans, Software and Spleen: Law and the Construction of the Information Society, Cambridge MA: Harvard University Press

Braune F. and Menezes N. J. (1998) "The Patentibility of Chemical, Biochemical, Pharmaceutical and Biotechnological Inventions in Brazil", Patent World (108) pp. 46-48

Brewer J. and Hunter A. (1989) Multimethods Research: a Synthesis of Styles, Newbury Park, CA: Sage

Callon, M. (1986) "Some Elements of a Sociology of Translation: Domestication of the Scallops and the Fishermen of Saint Brieuc Bay", in J. Law (Ed.) Power, Action and Belief: a new Sociology of Knowledge? Sociological Review Monograph (32) London, Routledge and Kegan Paul, pp. 196-233

Callon M. (1991) "Techno-economic Networks and Irreversibility", in Law J. (eds), A sociology of Monsters, Essays on power, technology and domination, London: Routledge, pp. 132-161

Callon, M. (1998) "An Essay on Framing and Overflowing: Economic Externalities Revisited by Sociology", in Callon M. (Ed.) The Laws of the Markets. Oxford and Keele, Blackwell

Callon, M. (1999) “Actor-Network Theory: the Market Test”, in Law J. and J. Hassard J. (Eds.) Actor Network and After, Oxford and Keele: Blackwell and the Sociological Review: 181-195

Callon, M. and B. Latour (1981), “Unscrewing the Big Leviathan: how actors macrostructure reality and how sociologists help them to do so”, in Knorr-Cetina K. D. and Cicourel A. V. (Eds.) Advances in Social Theory and Methodology: Toward an Integration of Micro- and Macro-Sociologies, Boston, Mass.: Routledge, pp. 277-303

Callon M. and Latour B. (1992) “Don't Throw the Baby Out with the Bath School! A Reply to Collins and Yearley”, in A. Pickering (Ed.) Science as Practice and Culture. Chicago, Chicago University Press, pp. 343-368

Callon, M. and Law J. (1995) “Agency and the Hybrid Collectif.”, South Atlantic Quarterly (94) 481-507

Castells M. (1996) The Information Age: Economy, Society and Culture (1) Oxford: Blackwell

Castells M. (1996) The Rise of the Network Society: the information age, Cambridge, MA.: Blackwells Publishers

Castells M. (2000) “Materials for an explanatory theory of the network society”, British Journal of Sociology, 51(1) pp. 5-25

Caves R. E., Whinston M. D., Hurwitz M. A. (1991) Patent expiration, entry and competition in the US pharmaceutical industry, Brookings Papers on Economic Activity, Microeconomics, pp. 1- 48

Challu P. M. (1995) "Effects of the monopolistic patenting of medicine in Italy since 1978, International Journal of Technology Management, 10(2/3) pp. 237-251

Chavanne A, Burst J. J. (1998) Droit de la propriete industrielle, Paris : Dalloz

Collins, H. M. and S. Yearley (1992) "Epistemological Chicken", in Pickering A. (Ed.) Science as Practice and Culture, Chicago: Chicago University Press, pp. 301-326

Coloma F., Gabrielli A. and Williamson C (1987) Efectos de las Patentes de Medicamentos sobre el Mercado Farmaceutico y su Impacto sobre la Salud y el Gasto Fiscal, Santiago: Instituto de Economia, Universidad Catolica de Chile

Colonomos A. (2001) "Transnational Networks: Old Game, New Rules", in Smouts M.C. (eds) The New International Relations: Theory and Practice, London: Hurst, pp. 112-125

Commission for Intellectual Property Rights (2002) Integrating Intellectual Property Rights and Development Policy, Chapter 2: Health, available at http://www.iprcommission.org/papers/pdfs/final_report/Ch2final.pdf

Commission for Intellectual Property Rights (2002) Integrating Intellectual Property Rights and Development Policy, Chapter 1: Intellectual Property and Development, available at http://www.iprcommission.org/papers/pdfs/final_report/Ch1final.pdf

Correa C.M. (1997) The Uruguay Round and Drugs, WHO Task Force on Health Economics, Geneva, WHO, (WHO/TFHE/97.1)

Correa C.M. (1998) "Implementing the TRIPS Agreement in the Patent Field: Options for Developing Countries", the Journal of World Intellectual Property, 1(1), pp. 75-100

Correa C. (2000) "Développements récents dans le domaine pharmaceutique: mise en oeuvre de l'accord sur les ADPIC", Revue Internationale de Droit Economique, 2000/1, Numero Special: Brevets Pharmaceutiques, Innovation et Sante Publique, pp. 23-35

Correa C. (2000) Integrating Public Health Concerns into Patent Legislation in Developing Countries, Geneva: South Centre

Correa C.M. (2000) Intellectual Property Rights, the WTO and Developing countries: the TRIPS agreement and policy options, London: Zed Books Ltd

Correa C. (2001) "Public Health and Patent Legislation in Developing Countries", Tulane Journal of Technology and Intellectual property (3) pp. 1-53

Crampes C. (2000) " La recherche et la protection des innovations dans le secteur pharmaceutique", Revue Internationale de Droit Economique (1). Numero Special: Brevets pharmaceutiques, Innovation et Sante Publique, pp. 125-145

Davies S. (1934) "Early history of the Patent specification", Law Quarterly Review (50) pp. 260-337

de Laet, M. and A. Mol (2000) "The Zimbabwe Bush Pump: Mechanics of a Fluid Technology", Social Studies of Science (30) pp.225-263

Dean J. P. and Whyte W. F. (1958) "How do we know if the informant is telling the truth?", Human Organization 17(2) pp. 34-38

Deardoff A. V. (1990) "Should Patents Protection be Extended to All Developing Countries?", The World Economy 13(4) 497-508

Denzin N. K. (1989) Interpretive Interactionism, Newbury Park, CA: Sage Publication

Denzin N. K. and Lincoln Y. S. (1998) "Introduction: Entering the Field of Qualitative Research", in Denzin N. K. and Lincoln Y. S. (eds), Collecting and Interpreting Qualitative Materials, Thousand Oaks CA: Sage, pp. 1-34

Dimasi J. A. (1995) "Success Rates for New Drugs Entering Clinical Testing in the US", Clinical Pharmacology and Therapeutics (58) pp. 1-14

Dimasi J. A., Hansen R and Grabowski H. (2003) "The Price of Innovation: New estimates of Drug Development Cost", Journal of Health Economics (22) pp. 151-185

Dingwall R. and Miller G. (eds) (1997) Context and Method in Qualitative Research, London: Sage

Direction de la Pharmacie et des Laboratoires, Ministere de la Sante Publique, Republique du Tchad, (2004) "Enquete sur le Prix des Medicaments au Tchad", Mai 2004, , available at http://www.haiweb.org/medicineprices/surveys/200405TD/survey_report.pdf#search='enquete%20sur%20le%20prix%20des%20medicaments%20au%20tchad'

Dolmo B. C. (2001) “Examining Global Access to Essential Pharmaceuticals in the Face of Patent Protection Rights: the South African Example”, Buffalo Human Rights Law Review (7) pp. 137-160

Domeij B. (2000) Pharmaceutical Patents in Europe, Cambridge (US): Kluwer Law International.

Donmoyer R. (1990) “Generalizability and the single case-study”; in Eisner E. W. and Peshkin A. (eds), Qualitative enquiry in education, New York: Teachers College Press, pp. 175-200

Drahos P (1996) A philosophy of Intellectual Property, Dartmouth: Aldershot

Drahos P. (2002) Negotiating Intellectual Property Rights, Between Coercion and Dialogue, in Drahos P. and Mayne R. (eds), Global Intellectual Property Rights: Knowledge, Access and Development, London: Palgrave pp. 161-182.

Dubois C. (1997) Djibouti 1888-1967, Heritage ou Frustration, Paris: L'Harmattan.

Dumoulin J. (2000) “Les Brevets et le Prix des Medicaments”, Revue Internationale de Droit Economique, 2000/1, Numero Special: Brevets Pharmaceutiques, Innovation et Sante Publique pp. 45-69

Dutfield G. and Posay D. (1996) Beyond Intellectual Property, Towards Traditional Resources Rights for indigenous people and local communities, Ottawa: International Development Research Centre

Elmore R. (1980) "Backward mapping: implementation research and policy decisions", Political Science Quarterly, 26(2), pp. 185-228

Emerson R. M. (1995) Writing Ethnographic Fieldnotes, Chicago: University of Chicago Press.

Engelberg A.B. (2002) "Implementing the Doha Declaration – a potential strategy for dealing with legal and economic barriers to affordable medicines", www.cptech.org/ip/health/pc/engelberg.html

Epstein A. L. (1961) "The Network and Urban Social Organization", Rhodes-Livingstone Journal, 29, pp. 29-62

Esterberg K. G. (2002) Qualitative Methods in Social research, London: Mc Graw-Hill

Faure J. (1999) "Le Service de Sante des Armees: les defis de la professionalisation", *Rapport d'Information au Senat fait* au nom de la commission des Affaires étrangères, de la défense et des forces armées, available at http://www.senat.fr/rap/r98-458/r98-458.html

Fleet J. (2003) “U.N. Approach to Access to Essential AIDS Medications, Intellectual Property Law and the WTO TRIPS Agreement”, Emory International Law Review (17) Summer 2003 pp. 451-466

Flick U. (1992) “Triangulation Revisited: Strategy for Validation or Alternative?”, Journal for the theory of Social Behaviour (22) pp 175-198

Fontana A. and Frey J. H. (1998) “Interviewing: The Art of Science”, in Denzin and Lincoln, (eds) Collecting and Interpreting Qualitative Materials, Thousand Oaks: Sage publication, pp. 47-78

Ford N. (2003) “Patents, Access to Medicines and the Role of Non-governmental Organisations”, Journal of Generic Medicines, Vol.1 (2) pp.137-145

Foster S.D (1990) Improving the Supply and Use of Essential Drugs to Sub-saharan Africa, World Bank Policy Research Working Paper WPS 456

Gereffi G. (1992) The Pharmaceutical Industry and Dependency in the Third World, Princeton: Princeton University Press

Glaser B. G. (1992) The Discovery of Grounded Theory: Strategies for Qualitative Research, Chicago: Aldine

Gorden R. L. (1980) Interviewing: Strategy, Techniques and Tactics, Homewood: Dorsey

Grabowski H. (2002) "Patents, Innovation and Access to New Pharmaceuticals", Journal of International Economic Law, 5(4) pp. 849-860

Grabowski H.G. and Vernon J.M. (1992) "Brand Loyalty, Entry, and Price Competition after the 1984 Drug Act", Journal of Law and Economics (35) pp.331-350

Griliches Z. (1984) Research and Development, Patents and Productivity, Chicago: University of Chicago Press

Grubb P. (1999) Patents for Chemicals, Pharmaceuticals and Biotechnology, Oxford: Oxford University Press

Guba E. (1981) "Criteria for Assessing the Trustworthiness of Naturalistic Inquiry in Educational Evaluation", Educational Communication and Technology Journal (29) 75-91

Guba E. and Lincoln Y. (1994) "Competing Paradigms in Qualitative Research", in Denzin and Lincoln (eds), Handbook of Qualitative Research, Thousand Oaks CA: Sage publications, pp. 105-118

Gudmundstottir S. (1996), “The Teller, the Tale, and the One being Told: the Narrative Nature of the Research Interview”, Curriculum Inquiry 26(3) pp. 293-306

Halbert D. (2002) “Moralized Discourses: South Africa’s Intellectual Property Fight for Access to AIDS Drugs”, Seattle Journal for Social Justice (1) Fall/Winter 2002 pp. 257-288

Hammer P. J. (2002) “Differential Pricing of Essential AIDS drugs: markets, politics and Public Health”, Journal of International Economic Law, 5(4): 883-912

Hammersley M. (1992) *What’s Wrong with Ethnography*, Methodological explorations, London: Routledge

Hammersley M. and Atkinson P. (1995) Ethnography: Principles and practice, London: Routledge

Handel W. (1982) Ethnomethodology, Englewood Cliffs: Prentice Hall

Heath C. (1997) “Parallel imports and international trade”, The International Review of Industrial Property and Copyright Law, 28(5), pp. 623-632

Henderson E. (1997) “TRIPS and the Third World: The Example of Pharmaceutical Patents in India”, European Intellectual Property Review 19(11) pp.651-663

Heywood M. (2002) “Drug Access, Patents and Global Health: Chaffed and Waxed Sufficient”, Third World Quaterly, 23(2): 217-231

Hogwood B. W. and Gunn L. A. (1984) Policy Analysis for the Real World, Oxford: Oxford University Press

Holyoak and Torremans (2001, 3rd Ed) Intellectual Property Law, London: Butterworth

House E. R. (1980) Evaluating with Validity, Beverly Hills: Sage

Huberman M and Miles M. (1998) “Data Management and Analysis Methods”, in Denzin N and Lincoln Y eds, Collecting and Interpreting Qualitative Material, Thousand Oaks: Sage publications, pp. 137-157

Hugo P. and Oberle P. (1996) Histoire de Djibouti, des origines a la Republique, Paris : Presence Africaine

Institut Superieur des Affaires de Djibouti (2000) *Collection "Etudes de Metiers": Pharmacie*, available at www.ministere-finances.dj/publications/PHARMACI.HTM

International Federation of Pharmaceutical Manufacturers (2001) "TRIPS, Pharmaceutical Patents and Developing Countries: Implications for Healthcare Access, Drug Quality and Drug Development", available at http://www.ifpma.org/documents/NR86/TRIPS.pdf

International Federation of Pharmaceutical Manufacturers Associations (1998) "The Question of patents: the key to medical progress and industrial development", Geneva

Jiang P. (2002) "Fighting the AIDS Epidemics: China's Options under the WTO TRIPS Agreement", Albany Law Journal of Science and Technology (13) pp. 223-248

Johnson J. (1975) Doing Field Research, New York: Free Press

Joni J. (2002) "Access to Treatment for HIV/AIDS: a Human Right Issue in the Developing World", Connecticut Journal of International Law (17) pp.273-280

Jorgensen D. L. (1989) Participant Observation, Newbury Park: Sage

Juma C. (1999) Intellectual Property Rights and Globalization: Implications for Developing Countries, Centre for International development, Harvard University, available at http://www2.cid.harvard.edu/cidbiotech/dp/discuss4.PDF

Kapferer J.N. (1997) « Marque et médicaments : le poids de la marque dans la prescription médicale », Revue Francaise du Marketing, No 165, pp. 43-51

Karandikar S. M. (1994) Indian Drug Industry After GATT, Bombay: MVIRDC World Trade Centre

Keayla B.K. (1999) Pharmaceutical Industry and Patent System in India: A Case Study, in TRIPS Agreement on Patent Law: Impact on pharmaceuticals and health for all, New delhi: Centre for the study of global trade systems and development

Kennedy M. M. (1979) "Generalizing from Single Case Studies", Evaluation Quarterly 3, pp.661-678

Kirim A.S. (1985) "Reconsidering Patents and Economic Development: a Case Study of the Turkish Pharmaceutical Industry", World Development 13: 219-36

Kirk J. and Miller M. L. (1986) Reliability and Validity in Qualitative Research, Beverly Hills: Sage

Kolker P.L. (1997) “Patents in the Pharmaceutical Industry”, Patent World, January 1997, 34-37

Kondo E. (1995) “The Effect of Patent Protection on Foreign Direct Investment”, Journal of World Trade (29) 97-122

Korenko G. (1999) “Intellectual Property Protection and Industrial Growth: a Case Study”, Journal of World Intellectual Property (2) pp. 47-75

Koshy S. (1995) “The Effect of TRIPS on Indian Patent Law: A Pharmaceutical Industry Perspective”, Boston University Journal of Science and Technology Law (4) pp. 1-56

Kvale S. (1998) Interviews: an Introduction to Qualitative Research Interviewing, Sage: London

Kvale S. (eds), Issues of Validity in Qualitative Research, Lund (Sweden): Studentliterrtur

LaCroix Sumner J. and Kawaura A. (1996) “Product Patent Reform and its Impact on Korea’s Pharmaceutical Industry”, International Economic Journal, 10(1), Spring 1996, pp. 109-124

Laing R., Waning B., Gray A., Ford N. and Hoen E. (2003) "25 years of the WHO Essential Medicines Lists: Progress and Challenges", The Lancet (361) pp. 1723-1729

Landes W. M. and Posner R. A. (1989) "An Economic Analysis of Copyright Law", Journal of Legal Studies 18(2) pp.325-363

Lanjouw J.O. (1998) "The Introduction of Pharmaceutical Product Patent in India: Heartl*ess Exploitation of the Poor and Suffering?"* Yale University: Economic Growth Centre

Lareau A. and Shutlz J. (eds) (1996), Journeys through Ethnography: Realistic Accounts of Fieldwork, Boulder CO: Westview Press

Larrieu J. and Houin G. (2001) "Medicament generique et propriete intellectuelle", Revue Internationale de Droit Economique (1). Numero Special: Brevets pharmaceutiques, Innovation et Sante Publique pp.173-185

Latour B. (1979) Laboratory Life: the Social Construction of Scientific Facts, Sage, Los Angeles

Latour, B. (1987). Science in Action: How to Follow Scientists and Engineers Through Society. Milton Keynes, Open University Press

Latour B. (1988) The Pasteurization of France, Cambridge Mass.: Harvard University Press

Latour, B. (1988). Irréductions, published with The Pasteurisation of France, Cambridge, MA: Harvard University Press

Latour, B. (1990) "Drawing Things Together", in M. Lynch and S. Woolgar (Eds.) Representation in Scientific Practice. Cambridge, Mass, MIT Press, pp. 19-68

Latour B. (1993). We Have Never Been Modern, Brighton: Harvester Wheatsheaf

Latour B. (1996), Aramis or the Love of Technology, Cambridge MA: Harvard University Press

Latour B. (1999) "On recalling ANT", in Law J. and Hassard J. (eds) Actor-network theory and after, Oxford: Blackwells, pp.15-25 (Re-published in 2004 as Latour B. (2004) "On recalling ANT", published by the Department of Sociology, Lancaster University, LA1 4YN, UK, at http://www.lancs.ac.uk/fss/sociology/papers/latour-recalling-ant.pdf)

Latour B. (2000) *Pandora's Hope: Essays on the Reality of Sciences Studies*, London: Harvard University Press

Latour B. (2002) La Fabrique du Droit, Paris: La Decouverte

Latour B. (2005) Reassembling the Social: An Introduction to Actor-network Theory, Oxford: Oxford University Press.

Law J. (1986) "On the Methods of Long Distance Control: Vessels, Navigation and the Portuguese Route to India", in J. Law (Ed.) Power, Action and Belief: a new Sociology of Knowledge? Sociological Review Monograph. London, Routledge, pp. 234-263

Law J. (Ed.) (1991) A Sociology of Monsters? Essays on Power, Technology and Domination, Sociological Review Monograph, London: Routledge

Law J. (1992) "Notes on the Theory of the Actor-Network: Ordering, Strategy and Heterogeneity", published by the Centre for Science Studies, Lancaster University, Lancaster LA1 4YN, UK, at http://www.lancs.ac.uk/fss/sociology/papers/law-notes-on-ant.pdf, also published in Systems Practice (5) pp. 379-393

Law J. (1994) Organizing Modernity, Oxford: Blackwells

Law J. (1997) "Topology and the Naming of Complexity", published by the Centre for Science Studies, Lancaster University, LA14YL, UK, at http://www.comp.lancs.ac.uk/sociology/papers/law-topology-and-complexity-pdf

Law. J. (1997) “Traduction/Trahison: Notes on ANT”, published by the Centre for Science Studies, Lancaster University, Lancaster LA14YN, UK http://www.comp.lancs.ac.uk/sociology/stslaw2.html

Law J. (1999) “Materialities, Spatialities, Globalities”, published by the Centre for Science Studies, Lancaster University, LA14YN, UK, at http//www.comp.lancs.ac.uk/sociology/soc029jl.html

Law J. (1999) “Objects, Spaces and Others”, published by the Centre for Science Studies, Lancaster University, LA14YL, UK, at http://www.comp.lancs.ac.uk/sociology/papers/law-objects-spaces-others.pdf

Law J. (1999) “After ANT: Complexity, naming and topology”, in Law J. and Hassard J., Actor Network Theory and After, Oxford: Blackwell

Law J. (2000) “Ladbroke Grove, or How to Think about Failing Systems”, published by the Centre for Science Studies, Lancaster University, UK, at http//www.comp.lancs.ac.uk/sociology/papers/law-ladbroke-grove-failing-systems.pdf

Law J. (2000) “Networks, Relations and Cyborgs: on the social study of technology”, published by the Centre for Science Studies, Lancaster University, Lancaster LA14YN, UK at www.comp.lancs.ac.uk/sociology/papers/law-networks-relations-cyborgs.pdf

Law, J. (2001) Aircraft Stories: Decentering the Object in Technoscience, Durham: Duke University Press

Law J. (2003) "Making a Mess with Methods", published by the Centre for Science Studies, Lancaster University, LA14YL, UK, at http://www.comp.lancs.ac.uk/sociology/papers/law-making-a-mess-with-method.pdf

Law J. (2003) "And if the Global were Small and Non-Coherent? Method, Complexity and the Baroque", published by the Centre for Science Studies, Lancaster University, LA14YL, UK, at http/www.comp.lancs.ac.uk/sociology/papers/law-and-if-the-global-were-small.pdf

Law J. (2004) After Methods: Mess in Social Science Research, London: Routledge

Law J. and Mol A. (eds) (2002) Complexities: Social Studies of Knowledge Practices, Durham: Duke University Press

Law J. and Hassard J. (1999) Actor-Network Theory and after, Oxford: Blackwell.

Law J. and Singleton V. (2000) "This is not an object", Published by the Centre for Science Studies, Lancaster University, LA14YL, at http://www.lancs.ac.uk/fss/sociology/papers/law-singleton-this-is-not-an-object.pdf

Law J. and Singleton V. (2000), "Performing technology's stories" published by the Centre for Science Studies, Lancaster University, Lancaster LA14YN, UK, at http//www.comp.lancs.ac.uk/sociology/soc036jl.html

Law J. and Urry J. (2002) "Enacting the Social", Published by the Centre for Science Studies, Lancaster University, LA14YL, UK, at http://www.lancs.ac.uk/fss/sociology/papers/law-urry-enacting-the-social.pdf

Lee J.Y and Mansfield E. (1996) "Intellectual Property and US foreign direct investment", Review of Economics and Statistics (78) 783-820

Lofland J. and Lofland L. H. (1984) Analysing Social Settings: a guide to qualitative observation and analysis, Belmond CA: Wadsworth

Maccoby E. E. and Maccoby N. (1954) "The Interview: a Tool of Social Sciences", in Lindzey G. (ed) Handbook of Social Psychology: vol 1, Theory and Method, Reading: Addison Wesley, pp. 449-487

Machlup F. and Penrose E. (1950) "The Patent Controversy in the 19th century", The Journal of Economic History 10(1) p.1-29

Malinowsky B. (1967) A Diary in the Strict Sense of the Term, New York: Harcourt Brace

Mansfield, E. (1986) "Patents and Innovation: an Empirical Study", Management Science, February, pp.173-181

Mansfield E (1994) "Intellectual Protection, Foreign Direct Investment and Technology Transfer", Journal of International Economics 16: 205-226

Mansfield E., Schwartz M. and Wagner S. (1981) "Imitation Cost and Patent: an Empirical Study", Economic Journal (91) pp. 907-918

Markusen J. (2000) "Contracts, Intellectual Property rights and Multinational Investments in Developing Countries", Journal of International Economics (16) pp. 205-226

Marques M. B.(2000) "Brevets Pharmaceutiques et Accessibilite des Medicaments au Bresil", Revue Internationale de Droit Economique, (1) Numero Special: Brevets pharmaceutiques, Innovation et Sante Publique pp. 97-107

Marshall C and Rossman G. B. (1999) Designing Qualitative Research, London: Sage

Maskus G. (1998) Ethnography through thick and thin, Princeton University Press: Princeton

Maskus K. E. (1998) "The Role of Intellectual Property in Encouraging Foreign Direct Investment and Technology Transfer", Duke Journal of Comparative and International Law (9) pp. 109-161

Maskus K. E. (2000) Intellectual Property Rights in the Global Economy, Washington D.C.: Institute for International Economics.

Maskus K. E. and Reichman J. H. (eds) (2005) International Public Goods and Transfer of Technology, Cambdrige: Cambridge University Press

Mason J (2002) Qualitative Researching, London: Sage Publications

Matthews D. (2004) "Is History Repeating Itself? The Outcome of Negotiations on Access to Medicines, the HIV/AIDS Pandemic and Intellectual Property Rights in the World Trade Organisation", Law, Social Justice and Global Development Journal (1), available at http://www2.warwick.ac.uk/fac/soc/law/elj/lgd/2004_1/matthews/

Mayer C. S. (1998) "The Brazilian Pharmaceutical Industry Goes Walking from Ipanema to Prosperity: Will the New Intellectual Property Law Spur Domestic Economy?" Temple International and Comparative Law Journal (12) 377-389

Maykut P and Morehouse R (1994) Beginning Qualitative Research: a Philosophical and Practical Guide, Lewes: Falmer Press

Mazzoleni R and Nelson R.R. (1998) "Economic Theories about the Benefits and Cost of Patents", Journal of Economic Issues (32) pp. 1031-1052

McLaughin J. H., Richards T. J. and Kenny L. A., (1988), The Economic Significance of Piracy, Intellectual Property Rights: Global Consensus, Global Conflict? Boulder: Westview Press

Melrose, D. (1982) Bitter Pills: Medicines and the Third World Poor, Oxford: Oxfam

Mercurio B. C. (2004) "TRIPS, Patents and Access to Life-saving drugs in the developing world", Marquette Intellectual Property Law Review 8(2) Summer 2004 pp. 211-250

Miles M. B. and Huberman A. M. (1993) Qualitative Data Analysis: a sourcebook of new methods, Newbury Park: Sage Publication

Miller J. and Glassner B. (1997) "The "Inside" and the "Outside": Finding Realities in Interviews", in Silverman D. (ed) Qualitative Research: Theory, method and practice, Thousand Oaks: Sage Publications, pp. 98-111

Mischler E. G. (1986) Research Interviewing – Context and Narrative, Cambridge: Harvard University Press

Mischler E. G. (1991) "Validation in Enquiry-guided Research: The Role of Exemplars in Narrative Studies", Harvard Educational Review, 60, pp. 415-442

Monfreid H. (ed. 1994) Secrets de la Mer Rouge, Paris: Grasset

Moore A. (1997) "Towards a Lockean Theory of Intellectual Property", in Moore A. Ed, Intellectual Property, Lanham: Rowman and Littlefield

Morse J. M. (eds) (1994) Critical issues in Qualitative Research Methods, London: Sage.

MSF (2003) "Doha Derailed: a progress report on TRIPS and access to medicines", 27 August 2003, available at http://www.accessmed-msf.org/prod/publications.asp?scntid=27820031110385&contenttype=PARA&

MSF (2003) "TRIPS, Pharmaceutical Patents and Access to Medicines: Seattle, Doha and Beyond", 24 July 2003, available at: http://www.accessmed-msf.org/prod/publications.asp?scntid=24720031521553&contenttype=PARA&

MSF (2003) "Chairman's text brings new difficulties to WTO paragraph 6", 27th August 2003

http://www.msf.org/msfinternational/invoke.cfm?component=article&objectid=77830ACA-8EC5-419A-82AB7D7ED6A2E1ED&method=full_html

Muennich F. E. (2000) « Les Brevets Pharmaceutiques et l'Acces aux Medicaments », Revue Internationale de Droit Economique, 2000/1. Numero Special: Brevets Pharmaceutiques, Innovation et Sante Publique pp. 71-81

Murdoch J. (1997) "Inhuman/nonhuman/human: Actor Network Theory and the Prospects for a Non-Dualistic and Symmetrical Perspective on Nature and Society", Environmental planning D: Society and Space (15) pp.731-756

Murdoch J. (1997) "Towards a New Geography of Heterogenous Associations", Progress in Human Geography 21(3) pp.321-337

Murdoch J. (1998) "The Spaces of Actor-Network Theories", Geoforum 29(4), pp. 357-374

Murdoch J. (2000) "Networks – a New Paradigm for Rural Development?", Journal of Rural Studies 16(4) pp. 407-419

Murphy E. and Dingwall R. (2001), "The Ethics of Ethnography", in Atkinson P, Coffey A, Delamont S, Lofland J, Lofland L, Handbook of Ethnography, Thousand Oaks: Sage Publication, pp. 339-351

Murphy E. and Dingwall R. (2003), Qualitative Methods and Health Policy, New York: Aldine de Gruyter

Nelkin D. (1987) "Law in Action or living law? Back to the beginning in sociology of law", *Legal Studies* (4) pp.157-174

Nerozzi M. (2002)"The Battle over Life-saving Drugs: are Developing Countries being TRIped by Developed Countries?" Villanova Law Review (47) pp. 605-641

Nogueira J. (2002) "Intellectual Property Rights, the World Trade Organisation and Public Health: The Brazilian perspective", Connecticut Journal of International law (17) p. 311-318

Nogues J. (1990) "Patents and Pharmaceutical Drugs: Understanding the Pressures on Developing Countries", The Developing Economies (31) 24-53

Nogues J. (1993) "Social Costs and Benefits of Introducing Patent Protection for Pharmaceutical Drugs in Developing Countries", The Developing Economies, 31(1) pp. 24-53

Otten A. (2000) « Les Brevets Couvrant les Produits pharmaceutiques et l'Accord sur les ADPIC », Revue Internationale de Droit Economique, 2000/1. Numero Special: Brevets Pharmaceutiques, Innovation et Sante Publique pp.161-166

Oxfam International (2001) "Priced out of Reach: How WTO patent policies will reduce access to medicines in the developing world", available at http://www.oxfam.org.uk/what_we_do/issues/health/downloads/priced.rtf

Oxfam International (2003) "Flawed WTO drugs deal will to little to secure future access to medicines in developing countries", 27 August 2003, available at: http://www.oxfam.org/eng/pr030830_wto_final.htm

Oxfam International (2003) "WTO patent rules will still deny medicines to the poor", 27th August 2003, available at: http://www.oxfam.org/eng/pr030827_wto_patents.htm

Park J. S. (1993) "Pharmaceutical Patents in the Global Arena: Thailand's Struggle between Progress and Protectionism", Boston College Third World Law Journal 13(1) pp. 121-154

Pill R. (1995), "Fitting the Method to the Question: the Qualitative or Quantitative Approach?"; in Jones R and Kinmonth A L (eds) Critical Reading for Primary care, Oxford: Oxford University Press

Pires de Carvalho N. (2002) The TRIPS Regime of Patents Rights, London: Kluwer Law International.

Plath D. (1990) “Fieldnotes, Field Notes, and the Conferring of Notes”, in Sanjek (ed) Fieldnotes, the making of anthropology, Albany: State University of New York Press, pp. 371-384

Poillot Peruzetto S. (2001) “L’Apport du Droit Communautaire aux Problemes Poses par le Medicament Generique”, Revue Internationale de Droit Economique (1). Numero Special: Brevets Pharmaceutiques, Innovation et Sante Publique pp.187-196

Poland B. D. (1995) “Transcription Quality as an Aspect of Rigour in Qualitative Research”, Qualitative Inquiry 1, 290-310

Pound R. (1910) “Law in Books and Law in Action”, *American Law Review* (44) pp. 12-18

Pressman J. and Wildavsky A. (1973) Implementation, Berkeley, CA: University of California Press

Pretorius W. (2002) “TRIPS and Developing Countries: How level is the Playing Field?”, in Drahos P. and Mayne R. (eds) Global Intellectual Property Rights: Knowledge, Access and Development, London: Palgrave

Primo B. and Castern F. (1998) “The Relationship between Intellectual Property Rights and Foreign Direct Investment, Duke Journal of Comparative and International law (9) 163-188

Primo B., Fink C. and Sepulveda C. (2000) "Intellectual Property Rights and Economic Development", World bank Discussion Paper no. 412, available at http://www.bvindecopi.gob.pe/colec/cbraga.pdf

Punch M (1994) "Politics and Ethics in Qualitative research", in Denzin N and Lincoln Y eds, The Handbook of Qualitative Research, Thousand Oaks: Sage Publication, pp. 83-97

Radcliffe-Brown A. R. (1952) Structure and Function in Primitive Society: essays and Adresses, London: Cohen and West

Raghavan C. (1990) Recolonization: GATT, the Uruguay Round and the Third World, Penang: Third World Network

Ragin C. and Becker H. (eds) (1992) What is a Case? Exploring the Foundations of Social Inquiry, Cambridge: Cambridge University Press

Redwood H. (1994) New Horizons in India: The Consequences of Pharmaceutical Patent Protection, Felixtowe: Oldwicks Press

Rhodes R.A.W. (1990), "Policy-Networks, a British Perspective", Journal of Theoretical Politics, 2(3) pp. 292-316

Richardson J (2001), "Policy-Making in the EU: Interests, Ideas, and Garbage Cans of Primeval Soup", in Richardson J (ed) European Union: Power and Policy-making, London: Routledge, pp. 3-23

Richardson L. (1994), "Writing: a Method of Inquiry", in Denzin and Lincoln (eds), Handbook of Qualitative Research, London: Sage

Riviere P. (2001) "Apres Pretoria, quelle politique contre le SIDA?", Le Monde Diplomatique, 20th April 2001

Rogers E. (1995) The Diffusion of Innovations, New York: Free Press

Rovira J. (2004) "Trade Agreements, Intellectual Property, and the Role of the World Bank in Improving Access to Medicines in Developing Countries", Yale Journal of Health Policy, Law and Ethics (4) pp.401-413

Rozek R.P. (1992) "Parallel Trade in Pharmaceuticals: the Impact on Welfare and Innovation", Journal of Economic Integration 37(2) pp. 181-203

Rozek R. and Berkowitz R. (1998) "The Effects of Patent Protection on the Prices of Pharmaceutical Products: is Intellectual Property Raising the Drug Bill in Developing Countries", Journal of World Intellectual property (1) pp. 179-244

Rovira J. (2004) “Trade Agreements, Intellectual Property, and the Role of the World Bank in Improving Access to Medicines in Developing Countries”, Yale Journal of Health Policy, Law and Ethics 4(2) pp. 401-413

Rubin H. J. and Rubin I. S. (1995) Qualitative Interviewing, Thousand Oaks: Sage

Sanjek R. (1990) “On Ethnographic Validity” in Sanjek R. (ed) The Making of Anthropology, London: Cornwell University Press, pp. 345-418

Schatzman L. and Strauss A. L., 1973, Field Research: Strategies for a natural sociology, Englewoods Cliffs: Prentice Hall

Scherer F. M. (2000) « Le Systeme des Brevets et l’Innovation dans le Domaine Pharmaceutique », Revue Internationale de Droit Economique, 2000/1, Numero Special: Brevets Pharmaceutiques, Innovation et Sante Publique pp.109-124

Scherer F.M and Watal J. (2002) “Post-TRIPS Options for Access to Patented Medicines in Developing Nations”, Journal of International Economic Law 5(4) pp. 313-319

Scherer F. M. and Weisburst S. (1995) “Economic effects of Strengthening Pharmaceutical Patent Protection in Italy”, International Review of Industrial Property and Copyright Law 26: 1009-24

Schofield J. W. (1990) “Increasing the Generalizability of Qualitative Research”; in E. W. Eisner and Peshkin A. (eds), Qualitative Inquiry in Education, New York: Teachers College Press, pp. 201-232

Schwandt T.A. (1994) “Constructivist, Interpretivist Approaches to Human Inquiry”, in Denzin N. K. and Lincoln Y. S. (eds), Handbook of Qualitative Research, London: Sage publications, pp. 118-137

Seale C (1999), The Quality of Qualitative Research. London: Sage

Seeratan N. N. (2001) “The Negative Impact of Intellectual Patent Rights on Developing Countries: an Examination of the Indian Pharmaceutical Industry”, *St Mary’s Law Review on Minority Issues* (3) Spring 2001 pp.339-412

Seidman I. E. (1991) Interviewing as Qualitative research, New York: Teachers College Press

Sell S. (1998) Power and Ideas: North-South Politics of Intellectual Property and Anti-trust, Albany: State University of New York Press

Sell S. (2002) “TRIPS and the Access to Medicines Campaign”, Wisconsin International Law Journal Summer 20(2) pp. 481-522

Sell, S. (2002) “Industry Strategies for Intellectual Property and Trade: The Quest for TRIPS and Post-TRIPS Strategies”, Cardozo Journal of International and Comparative Law. 10(1) pp. 79-108

Sell S. (2003) Private Power, Public Law, Cambridge: Cambridge University Press

Sell S. (2004) “The Quest for Global Governance in Intellectual Property and Public Health: Structural, Discursive and Institutional Dimensions”, Temple Law Review (77) Summer 2004 pp.363-399

Sellen J. (ed)(2003) Djibouti, Terre des Extremes, Milan: Graphic International Publishers

Sherman P. B and Oakley E. F. (2004) “Pandemics and Panacea: the World Trade Organization’s efforts to Balance Pharmaceutical Patents and Access to Drugs”, American Business Law Journal 41(2/3) pp. 353-411

Sherwood R. (1990) Intellectual Property and Economic Development, Boulder: Westview Press

Shiffrin S. V. (2001) “Lockean Arguments for Private Intellectual Property”, in Munzer S. R. (ed) New Essays in the Legal and Political Theory of Property, Cambridge: Cambridge University Press.

Shoell S. (2002) “Why can’t the Poor Access Lifesaving Medicines? An Exploration of Solving the Patent Issue*” Minnesota Intellectual Property* Review (4) pp. 151-182

Silverman D. (1993) Interpreting Qualitative Data, Thousands Oaks: Sage Publications

Silverman D (1998), Qualitative Research: Theory, Method and Practice, London: Sage Publications

Smith J. K. (1984) “The Problem of Criteria for Judging Interpretive Inquiry”, Educational Evaluation and Policy Analysis 6(4) pp.379-391

Smith L. M. (1990) “Ethics in Qualitative Field Research: an individual perspective”, in Eisner E. W. and Peskin A (eds), Qualitative inquiry in education, New York: Teachers College Press.

Spradley J. P. (1979) The Ethnographic Interview, New York: Holt, Rinehart and Winston

Spradley J. P. (1980) Participant Observation, New York: Holt, Rinehart and Winston.

Stake R. (1994) “Case Studies”, in Denzin N and Lincoln Y eds, The Handbook of Qualitative Research, Thousand Oaks: Sage Publications, pp. 236-247

Star S. L. (1991) “Power, Technologies and the Phenomenology of Conventions: on Being Allergic to Onions”, in Law J. (ed) A Sociology of Monsters, London: Routledge, pp. 26-56

Stinger M. and Stauder D. (2003) European Patent Convention: a Commentary, London: Sweet & Maxwell

Strathern M. (1999) “What is Intellectual Property After?” In Law J. & J Hassard J. (eds) Actor network theory and after, Oxford: Blackwells, pp. 156-180

Strauss A. L. and Corbin J. (1990) Basics of Qualitative Research: Grounded theory, procedures and techniques, Newbury Park: Sage

Subramanian A. (1995) “Putting Some Numbers on the TRIPS pharmaceutical debate”, International Journal of Technology Management (10) pp. 252-268

Taylor C. T. and Silbertson Z. A. (1973) The Economic Impact of the Patent System, Cambridge: Cambridge University Press

The Guardian (2003) "Djibouti throws out its immigrants", 17th September 2003

Third World Network, Tackling AIDS with cheap generic drugs, Monday 6th December 2004, available at www.twnside.org.sg/title2/gtrends35.htm

Thomas C., Wilkin P. (eds) (1997) Globalization and the South, Basingstoke: MacMillan

Torremans P. (2005) Intellectual Property Law, Oxford: Oxford University Press

UNAIDS/01.65 (2001), Sources and Prices of selected drugs and diagnostics for People living with HIV/AIDS, available at http://www.accessmed-msf.org/upload/ReportsandPublications/3920012333116/Sources%20and%20prices.pdf

Vaistos C. (1971) "Patents revisited: their Function in Developing Countries", Science, Technology and Development pp. 71-97

Van Maanen J. (1988), Tales of the Field: On Writing Ethnography, Chicago: University of Chicago Press.

Velasquez G. (2000) « Medicaments Essentiels et Mondialisation », Revue Internationale de Droit Economique, 2000/1. Numero Special: Brevets Pharmaceutiques, Innovation et Sante Publique pp.38-44

Waal A. (2003) "The perverse logic that divides impoverished Africa, The Guardian 16th June 2003

Waberi A. (2002) Balbala, Paris: Gallimard

Waberi A. (2003) Transit, Paris: Gallimard

Walker C.E. and Bloomfield M. A. (1988), Intellectual Property and Capital Formation in the next decade, Landham: University Press of America

Watal J. (1994) Intellectual Property Rights in the WTO: the way forward for developing countries, New delhi

Watal J. (1999) "Introducing Product Patents in the Indian Pharmaceutical Sector: Implications for prices and Welfare", World Competition 20: 5-21

Waters M. (2001) Globalization, London: Routledge

Weisburst S. (1995) "Economic effects of Strengthening pharmaceutical patent protection in Italy", International Review of Industrial Property and Copyright Law (26) 1009-24

WHO (2001) “Globalization, TRIPS and Access to Pharmaceuticals”, available at http://www.who.int/3by5/amds/en/regulations1.pdf

WHO/WTO (2002) “Implications of the TRIPS Agreement and the Doha Declaration and Public Health”, available at http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf

WTO/WHO (2002) “WTO Agreements and Public Health”, Geneva available at http://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf#search='WTO%20agreements%20and%20public%20health

WIPO “Striking a Balance: Patents and Access to Drugs and Healthcare, available at: http://www.wipo.int/about-ip/en/studies/publications/health_care.htm

World Bank (2001) Memorandum of the President of the International Development Association to the Executive Directors on a Country Assistance Strategy for the Republic of Djibouti. 21414 DJI, available at: http://www-wds.worldbank.org/servlet/WDSContentServer/WDSP/IB/2000/12/19/000094946_0012010530366/Rendered/PDF/multi0page.pdf

World Bank (2002) Report No PID10697, Djibouti- Health Sector Development

World Bank (2003) Report No AB7, Updated Project Information Document (PID), Djibouti – HIV/AIDS, Malaria and Tuberculosis Control Project

Yin R. K. (1994) Case Study Research, Newbury Park: Sage.

Court Cases:

Darcy and Allin decision, (1602) Noy 173, 74 ER 1131

Harvard/Onco-mouse (1990) EPOR 4

General Tire& Rubber v. Firestone Tyre and Rubber (1972) RPC 457

Tektronix/Scottky barrier diode (1995) EPOR 384

Thomson/Electron Tube T953/90 (1998) EPOR 415

Windsurfing international Inc vs Tabur Marine (1985) RPC 59

General Tire and Rubber Co v Firestone Tyre and Rubber Co (1972) RPC 457

Van Der Lely (L) NV v Bamfords (1963) RPC 61

Synthon BV v Smithkline Beecham Plc (no2) (2003) RPC 43

Merrell Dow pharmaceuticals Inc Vs H N Norton & co ltd (1996) RPC 76

Chiron Corpn vs Evans Medical Ltd (1998) RPC 517

Asahi Kasei Kogyo KK (1991) RPC 95

Williams vs Nye (1890) 7 RPC 62

Burroughs Application (1974) RPC 147

Great Britain Ltd [1985] RPC 59

EPO Board of Appeal, decision T36/82, OJEPO 7/83

Biogen Inc v Medeva plc (1997) RPC 1

Genentech Inc's Patent (1989) RPC 147

Stafford-*Miller's application* (1984) FSR 258

Bruker's application (1988) OJ EPO 308

Centrafarm v. Sterling Drug, Case 15/74 (1975) ECR 1147