CANADA'S ACCESS TO MEDICINE REGIME: A STUDY OF POLITICS OF IPR ON HUMANITARIAN PUBLIC HEALTH POLICY, 2004-2012

Dissertation submitted to Jawaharlal Nehru University
in partial fulfillment of the Requirements
for the award of the degree of

MASTER OF PHILOSOPHY

AJITH E A

CANADIAN STUDIES PROGRAMME
CENTRE FOR CANADIAN, US AND LATIN AMERICAN STUDIES
SCHOOL OF INTERNATIONAL STUDIES
JAWAHARLAL NEHRU UNIVERSITY
NEW DELHI – 110067
2015

CENTRE FOR CANADIAN, US AND LATIN AMERICAN STUDIES
SCHOOL OF INTERNATIONAL STUDIES
JAWAHARLAL NEHRU UNIVERSITY
NEW DELHI - 110067, INDIA

Date: 27-07-2008

DECLARATION

I declare that the dissertation entitled **"Canada's Access to Medicine Regime: A Study of Politics of IPR on Humanitarian Public Health Policy, 2004-2012"** submitted by me for the award of the degree of **Master of Philosophy** of Jawaharlal Nehru University is my own work. The dissertation has not been submitted for any other degree of this University or any other University.

AJITH E A

CERTIFICATE

We recommended that this dissertation be placed before the examiners for evaluation.

27/7/08

PROF. ABDUL NAFEY
(Chairperson)

PROF. CHRISTOPHER S.RAJ
(Supervisor)

CONTENTS

TABLES

FIGURES

ACKNOWLEDGEMENTS

No few words can express my deep sense of gratitude to my respectable supervisor Professor Christopher S. Raj for his guidance, endurance and patience through the course of my M. Phil. Degree as well as preparation of my Dissertation.

I am also thankful to Prof. Abdul Nafey, Prof. Priti Singh, Prof. Chinthamani Mahapatra, Prof. K.P. Vijayalakshmi for their valuable lectures and encouragement.

I am also acknowledging with thanks to the JNU Library, Exim Bank Library, M.G. University Library and Kerala University Library, for providing me the required Books, Journals, and other materials for completing my dissertation.

I am extending my deep gratitude to my former teachers for their guidance, and motivations during my academic life.

I am very thankful to my friends and comrades Dr. Nabil Abdul Majid, Tresa Benjamin, Ranjith Thiruvalloor, Viswanathan V, Nimmi Indukumar, Haritha Thazhakkal, , Subin Dennis, Athul S.G, Aswathi Rabeca Ashok, Sunaina Iqbal, Pindiga Ambedker, Ajmal S Rasaq, Abhirami Suman, Nitheesh Narayanan, Salini L R, Sonia Balan, Abilash Lilli Augustine, Sreejesh N.P, Nisam Asaf, Sandeep, Deepanjan Krishnan, Heidi Santé Mariam, Navpreet Kaur, U.S Premsingh, Ranjith, Vasudevan Kaimukku, Shiju K K, Sreeraj, Varun, Midhun, Yamuna, Balu, Asha, Sam, Appu, Aneesh, Remya, Dhani, Babitha, Akilesh, for their helps and support both in my academic and personal life.

I am grateful to my Amma and Achan who gave me my body and thought, and other family members who have been always with me.

ABBRIVIATIONS

A2M :Access to Medicines

AIDS :Acquired Immune Deficiency Syndrome

ARV :Antiretroviral

CAMR :Canada's Access to Medicines Regime

CD :Compact Disk

CGPA Canadian Generic Pharmaceutical Association

CIDA :Canadian International Development Agency

CIPO :Canadian Intellectual Property Office

CL :Compulsory License

CUFTA :Canada US Free Trade Agreement

DFAIT :Department of Foreign Affairs and International Trade

DNA : Deoxyribonucleic acid

DSB :Dispute Settlement Body

DVD :Digital Versatile Disc

FTA :Free Trade Agreement

FTA :Free Trade Agreement

GATT :General Agreement on Trade and Tariffs

GSK :GlaxoSmithKline

HIV :Human Immunodeficiency Virus

IC :Integrated Circuit

IFPMA :International Federation of Pharmaceutical Manufacturers Association

IP :Intellectual Property

IPHA :Irish Pharmaceutical Helath Care Association

IPR :Intellectual Property Right

LDCs :Least-Developed Countries

MDGs :Millennium Development Goals

MFN :Most Favored Nation

MNC :Multinational Corporation

MP :Member of Parliament

MSF Médecins Sans Frontières

NAFTA :North American Free Trade Agreement

NDP :New Democratic Party

NDs :Neglected Diseases

NGO :Non-Governmental Organisation

NIEO :New International Economic Order

NTDs :Neglected Tropical Diseases

R & D :Research and Development

Rx & D :Research Based Pharmaceutical Companies

TNC :Transnational Corporations

TPP :Trans-Pacific Partnership

TRIPS :Trade Related Intellectual Property Rights

UN :United Nations

US :United States

USD : United States Dollar

USTR United States Trade Representatives

WHO :World Health Organisation

WIPO :World Intellectual Property Organisation

WTO :World Trade Organisation

To

Those who are struggling with...

Those who are struggling for...

Chapter 1

INTRODUCTION

The Parliament of Canada passed the Bill C-9 in 2004, which ratified the August 30 Decision of World Trade Organisation (WTO) – *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*. By this action Canada became the first country that has passed legislation which authorizes export oriented production of generic pharmaceuticals via compulsory licensing to the countries those are lacking access to medicine due to their incapability in pharmaceutical manufacturing and a lack of expertise in the same (Parliament of Canada 2004; CIPO 2015; GoC 2008; Elliot 2012; Esmail 2010). The Act amended the "Patent, Food and Drug Act" – the "Bill C-9. It was a premier "Jean Chretien Pledge to Africa". The same act later called as Canada's Access to Medicine Regime – the CAMR (ibid).

WTO's Doha Round-Trade Related Intellectual Property Rights (TRIPS) flexibilities has permitted the countries to grant "compulsory licenses" to manufacture and export low-cost generic versions of branded patented medicines to the developing and least-developed countries those who do not have adequate domestic pharmaceutical manufacturing capabilities (WTO 2001). Although CAMR was a laudable project, it failed to deliver its purpose and promises or "proved to be ineffective in practice" (Gatto, 2011; HRWA, 2011; Esmail, 2010). Since the CAMR came in to exist, only one supply has delivered under the regime. Among that supply itself, the licensee has faced multifarious obstacles from various sources. It is a question of intellectual property rights. The literatures indicated the involvement of the politics of intellectual property rights (IPRS) in the failure of the regime. This study has analysed the forces behind the failed promises, from its enactment to the defeated amendment.

In 1994 World Trade Organization (WTO) came into existence as a culmination of series of deliberations held under Uruguay Round of General Agreement on Trade and Tariffs' (GATT) trade negotiations (Watal 2003). WTO has incorporated an Agreement on Trade Related Intellectual Property Rights along with two counterpart

multilateral agreements to govern the world's intellectual property regime (WTO 1994). The agreement provides a "minimum standard" of guidelines to the WTO members on IP matters (ibid). Due to the mandates of TRIPS' rigid guidelines, accompanied retaliatory measures, and also as a result of US trade representatives' (USTR), most of the member countries amended their domestic laws accordingly (Watal 2003). Consequently the developing and least developed countries, even though they have a fighting legacy against a rigid intellectual property (IP) regime during the GATT negotiations, were also dragged into the new IP regime gradually.

The TRIPS eliminates the scope of Process Patents[1] which had been followed by the generic manufacturing industry to produce low-cost generic version medicines by using reverse engineering and parallel importation (Chandra 2010). This limits the access of low cost medicines in developing and least developed-countries accordingly (Watal 2003; Chandra 2010). Moreover, subsequent reduction in generic competition on pharmaceutical products results an unprecedented price hike global pharmaceutical market (Chandra 2010; 't Hoen 2009). The per capita income of the middle and low income countries made them incapable to manage this crisis on access to medicines ('t Hoen 2009).

The original TRIPS document has incorporated a few numbers of flexibilities like compulsory licenses[2] in order to meet the public health crises (WTO 1994). But, on the one hand that was not useful to the countries which do not have adequate pharmaceutical manufacturing capability and technical expertise (Chandra 2010; 't Hoen 2009). On the other hand the original TRIPS agreement checks the countries with sufficient manufacturing capability, to export generics by using compulsory licenses (WTO 1994: #31(f)). This situation worsens the problems relating to health security and access to medicine in the developing and least developed countries (Lexchin 2013).

[1] Process patent has been granted the patent holder to use a particular manufacturing process exclusively. In this system the governments can grant other patents on the same product if that same product was made by another manufacturing method or a new combination.

[2] Compulsory licensing allows the governments to grand a third party license to produce the patented product or process without the consent of the patent owner. It is one of the flexibilities on patent protection included in the WTO's Agreement on intellectual property — the TRIPS

The above circumstances produced the post-TRIPS era debates on public health. WHO estimates, two billion people in the world lacks the regular access to essential medicines. The spread of HIV/AIDS, Malaria and tuberculosis in the underdeveloped countries especially in the African countries, heated the discourses and which turned into 'IP protection versus public health' in the world health forums of the times (Lexchin 2013; Esmail 2010; Kohler 2010; 't Hoen 2009). According to Medecins Sans Frontieres (MSF) assessment the cost for the triple therapy for HIV was greater than 10,000 US $ per person per year in 2000. It was beyond the imagination of peoples from the world's poorer countries to administer HIV/AIDS treatment.

Although the world's health condition was getting worst, the developed countries and research-based pharmaceutical industries defended IP protection by arguing that this is necessary for promoting a rational milieu for capital and R&D investments and the development of new pharmaceuticals accordingly (Esmail 2010). On the other side, for the developing and the least developed countries, NGOs and some human right organizations fought for a minimal IP protection ('t Hoen 2009). The developing countries argument has received large public attention in the late 20th century. That opened an atmosphere for reducing the domain of IP protection; and for taking international measures to ensure the access to medicine (A2M) for the poor people (Esmail 2010; Kohler 2010).

In 1998, Thirty nine multinational companies with the support of USTR, complained against the South African government's patent law amendment for the violation of TRIPS agreement (Lexchin 2013: 2; 't Hoen 2009: 21; Weber and Mills 2010: 112; Williams and Lofgren 2013: 16; Chandra 2010: 195). This case triggered the world's public opinion negatively towards the brand name companies and the US. The new development in the international discourse on IP versus public health and A2M led a concrete effort to revise the TRIPS provisions to meet the public heath requirements of the world's poor countries (Weber and Mills 2010; Lexchin 2013). This lead to Doha Public Health Declaration 2001 (ibid). It declared:

> "TRIPS Agreement does not and should not prevent the members from taking measures to protect public health… we affirm that the agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and in particular, to promote access to medicine to all" (WTO 2001)

They agrees to re-define the Article-31 of the TRIPS to allow the states to grant Compulsory licenses to any third party for exporting to meet the public health crises of developing countries (WTO 2001; WTO 2003). Two years later that decision was ratified in the WTO General Council 2003 and which was called as "August 30 decision" (WTO 2003).

As mentioned earlier, Canada was the first country that translated the August 30 Decision as a Domestic legislation (Bill C-9) (Parliament of Canada 2004; CIPO 2015; GoC 2008; Elliot 2012; Esmail 2010). The legislation was called Canada's Access to Medicine regime. Even if it was a manifestation of Canada's humanitarian foreign policy objective, Canada never since used this celebrated legislation except on once (Elliot 2013). Rwanda was the only country which has benefited from the regime and received two shipments of anti-retroviral medicine for treating 21,000 HIV/AIDS patients (ibid; Himelfarb 2015; Weber and Mills 2010).

In December 2004 Apotex announced its willingness to produce a new combination of triple therapy anti-retroviral HIV/AIDS medicine - Apo-TriAvir, under CAMR (Abbott 2007: 1127; Himelfarb 2015). The combination was not a scheduled medicine in the Schedule-1 of the CAMR at that time (Himelfarb 2015). After a long deliberation and the subsequent recommendations from the Ministry of Health and Industry, the federal cabinet approved the entry of the new combination in to the schedule 1, and finished its administrative approval in 2006 (ibid). A two and half years later the CAMR legislation, Rwanda notified in the WTO in July 2007 of its need to purchase Apo TriAvir (ibid). Due to the Apotex' negotiations for voluntary license with brand-name companies failed; the Commissioner Canadian Patent Office granted compulsory license in September 2007 (Abbott 2007). Apotex sent its first shipment of Apo TriAvir in September 2008, a year after granting compulsory license and four year after the CAMR was established. Finally the second shipment was also sent in 2009 (Himelfarb 2015; Weber and Mills 2010). Apotex faced costly as well as unnecessary delays and pressures from various sources during this process.

This traumatic experience on Apotex' humanitarian commitment to the public health and access to medicine lead them to withdraw their willingness from further manufacturing. As a response Apotex (2008) publically stated "it is reluctant to

participate in the initiative again unless changes are made to streamline the regime" (Apotex Group 2008).

The CAMR's tragic deadlock shows the inefficiency and complexity of the present law and the need for an amendment. Other than Rwandan episode (Export of Apo TriAvir under CAMR), not even a single medication was produced or exported under the CAMR. Kohler and Lexchin (2010) commented "in rhetorical terms, CAMR promised an elephant, but so far the legislation has delivered little more than a mouse".

The demands for revision of CAMR were raised on this context. On March 2009, a Senate Member from Liberal Party, Yoine Goldstein introduced a Private member bill (S-232) to amend CAMR, and on the same year a similar Bill (C -393) was introduced at the House of Commons by a NDP (New Democratic Party) member Judy Wasylycia-Leies (Canadian HIV/AIDS Legal Network 2011; Esmail 2010: 288). Both the bills proposed certain amendments to simplify the compulsory licensing procedures. The members of the House of Commons voted in favour of the Bill C-393 and referred the same to the Senate. But it did not completed the necessary stages within the senate which was required, before the parliament was dissolved for the General Election in 2011.

A new and similar private bill (C-398) was introduced in the parliament in the first session (February 2012) of the parliament, sponsored by a NDP Member of Parliament (MP), Helene Laverdire (Parliament of Canada 2012). All the Political Parties, who then represented in the parliament, supported the bill except the Conservatives. The bill was defeated by the Conservative majority in the House of Commons in 28th November, 2012 and the bill was not amended to a law (Elliot 2013). This failure defeated the humanitarian efforts of Canada to help the poor countries, to ensure access of affordable generic medicines.

Since the emergence of research-based market oriented pharmaceutical production, the politics of Intellectual Property (IP) protection has had considerable implications on public health. In global public health these days, laws that govern IP are dominated by the interests of neo-liberal capital (*Ibid.*), pushing aside humanitarian concerns regarding access to affordable healthcare. The capital interest of dominant

brand name pharmaceuticals industries of Global North monopolizes the knowledge as well as IP. The appropriation of knowledge gives them a control over the IP regime. That widens the global North-South divide, in terms of access of knowledge. The control over the IP on pharmaceuticals reduces the access of affordable medicines and health services to the global South. Moreover the global North which has the monopoly over the IP could frame the IP regime in their favour. They undermined the needs of the rest for the sake of creating a favourable environment for the capital investments and the investments on research and developments (R&Ds). They have defeated every threat to the status quo of their monopoly over IP, in a systematic manner (Watal 2003; Chandra 2010; 't Hoen 2009).

1.1. REVIEW OF LITERATURE

Watal (2003) described all the processes leading towards the formation of the world's intellectual property regime under the WTO. She has narrated the background and context of controversial negotiations and the dynamics of North-South divide on the new developments on intellectual property; and how the world's North conclude on the discourses in the Uruguay Round, GATT negotiations (Watal, 2003). She examined the politics of trade threats and retaliations which drag the developing and least-developed countries in to the regime. This book provides some insights on the realities of the existing inflexible IP regime, which made barriers on the free flow of knowledge. Even after, the WTO came into existence; the debates heated the deliberations in the international phase, about the rigidity of existing IP regime on access to medicine. This discourse lead to the Doha Declaration of 2001 and its August 30 Declaration of 2003 (ibid).

Chandra's (2010), *Knowledge as Property: Issues in Moral Grounding of Intellectual property* puts the notion, "the idea of knowledge as a property"; which grounded in the legitimacy of intellectual property rights. The first part of the book contextualizes the IPR and provides some insights from the theories on IPR. The first section also deals the question of proprietary control over the self-ownership with its counter argument "knowledge is clearly not a product of an individual mind alone" (ibid). When we look at the sociology of knowledge creation, it is very certain that the cognitive hierarchies structured by the IP Regime awards hegemony to the Western Modern Societies; and limits the participation of World South in the creation of

knowledge (Chandra, 2010). The later section of the book elaborates three case studies which are Novartis patent claim on *Glivec*, Monsanto's claims on breeder varieties and bio-politics on Neem (ibid).

Incorporation TRIPS into WTO with special reference to the worries of the developing and least-developed countries were the focus of the study of Rao & Guru (2003). This work provide some basic understanding on intellectual property rights, its great conventions, Uruguay round of trade negotiations, TRIPS and its revision in the Doha ministerial Conference in 2001. A basic study on the progress of global IP regime is necessary to understand how the developing countries lost their scope of generic manufacturing and access to affordable medicines (Rao & Guru, 2003).

Lalitha (2005), Examines Canada's patent regime; and how it has intertwined with the pharmaceutical industry and public health. She gives an overview of role of Canadian state in pharmaceutical pricing and in regulating the patent (ibid). The 1990s witnessed a significant shift in Canadian patent policy and the price regulation through controlling pharmaceutical patents and by allowing compulsory licenses (ibid). That shift was a reflection of state level politics and the consequent public policy changes (Lalita, 2005).

Revealing the complexities of the CAMR in its present form was the focus of Huth (2010). Certain requirements mandated in CAMR has gone beyond the TRIPS guidelines such as two year limited duration or Schedule 1 which are described in the later chapters (Huth, 2010). These mandates were meant to keep a balance of interests between the brand-name pharmaceutical companies and their humanitarian commitments towards access to medicine (ibid).

Lexchin (2013), analyses the ambiguities of Canada's humanitarian commitments towards access to medicine. His Articles' title "Canada and Access to Medicines in Developing Countries: Intellectual Property Rights First" itself explains the disabilities of Canada's initiatives for access to medicines. Canada is a country which follows neo-liberal ideals that prioritize knowledge as a private property in the form of IPRs (ibid). He considered a series of domestic and international developments regarding IP, to analyse Canada's commitments towards access to medicine and to elaborate how CAMR was emerged. Certain important developments were scrutinised

to understand the same, which are: A case against South Africa filed by 39 pharmaceutical companies in 1998; Doha Declaration 2001; CAMR 2004 and its amendment initiatives in 2011 and 2012; Anti-Counterfeiting Trade Agreement in 2009; Canada's involvement in UN High-level meeting on non-communicable dieses in 2012; and Canada's position in the extension of exemption for LDCs from TRIPS guidelines (Lexchin, 2013). Canada took a position in favour of high IP protection; which revealed Canada's policy priorities and how the humanitarian efforts were being undermined (ibid).

An empirical case study on CAMR, which examined the extent of impact of NGO campaigns in the creation of CAMR, has provided some seminal information on the role of the non-state actors in the formation of CAMR (Bubela & Morin's 2010). The study also threw light to the transformation of the NGOs from a radical to a reformist position. They succeeded in implementing the WTO decision famously known as August 30 decision implementing the Doha Declaration meant for ensuring access to essential medicine for developing and least countries but the CAMR envisaged from the particular declaration failed to realise the goal (ibid).

The Canadian Parliament Member of NDP, Laverdiere wrote an open letter to censure the Conservative majority of the House of Commons for the defeat of the Bill C 398 (CAMR amendment). She openly accused them for their "cynicism and petty politics" against the lifesaving legislation. Moreover, she stated that "I have been witnessed disturbing misinformation being repeated by the Ministry of Industry in the parliament and were sent three year old irrelevant talking points to the back bench MPs in the house" (Laverdiere, 2013).

Researcher Kohler (2010) explored the gap between the promises and the political will of Canada to materialize the opportunities given by August 30 decision of WTO. Even though a law was passed, Canada failed to address the issue of access to medicine and to fulfil its humanitarian commitments (Kohler, 2010). He stated "Intentions are only as good as their results", if Canada's intentions were genuine "then a reformed CAMR may be of value". He further provides some leads towards the unexploited competitive potential of the CAMR. The shipment of the first line therapy drugs of AIDS generic version of medicines shows Canada's competitiveness with the similar medicines from India and other low priced manufacturing countries.

Canadian generic manufactures have manufacturing capability for producing second and third line therapies of which no generic versions are available (Kohler, 2010). Even though the price of Canadian generic version is high price, quality vice it always outnumbered the lower priced medicines (ibid). This probability point towards the scare of the brand named industries towards the CAMR's amendment as per Kohler (2010).

Gloria Galloway (2011), in *The Global Mail*, reported that Industrial Minister Tony Clement asked Conservative MPs to defeat Bill C-398 in the House. He also quoted some lines from the conservative minister's letter to his colleagues. This illustrates the real behaviour of the Conservatives in the parliament and the reason for voting against the bill. If the bill would have been passed, Clement argued, the drugs "could be redirected to the black market with proceeds going to non-humanitarian causes such as weapons… and could run afoul of domestic laws and traditions… if the current patents are threatened, the patent holders will leave Canada…". He also mentioned the Industrial Minister's bonding with the brand name industries.

Esmail (2010) examined the politics involved in the formation of CAMR, especially in the parliamentary processes. In her Doctoral thesis, *Politics of Canada's Access to Medicines regime: The Dogs Didn't Bark,* observed the parliamentary processes of CAMR by analysing the transcripts from the legislative development of CAMR (2004) and legislative review (2007). As a study on the state level institutions, it analysed debates of House of Commons on CAMR and the hearings and submissions on the Parliamentary Standing Committee. The study also analysed how the framing, institutions and interests determined the final policy design on CAMR. A reconciliation of social and commercial goals balances the form of the legislation. In the policy debates, concerns of Department of Industry and International Trade as the protection of intellectual property to ensure good trade relations were dominated. But the "promotion of public health, access to medicine and the impact of CAMR on innovations" were hardly discussed. It resulted in a limited implication of the legislation to "encourage generic competition and drug affordability". Since the sphere of political influence of the generic industry and the NGOs were weak, the interests of research based brand name industries' interests succeeded to maintain the status quo. Even though it was an intensive study on CAMR, from the methodological

perspective it concentrated on the influences of formal state level institutions on the formation and the progress of CAMR. Influences of the international system and the aspects of non-state actors were not given sufficient focus.

1.2.DEFINITION, RATIONALE AND SCOPE OF THE STUDY

This is a case study on Canada's Access to Medicine Regime which targets to examine the involvement of intellectual property politics and the articulations. It looks into the determining factors which influenced the decision making process concerning the enactment and the proposals to revise and amend the CAMR. This study has not focussed on an overall analysis on the IP policy or public health policies of Canada or foreign health care programmes/aids but will look into the failed humanitarian promises of CAMR for ensuring the access to essential medicines to developing and least developed countries under its provisions.

United Nations Programme on HIV/AIDS - UNAIDS (2010) estimated that, 15 million people over the globe are living with AIDS. According to World Health Organization approximately two billion people still lacks regular access to essential medicines. One third of the total AIDS effected people are from the lower and middle-income countries of which a majority remains without access to anti-retroviral therapy. In this context a study on the promises of CAMR is relevant. The global nations are spending billions of money for military purposes and 'humanitarian' interventions in the name of peace and security. The same logic is hardly evoked in the context of Global Health Security. The literatures indicates that, the rationale of free trade regime constantly prevents the initiatives to assure the access to medicine in the name of IP protection and the need for creating a fair environment for capital and R&D investments (Chang 2001; Thomas 2012). The two notions – security and free trade, the chief navigating force behind today's international politics, curtails the policy initiations which aims to ensure the access to medicine.

Regarding the spread of epidemics, the global-North is constructing a 'phobic image' pointing global south as the source and carriers of epidemics in the world. Meanwhile they are unwilling to transfer their pharmaceutical patents as well as their technological expertise and knowledge. Since the emergence of TRIPS, the countries

with liberal patent policies who were in favour of producing cheaper generic medicines (e.g.: Indian process patent regime under Patent Act 1970) were compelled to change the patent laws and switch into the product patent regime. It deepens the crises on access to medicine. The patients lost their access to generic market since then. In this context studies on the movements to ensure the access to medicine, such as CAMR need to bestowed with greater importance.

1.3.RESEARCH PROBLEM AND QUESTION

CAMR failed deliver its basic objectives. Internal complexities of the original version and some external pressures made it unviable. The politics of opposing interests especially from the research-based pharmaceutical industry constantly intervened in the working of CAMR to make it dysfunctional. As of now, it is very difficult to produce and export humanitarian generic version of medicines under CAMR. Therefore maintaining the status quo on CAMR is vital to protect the interest of research-based pharmaceutical industry. In the end, a negative lobbying emerged which successfully defeated the Bill C-398 -- amendment on the CAMR (Patent Act) "to make easier to manufacture and export pharmaceutical products to address public health problems afflicting many developing and least-developed countries (Parliament Canada 2010)

The Research problem has arisen from the failed humanitarian objectives of CAMR which involved a deeper politics. The present study has explored the politics involved in enactment, hitches in implementation, and the defeat of the private member bill for amendment of CAMR. The politics involved in the stages of decision making and its implementation is not mono-dimensional. Of course the state has an autonomy on their domestic decision making process to a larger extent. The legislation has been influenced by different forces at the international system level, state level and the non-state actor level in broad terms. The study integrates the different levels of analyses, to understand consequent dynamics of influences on CAMR.

1.4. RESEARCH QUESTIONS

- Why the purpose and promises of CAMR was not delivered, even though international law and public opinion was in favour to it?
- Which are the actors involved in the politics of IP and access to medicine which determined the nature of CAMR?
- How the different levels of influences frame the discourse on access to medicine regime?
- What all factors influenced the actor's behaviour, which has reflected in the legislation process of CAMR?

1.5. HYPOTHESIS

The politics of intellectual property rights determines the domestic and international direction of Canada's humanitarian commitments on the access to life saving medicine.

1.6. ORGANISATION OF THE RESEARCH

1.6.1. Methodological Framework

This will be a single case study. The study will be analysing the different phases in the passage of a single case, CAMR – enactment, implementation and amendment. Using the analytical framework of Levels of Analysis (LoA) approach, the proposed dissertation would examine the factors that were instrumental in shaping CAMR enactment. A range of factors at the structural, domestic political and individual level that have been instrumental in shaping CAMR decision would be examined. To address the phenomenon of multiplicity of actors, influences and processes in the politics on CAMR, an LoA approach as described by Kenneth Waltz (1959) is employed to analyse the research problem at three different levels: the international system level, the state level, and the non-state actor level.

Major source of this research has been the transcripts of Parliamentary debates; Industry Committee hearings; and the Review Committee submissions. The texts of public speech, statements and comments, documents circulated by the international, government and non-governmental institutions have been examined.

1.6.2. Theoretical Framework

The major theoretical framework used in the particular dissertation for chapterisation and analysis are: Utilitarianism, Humanitarianism and Dependency. The first two are associated with the politics of IPRs and access to medicine and the last one with the foreign policy as well as domestic decision making process of Canadian Government. The literatures suggest that, these three theories have specific reflection on the 'working' of CAMR. The first three chapters are designed accordingly. The analysis chapter will elaborate this theoretical framework, and will encode the determinants of different themes which will quantify and help the analysis on the legislative process of CAMR revision.

5.3. Chapter Framework

2. Utility First: Conceptualising the Politics of Intellectual Property

In the second chapter attempt has been made a review of the philosophical discourses on intellectual property as well as the notion, “knowledge as a property”. Two major philosophical justifications, self-ownership based rights and ‘utilitarianism’ will be discussed in this chapter. Moreover this chapter is described the application of the philosophy of the property into the intellectual property rights. The discourse on the extension of tangible property to intangible property is analysed in this chapter. Finally this chapter provides details of the critical discourses on intellectual property as well.

3. Utility V/S Humanity: Implications of the Politics of IPRs on Global Access to Medicine

The third chapter has examined the post-Doha development of intellectual property regime and its impact on access to medicine. The chapter discusses the world health condition, especially the dangerous spread of HIV/AIDS, in places like sub-Saharan Africa. This context has helped to understand the moral obligations of the nations-

states to give attention towards certain issues related to epidemics and access to medicine. The critics of intellectual property rights question the utilitarian defences of intellectual property, by referring to these specific contexts. Moreover the need for flexibility in the intellectual property obligations emerges from this very context. Some legal battles escalate the tension and culminated in the Doha Declaration. The following section of this chapter provides an examination of domestic implementation of Doha flexibilities in Canada i.e., the CAMR and its manifestations.

4. Dependency: Implications on Foreign Policy Decision Making of Canada

This Chapter scrutinises of the domestic determinants of Canadian foreign as well as domestic decision making process. The power and capabilities, geography and natural resources, economic structure etc. are the central focus of the chapter. Overall this chapter analyses the dependency of Canada, and how it influences the decision making process. The chapter also examines the Harold Innis' tradition of Canadian dependency to understand the domestic roots of the dependency and the branch-plant nature. The chapter has provided some statistical evidences of Canadian dependency as well.

5. Analysis at different levels: Cutting across Conceptual Axes of Utility, Humanity and Dependency on Canada's Access to Medicines Regime

Fifth chapter is analyses different levels of the legislative process of CAMR. It examines the three levels of determining factors on the decision making of CAMR. The international system level, state level and non-state actor level has been analysed. The chapter will also introduce a theoretical framework to study of the behaviour of the actors involved in the decision making process. The utilitarian defences of IP, humanitarian critics of IP and the Canadian dependency will has been examined in this theoretical framework.

Chapter 2

UTILITY FIRST: CONCEPTUALISING POLITICS OF INTELLECTUAL PROPERTY RIGHTS

Since Canada's Access to Medicine Regime (CAMR), the central analysing focus of this study is deeply connected with the international Intellectual Property (IP) laws and the dynamics of the intellectual property regime, it is necessary here to describe the philosophical justifications of Intellectual Property Rights (IPRs). This would be helpful to see how these philosophical inputs act as the justifications for validating IPRs, while these very legalities are questioned on the basis of existing humanitarian concerns. Numerous studies points out that wherever the humanitarian policies like access to medicine (A2M), contradict with the intellectual property regime, the decision makers uses the philosophical justifications in order to manage the crisis. Moreover the laws on IPRs were not originated in a particular time. It was evolved simultaneously with the development of the world's scientific and technological progress. This chapter take an account of the history of the IPRs too. The history would provide some insights into the development of philosophy of the IPRs as well as how this has been associated with the general philosophical developments of the world.

Historically, in the development of global scientific and technological progress, ownership of knowledge[3] has been appropriated by a minority section of the world. This demarcates the world population into two separate social, political and economic entities - world South and North. While coming to the issue of access to medicine this division is significant. On the one side the uneven share of knowledge affects the production-supply patterns and on the other side an "artificial scarcity" created by the "monopolistic nature of intellectual property rights regime" creates the determinant of the price of essential medicine in the world (Julio Cole 2001: 80 in Chandra

[3] This study will be uses knowledge in the context of intellectual property

2010:121). The nature of demand for the medicine made the price inelastic[4] and this intensifies the inaccessibility of medicine for the poor.

The knowledge protection and the access to medicines are deeply correlated (Williams and Lofgren 2013; Chandra 2010; 't Hoen 2009; So and Sachs 2012). The development of the institution of private ownership on the knowledge reduces the scope of public domain knowledge, which can be "freely and simultaneously accessible to multiple users" (Chandra 2010). The exclusive rights allowed for the right holder, exclude others from enjoying the fruits of that knowledge. IPRs, especially the Patent protection on the pharmaceutical products are hot topic since the establishment of patent protection on pharmaceuticals. Since billions of people are struggling to access affordable essential medicine to save their life from various diseases, politics of knowledge is very crucial. The IPRs grant an exclusive right for a specified duration to the patent holder/s to have "control over the production, supply, and distribution and, by virtue of exclusivity price" (WHO 2005:236). The attachment of 'exclusivity' on the private ownership of knowledge effectively helps the patent holder/s to convert their knowledge consistent with the market system. Successively the 'exclusivity' is acting as the gatekeeper of intellectual property in order to regulate the new entry of similar tangible or value added products.

An analysis of the history of the development of institutions of IPRs and the philosophical and theoretical justifications of private ownership on knowledge and of IPR is also necessary. It is important to understand the defences of market forces to justify the private ownership on knowledge, artificial scarcity, and the exclusivity. This explanation would facilitate a background study in order to analyse the issues in access to medicine and the impact of the global intellectual property regime on it.

2.i. Utility of Intellectual Property Rights

The idea of *utility* is an important factor in analysing the politics of intellectual property rights. The utility deals the question, how intellectual property will be useful to the society. The proponents of this idea argued that, innovations should be motivated through providing exclusive market rights for a certain period of time

[4] Since the demand of the medicine is not flexible to the changes in the price, this is inelastic in nature. Some exceptions also there: for example the cosmetic medicines.

(Sterckx 2004). Moreover this incentivises further innovations and sources to an overall development of the society through scientific and technological development (Ibid; Chandra 2004). The philosophical foundations of the utilitarian justifications of intellectual property rights mainly derived from the writings Jeremy Bentham's utilitarian theory on property, which was later extended to the applications of intangible or intellectual property.

Since the beginning of the practice of rewarding intellectual property rights in the national legal systems, the utility or usefulness of the intellectual property has been discussed widely (Sell and May 2001). The governmental authorities had rewarded a certain kind of intellectual property rights in order to incentivise their economic development of their territory. The forthcoming section will discuss about the history of intellectual property and how the national as well as international systems treated intellectual property rights. But since the market oriented surplus production started, the modern producers considered intellectual property as a potential tool to create monopoly and enhance their profit share. Since the emergence of large scale international trade, the states were compelled by these market logics through international regimes, for providing an "exclusive market rights" for the intellectual property holders. Even though the market logic of utility contradicts with other larger social goals, the states accredited the utility of intellectual property with a prime importance.

As mentioned earlier, this utility principle resulted in reversing the larger *humanitarian* goals of access to medicine health. The exclusive market rights prevent the competition and escalated the costs of medicine as well as the health care services Chang 2001). The late comers of intellectual property rights, the world's South, has been struggling a lot with the rigid IP laws (Chang 2001). The utility justification did not offer a solution for their larger social-economic as well as health problems. Even though some flexibility is provided in order to meet their structural inequalities, the dominant forces in the intellectual property regime overturned those in the name of utility, research and development (R&D) and the course of overall development.

Canada acknowledges both public health and R&D interests of intellectual property regime (GoC 2008; GoC 2008a; Industry Canada 2007). They followed a liberal approach towards the compulsory licencing, in order to reduce the costs of medicines.

A *reconciled* approach towards the *utility* and *humanity* was visible in their pharmaceutical polices. But in their recent history they reversed their approach on the intellectual property rights (Parliament of Canada 2008). Their dependence on international trade and on their neighbour United States, compelled them to create a rigid intellectual property regime, based on market logic of *utility*.

Therefore this chapter will discuss the philosophical justifications which are influential in moulding the positions of national and property regimes. The first section would be the history of intellectual property rights and the remaining sections will deal the philosophical justifications. This aims to provide the roots of legitimisations of intellectual property laws.

2.1.HISTORICAL DEVELOPMENT OF IPRS

The historical development of institutions is interconnected with various socio political factors. The history of IPRs is not different from that. This interconnection exposes the courses of development of institutions in order to deal IPRs associated with the development of logical justifications. The history of the intellectual property as a private ownership right has been a competition between two contradicting beliefs, (1) the Anglo-American ideals which stands for a private self-ownership on the intellectual creations/knowledge (2) and it's critical counter-side, which believed the knowledge "cannot and should not be monopolised"; which should be accessible for public interest requirements; and should be in a public domain (Sell and May 2001: 468).

In medieval Rome craft processes were considered as an intellectual property "with commercial value subject to the conditions of ownership" (Ibid: 475). The early practice of patenting system was initiated in the 15th century in Venice in order to protect "new indigenous devices" (Manell 1999:131; Ibid: 476). In the same century Guttenberg's printing revolution changed the landscape of the printing and consequently the mobility of ideas turn out to be easy. The printing revolution facilitated copying and that led to the institutionalisation of practice of copyright in the later centuries. From the middle of the 16th century "Council of Ten in Venice" issued decrees of prohibition on publishing works without the prior written consent from the author (Manell 1999).

National legislative recognition of IPRs began in the seventeenth century. British law formalised the exclusive rights on the patents with the "Statue of Monopolies of 1624" and the copyrights with "Act of Anne in 1709" (Sell and May 2001: 479). Subsequently these practices have spread to whole Europe.

A major shift in the history of institutionalisation of private ownership on human creations began from the technological discoveries and the development. The outgrowth of technological revolution formalises the patents. Initially this emerged to break the *secrecy* in the innovations, in order to publicise undisclosed knowledge for public learning and the development of industry (Ibid). But this did not have a philosophical backing as a natural or moral right of the inventor (Ibid). A central motivation behind the early practice of the patent system was the technology transfer "to reduce the import and expand export" and the consequent national development (Ibid). The rulers invited the inventors, artists by giving them exclusive rights on their knowledge to contribute their creative ideas and expertise for their territorial development so as to enhance their relative power possessions. This same period marked the development of utilitarian defence on the private ownership on knowledge. Simultaneously the utilitarianism has marked "a symbolic relationship with the evolution of modern state: from the formation and maturation of mercantilist nation states through the Industrialist Revolution to the rise of modern capitalist economy" (Manell 1999: 131).

From the aforesaid developments one can see some philosophical developments in the context of the increased inventions and the resultant industrial revolution and inter transactions. Obviously it is an Anglo-American philosophy, from the countries that benefited from the fruits of the industrial revolution and cross-border economic transactions. Some flashes of this phenomenon are visible in the writings of Adam Smith. Even though Smith was a critic of "monopoly of power as detrimental to the operation of the invisible hand", he justified the necessity of a limited intellectual property protection to promote the intellectual discoveries and commercial activities as required to reduce the jeopardies of investment (Manell 1999: 131). In his book, *Principles of Political Economy* (1862) John Stuart Mill suggested that the governments should grant a limited "exclusive privilege" for patents as a monopoly right to channelize the "worth to the consumers" (Ibid). Finally in the beginning of the

19th century Jeremy Bentham introduced a new biblical philosophy for the free market capitalism. His theory 'Utilitarianism' provide Philosophical justification for a high level intellectual property protection.

Afterward, another level intellectual property protection has emerged with the growth of international commerce and increased economic transactions that demanded an inter-territorial protection of intellectual property (Sell and May 2001). These transactions raised the volume of piracy and copying of the intellectual goods. They stress the "role of property in economic activities" in order to defend the demand for an expansion in IP protection (Ryan 1984 in Sell and May 2001: 482).

In 1873, the Austro-Hungarian Empire was hosting an Exhibition and invited creators globally to exhibit their inventions (Marcellin 2010:43). But most of the inventors did not show interest to participate. They thought their innovative ideas would be stolen if they exhibit their inventions (Marcellin 2010: 43). This event sparked the need for *national treatment* for foreign inventors to protect their IP. In 1883 eleven nation-states signed the Paris Convention and established International Union for Protection of Industrial Property. Paris Convection agreed upon 'national treatment' and 'non-discrimination' to the foreign IP holders and gave them priority on the basis of first application (Nair and Kumar 1994:3; Sell and May 2001: 484). The Bern Convention to provide protection of "artistic and literary works" was held and signed in 1886 and become the first multilateral treaty for copyrights (Nair and Kumar 1994:3). The two great conventions were revised and amended several times. A convention was held in 1967 at Stockholm to establish a multilateral organisation to deal with the issues related to intellectual property rights. World Intellectual Property Organisation (WIPO) came into being in 1970 and became one of the specialised agencies of UN in 1974 (Nair and Kumar 1994:4).

Idea of multilateralism expanded the scope of intellectual property from a national subject to global and from a state monitored measure to international trade. Moreover this situation escalated the international tension between the two basic notions of intellectual property. On one side the developed North led by Anglo-American Self-Ownership and Utilitarian Principle demanded for a "better enforcement and enlarged scope" (Nair and Kumar 1994:5). It also aimed at providing a better ground for investment and free trade and the subsequent overall development of the human

conditions. Indeed the world's South protested against and developed countries demanded for a better enforcement of IPRs and expanding the scope of IPRs into new areas such as "protection of breeders of plant varieties" (Nair and Kumar 1994:6). The developing countries, the "late comers" in the domain of intellectual property and the industrial development, argued that a high level protection and enforcement curtail the developmental desires of the developing and underdeveloped countries as well as the need for a better technology transfer. These aspirations where reflected in some of the institutionalised-collective efforts form the Third World such as G-77 and NIEO, in the same period, by demanding increased transfer and minimum protection.

This international *tug of war* later continued through General Agreement on Trade and Tariffs (GATT) trade negotiations and finally culminated in the Uruguay Round of GATT trade negotiations. This same period also witnessed a great transformation in the world. The Soviet Union disintegrated and its counterpart the United States of America became the sole super power of the world. This shift to a mono polar world order was very significant in the history of IPRs. The pressure of US Trade Representative (USTR) gained it's real momentum with the amendment of the 1974 US Trade Act, to the so called "Super 301 Section" in 1984 (Chang 2001:25; Watal 2003:18). The new act empowers the "US President to take *Suo Moto* action" including sanctions and withdrawal of tariff preferences for violation of US citizen's Patents (Watal 2003: 18).

USTR's trade activities gradually took over the control of the international trade regime. Its trade threats, withdrawal of tariff exceptions, and sanctions shrunk the unity of the developing countries. At the same time the developed countries united in the world trade negotiations for making a better IPR regime. This was a major period of institutional transformation in the international trade organisation. In the beginning of 1986 the United States and Japan tabled a proposal to incorporate an agenda of discussion on IPRs into the trade negotiations (Sterckx 2004: 60; Watal 2003: 19). Finally the trade minister's meeting held at Punta dli Este declared the launch of Uruguay Round of trade negotiations (Nair and Kumar 1994: 9-10; Rao and Guru 2003: 25; Watal 2003: 19). Part-I of the declaration decided to launch a trade negotiation including agreement on Trade Related Intellectual Property Rights (TRIPS) and on counterfeit goods (Rao and Guru 2003: 26; Watal 2003: 19).

The developing countries continued their fight in the new Trade Negotiation Committee as well. Developing countries were confident in terms of their reasonable representation and access to Worlds Intellectual Property Organisation (WIPO) for negotiating IPR issues (Sterckx 2004: 60). Therefore they continued their struggle to maintain the status quo of WIPO as a body to govern world's IPR matters. But their voices became unheard gradually. India, Brazil and Chile, the leaders of developing countries faced trade threats from "Section 301 Trade Act" (Watal 2003).

Apart from the historical hostility between the developed and developing camps, the Uruguay round witnessed a battle inside the developed camp as well. The European Community and some other industrialised countries disagreed to the United States' proposal to reduce the subsidies given to the domestic agricultural production (Nair and Kumar 1994:10). In this dead-lock the Director General of GATT, Arthur Dunkal proposed a draft package in December 1991 as a "resolution of conflicts" to settle the "boundless deadlocks and unnecessary discussions" (Nair and Kumar 1994: 10; Watal 2003: 35). This was called the Dunkal Draft. Prior to the Dunkal Draft, on October 1990 Canada proposed a "single undertaking Multilateral Trade Organisation" (Watal 2003: 34). Later this was renamed as World Trade Organisation by integrating all aspects of international trade including IPRs, services and tariffs. The fear of losing *m.f.n* (most favoured nation) status and due to the trade threats, the negotiating countries gradually agreed on both the proposals (Watal 2003). The world South lost their final hope for increasing the access to knowledge. Dhar and Rao (1994) pointed out that,

> "The Dunkal Draft on TRIPS clearly shows that the interests of the developing countries have been completely disregarded…The TRIPS negotiations… exclusively focused on the monopoly rights of patentees from the developed countries… The developing countries have to contend with an unequal world order: this is the most important message that the Dunkal Draft on TRIPS has unerringly given".

TRIPS gave a strong mandatory guideline to the signatories to provide a minimum standard of IP protection including patents, copyrights, trade secrets, geographical indications, industrial designs and trademarks. Further this mandated a minimum duration of 20 year patent protection, national treatment and strict guidelines for compulsory licenses (Chang 2001: 25-26; Nair and Kumar 1994: 9-10; Watal 2003).

This demarcated a new era of IPRs. TRIPS reinforced the International intellectual property regime. Most of the nation states made changes to their domestic intellectual property laws according to the WTO-TRIPS guidelines. The post-TRIPS era delineated with a product patent[5] regime. Before the TRIPS most of the countries had been accepted only process patents[6] on pharmaceuticals and other chemical combinations (Dhar and Rao 1994: 107). They lost their opportunity to sustain their generic pharmaceuticals and to access affordable generic medicines. This missed opportunity set the post-TRIPS agenda of deliberations, i.e. global access to essential medicine.

2.2. PHILOSOPHICAL JUSTIFICATIONS OF INTELLECTUAL PROPERTY RIGHTS

When we examine the history of the IPRs, we can see the development of the demand as well as a defence for the protection of intangible property that coincides with the development of the nation-state system and the modern capitalist production. The proponents of the intellectual property used this idea of production-property relation in order to build a strong base for modern industrial capital and its later stage free-trade. The individual as well as utilitarian defences (this will discuss in the following section), provide them with a defence for their legitimacy.

The "idea of knowledge as property" has been the subject matter of every philosophical justification as well as the counter arguments of the intellectual property rights (Chandra 2010). Moreover the same has been the central trope of the debate, when knowledge is considered as a property, whether it should come under the purview of private property or in a public domain (ibid). The philosophers like John Locke, Hegel, Robert Nozick and Jeremy Bentham strongly defended the private ownership on the knowledge acquisitions (ibid). In contrast, the critical and postmodern thinkers strongly opposed the self-private ownership of the knowledge. The justificatory theories have two major arguments to defend individual ownership

[5]Product patent is granted when a new product has been invented by the person or manufacturer. The product so invented may be useful than an already known product or a new product altogether.

[6]Process patent is granted for a new process of manufacturing and already known product or for manufacturing a new product or for manufacturing more articles of the same product that is reducing the cost of already known product.

of intellectual property. The first one is the '*self-ownership'* (of knowledge), since the creations of human mind are the part of '*self*', the individuals have an exclusive ownership rights on its exercise (Chandra 2010: xxiii). The second one is the '*utility'* of IPRs, *incentive-to-invent* justification, arguing that any property including the intellectual property creates incentives for productivity as well as promotes 'greatest overall satisfaction' or 'welfare' (Chandra 2010 xxiii & 92; Sterckx 2004: 66).

Major justificatory theories of IPRs are the extension of the justifications of the tangible private property and later it was applied to intangible private properties like ideas, knowledge, skills etc. Chandra (2003: 6). She argued that this extension "represents the second reification[7] of the concept of property" (ibid).

2.2.1. Natural Rights

The natural right defence on intellectual property is primarily derived from John Locke's "Labour theory of property", which he formulated in his work *Second Treatise of Government* (Sterckx 2004:62). Locke argues that, since it is *natural to men*, the primary purpose of the society or the state would be the rights to protect the property of the human beings (Chandra 2010: 31). Moreover the preservation of their private property is the "basic motive of men uniting under the commonwealth" (Richards 2002:525)

Firstly, Locke writes about the existence of a *common* that will be freely accessible to all. Even though it is common to all, once one has applied his labour on it, he can appropriate the things from the common. According to Locke;

> "God, who hath given the world to men in common, hath also given them reason to use of it to the best advantage of life and convenience. …though all the fruits it naturally produces …belong to mankind in common …as they are produced by the spontaneous hand of nature, nobody has originally a private domain" (Locke 1698).

Moreover, "Every Man has a property in his own person" (Locke 1968). Since nobody has any rights on his own body else than he, the "labour and the work of his body are exclusively his" (Locke 1698). He can appropriate the things from the common land *as a property* by "mixing with his labour", "as much he can", unless the limitations of the "fundamental law of nature": "at least where there is enough, and as

[7]Reification generally refers to making something real, bringing something into being, or making something concrete.

good left in common for others" (Locke, 1698; Chandra 2010: 31; Stengel 2004: 27; Sterckx 2004:62). Even though Locke laid the foundation for the moral groundings of modern concept of property he recognises the chances for an over accumulation from the 'common' (Richards 2002: 524). He believed that over accumulation has results to *waste* and it will become a breach of others right in the society (Richards 2002: 524).

> "The labour of his body and the work of his hands, we may say are properly his. Whatsoever, then he removes out of the state that Nature hath provided and left it in; he hath mixed his labour with it, and joined to it something that is his own, and thereby makes it his property…. For this labour being unquestionable property of the labourer, no men but he can have a right to what that is once joined to, at least where there is enough, and as good left in common for others" (Locke 1698)

Robert Nozick, an extremist libertarian extended Lock's self-ownership theory with "workmanship ideal" (Chandra 2010: 39). He links *personal* productivity with the entitlement of property rights (Chandra 2010: 39). According to him the principle of justice lies in *person's holdings* (Nozick 1974: 150).His definition of principle of *holdings* covers three fundamental principles; "principle of acquisition", "principle of transfer" and the "principle of rectification" (Nozick 1974:150 & 152). This is called *Entitlement Theory* (Chandra 2010: 41). Nozick has challenged John Rawls' *distributive justice*, arguing that justice involves "inviolable entitlement to external goods" as human beings' creations (Chandra 2010: 39-40). In order to uphold the justice the people should be encouraged for personal holdings as well as its transfer under an entitlement system (Nozick 1974: 159). Apart from Lock's self-ownership rights on property, Nozick introduced a "*principle of transfer*" of the holdings of individuals. In his words, "in a free society, diverse persons control different resources and new holdings arise out of the voluntary exchanges and actions of persons" (Nozick 1974:149-50). He criticised the Socialist system of common ownership also arguing that socialist distribution system is unjust (Nozick 1974). Chandra (2010: 43) pointed out that "it would form a legitimate basis for absolute ownership in all productive resources". While reading Nozick's entitlement theory and the *personal* justifications, we can find out a philosophical legitimization for a capitalist minimal state or a *miniarchy* and free market (Nozick 1974).

2.2.2. Personality Justification[8]

Hegel's theoretical intervention takes the philosophic debate to further extend. His property theory was mostly based on individual personality. In his ideas, *self-realisation* or *self-development* needs a protection of property as an extension of one's labour (Hughes 1988: 330). It is the necessity of an ideal society to acknowledge the private property as an incentive to self-realisation to actualize social development (ibid)

The initial part of the first section of Hegel's work *Philosophy of Rights'* deals with his ideas on property, focusing on two prime concepts: *freedom* and *will*. He rejected the libertarian notions of absolute freedom; rather he places an idea of freedom as a "realisation of necessity" (Richards 2002: 528). The accomplishment of freedom rests on the amalgamation of 'objective' and 'subjective' freedom (Stengel 2004: 39). In contrast to an absolute freedom, an individual can exercise his free will under the institutional framework of law (Stengel 2004: 39). For him, "freedom constitutes the substance and essential character of will", it is the prime necessity of will (Hegel 2001: 28, section 1:4).

Furthermore on property Hegel argue that it is the "embodiment of personality" (Stengel 2004: 40; Richards 2002: 528). This is accomplished in two ways. Firstly the property facilitates a person to satisfy his fundamental needs and secondly it enables a person to transform from an "inner subjective world to external objective world" (Richards 2002: 528; Hegel 2001: 51, section 1: 41).A person becomes a rational being when and only in the realisation of possessions (Hegel 2001: 55-56, section 1: 41). Once the society acknowledges the property as an extension of one's will on objects in order to realise personality, it incentivises the free actions of an individual (Hughes 1988: 334). In other words, for Hegel, an individual doesn't have any rights on property, without the manifestation of his will on the object (Hughes 1988: 334). Similar to Locke's idea of mixing up of labour into the common gift of God, Hegel wrote, "[a] person's putting his will into an object is the conception of property (Hegel 2001: 62, section 1: 51, Stengel 2004: 41; Locke 1698; Sterckx 2004:62;

[8]Borrowed from Hegelian philosophical defense on private property

Chandra 2010: 30).Since the 'will' is in an individual, the nature of Hegel's conception of property will be private (Richards 2002:528).

Hegel criticised Plato's *Republic*, because that makes a person unable to hold property. It is more reasonable for a society which enables a 'private possession' of property (Hegel 2001:58-59,). Further, he extends his conception of property (property as a vehicle to realise one's personality) into the composition of a state. His ideal state is 'bourgeois in nature that consists of independent property owners who realize his will and personality (Richards 2002:528). To him inequality is natural since it is rooted in the inequality in one's personal ability to direct his will on objects (Hegel 2001: 57, section 1:47; Richards 2002: 528).

2.2.3. Utilitarianism

Utilitarianism is considering as a theory that has given a most credible philosophical defence to the neoclassical economic order and the market system as well as the intellectual property (Richards 2002: 525). This theory was mostly guided by the writings of Jeremy Bentham. In an ideal utilitarian society, law of the land and the social policies should use utility as a guiding principle to increase the productivity and efficiency and to enhance distribution function (Chandra 2010: 51). The utilitarians considered that the institution of property provides an incentive to the property holders to enhance the productivity in order to attain "greatest happiness of the greatest number of the society" (Chandra 2010: 51).

Utilitarian philosophy considers utility will be the prime principle of all actions of the individuals and the governments as well as the prime force behind the reason and law (Bentham 1823).According to him,

> "By utility is meant that property in any object, whereby it tends to produce benefit, advantage, pleasure, good, or happiness, …or …to prevent the happening of mischief, pain, evil, or unhappiness to the party whose interest is considered: if that party be the community in general, then the happiness of the community: if a particular individual, then the happiness of that individual" (Bentham 1823).

Utility is the norm that "approves or disapproves" all the activities in the universe (Bentham 1823, 14; Chandra 2010: 52). The governments formulate policies and legislates laws according to the utility of those things. It should produce "greatest happiness to the greatest number in the society" (Richards 2002: 526; Chandra 2010:

53). They considered that the protection of the rights to property ownership will provide the 'greatest happiness' (Chandra 2010:53). Therefore the governments and its legislative measures should provide proper security to benefit their labour, to make sure the individual's willingness to their labour (Richards 2002: 526).

2.3. TANGIBLE PROPERTY TO INTANGIBLE INTELLECTUAL PROPERTY

The liberal thinkers believed in the individual's rights on their own body. His body produces labour. The great libertarian, Locke, believed that if he mixes labour with the common objects that is given by god that becomes his property (Locke 1698; Sterckx 2004: 62; Chandra 2010: 30). The "law of nature" has given him an absolute right on his property as a product of self and labour (Chandra 2010: 31). Locke's originally propositions were about tangible properties such as land but later his ideas were interpreted and extended to intangible properties like intellectual property (Sterckx 2004: 62). Since it has been one's intellectual or mental labour, that person has an absolute right on that intellectual good. Even though the right holder or his licensee sell the real output (like a television, software, book, musical composition etc.) of the intellectual property to another person, the idea that applied to the tangible output still remains with the property holder. Hegel called it as a "*second value*" (Stengel 2004: 42).

> "Since the owner of such a product, in owning a copy of it, is in possession of the entire use and value of that copy *qua* an individual thing, he has complete and free ownership of that copy *qua* a individual thing, even if author of the book or the inventor of the technical devise remains the owner of the *universal* ways and means of reproducing such products and things. *Qua* universal ways and means of expression, he has not immediately alienated them, but may reserve them to himself as a means of expression which belong to him" (Hegel 2008: 80).

This is indicating that, the owner of the tangible goods (the real product) of intellectual property has given an absolute right to use, sell, rent or even scrap the product. At the same time he doesn't have any right to use the knowledge or IP behind the product without the consent of the intellectual property holder.

The foundations of Locke's self-ownership theory can be applicable to intellectual property. Justin Hughes gives a potential interpretation of Locke's theory on property in order to validate it in to intellectual property. He has given normative as well as instrumentalist account for justifying intellectual property by expanding John Locke's labour theory. Hughes argues creativity or an invention involves Lockean labour. Any

labour involves an amount of 'pain'; therefore it is unpleasant to do without a fair incentive (Hughes 1988: 302; Stengel 2004: 28).

> "For most of the people creation is less than fun than recreation. Although idea work is often exhilarating and wonderful, it is something we generally have to discipline ourselves to do, like forcing one-self to till the fields of work the assembly lines" (Hughes 1988:302).

Creation of an idea comes at the expense of one's valuable time and social and or family life. Apart from that an amount of risk of losing money and the rival inventions[9]are also involved in it. As a matter of fact, the creative labour becomes motivated to perform only under a system of private property (Hughes 1988: 303). His instrumental proposition becomes an addition to the 'value-added theory', which is normative in nature, and reaffirms the utilitarian justifications. In the similar vein of other utilitarians, Hughes adds public welfare defence on it. As of the intellectual labour produces an amount of value to others (inventions as a vehicle for the development) in order to enhance the public welfare, intellectual creativities should be acknowledged by giving ownership property (Hughes 1988: 303-305; Stengal 2004: 29). This value of intellectual labour is acknowledged in various international and national IP laws and other legal as well as constitutional documents. US constitution acknowledges this in following lines,

> "To promote the Progress of Science and Useful Arts, by securing for limited Times to Authors and Inventors the Exclusive Right to their respective Writings and Discoveries…[10]" (Constitution, US 1776:#1:8)

The intellectual property justification meets the Locke's distribution justice or the "enough and as good" criteria as well. Intellectual goods are eternal in nature. So, one's consumption could not spoil the "natural common" or public domain (Stengel 2004: 29).

Moreover intellectual labour adds a value to the common or public domain knowledge. Hughes (1988) explained this argument in his "principle of labour desert" or "value-added theory". The '*value*' or '*usefulness*' will enhance public welling. Therefore the people should be compensated according to the labour behind that value or usefulness (Watal 2003: 71). The new addition to the knowledge or a new

[99] The simultaneous inventions under competitive manner to invent fist, the first will get the patent protection, and the others will lose accordingly.
[10] Constitution, US Article 1 (1776)

alternative process will enhances productivity, effectiveness and efficiency. Patentability of an invention in TRIPS document follows this idea:

> "…patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve inventive step and are capable of industrial application…" (WTO 1994: Section V, Article 27)

TRIPS' Article 27's footnote (5) makes it much clearer. We can read out the 'value' of an invention with the patentability 'product' and 'value-added' patentability of process when the foot note mentions about the 'usefulness' of the same:

> "For the purpose of this article, the terms 'inventive step and 'capable of industrial application' may be deemed by a member to be synonymous with the terms 'non obvious' and 'useful' respectively" (WTO 1994: Footnote 5).

It is envisaged as a mutual benefit theory; once the society acknowledges the claims of property rights on intellectual goods, the services of those creations generate returns on the public welfare.

He argues that, similar to the application of physical labour on the natural commons and the resultant entitlement of physical property, intellectual labour is also entitled to property (Richards 2002:530). According to him, Locke's justification of private property is more than enough to justify an exclusive right on intellectual property (Richards 2002:30). Since it is immaterial in nature, it is not vulnerable to scarce. The Lockean proviso, "enough and as good" is insignificant in the context of appropriation of intellectual goods (Richard's 2002: 530). A value of an intellectual property is derived solely from the act of creation (Hughes 1998: 328). Moreover after a limited period, (patent duration), the creator will have lost the control consequently that enhances the common or the public domain. Hughes argues that "enough and as good condition seems to hold true only in intellectual property system" (1988:329).

Moving from the aforementioned discussion on the self-ownership based normative propositions of IPRs; the discussion now turns the on *utilitarian* justifications of IPRs. Utilitarian justifications are the second generation defences of IPRs. Today's intellectual property laws are grounded fundamentally on explicit utilitarian concerns (Watal 2003: 92). As explained earlier, utilitarianism believes in ownership as a tool to maximise overall happiness, in terms of improved productivity, efficiency, economic development, technological advancement and so on (Sterckx 2004: 67).. The Utilitarian theory believed that acknowledgement of one's IPRs and its resultant

profit delivers an incentive for the advancement of useful knowledge (Richards 2002: 537). Indeed, it is almost certain that the capitalist rationale of intellectual property will be true only if they are motivated by a high return on his talents (Richards 2002: 537). Therefore the social policy and laws should follow the rationale of utility in order to optimize the social utility of the intellectual property (Watal 2003: 93). Sterckx (2004: 66) highlighted utilitarianism's two basic validating arguments which are; (1) "incentive-to-invent-and-innovate" and (2) "incentive-to-disclose". The first one highlight the necessity of encouragement to invent by securing their patents and other kinds of rights and the second one highlight the necessity of a system of motivation in order to keep out the secrets of their inventions.

One of the rationales of the intellectual property is derived from Garrett Hardin's "tragedy of the commons"[11] hypothesis which is related to scarcity (Chandra 2010: 94). Without incentive to innovations, the people will not be motivated to invent. *Scarcity* lies in under-inventions in this context. If the intellectual property regime is an unregulated common, it will discourage the people to invest their time and money in the search for new technology and ideas (Symonds 2014). He identified this situation as a "market failure" under-investment in innovation. Chandra (2010:93) describes the utilitarian counter-argument favoured a private ownership in order to rectify the 'tragedy of commons' and resulted in intensified *scarcity*. Symonds used this idea to justify the 20 year duration of patent. Once the patent duration is over, the idea or invention would be automatically entered the common (Symonds 2014). Everybody will be free to use and develop this public domain. This will expand the 'common'.

Utilitarian defence asserts that in the absence of IP laws or a proper security to intellectual activities the free riders stall the fruits of IP with zero or minimum labour

[11] Hardin originally used this idea to explain how over exploitation leads to scarcity while such things are held under a 'common'. The 'common' encourages only exploitation of things from it without any efforts to cultivate the common. This is the tragedy in common; over exploitation ruins common. His original idea was a criticism of unregulated common, but later its metamorphic interpretations used to explain similar other things. He suggested property rights to enhance the common. He gave an example of grass field to explain his idea of common. Since it is unregulated the grass field may be ruined by over grassing and its irrational use. In an unregulated field, as well as in an absence of exclusive rights on it, the people will act irrationally. They will take more and at the same time put very little. Once the individuals are granted property right on it or a portion of it, they will plant grass and expand the field, in turn the common too.

(Chandra 2010). It would seriously harm the future of potential knowledge industry and impede innovation and the resultant growth (Chandra 2010: 95). As mentioned earlier this market-capitalist logic was very evident in the construction of the modern Anglo-American intellectual property laws, as well as in arguments of the highly regulated international intellectual property regime[12]. These laws justified the regulations on knowledge in the name of progress of the science, technology and arts, and its resultant usefulness of the societies' overall development (WTO 1994; US Const. Article 27).

2.4. CRITIQUE TOWARDS INTELLECTUAL PROPERTY RIGHTS

The most of counter arguments on the justifications of intellectual property rights is arising from the very nature of *individuality* in the knowledge. In doing that the critiques questions the notions '*self*', '*private'*, and '*exclusivity'*, which forms the institution of intellectual property. The questions were raised from the incorporation of the aforementioned ideas with the IPRs. All major criticism on IPRs is cantered around these three aspects.

As mentioned in the previous discussion, we can see that the moral or normative justifications of intellectual property largely focussed on the role of *individual* or '*self*' in the creation of knowledge. The moral justifications of Locke, Nozick and the personality defence of Hegel were locating the discovery of knowledge in one's body or self. Critics questioned their basic foundations of *person*, *self*, or *individual*. In doing so, the critiques argued that the ideas do not have a single origin or a location. They are a part of complex social process, therefore they may be located in many persons from many generation; in other words there are "the multiple locations of ideas" (Chandra 2010: 67; Perelman 2003: 310). From this point, they argued morality is laid when ideas or knowledge are located in a 'common' or 'public domain' and in its open accessibility (Perelman 2003; Perelman 2003a). Since the ideas or knowledge are located in a common or a multiple location, the *novelty* will be nothing. Regarding *Utility*, from a critical point of view we cannot say that the

[12]US constitution highlights the utilitarian defence in Article 27. That mandated the necessity of an exclusive right to the inventors and the authors to promote the progress of science and useful arts. TRIPS agreement also acknowledged the usefulness or the utility of the inventions and its patentability.

capitalist-market logic is correct. In utilitarian justification according to Bentham (1823) use-value is the "greatest happiness of greatest number" in the society. When a majority of the world's population lacks the access to essential or lifesaving medicine, facing under-development due to an unfair transfer in technology of expertise and living in poverty, the market logic of *utility* will be questioned (Perelman 2003; Chandra 2010; Brook 2005).

2.4.1. Critique on Self-ownership

The criticism on the self-ownership defence begins from challenging the natural right theory of intellectual property rights as an *individual* derivation. They are pointing out the prominence of the social constituency in the creation of knowledge (Perelman 2003; Richards 2002). An art, a literary work or an invention does not occur in a vacuum but in an intergenerational complex social process (Chandra 2003: 68-69; Perelman 2003: 310; Richards 2002: 531). Richards (2002:531) considers knowledge as a social creation rather than *individual*. Separation of an individual from his social and historical process in the creation of knowledge is difficult (Chandra 2010:69).

While justifying intellectual property with Locke's labour theory, it contradicts itself with his proviso "enough and as good". For his intention will be correct when ones ownership on a particular idea cannot leads to a loss of others. In other words a private appropriation of intellectual goods will be justifiable only if that doesn't make scarcity. One's consumption does not make it scarce. It can be used for multiple people at the same time. But once it is entitled as an IPR, it prevents others from making use of it (Chandra 2010: 84). In short an IPR creates an "artificial scarcity". G.A. Cohen has challenged the very nature of the aforementioned monopolisation of knowledge in a capitalist system by arguing that, "any appropriation will make someone worse off for the reason that no one will be able to appropriate the already appropriated item" (Cohen 1995 cited in Chandra 2010: 84). Moreover, Cohen states that the liberty of the capitalist system will be the liberty of the property holder, rather the 'have notes' and this sacrifices liberty of the people who lacks necessary conditions to attain the freedom (ibid)

Chang (2001: 18) describes the "potential wastefulness" in the field of scientific discoveries while giving patent right to the first applicant. The critiques argued that in the present IPR regime, "winner-takes-all" by excluding the rest from innovation

process (Chang 2001:19). This all out competition may secure the first applicants knowledge but prevent the creation of genuine knowledge (Chang 2001:19). Chandra (2001: 72) also presents a similar idea; "[t]he market can give great rewards to the person who successfully claims property rights for a discovery, with little or nothing for the person who just missed out". It is only in an "all-out competition", the "first knower" appropriate all and the rest nothing. Apart from that it reduces the alternative chances of welfare even if that will be better than the first one (Chang 2001; Chandra 2010: 74).

With this fact, the very nature of *individual* freedom, in the domain of knowledge creation again falls into internal contradiction. Originally Locke's theories derived from a period of absolutism of monarchies that was prevailed in the France and other parts of Europe (Bhargava and Acharya 2008: 193). He put forward his idea of individual supremacy and the natural labour theory to contend the notion of *state* as an end as well as the "concentration of power in the hands of Monarch" (Bhargava and Acharya2008: 1993). But in contradiction, Locke's theories built a foundation for the supremacy of intellectual property over other rights, such as right to expression, right to food, right to health, right to development and even right to live.

2.4.2. Critique on Utility of IPRs

The core of the utilitarian justification is by the "incentive-to-invent-and-innovate" argument (Sterckx 2004). The rewarding of ownership rights to intellectual products has a *utility* which generates incentives for productivity as well as efficiency and consequently an overall development (Sterckx 2004: 66; Chandra 2010: 92). Therefore in order to optimise social utility, the laws of the land should acknowledge such property rights (Chandra 2010: 93-94). Moreover, in the absence of such ownership rights, the knowledge creation will be reversing into a worse.

While describing the failure of utilitarianism, Richards (2002: 539) completely denied the idea of "tragedy of common"[13]. He questioned the utilitarian arguments in the background of market failures and argued that, market failure is not a result of the tragedy of commons but a result of "tragedy of anti-commons" (Richards 2001:539). He explains his criticism by illustrating some facts from human genome project. It

[13]See tragedy of commons (foot note 7)

was basically a public domain research. But some private profit making companies like *Celera Genomics* claimed some fractions of DNA sequences (Zoe 2004). A speculation on patent race on DNA maps impeded the process of scientific enquiry until the public statement by the US president. He announced in 2000, that DNA sequence could not be patentable and it will be available in a public domain. From this case it is very clear that a petty competition (pre-patent period) and the under competition (post-patent period) and the resultant tragedy in scientific enquiry will be happening only in "anti-common' and not in the "common".

Generally most of the critics argued that there was no sufficient empirical data to prove the protection-innovation-development relationship. The history of the intellectual property proves that most of the developed countries achieved their present status in a pre-protection or minimal-protection era (Chang 2001). Thus they denied a high level intellectual property protection, which incentivise the development argument. Most of the critiques considered the utilitarian justification as a tool for capitalists in order to maximise their profit with minimum effort. It will be a perfect monopoly under an absolute right on IP, which prevents the entry of other competitors. Sterckx (2002: 537) believed that, the producers of intellectual goods are characterised by 'intellectual capitalists' who are primarily motivated by maximum return rather than dissemination of knowledge or an overall development of the society. The dissemination of knowledge will be true only if the hypothetical beneficiaries are able to pay or are willing to pay; in short if their purchasing power is optimal (Sterckx 2002:537; Sunder 2006: 283). Therefore it is the *utility* of the market alone, not the society as whole.

2.4.3. Marxian Critique

Marxian critique on intellectual property, similar to the critique on the private property, is evidently taking on the capitalist system and its natural tendency of commodity fetishism. As "capitalism is a greedy system", they will appropriate everything under the sun into private property (Brooks: 2005). "In doing so, it inevitably destroys all those things we hold in common – the commons" (Brooks: 2005). Furthermore, in a capitalist system the knowledge will be alienated from the society or commons that it made. Raduntz (2006:8) argued the "conversion [of intellectual property from its social context into a capitalist-market form of private

property constitutes a major break with the tradition because it affords its individual owners' exclusive use of an essentially social product for capital wealth creation".

They believed that the regime of intellectual property is a by-product of capitalist logic of commodification of knowledge and information. Perelman (2003, 2003a) critically questioned the utilitarian justifications of intellectual property by which the IPRs stimulates the scientific and technological development, indeed such kind of protections paradoxically strengthen the class divisions, inverse the real spirit of science and technology and public university education etc.

> "The dramatic expansion of intellectual property rights represents a new stage in commodification that threatens to make virtually everything bad about capitalism even worse. Stronger intellectual property rights will reinforce class differences, undermine science and technology, speedup the corporatisation of university, inundate society in legal dispute, and reduce personal freedoms" (Perelman 2003 a).

Overall the Marxist critiques focused on the concept, what Marx referred as the "universal labour" to mention the intangible property, in order to challenge the new capitalist logic of knowledge monopolisation towards profit maximisation instead of public interest. First of all they challenged the legitimacy of Intellectual property as an independent economic entity.

> "[V]irtually no technology is a product of a single person or even a single corporation. Ideas and discoveries, what Marx called "universal labour," draw upon a multitude of sources… science and technology depends on a complex network of information flows, reinforced by a publically supported educational system. In this social labour process scientists or artists draw on the work of their predecessors" (Perelman 2003: 305).

Every progress in technology and every new discovery involves something what we discovered in the past. A "[pure] scientific research, which lies behind the technology, takes even longer before it begins to affect our daily lives" (Perelman 2003: 305). But under the present regime if once it becomes their property, the people will be excluded from that product, which are produced by using their knowledge – public domain, until and unless they pay for that. This is what Brook (2005) called "expropriation"; an exclusion of common people from "the commons".

The proponents of intellectual property rights argued that, the utility again extends by making very slight changes in the existing patented model/design/composition. There for the minimum protection is justified again for the 'newly' improvised model/design/composition. But in fact, the present regime is nearly a failure in

tackling this "ever-greening" process of the patent and by this process the patent holders retain the control over the patents even if the patent term gets over (Chandra 2010).

Today the development of technology is accelerated in a high level and new innovations /improvisations are coming in a very short period. For example the CD is replaced fatly by the DVDs. It is predicted that the "chip [integrated circuit] performance would double every 18 months" (Boyce and Huw 2015: 452). In this context of rapid progress in technology, the patent life which prolongs up to 20 years in the name of utility cannot be justified.

Moreover, the very logic of "incentive-to-invent-and-innovate" (Sterckx (2004: 66) as a motivation to activate in the scientific and technological innovations, is a sheer lunacy in this context. The "winner takes all" logic creates an "all-out competition" in the present IP regime (Chang 2001: 18-19; Perelman 2003: 306). Indeed strong IPRs may prevent the fellow competitors from innovate a socially useful innovation (Levin et al. quoted in Chang 2001:19). In this context the credibility of 'utility' or the 'usefulness' of the IPRs will be challenged again. While offering an absolute right over one's discoveries within a zero-sum game, the same monopoly capitalism is unable to return anything to "the others who have contributed to its creation"(Perelman 2003: 306-7). However the utilitarian justifications of modern capitalism failed to acknowledge the true spirit of science and even the spirit of the competition itself. Perlman (2003: 308-311) classified scantiness IPRs' development aspect into the following points: (1) it fails to recognise the multifarious social process of a scientific and technological development while granting IPRs into a single individual or a corporation; (2) it fails to reap benefits out of public spending on scientific enquiries by subsidizing or giving grants to Research and Development (R&Ds), while refusing to make the outputs of 'universal labour available to all or undermining the role of public spending in pure scientific research data in the value-added IPRs[14], (3) it failed to expand the scientific 'common', by cumulating the

[14] One of the major examples is Human Genome Project. That was initially a collaborative public spending research endeavour in order to decode the secrets of DNA. Once the former employee of the National Institute of Health Grieg Venter applied for a patent for a fraction of human genome, the project itself threatened by private property. In fact there is nothing as an absolute private property in most of the private spending R&Ds while they using the public domain pure scientific research.

knowledge into it, (4) while holding a major portion of the world's population in poverty, diseases and epidemics such as HIV/AIDS, malaria, cancer etc., the so called capitalist logic of utility of IPRs will be again challenged; (5) it failed to protect the existence of species, while filing patent application for human genome, plant varieties, seeds, etc., (6) it will divert the potential spending of time of an scientists to petty legal complexities instead of spending on their research; (7) the holy idea of capitalism – profit, undermines the history of the broad minded interests of the world's great scientific enquiries while prioritising the interest of the MNCs (Multi-National Corporations) and TNCs (Trans National Corporations).

Chapter 3

UTILITY V/S HUMANITY: IMPLICATIONS OF POLITICS OF IPR ON GLOBAL ACCESS TO MEDICINE WITH SPECIAL REFERENCE TO CANADA'S ACCESS TO MEDICINE REGIME

Recent years, there has been an increasing attention on the issues of access to health care particularly with regard to access to medicine. This issue has been considered as a responsibility of the concerned national constituencies, but since there is an enormous spread of diseases beyond the national barriers and an increasing trend of free mobility of human beings as well as epidemics across the world, the attention of international community has been turned towards global public health and access to medicines. Since the spread of HIV/AIDS acknowledged as a severe threat to their lives and personal liberties; the international community realised the need for an international cooperation in the containment of such diseases across world.

An estimated "two billion of world population[15]" is lacking essential medicine in the world; among that a large majority constituted under developing and least developed countries; a "34 million[16] people is living with AIDS", 9.8 million[17] (among 15 million[18] estimated HIV/AIDS people) who are living without access to ARVs are from developing and least developed countries; around "0.5 million to 1 million[19]" Neglected Tropical Diseases[20] (NDs/NTDs) affected people losing their life per year because of lack of access to essential and affordable medicine (Chandra 2010: 185-186; UN 2012: 63). United Nations', "Millennium Development Goal (MDG) Task Force Report 2012" noted that "the poor continue to face difficulties in obtaining or purchasing essential medicines because of scarce availability and high price" (UN 2012: 61)

[15]According to WHO estimation: "The world Medicines Situation" published in 2004
[16] According to MDG Task force Report 2012
[17]According to WHO estimation: "The world Medicines Situation" published in 2004
[18]*op.cit.*
[19]According to a study estimation of George Washington University
[20] NDs are generally considered diseases of poor region. It is because of poor, focus of R&Ds on it has been very poor.

3.1. HUMANITARIANISM V/S UTILITARIANISM AND ACCESS TO MEDICINE

In the existing phase of world politics the *humanitarianism* claims an important space. Andrew Heywood (2012: 318) defined *humanitarianism* as an act of "being concerned with the interests of humanity, specifically through desire to promote welfare and reduce the suffering of others…" While millions of people lost their life due to war, genocides, terrorism, environmental crises, ethnic cleansing, spread of diseases and epidemics, the critical versions of humanitarianism questioned every paradigm of world politics. It questioned the paradoxes of the existing humanitarian actions or interventions and its unproductive outcomes with respect to the humanity (Fassin 2007). They put forwarded new *modus operandi* in order to meet the humanitarian crises.

According to Fassin (2007: 500) "[t]he rising question of humanitarian action as it constitutes one of the paradigmatic forms of a political life, by introducing this dialectic between lives to be saved and life to be risked". He questions the existing international structures and its interventions which are dominated by western paradigms, for its nature of violence. In the existing hierarchy of international structure; the "humanitarian arena" is submissively established therefore that couldn't be acknowledged the real sense of humanitarian actions (Fassin 2007: 516). Moreover he argued that the existing structures and politics may be identified humanity and the need for humanitarian actions but with an understanding of the "market value" of that humanity having (Fassin 2007: 516)

The international discourses over access to medicine has ascended the academic world as well as political attention on *humanitarianism* and the impact of world intellectual property regime on it (Okediji 2014: 307). The world's dominant developmental ideals have places *utilitarianism* in a prime position. Consequently this has been reflected in the dominant policy discourses as well as the policy outcomes. On one hand the *utilitarian* philosophies has been defended the high level protection and the private ownership of IP or knowledge in the name of development and innovation[21], while on the other hand it neglect the public health and the need for access to medicine. While billions of people are struggling with diseases without

[21] This was discussed in the Chapter - 1 in detail

proper availability and affordability of medicines, the humanitarian concerns becomes an important subject matter in every international as well as national discourses on health and diseases. Since the establishment of TRIPS, this debate goes to an extended level and resulted in a number of international declarations and initiatives (Doha Declaration 2001, August 30 Decision, Millennium Development goals: Access to medicine and many initiatives by WHO and CAMR etc.); as well as counter balances (TRIPS plus agreements, Trade sanctions etc.).

Humanitarianism offers some ethical and moral questions to the world politics. In contrast with the utilitarian philosophers and their "incentive-to-invent-and-innovate-and-disclose" and the consequent overall-greatest happiness or development argument, the humanitarianism put forwarded some ethical questions (Sterckx 2004: 66; Richards 2002: 526; Chandra 2010: 53). While a one third of the world's population still lacking access to affordable medicine, millions of people have been losing their life because of lack of medicines and health care, the humanitarianism questions the utilitarian logic of the "overall or greatest" happiness via a high level intellectual property protection (Esmail and Kohler, 2012). The following part of this chapter will be dealing this discourse in order to study how this affects the international politics.

3.2. STRUCTURAL INEQUALITIES OF IP REGIME AND ACCESS TO MEDICINE

There exists a definitive inequality in terms of access to medicine in this world. Among the one third population who lacks the access to medicine in the world are from the world South[22] (Esmail and Kohler, 2012). Obviously, the lower income rates and the poor economic development of these countries source the lack of access to medicine. But the structural inequality existing in the IPR regime has been overhead all other factors in the issues of access to medicine in the world. In this context, while imposing these unaffordable prices to the essential medicines we cannot be consider the historically privileged developed countries and the developing and underdeveloped countries in a similar manner in the world's intellectual property regime. In order to address the issue of access to medicine, the IP regime would have to acknowledge the need for a differential treatment.

[22] Generally used to mention the developing and least developed/underdeveloped countries of the world

It has been commonly assumed that the politics of intellectual property regime has been a potential impact on the global access to essential medicine. Unlike the traditional manufacturing, the market based production of modern evidence based medicine attached by in-house R&Ds, needed exclusivity in their intellectual property there by facilitating national and international institutional mechanisms to monitor and maintain the same. In doing so they bargained/lobbied the political institutions for the sake of increased production and the so called "greatest" good for the health of the people. This (pharmaceutical) industry-political relationship sets the political economy of the pharmaceutical production as well as the access to medicine (Chang 2001).

In the existing structural inequality, without a differential treatment (rather a uniform system for all), the developing countries could never reach the status of the developed world, which they are now holding. History of intellectual property illustrates that; developed world achieved this status without a strong patent law, or minimal protection. Chang (2001) argued that, there is no adequate evidence to prove the utilitarian rationale of "incentive-to-innovate-and-invest" on IPRs; or it incentivises investment. The history of the developed countries such as Switzerland, Canada and Italy never show an IP protection-investment correlation; and with reference to Switzerland's case it was in the absence of patent law (Chang 2001: 27).

Apart from the issues in the supply chain; the inequality has existed in innovative activities also, in the IP regime. It has been proved to be true that in the case of the neglected diseases (NDs) or tropical diseases are almost neglected from the domain of international pharmaceutical research network while the non-communicable lifestyle medicine or on cosmetic medicines are getting more attention. Thomas (2012: 259) pointed out the paradoxes in the so called utilitarian incentive to innovation and invests argument. According to him it is true that the shares of spending on R&D of the pharmaceutical companies are optimal, but their 90% of pharmaceutical research are focusing on the drugs for the North, who constituting only a 10% of the total global population (Thomas 2002). Moreover, between 1975 to 1997 a total 1233 new medicines entered the market, but only 13 among them were medicines for the tropical diseases (Thomas 2002: 259) This reveals the paradoxes of the so called utilitarian justifications of intellectual property rights as well as the failure of the IP

regime in addressing the innovation lag of this region rather than a petty profit driven logic.

It is very difficult for the developing and least developing countries to incentivise investment and development while 97%[23] of the world's patents are coming from the industrialised developed countries (Chang 2001). Global pharmaceutical market estimated a value of around 406 billion dollar in 2002 (Bruce 2003). Among that the developing countries' share constituted only a 20% against a minority of Developed countries' (US, EU and Japan) 80% (Bruce, 2003). Bruce (2002) argues that this trend is a result of the political economy of the patent system. As per the general market logic, it not profitable to encourage pharmaceutical research on developing countries' requirement, but it is the requirements of the developed countries. This embedded inequality in terms of *research gaps* as well as the medicine *access gaps* in the intellectual property regime will provide a good foundation for an analysis of the politics of intellectual property regime and the politics on access to medicine.

As mentioned in the History of Intellectual Property Rights, incorporation of IPR as a trade related issue and the resultant international institutional settlement of the IP related issues lead to the emergence of WTO-TRIPS in 1995 (Watal 2003) . This marked an era of transformation in the world's free trade as well as the intellectual property regime. The major question of access to medicine emerged when the TRIPS mandated a minimum standard of patent protection (for both process and product) to the member states "in all fields of technology" without any discrimination to foreign patents (WTO 1994; Article 27; Watal 2003; Chang 2001; Chandra 2010; Correa and Matthews 2011: 6). Moreover in TRIPS' Article 27 (the subject matter) specifically clarified that the pharmaceuticals are also a matter of technology: "diagnostic, therapeutic and surgical methods for the treatment of humans and animals" (WTO 1994). Moreover the TRIPS introduced product patenting on the pharmaceutical products in the developing countries ('t Hoen 2009: 5; Sterckx 2004: 60 – 61; Watal 2003). The patent regime in the pre-TRIPS era did not mandate 'product patent system on the pharmaceuticals'[24]: it was a choice of the national governments

[23]An estimation of United Nations Development Programme, sited in Chang (2001)

[24] Sterckx (2004) explains, in the pharmaceutical industry patenting on product denotes the actual structure or the chemical composition of the drug. The production process or the application of the drug is not a matter in domain of product patent. It is difficult to produce the same drug with another

(Chandra 2010: 190). For example Indian Patent Act 1970 and the Brazils Patent Act 1970 clearly stated it doesn't allow product patent on pharmaceutical sector. This has facilitated an enormous growth of generic pharmaceutical industries in these countries and which consequently increased access to affordable medicine in their national constituencies as well as other poor countries through exporting. (Sterckx 2004: 61; 't Hoen 2009: 5-7).

However, once they were compelled to accept the TRIPS they lost the opportunity to produce the low cost generic alternatives by altering the *process* of patented drug production method or by slight variant combinations via *reverse engineering*[25] as well as traditional affordable generic pharmaceutical market (Chandra 2010). Once the transition period that was given to the TRIPS agreement expired, the "world's largest producers" of generic alternatives, (had to) amended their national patent laws and "introduced product patents on pharmaceuticals" ('t Hoen 2009: 6). India, the world's largest generic pharmaceutical producer accepted the product patent system and it has been in effect from 2005. India has been the "largest generic manufacturer in the world"; accounting for around "60% of total Anti-Retroviral (ARV)" AIDS medicines market "including 80% of the fist-line therapy" ('t Hoen 2009: 7). Regarding the first-line ARVs, the TRIPS has been a minimal impact because of the patent expiration but the future production of second and third generation ARVs would be affected by TRIPS compliance by these supplier countries.

Even though the collective of the developing and least developed world had a potential influence[26] in the international *foras*, especially in their number, they could

process, which is even more a feasible or an inexpensive method under the product patent in the duration of the patent. Suppose one discovered a patented drug can be applicable for other diseases or another purpose, the inventor has no authority to commercially apply without the consent of the original patent holder. This means an exclusive control of the patent holder on their product within the duration of the patent life.

[25]Reverse engineering is a method; just reverse the original inventive activities to reveal the steps of an invention. It revealed that the product could be made by altering the process of manufacturing or by changing the combinations of the original invention.

[26]The alliance of third world countries as the grouping G-77could be managed to make a multilateral Organisation - WIPO in their favor and to sought to ease the technology trader as a part of NIEO. The old multilateral intellectual properties Organisation were considered a third world dominated institution, because of their influence in number. During the Uruguay round trade negotiations the developing countries defended to maintain the statuesque of WIPO in international IPR related issues. But they failed to materialize their number into the negotiations and TRIPS became the supreme document of the international IP regime.

not defend the incorporation of TRIPS as a subject of agreements in the WTO. There were multiple factors that determined the primacy of the IPRs in the Uruguay round negotiations and the resultant agreement on TRIPS as well as the institutionalisation of a sophisticated intellectual property regime under WTO.

3.3. REGIME CHANGE

As mentioned in the section on history, TRIPS was an important juncture in the political history of IPRs. It was not simply an issue of amending/making an international law or the creation of an international regime to govern those laws. International milieu that facilitated the international politics over the intellectual property regime change is also an important one to understand. There are so many factors that coincided in that period of the late twentieth century, ranging from (1) soviet union: the ideological and political counter part of the capitalist world disintegrated; (2) United States: the leader of international capitalism became a super power in that vacuum with full unilateral capabilities; (3) the Third World: a coalition of world's largest population lost its traditional power holdings in world politics; (4) the global financial institution's Structural Adjustment Programme transformed the institutional structures of the third world into a liberal line; (5) emergence of information technology and increased mobility through sky and sea and the resultant Globalisation of capital, trade, finance and service; (6) reinforcement of MNCs and TNCs backed by western capital.

In this context the Western collective lead by United States and their trade representatives played well in the game settling of IP related issues by threatening, trade sanctions, offering trade/tariff preferences etc. (Watal 2003; Chang 2001). The last rounds of GATT trade negotiations (Uruguay round) onwards US Trade representatives applied the sections of Section/Super 301 trade act of 1974 for putting pressure on the protesting countries and to nullify their voice (Chang, 2001; Watal, 2003; 't Hoen 2009: 10).

Originally Uruguay round of trade negotiations was held under a multilateral platform; but the frequent trade threats and the sanctions reveals the invisible hands of the bi-lateral negotiations and even unilateral actions of the United states (Watal 2003: 11). US continuously forced the Group ten (Argentina, Brazil, Cuba, Egypt,

India, Nicaragua, Nigeria, Peru, Tanzania, Yugoslavia) countries, those who were the major opponents of incorporation of TRIPS under the world trade regime, to comply with the proposals put forwarded by US and the Western ally, to ensure the agreement on TRIPS in order to make sure a minimum standardization of IP laws throughout the world (Watal, 2003). US Trade Representatives used trade sanctions and threats and the "priority watch list"[27] under Section 301 against Korea (1985), Argentina (1988; 1997; 1999), Japan (1989), Brazil (1989; 1992), India (1989; 1991), Thailand (1989), Chile (1989), China (1991; 1993), and etc., until US made convinced that they initiated patent amendments to genuinely comply with the TRIPS guidelines (Watal 2003: 11 – 47; 't Hoen 2009: 11-12). The politics of unilateral sanctions and trade threats continued until the end of the 20th century (Watal 2003: 42). This politics over IPRs transformed the intellectual property regime into a stronger one and settled the rebel voices of the third world countries for a minimal IP protection.

Williams and Lofgren (2013) critically pointed out that TRIPS was the "most politically charged agreement in the history of the IP regime". It has been a striking impact on all fields of technology especially in the field of the pharmaceutical industry. In his words:

> "TRIPS has proven to be one of the most politically charged and divisive multilateral agreements yet negotiated". Now [it] constitute a global regime of private monopoly rights which is widely recognised as an impediment to access to essential medicines (Williams and Lofgren 2013: 255).

Moreover the TRIPS made complicated the production of generic alternatives of branded patented medicine and delayed the entry of the affordable generic medicines into the drug market ('t Hoen quoted in Williams and Lofgren, 2013). Some references from the developing countries, such as Brazil, South Africa, Thailand etc. substantiates this fact. While they initiated to ensure the access to medicine by issuing compulsory licensing or using other flexibilities given by TRIPS, they faced continues threats and legal proceedings from the US and multinational Pharmaceutical corporations.

[27]Once a country (who has bi-lateral trade negotiations with the US) is listed under the watch list, the country would be closely monitored regarding their further actions and its developments. It was considered an important weapon of US trade negotiations to comply with the counterparts of those trade negotiations

In 1998, thirty nine MNCs with the support of USTR filed a case against South African government (Lexchin 2013: 2; ‘t Hoen 2009: 21; Weber and Mills 2010: 112; Williams and Lofgren 2013: 16; Chandra 2010: 195). They challenged the validity of 1997 Medicines Act which allows compulsory licences, parallel importation and contained some provisions for price control ((Lexchin 2013: 2; ‘t Hoen 2009: 21). This Act was supposed to be a “treatment” for their issues of access to medicine especially for the horrific growth of HIV/AIDS in their region. The law suit fueled international criticism against US and the multinational pharmaceutical companies and finally they dropped their suit against South Africa (Lexchin 2012: 2; Chandra 2010: 195). While, international programmes for HIV/AIDS spend huge amount of money to contain HIV/AIDS with special focus on African region, and search multiple ways for access to medicine, this case triggered a need for the revision of existing international IP regime, finally culminating into the Declaration of Doha (Weber and Mills 2010: 112-113).

A legal proceeding in WTO Dispute Settlement Body (DSB) against Brazil was another example of the IP politics over the compulsory licences and the access to medicine. In 2001 US complained against Brazil (Article 68 of the Brazilian Patent Act) on DSB for the violation of US nationals patent rights (‘t Hoen 2009: 22; Chandra 2012: 195-196). According to Article 68 of Brazil’s Patent Act, if one pharmaceutical patentee “failed fulfils the specified requirements” under the patent act, that patent “would be subject to compulsory license” (‘t Hoen 2009: 22). United States representatives in DSB alleged that, it is a desecration of the TRIPS provisions (Chandra 2012: 196). This case also invited larger international criticism and protests. The NGOs that protested argued that if DSB take action against the Brazilian government, it will “negatively affect Brazil’s successful AIDS programme” (‘t Hoen 2009: 22). After a long negotiation US withdrew the complaint from DSB (‘t Hoen 2009: 22-23).

In 1998, three Thai (Thailand) pharmaceutical companies began to produce generic versions of Fluconazole (Pfizer) (‘t Hoen 2009: 24). This dramatically reduced the price, around 97% of reduction from equitant of “6 USD” into “0.19 USD” per tablet (‘t Hoen 2009: 24). Thai government continued its compulsory licencing policy in order to reduce the price of the AIDS medicines. In 2001 “USTR warned Thai

government" and "wrote letter" to move away from their compulsory licencing policies ('t Hoen 2009: 24-25). This case reveals the real coasts of the patented medicines and the inhuman politics of profit maximisation policies of the multinational pharmaceutical companies although a huge number of people are struggling for their life from HIV/AIDS ('t Hoen 2009: 24)

This cases of South Africa, Brazil and Thai and the consequential protests and international public attention, lead to a demand for revising the TRIPS agreement in order to meet the public health requirement of the poor countries. Apart from the bad experiences faced by the developing countries from the multinational companies, the Developed countries also re-examined their rigid stand on compulsory licences since the "Anthrax crisis" threatened the health of US and Canada ('t Hoen 2009: 22). Finally the demands for the creation of pro-Health IP regime culminated in the "Doha Health Declaration"[28] in 2001 (Chandra 2012: 197).

The politics of IPR did not settled with the TRIPS and the subsequent national legislations by complying with it. That reaches to the next level: from a minimum standard of protection to TRIPS plus era. Even though TRIPS offers a "minim standard" of protection from all the national intellectual property laws, the US and other western industrial countries alliance has consider it as only a minimum (Thomas 2002: 255).They could move beyond. This thought leads to the next generation of intellectual property protection: the TRIPS plus.

In this context, Caroline Thomas (2002) criticised the invisible hands of US super power for the politics played in the present settling of international intellectual property regime under the WTO/TRIPS as well as the post TRIPS bi-lateral and multi-lateral developments beyond the domain of TRIPS. Regarding the access to medicine he argued it is not only a *political problem* under the legal domain of WTO, but also more of a political issue of "what is permissible / desirable under the terms of US trade policy" (Thomas 2002: 251). Thomas (2002: 255) argues, in the post-TRIPS bi-lateral trade negotiations United States dragged the counterparts to surpass the minimum standard of protection given by the TRIPS document. He quoted US Patent Office' Lois Boland's statement in the Geneva Conference on Compulsory Licencing, 1999:

[28] Doha Health Declaration on TRIPS and Public Health 2001, it will be discussed later

> "In our bilateral discussions, we continue to regard the TRIPS agreement as an agreement that establishes minimum standards for protection and, in certain situations, we may, and often do, ask for commitments that go beyond those found in the TRIPS agreement" (Lois Boland Quoted in Thomas 2002: 255).

3.4. RE-STRATEGIZING IP POLITICS

From the previous section we can be see a politics over TRIPS and its implications on the access to medicine, especially on the developing and least developed countries'. It is turning now to the emerging trends of the post-TRIPS era such as *relocation* in the pharmaceutical market, movements for *revisiting the TRIPS agreement* in order to meet the public health requirements and the resultant *revision in strategies* of the important actors of the international intellectual property politics. Williams and Lofgren (2013) provides an account for changing political strategy of the US in the changing strategy and the emerging trends. It is visible that we need to sort out three major kinds of post-TRIPS political strategies. They are: (1) politics over *relocation* of international pharmaceutical market *newly-emerged- unconventional* zones of the pharmaceutical markets (2) politics *mergers and acquisitions* (3) politics of *TRIPS plus agreements* (Williams and Lofgren, 2013).

3.4.1. Politics of Relocation

The economic globalisation facilitates the big pharmaceutical corporations to acquire the pharmaceutical industries of the developing world as well as an external collaboration or outsourcing with the same in order to reap the newly emerged markets of the developing countries (Williams and Lofgren, 2013). The Third World is no more a continuing traditional composition of the poor countries of the world. As of the improved international trade and services, some of the countries improved their status into almost similar to that of a developed economy, for example the South-East Asian countries. Moreover, a potential growth in the middle class was also witnessed almost in all the countries due to the globalisation especially with a high rate in India, China and Brazil (Williams and Lofgren, 2013: 7). Even though they have sizeable number of poor people, these middle-income countries constitute a new market with an optimal consuming capability in favour of integrating to international pharmaceutical market (So and Sachs 2012: 118). A strategy consultant Roland Berger's (2013) survey says that, "a 78% of the participants [Pharmaceutical

companies] planning to relocate their activities" into the newly emerged countries too. The conventional targeted group of pharmaceutical consumers has been expanded to unconventional areas of the developing world.

The Newly emerged middle-class of the world is habitually facing *non-communicable diseases*[29] like diabetics, cardiac diseases, cancer etc., because of their "changing life style"[30] (Williams and Lofgren, 2013: 7). The trends in the newly developing markets of the developing world have invited the attention of the big pharmaceutical corporations into this. Roland Berger's partner Moris Hosseni commented that: "it comes as no surprise that many pharmaceutical companies are increasingly focusing on emerging markets to better leverage the considerable growth potential in this regions" (Roland Berger, 2013). This new trend will be good only if the relocation of the global pharmaceutical companies can acknowledge the problems of poor in this region and could make access to affordable medicines to them and could focus on the research on regulated tropical diseases, rather than their intention to extract the benefits from the growing middle class in those markets.

3.4.2. Politics of Mergers and Acquisitions

The potential *newly-emerged-unconventional* pharmaceutical market of the developing countries, lead to the politics of merges and acquisitions. Moreover, a comparable cheap labour, land, low standard labour laws, rent, and services and so on, has encouraged the pharmaceutical companies to invest on developing countries market (Christopher and Arishma 2013:119). They used two strategies: a strategy of 'outsourcing' especially on the R&D and a strategy to 'acquire' shares of the pharmaceutical companies or 'merges' with the domestic companies of the developing world. Williams and Lofgren (2013: 249) pointed out that the recent trend of world-South's research based industry is the integration with "innovation oriented industry" dominated by MNC's controlled "global research networks" through outsourcing and acquisitions. He substantiated his arguments in his work with some

[29]Non communicable diseases also called life style diseases.

[30]An pharmaceutical company AstraZeneca's (2011) study estimated that by 2030, a combined share of India's and china's diabetic patient will be account a one third of the total worlds diabetic patients.

case study's observations on the highly integrated innovative industries of emerging countries such as India, Brazil, China and South Africa (Williams and Lofgren 2013).

The politics of *merge* and *acquisitions* have an inverse impact on the access to affordable medicine. These *acquisitions* and *merge* would reduce the competition particularly the generic competition, if they become a part of their firm (Christopher and Arishma 2013:123). Moreover, most of the international pharmaceutical giants are facing a large number of "patent expiration[31]" in recent times (Christopher and Arishma 2013:119). A study reported that world's top 10 pharmaceutical companies' with an average of 46% patents was expired in 2014 (Kearney 2010: 1). It would be profitable to acquire or merge with their competitors to avoid the future losses from the *post-patent-expiry* generic competition. The cases of huge mergers and acquisitions from the Indian pharmaceutical industry have been substantiating this logic *mergers* and *acquisitions*. For example, in between 2008 to 2012, many Indian companies were acquired by or merged with some important pharmaceutical companies. Dabur Pharma was acquired by the Singapore based company Fresenius Kabi in 2008 "by a coast of 219 million USD", Ranbaxy Laboratories Ltd., by the Japanese based Daiichi Sankyo with a "coast of 4.6 billion USD"; Shantha Biotech by French based Sanofi Aventis, Piramal Health Care by US based Abbott Laboratories, Nicholas Phiramal India, Bochringer Mannhien, Roche Products, MJ Pharmaceuticals, Sumitra Pharmaceuticals, Matrix Laboratories etc., were merged with worlds important pharmaceutical companies and its Research wings recently (Christopher and Arishma 2013:121-22). As the largest generic exporting industry of the world these huge mergers and acquisitions would have an adverse impact on access to affordable medicine in the world.

3.4.3. Politics of TRIPS Plus

The TRIPS plus agreement is one another development in the post-TRIPS era which was generally believed as a hindrance to the countries from choosing the TRIPS flexibilities given by the TRIPS agreement itself and the Doha Declaration ('t Hoen

[31]Patent expiration denotes the completion of patent life after 20 year patent protection is over. Regarding pharmaceutical sector, once a patent is expired, the product will be open to all. This will encourage the generic competition and result in a huge reduction in the price of that particular medicine. From the pharmaceutical corporation's point of view, a patent expiration evaporates their profit which they enjoyed during the patent life

2009: xvii-xviii). The Doha Declaration reaffirms the autonomy of the nation-states to issue the compulsory licences in order to meet their public health requirements. Compulsory licences are supposed to be a major weapon for the developing and the least developed countries against the patent monopoly in order to reduce the medicine prices. The United States and the western industrialist countries have been continuously opposing the entry of generic pharmaceutical alternatives by using the compulsory licences provision ('t Hoen 2009: xviii). They are now using TRIPS plus agreements to doing this. United Nations MDG Task Report 2012 observes TRIPS plus provisions in following lines:

> "…over the past several years, the deadlock of the Doha round at the WTO has led to an increasing number of bilateral and regional free trade agreements. Many developed countries tend to include so-called TRIPS plus provisions in these agreements… that exceed[s] the minimum standards required by the TRIPS Agreement" (UN 2012: 67-68).

Indeed, the report points out the future probable impact on different areas due to the TRIPS plus provisions,

> "…TRIPS Plus provisions that may have impact on public health or may hamper the use of flexibilities… on the right to issue compulsory licenses; providing for patent extensions…; requiring test data protection that restricts the use of clinical test data on pharmaceutical products… for a certain period of time; and allowing patent holders to restrict parallel imports, which may prevent countries from buying medicines from the most affordable international source" (UN 2012: 67:68).

The newly emerged strategic environment and the fear on estimated loss of the patented medicine's market forced the developed countries especially the United States to move towards a new strategy: the TRIPS plus agreements (Williams and Lofgren 2013; 't Hoen 2009: xviii). TRIPS plus is generally a section of IP related issues in a Free Trade Agreement (FTA). Once a country has signed on a TRIPS plus agreement, that country is forced to move beyond the minimum standards of the TRIPS agreement. This is what Williams and Lofgren called "*TRIPS Maximalism"* (Williams and Lofgren 2013; So and Sachs 2012: 114;t Hoen, 2009). This is including patent life expansion; provisions to resist compulsory licencing and parallel importing, increasing data exclusivity period (Williams and Lofgren 2013; So and Sachs 2012: 114; Burger 2013; 230).

Some case studies of his book, Williams and Lofgren (2013) explains the "TRIPS Maximalism" through TRIPS plus agreements. Trans Pacific Agreement (TPP) is an important example of this. This anticipates a far beyond strict IP regulations from the

minimum standards given in the original TRIPS agreement. MSF reported that some USTR's proposals for TPP would seem to be broadminded in its name like "Trade Enhancing Access to Medicine" or "TEAM", but in reality it will restrict the generic competition and the resultant access (MSF, 2012). USTR proposal encouraging voluntary licenses, instead of the compulsory licences provide by TRIPS, moreover assuring an "extended monopoly protections" from the developing countries (MSF, 2012). Once this was accepted, they incorporated the TRIPS plus provisions that "would directly undermine public health safeguards available in international law and would made harder for TPP countries to gain access to price-lowering completion" (MSF, 2012)

The countries Korea, South Africa, Taiwan, Malaysia, and Turkey so on had been a fighting history in the IP regime for more flexibilities and minimal protection. They dropped their fighting tradition in the IP regime and even surprisingly they moved beyond the trips minimum standards by signing or negotiating TRIPS plus provisions (Williams and Lofgren 2013: 9-15). The studies reported that the medicine expenditure would be dramatically increased after the adoption of TRIPS plus in the signatories (MSF, 2012; So and Sachs 2012: 116). For example, in Peru and Colombia: an extra five year extension of the patent life costs additional 321 million US dollar in Peru and 280 million US dollar in Colombia respectively (So and Sachs 2012: 116).

3.4.4. Politics on Compulsory Licences in Multilateral Arrangements

The previous section provides a brief overview of the issues in the application of the compulsory licences; especially the research-based-branded pharmaceutical industries' interventions with the support of United States. In that we assessed the impact of market driven *utilitarian* ideologies against the *humanitarian* concerns over the access to medicine. It then goes on to the multilateral acknowledgements on the compulsory licences. A compulsory licence refers to the "third party" licenses, granted by a legitimised authority, for using patented technology, without the consensus of the patent holder (Lalitha 2005: 1355, Zischaka et al 2009 Watal 2003). Generally this is allowed as a remedy to "patent abuses", "anti-competitive activities", "non-working of patents" and in the circumstances of emergencies and to promoting public interest (Zischaka et al. 2009; Watal 2003). It can be seen a connection with

the utilitarian philosophies in the applications of CLs in the early history of the intellectual property rights. It is believed that, the promotion of the domestic industry was the prime motive of the national governments in introducing the IP. In this context the "non-working" of the intellectual property considered as non-utility function Zischaka et al. 2009). On the one side the non-working prevents others from using the IP, and the other side it presents the public goods from its industrial application. In these contexts the governments allowed a CL to a third party, after a particular period of non-working[32] on non-application of IP.

It can be found that the earlier applications of the CLs from the "Paris Conventions for the protection of industrial Property, 1883 (Zischaka et al 2009; Watal 2003). That was included in the original Paris documents. Since the practice of foreign patent applications started by several countries, the scope of non-working extended to "local working[33] of patents" for granting the CLs. CLs was a hated subject matter of the Uruguay Round of trade negotiations (Watal 2003). Finally that ended up with a reduced scope of application of compulsory licences. The countries lost the opportunity to decide the "grounds" in which the CLs granted. The TRIPS scrapped the "non-working", "local working" and "public interest" conditions for granting compulsory licences, and put twelve strong clauses of conditions in which the CLs are granted, in the Article 31, mentioned in the title as: "other use without authorization of the right holder" (WTO 1994; Watal 2003: 317-328).

The impact of the tightened CL scope was enormous to the access to medicine. On the one side the developing countries lost their opportunity of "process patents", and the other side the scope of CLs tightened (Dhar and Rao 1994: 107; Watal 2003). Consequently the entry of generic pharmaceuticals has reduces. Moreover in that monopoly without competition, the price of medicine increased beyond the affordable range. Even though TRIPS has reduced the scope of compulsory licences, acknowledged the demands of developing countries in some extent. That allows the

[32] Non-working refers to a condition by which patentees fails apply his patent for industrial or commercial application, or keeping in freeze his IPRs. The Utilitarians considered that the IPRs incentivize development. Therefore the non-working considered as a paradox of the purpose of the practices of IPRs.

[33] Local working of foreign patent is an extension of non-working. In such cases of foreign patents, the patent might be "working" in the country of origin, but not in the foreign country. In such conditions also considered as a "ground" for compulsory silences in the pre-TRIPS era.

countries to grant CLs in the circumstances of “extreme urgencies” or “national emergencies” with a flexible scope of interpretation of “circumstance” (Watal 2003: 463; WTO 1994).

From the above discussion, it can be seen that, TRIPS’ compulsory license provisions have *reconciled* both the interests of market forces and the public interests in terms of patent *utility*. That acknowledged both need for the “exclusive market rights” as an incentive for innovation and development and in certain circumstances “short term public interest *utility*” such as access to medicine, crises management in calamities, emergency or extreme urgency (Chandra 2010 xxiii & 92; Sterckx 2004: 66; Watal 2003: 317-328; Chang 2001; Zischaka et al 2009).

Although the TRIPS have allowed flexibilities for compulsory licences in a balanced basis, the international IP power structures apprehended its applications. The law suit against Africa (1998); against Brazil (2001) in Dispute Settlement Board (DSB); and various trade threats and retaliatory measures against Brazil, Thailand, by the major big pharmaceutical corporations with the support of USTR, shows the difficulties faced by the developing countries, while they initiated for compulsory licences (it was discussed in detail at page number 7-8) (Lexchin 2013; ‘t Hoen 2009; Williams and Lofgren 2013, Chandra 2010; Weber and Mills 2010). This issue again raises the demand for further clarity and further the flexibilities on the CLs. As discussed earlier, these protests culminated in the Doha round, and resulted into a clearer definition on the CLs (TRIPS Article 31 (f)) and further flexibilities on CLs in the public health crises (Lexchin 2013; ‘t Hoen 2009; Watal 2003). The following section will be discussed detail.

3.5. DOHA HEALTH DECLARATION

From the previous discussions, we can see the implications of intellectual property rights on access to medicines. The discussion examined the structural inequalities in the intellectual property regime; dynamics in the institutional settlements; and how it determined the access to medicine in the world. In this section there will be discussions on (1) the original TRIPS flexibilities; (2); its problems and prospects; (3) revision of TRIPS flexibilities: the Doha Declaration.

As mentioned above, there are some flexibility that was incorporated in the original TRIPS agreement to meet the technological gaps and the public health requirements in the regime. Two major of these are the “transition period” for TRIPS compliance, especially to adopt the product patent system; compulsory licenses (CLs) or “other use without authorisation of the right holder” (TRIPS 1994: Article 31;Watal, 2003; Bucci 2013: 218). Transition period is the time relaxation provided by the TRIPS to the developing and least developed countries to meet the requirements for TRIPS compliance. CLs are positive in nature and under this provision any country can grant a government licence or “third party” licence “without the authorisation of the patent holder”, in cases of “national emergency” situations or “circumstances of extreme urgency” or “in case of public non-commercial use” (TRIPS 1994: Article 31). This provision has been considered a positive step towards the access to essential affordable medicines across the world.

Even though the compulsory licences are used in rare situations, its potential was proved with the generic alternatives to meet the issues of access to medicine and to reduce the price of the medicine. It has two sided effect. On the one side its application would make available low priced alternatives and reduce the price of the medicine in the market by giving competition and on the other side threats of compulsory licences would motivate the patented manufacturer to reduce the price of the patented branded medicine or to offer concessions or voluntary licences (Lofgren and Williams 2013; ‘t Hoen 2009).

The generic alternatives are an important tool to improve the access to medicine. It will be very visible in the pricing of different companies on the same product. For example, while initiating the production of Fluconazole which is used to treat Cryptococcl Meningitis, an Aids related disease in Thailand, price of the medicine would costs around 6 USD (‘t Hoen 2009: 24). After the generic products reached the market the price reduced to 0.19 USD (around 97% of reduction) in 1998 (‘t Hoen 2009: 24). This big price disparities shows the real cost of the medicine and the over profiting by the pranced medicine companies. The patents abandoned the real price of a medicine and put a huge exchange value on it.

Brazil’s initiative for compulsory licences, ARVs in 2001 forced the originator companies Merck and Roche to accept substantial price reduction (Lofgren and

Williams 2013: 19) Korea, Thailand, Malaysia and many countries initiated compulsory licences. In most of the cases the originator companies were forced to reduce the prices dramatically. In 2012, India issued its first compulsory licence to generic pharmaceuticals, Natco Pharma, on Sorafenib, a cancer treatment medicine, marketed by Bayer (Lofgren and Williams 2013: 20). The estimated cost reduction from this CL issue is very huge. Natco agreed to supply their generic version for only 3% of the Bayer's patented drug's price (3% of Rs.280, 000 per month).

Even though the compulsory licences have a positive impact on access to medicine, and it could reduce the prices of medicine, especially on the ARVs, its application has been rarely used, as it of limited to national "domestic purposes" by the original TRIPS agreement (Weber and Mills 2010: 112). According to the Article 31(f) of the original TRIPS (1994) agreement the scope of the CLs will be "any such use shall be authorised predominantly for the supply of the *domestic market* of the member authorising such use…" This would be considered an obstacle to the access to medicine for the countries that doesn't have appropriate manufacturing capacity (Chandra 2010: 198). In the TRIPS compliance they could manage to get generic versions from other manufacturing countries by exporting. But TRIPS nullify these possibilities by narrowing the scope of CLs in to the "domestic market".

Moreover as mentioned earlier, the South African (1998) and Brazilian (2001) cases (their initiatives to issue compulsory licences dragged them to legal disputes) escalates the international discourse on TRIPS and public health requirements (Chandra 2010: 196). Non-Governmental Organisations (NGOs) and the developing and least developed countries representatives continually campaigned for revision of the patent regime in order to meet the public health crises ('t Hoen 2009: 30; Chandra 2010: 196). These international discourses culminated in Doha WTO Ministerial 2001 and led to the Declaration on TRIPS Agreement and Public Health: the Doha Health Declaration. Doha Declaration acknowledged the problems of TRIPS regarding access to medicine and in a broader since, the public health as a whole (WTO 2001: #4).

> "We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. …we affirm the Agreement can and should be interpreted and implemented in a manner supportive of WTO members right to

> protect health and, in particular, to promote access to medicine to all" (WTO 2001: #4).

This paragraph 4 of the Doha Declaration states its principle position that has to be taken, in order to meet the public health requirements of the member countries. While coming to paragraph 6 of the declaration, there is a very clearly instruction to the General council to find solutions for the impediments faced by the countries that doesn't have adequate pharmaceutical manufacturing capacities in using CLs (WTO 2001). The Declaration's paragraph six states that:

> "We recognise that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licencing under the TRIPS agreement. We instruct the council for TRIPS to find an expeditious solution to the problem and report to the General Council" (WTO 2001: #4).

In 30 August 2003 WTO General Council decided upon the solution submitted by the council. This is called as "August 30 Decision": This allows the countries who are lacking sufficient manufacturing capabilities to "import generic drugs" from other countries by using CLs (Chandra 2010: 199). The decision expands the scope of Article 31(f) of the TRIPS agreement regarding the use of compulsory licences from domestic purposes for exporting to the "eligible countries" (WTO 2003: #2).

> "The obligations of an exporting member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory license to the extent necessary for the purposes and production of pharmaceutical product(s) and its export to an eligible importing member(s)" (WTO 2003: #2).

Moreover, the Doha declaration clarifies the circumstances for issuing the compulsory licences. That provides more autonomy to the countries issuing CLs than the patent holder. According to Paragraph 5(b) of Doha Declaration, the member countries have the full "freedom to determine the grounds in which such licences are granted" (WTO 2001: #5a). Indeed the next point clarifies that for this the subject matter should come under the "national emergencies" or the "other circumstances of extreme urgency in order to issue a compulsory licence: that is, "public health crises, including those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics, can represent a national emergency or other circumstances of extreme urgency" (WTO 2001: #5a).

The reaffirmation of Doha Declaration on TRIPS flexibilities widened scope CLs and encourages the countries to issue CLs or threaten pharmaceutical corporates in the

name of CLs in order to generate market competition in the pharmaceutical sector or to compel the companies to reduce prices (Williams and Lofgren 2013: 18-21; Correa and Matthews 2011: 24-26). Brazil (2001, 2005, 2007), South Africa (2001), Malaysia (2003), Indonesia (2004), Korea (2002, 2008), Thailand (2008) and some other countries issued compulsory licenses or initiated CLs (Williams and Lofgren 2013: 18-21; UNDP 2011: 24-26). In most of the cases the prices reduced dramatically. Even an initiation on the CLs forced the branded companies to reduce prices of medicine or to offer concessions. It is very hopeful that India and China the most powerful countries of the emerging world have initiated CLs, recently (Williams and Lofgren 2013:20-21). But on the other side as discussed earlier, new FTAs and the so called TRIPS plus provisions undermines the spirit of the Doha Declaration, by putting additional IP regulations beyond the minimum standards.

3.6. HISTORY OF COMPULSORY LICENSES IN CANADA

The history of Compulsory Licenses in Canada starts from the 1869 patent legislation called "An Act Respecting Patents of Invention, 1869 (Zischaka et al. 2009). It was a "non-working" as well as "local working" based provisional patenting system. If the patentee couldn't materialize the patent into a tangible form of the patented IP within three years, the patent becomes "null and void" (Zischaka et al. 2009). Since 1903, Canadian patent regime authorises the Commissioner of Patent to grant CLs, in cases of larger public interest requirements (Zischaka et al. 2009). Later this provision was incorporated into the 1923 Patent Act, and reaffirms the public interest principle, especially on the food and medicine patents. The Act mentioned that:

> "Every patentee shall satisfy the reasonable requirements of the public with reference to his patent and to that shall adequately manufacture the patented article or carry on the patented process within Canada[34]" (Zischaka et al 2009).

Moreover the Patent Act 1935 clarifies more on the "working" of the patent and limits the exclusivity of the patentee in cases of "non-working" of the patent (Zischaka et al. 2009). It clearly acknowledged the usefulness of the patent and redefined it in terms of the local working (Ibid). The Act clearly stated that the purpose of the patents is not limited to *incentivise the inventions*, but to secure its local working in Canada

[34] Patent Act, R.S.C. 1923, c.23 ("Patent Act (1923)", s. 40(a), cited in the Zischaka et al (2009).

(Zischaka et al 2009; Sterckx 2004). The subsequent judicial interpretations also reiterate the "local working" and "non-working" clauses of the patent act; the courts stated that the "mere assembly" of a patented good could not be considered as a working patent (Zischaka et al 2009).

A dramatic change in the pharmaceutical compulsory licensing occurred in Canadian patent regime since the 1969 patent Act (Bill C – 190) passed (Esmail 2010: 50) that allows granting compulsory licences on "imported products (Lalitha 2005: 1357; Zischaka et al 2009; Esmail 2010: 50). This has been resulted in the growth of domestic generic pharmaceutical industry (Lalitha 2005: 1357; Zischaka et al 2009). The Bill was a response to a series of Liberal government appointed commission reports on the escalating drug prices. It was designed to reduce the escalating drug prices in Canada, by encouraging generic competition through CLs (Esmail 2010: 49). Esmail (2010: 49) indicated that "the Liberal Government's primary argument for compulsory licencing was that the immediate welfare of the general public took over the private interests of research-based pharmaceutical industry and creating incentives for innovation". Moreover the liberals were not against the patent system but was emphasizing on the need of addressing the larger public concerns over the escalating pharmaceutical prices (Esmail 2010: 50). This encouraged the rate of issuing CLs; Esmail (2010: 50) estimated that, in the immediate two decades Canada issued around 613 CLs on pharmaceuticals. This led to the assumption that the Liberal Governments priority of *humanitarian* concerns over the access to medicine was against the mere market oriented *utility* of the patent.

The Mid 80s marked a dramatic shift in the CL policy in Canada. Three factors were attributed to the regime change: (1) Eastman Commission Enquiry Report on Canadian Pharmaceutical Industry; (2) Discussion on "Canada – US Free Trade Agreement; (3) Liberal's defeat in the 1987 election and the new Conservative governments (Brain Mulroney) policies(Weber and Mills 2010; Esmail 2010; Lalitha 2005). Eastman Commission report concluded that, the liberal approach on CLs may lead to the growth of generic industry, but it adversely affects the R&D environment in Canada (Zischaka et al 2009). Furthermore the commission recommended a certain period of "exclusivity" without CLs (Zischaka et al 2009). Finally the enormous pressures from the United States, the Eastman Commission report and the adjusted

policies of the Mulroney government with the US, concluded in the introduction of Bill C-22 with a compliance on "market exclusivity principle" of patents (Lexchin 2003: 1; Weber and Mills 2010: 114; Lalitha 2005: 1357; Esmail 2010: 50). This shift had been marked the reversal of Canada's IP policy, from a *humanitarian* interpretation of the patent regime towards a market driven *utility* principles in the name "incentivises innovation" via offering "market exclusivity" for the patents.

In 1994, Canada became a party of both North American Free Trade Agreement (NAFTA) and WTO's Agreement on Trade Related Intellectual Property Rights (TRIPS). It was discussed in the previous sections regarding the rigid patent guidelines of the TRIPS against the *humanitarian* applications of CLs. NAFTA also incorporated a chapter (Chapter 17) on intellectual property (Weber and Mills 2010: 114; Zischaka et al 2009). Canada introduced Bill C-91 prior to both the agreements. Esmail (2010: 51) argued that "[i]t effectively abolished compulsory licencing from Canada's Mechanisms to contain escalating drug costs". Moreover the amendment extended patent life to 20 years (Weber and Mills 2010: 114). This furthers the "market exclusivity" principle and abandoned the liberal-*humanitarian* approach to the CLs. The reversal of Canadian patent policy of the Trudeau Government, which aims to reduce *dependency* through empowering the domestic industries, and the shift to the Mulroney Conservative's neo-liberal agenda and the integration with the global market, especially with the US market, resulted in the victory of market driven *utility* in an environment of *dependency* over the public-good-based *humanitarian* commitments of Canada. The domestic conditions of dependency would be discussed in the upcoming chapter.

3.7. CANADA'S ACCESS TO MEDICINES REGIME

Canada's Access to Medicines Regime is a domestic implementation of WTO's August 30 Decision that followed by the Doha Declaration 2001 (CIPO 2008; GoC 2008a; Esmail 2010: 70) It amended the Patent, Food and Drug Act (Bill C-9): (An Act to amend the Patent Act and the Food and Drugs Act – The Jean Chretien Pledge to Africa), and provided an authority to the Commissioner of the Patent to grant "export oriented" Compulsory Licences (CLs) to any "third party" or a "government agency" in order to manufacture low-priced generic versions of medicine to the developing or least developing countries that "do not have adequate pharmaceutical

manufacturing capabilities" to exploit the TRIPS flexibilities and CLs, in a *humanitarian* basis (Parliament of Canada 2004; CIPO 2015; GoC 2008; Elliot 2012; Esmail 2010: 70).

As a response to the Doha Declaration 2001 (in WTO Ministerial Conference), the 2003 General Council of the WTO decided to waive the TRIPS' restriction on export of generic pharmaceuticals produced under CL provisions to the developing and least developed countries and amended the Paragraph 6 of the Article 31 of the original TRIPS Agreement (GoC 2008). This was later known as 2003 August 30 Decision. Moreover the WTO Members formally adopts this decision in 2005 (GoC 2008). In 2003 Canada announces its intentions to implement the August 30 Decision (GoC 2008). The Canadian Parliament passed the Bill C-9 and amended the Patent Act of Canada, and institutes Canada's Access to Medicines Regime and there by became the first WTO member to implement the amended TRIPS flexibilities (Industry Canada 2007: 1; Gatto 2011: 23; GoC 2008; Lexchin 2013:3).

The Bill C-9 (CAMR) stated that, the purpose of this legislation is:

> "to facilitate access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics" (Parliament of Canada 2004: #21.01).

Moreover the CAMR offers an opportunity to the poor countries to import "high-quality drugs and medical devices at a lower cost to treat the diseases that bring suffering to their citizens" (GoC 2015). The features of the regime are follows;

- This legislation does not aim to a domestic level marketing of the generic pharmaceuticals but to export the courtiers those lacking affordable essential medicines: the targeted beneficiaries of the regime will be the developing and least developed countries (GoC 2009).
- All the drugs should meet the same "quality, safety, and effectiveness, as those marketing in Canada (GoC 2008a)
- The eligible medicines and other devices would be primarily from the WTO's "Model List of Essential Medicine" and in certain circumstances other medicines or combinations could be added to the list (GoC 2008a).

- The NGOs can be purchased the generic versions under CAMR, with the prior permission of the country of destination of the distribution of that medicine (GoC 2008a; Esmail 2010: 70).
- Non-exclusivity and Non Transferability: the CLs will be allowed for only a humanitarian purpose, non-commercial use and the licence cannot be transferred (Parliament of Canada 2004).
- "Good faith" clause: If the coast of the exporting medicine under CAMR exceeds 25% of Canadian price of the patented version; and the patent holder can be legally challenged the CLs if generic company produced or selling the pharmaceutical product for a commercial purpose (GoC 2008a; Esmail 2010: 71).
- Duration: "the licence will be valid for two years"; and in certain circumstances a "one-time two-year renewal" will be allowed (Parliament of Canada 2004: #12.09 & 21.12; Esmail 2010: 71; Weber and Mills 2010: 115-116).
- "One-time-one-license-one-country" clause: the use of CLs on "patented pharmaceutical product must be limited to specific quantity and for use in a specific country" (Parliament of Canada 2004; Esmail 2010). This means that a CL will be provided only for a country's requirement not for a product.
- The compulsory licences will be granted if and only the branded pharmaceutical company fails to provide the voluntary licences (Parliament of Canada 2004; Esmail 2010: 70; Weber and Mills 2010: 115)
- The generic manufacturing company must be ensured "anti-diversion requirements" as well as established the details of the shipments (Parliament of Canada 2004; Esmail 2013).

The Government of Canada stated that "[t]he regime balances Canada's trade and intellectual property obligations with humanitarian objective of WTO decision" (GoC 2008). This *balance* within CAMR could be assumed as a *reconciliation* of the *utilitarian* as well as the *humanitarian* policy objectives of Canada. For attaining this balance, the parliament has negotiated, consulted and have taken responses from non-governmental organisations, generic manufactures and branded pharmaceutical corporations (GoC 2008; GoC 2008a). In Parliament's Statutory Review on the CAMR, Industry Canada commented:

> "[i]n developing the framework for CAMR, Canada faced the unique challenge of fashioning an unprecedented compulsory licensing for export regime which would advance the …humanitarian objectives, while respecting the international trade rules and maintaining the integrity of the domestic patent system" (Industry Canada 2007: 5).

Critiques argued, although the promises of the CAMR were big, it was visible that, the legislation puts more restrictions in some places, even beyond the requirements of the August 30 Decision of WTO (Huth 2010: 133; Esmail 2010; Lexchin 2013; Weber and Mills 2010).

Even though CAMR received wide support from various sources initially, certain generic pharmaceutical companies and NGOs expressed their disappointment, stating that, this legislation is inadequate to meet the pharmaceutical health needs of the world. The Canadian Generic Pharmaceutical Association argued that in the present form of CAMR may invite "court battles" as of the clauses of the law; it is easy for the branded pharmaceutical companies to approach court in the name of "commercial nature" of the generic supply (Esmail 2010: 73). Weber and Mills (2010: 116) stated, only "Canada has codified the patent holder's right to challenge the licence" to manufacture generic medicines and sell it commercially. Moreover it is hard to isolate the commercial and public health intentions while selling a product.

The NGOs criticised that the scope of CAMR would be reduced if it maintains a mandatory list of identified medicines under Schedule 1(Industry Canada 2007: 9; Weber and Mills 2010: 116). Moreover "it created restrictions that were not contained in the WTO decision" (Esmail 2010: 73). The Doha Declaration has permitted the countries to issue CLs under circumstances of "emergencies or extreme urgencies"; and the specific countries can do so by interpreting the circumstances which lead to the public health Crises (WTO 2001; Esmail 2010: 74). The August 30 WTO General Council Decision has clearly mentioned about the "eligible products" and has also stated, any "pharmaceutical product" within the eligibility list could be issued with a CL. An eligible pharmaceutical product is defined as:

> "…any patented product or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognised in paragraph 1 of the Declaration" (WTO 2003: #1(a)).

The CAMR has authorised only nation-states to purchase the generic version. Third parties like NGOs would be allowed to purchase the generic version only with the

permission of the importing country of destiny (Industry Canada 2007: 7; GoC 2008a; Esmail 2010: 70). The Médicine Sans Frontières (MSF) conducted a campaign among the poor countries to build awareness about the CAMR. From the campaign experience, MSF stated that "most of the countries were reluctant, given the threat of trade sanctions from the United States" (Esmail 2010: 75). It was hardly possible to initiate the purchase of generic medicine under CAMR because of this restriction implied by US.

The compulsory licensing under CAMR has followed a "one-time-one-country" policy. In World AIDS Conference 2006, the NGOs have raised some worrying concerns over these provisions. They argued that, "the one-product, one-country, time-limited procedure has restricted the possibilities for improving drug access" (Webber and Mills 2010: 116). It can't be applied to another supply of the same product; to another country or even the same country beyond the specified limited quantity (Elliot 2013; Gatto 2011: 24). Before granting the CL, the receiving country should have the estimate of the 'required quantity' to be supplied (Gatto 2011: 24). Furthermore the process of licensing also consumes a good amount of the time. Moreover the manufacturing process requires an initial investment, for building the infrastructure, expertise, and other requirements. Therefore it cannot be negated that, the generic manufacturer will be facing financial constraints even to compensate their investment.

Under CAMR, the demand for the medicine is not 'natural' that is through the *One country, One licence, One supply* provision, the supposed reduction in price of the medicine would not happen. The CAMR requires a Country's notification of willingness to purchase the medicine (Parliament of Canada 2008). A random production for the generic pharmaceutical market is also not possible under CAMR because of its "one-licence, one-country" provision as well as the "non-commercial purpose" clause (Parliament of Canada 2008; GoC 2008a). Therefore the 'consumer choice' would not be applicable to the CAMR products.

CAMR mandated a strict assurance from the generic manufacturer regarding their "anti-diversion measures" (Parliament of Canada 2004; Industry Canada 2007: 21; Esmail 2013). These measures includes, a strict labelling of packs and bottles and colour coding of pills in order to differentiate the medicines sold in Canada (Industry

Canada 2007: 21; GoC 2008; Himelfarb 2015). Along with, the Manufacturer should maintain a website giving information regarding their export (Parliament of Canada 2004; GoC 2008; Himelfarb 2015). Himelfarb (2015) argued that "these regulatory steps are not require[d] under the framework laid out by WTO."

These complexities attributing to the above mentioned hurdles were clearly visible in the "one and only experiment" under the CAMR: Export of triple therapy anti-retroviral (ARV) HIV/AIDS drugs to Rwanda. The Canadian generic pharmaceutical company Apotex - the producer and exporter of ARV for Rwanda under CAMR, declared that, they would not be a part of this programme until and unless the regime is amended (Esmail 2010; Gatto 2011).

3.7.1. The One and Only Experiment: Export of ARVs to Rwanda

After the CAMR was passed, within few months came the first response regarding the application of CAMR from one of Canada's largest generic producer, Apotex. They declared their willingness to develop a new combination (triple-therapy: combination of three HIV/AIDS drugs; Zidovudine (AZT) 300 mg, Lamivudine (3TC) 150 mg and Nevirapine 200 mg) of "anti-retroviral" (ARV) drug called by "Apo-TriAvir" (Abbott 2007: 1127; Himelfarb 2015). The first issue regarding application of CAMR was faced at that moment itself. Even though the three components of Apo-TriAvir were listed in the Shedule-1, the combination was not listed in the same (Himelfarb 2015). According to the Act, any changes on the Schedule 1 needed a Patent Act Amendment. Due to pressures from the various sections; in September 2005, the Schedule-1 was amended and the new combination was included in to the list (Himelfarb 2015). And finally Health Canada approved Apo-TriAvir in June 2006 (Himelfarb 2015).

In the initial period no country has requested for any generic medicine to be supplied under the CAMR. Without a prior agreement with any developing or least-developed countries, the generic companies cannot apply for a CL (Parliament of Canada 2008). This ambiguity continued till 2007. As a result of a rigorous awareness campaign among the developing and least developed countries, Rwanda an "eligible country" notified in WTO, regarding their intention to purchase 260,000 packs of "Apo-TriAvir" from Apotex under CAMR, in September 2007(Industry Canada 2007: 2; Weber and Mills 2010: 117; Himelfarb 2015).

According to the regulations of the Bill C-9 (CAMR), the applicant (Apotex) must persuade a "voluntary license" from the patent holder (Industry Canada 2007: 14). In the case of Apo-TriAvir, the triple combination had three original patent holders – GlaxoSmithKline (GSK), Boehringer Ingelheim and Shire Biochem (Abbott 2007: 1127). Apotex began negotiations with these companies from July 2007 (Himelfarb 2015). But the negotiations failed, and Apotex applied for CL in September 2007. Apotex stated that "by not providing any voluntary licenses, the brand side of the industry forced Apotex to apply for compulsory licences" (Himelfarb 2015). And finally on 19th September 2007, "The Commissioner of Patent" issued a CL for Apo-TriAvir and informed WTO in October about the license (Abbott 2007: 1127; Weber and Mills 2010: 117). The license has authorised the Apotex to produce and export 15,600,000 Apo-TriAvir pills to Rwanda (Abbott 2007: 1127).

Rwanda issued an open tender in October 2007, according to their domestic law (Himelfarb 2015). After 8 months Apotex won the tender and started the production. In September 2008 the first shipment of Apo-TriAvir was exported to Rwanda (6,785,000 tablets); and a year later, Apotex send the remaining (7,628,000 tablets) and completed the offered supply (Himelfarb 2015; Weber and Mills 2010: 117).

3.7.3. Responses

Even though CAMR was a laudable initiative, it failed to fulfil its purpose and promises. Kohler et al (2010) commented that "in its rhetorical terms, CAMR promised an elephant, but so far the legislation has delivered little more than a mouse". In the first experience of application itself CAMR has revealed its practical hurdles. Throughout their initiatives, Apotex, the first licensee under CAMR has faced multiple barriers and deadlocks. That bitter experience forced them to withdraw from further participation under CAMR. They expressed their disappointments and announced their unwillingness to participate in the regime until and unless the regime is amended (Apotex 2008). From their experience, the first public response has come from the Apotex in 2008, after the first shipment was send, which stated that:

> "…it is reluctant to participate in the initiative again unless changes are made to streamline the regime" (Apotex 2008).

Furthermore Jack Kay of Apotex (Chief Operating Officer) expressed that:

> "if other critical medicines are to go to Africa in a reasonable timeframe, the federal government must change the CAMR legislation significantly. CAMR is unworkable as it now stands" (Apotex Group 2008).

Similarly various criticisms have come from various sources regarding the problems pertaining within CAMR. The opposition party NDP, NGOs like MSF, Oxfam Canada, pressure groups like Grandmothers Association and Canadian Generic Pharmaceutical Association has critically pointed out the existing complexities of CAMR towards its humanitarian drug supply and demanded amendment in the CAMR (Parliament Canada 2010; 2011; 2012).

This "one and only experiment" of the CAMR has shown the complexities of the regime. Apotex took long four year for the "one and only" supply under the regime of Apo TriAvir (Elliot 2013). John Hems of Apotex criticised the "eligible country's" notification in WTO" about their willingness to purchase, was an unnecessary hurdle, while the eligible countries were already listed in the WTO (Himelfarb 2015). Moreover the unnecessary "administrative burdens" like 'anti-diversion' protection, seeking voluntary license and others, may makes the smaller generic manufactures to reluctant to participate under CAMR (Himelfarb 2015). Similarly, Kohler (2010: 43) found that the effective use of CAMR was further limited by the bureaucratic constraints and the associated transaction costs for both the service receiving countries and the generic companies. While evaluating the experience of Apotex under CAMR, Himelfarb argued:

> "it is not an economically viable regime, because it is not cost-effective to produce medicines for only one importing country at a time. Under CAMR, a compulsory licence cannot be granted unless an eligible importing country has indicated its need to WTO… Therefore if an eligible country other than Rwanda presently indicated to WTO its need for a drug like Apo-TriAvir, Apotex's compulsory license would no longer be valid" (Himelfarb, 2005).

Another issue was associated with the two year limit for the generic supply. This again makes the regime unlikely. Due to above mentioned "non-cost-effectiveness" of the production accelerated by multiple internal hurdles, unnecessary delays and time consuming procedures of the regime, Apotex refused the Rwanda's request while they asked to double the supply in 2008 (Himelfarb 2015). If the largest generic manufacturer (Apotex) couldn't pay for it; these difficulties will make CAMR a non-viable regime (Himelfarb, 2005).

> "If Apotex, amongst the world's largest generic pharmaceutical companies, has no economic incentive to use CAMR, it can be assumed that the regime is similarly too costly for the other pharmaceutical companies in the developed world. For a compulsory licencing regime to be effective at incentivising pharmaceutical manufacturers to focus on the health concerns prevalent in the developing world, the regime has to be economically rational" (Himelfarb 2015).

From the above view of Himelfarb, it could not be assumed that the he was arguing for a 'commercially' viable regime, rather it should be viable for the generic manufactures to produce medicines on humanitarian grounds. In an Interview with a Canadian Generic Pharmaceutical Association representative, he stated that, "it is hard to imagine that any sane generic company would ever try to use the regime – especially after seeing what Apotex has gone through and spent" (Weber and Mills 2010: 118).

3.7.4. Revision and Amendment of CAMR

The Apotex's Rwandan episode spurs the demand for amendment of Canada's Access to Medicines Regime. Public health activists, NGOs like Canadian HIV/AIDS Legal Network, MSF and many political activists and parties has demanded a revision on CAMR. In response to the criticisms and the demand for revision the government announced a review on CAMR and invited responses from various sections of the society along with Standing Committee hearing from selected persons with various interest on the facet of CAMR (Esmail 2010: 27-28). In 2007 the Industry Minister tabled a review report. But the report recommended only certain "non-legislative" measures to revise the existing legislation (Kohler et al. 2010: 44). Moreover the Report concluded that "it was too soon to judge the efficacy of the regime and until that took place" (Esmail 2010: 77). Kohler (2010: 44-45) argued it as lack of commitment from the government on their humanitarian legislation – CAMR, while they recommended some meagre reforms. Furthermore Kohler (2010: 45) signalling government's shift in the policy from humanitarian drug exports towards funding on global health initiatives; that supposed to be less harmful to the intellectual property rights.

The government's disinterests lead to two private member amendment bills on CAMR; Bill S-232, introduced by Senator Goldstein and Bill C-393 by Judy Wasylycia-Lies in 31st March 2009 and 25th May 2009 respectively in order to enable CAMR serve its purpose (Elliot 2013; Gatto 2011: 25; Esmail 2010: 288; Kohler

2010: 45). One most of the significant proposal of those bills was “one licence solution”, which is a single license for multiple supplies (Canadian HIV/Aids Legal Network 2011; Gatto 2011: 25). The first one Bill S-232 expired with the prorogation of Parliament in 2009 December (Esmail 2010: 288). Meanwhile an opposition member of NDP (New Democratic Party), Judy Wasylycia-Lies tabled a private amendment bill in the House of Commons Bill C-393, with a proposal of “one license solution” as well as the deletion of existing definition of “pharmaceutical product” i.e., the Schedule-1, by proposing a more flexible one according to the August 30 decision (Canadian HIV/AIDS Legal Network 2011; Esmail 2010: 288). The Bill was voted with a significant majority and “passed through House of Commons” (Elliot 2013). The Bill got supports from NDP Members majority of the Liberal members, Bloc Quebecois members. Even though the ruling Conservative Party opposed it in House of Commons, 26 of their backbenchers in the House of Commons supported the bill (Elliot 2013). But the bill failed to pass as of the parliament was dissolved in 2011 (ibid).

In the new parliament a similar new amendment, Bill C-398, “An Act to Amend the Patent Act (Drugs for International Humanitarian Purposes)” was sponsored by Helene Laverdire (Laurier – Sainte-Marie) (Parliament of Canada 2012) . The proposed Bill C-398 stated the purpose of the amendment, that:

> “This enactment amends the Patent Act to make it easier to manufacture and export pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics” Parliament of Canada (2012a).

On 28th November, 2012 the House considered the bill for voting, and was defeated in the house with a narrow margin of 7 votes, that was148 against 141votes (Elliot 2013; Parliament of Canada 2012). Canadian HIV/AIDS Legal Network Director Richard Elliot (2013) stated that, despite the Bill C-398 got widespread support from various sections as in media, public, political celebrities, faith leaders, NGOs, National news outlets and so on, the ruling party members of the government voted out the bill (Elliot 2013).

Finally Canada lost its chance to amend the bill in order to make the bill more flexible to serve its humanitarian purposes. Elliot (2013) pointed out that “Canada’s Parliament had a chance to do something to stop the tragedy of on-going human

suffering and death", but they failed to translate that into a legislative amendment. This defeat of Bill C-398 spurred widespread criticism on government from the NGOs, opposition parties, and international health activists and so on.

3.8. Conclusion

This chapter has tried analysed the politics of intellectual property rights on the humanitarian initiatives to increase access to medicine. It could be understood from the above analysis that how the dominant utilitarian images of intellectual property rights are maintaining its status quo despite the changing circumstances and changing the legal structures of the intellectual property regime and how they are creating barriers in the access to medicine in the world. Moreover it can be seen that how the proponents of high level intellectual property protection are able to overcome the hurdle in the knowledge market through lobbying in international IP deliberations, issuing sanctions and threats, initiating agreements (TRIPS PLUS) with the foreign countries, acquiring the shares of, and merging with the competing pharmaceutical companies and so on. The last section of the chapter examined the legislation and working of Canadian humanitarian effort towards access to medicine - CAMR. Despite that CAMR was a laudable project to assist the poor countries by enabling their medicine access, but it failed to prove its translation into a workable one. The fifth chapter would be analyse the involvement of the politics of intellectual property rights in the legislative process of Canada's Access to Medicines Regime, using multi –level framework at three levels: international-level, state-level and non-state-actor-level.

Chapter 4

DEPENDENCY: IMPLICATIONS ON FOREIGN POLICY DECISION MAKING OF CANADA

This chapter examines the determinants of foreign policy decision making of Canada. Understanding the dynamics of factors involved in the decision making and functioning of a country's implementation of policy objectives will provide some insights to the study on Canada's Access to Medicine Regime (CAMR). Since CAMR is made under the highly globalised intellectual property regime, an independent existence is hardly possible for any domestic law which deals with intellectual property. Moreover multiple interests of different actors in the international politics also determine the functioning of such laws. A country like Canada is highly dependent on the fluctuations in international trade and on its neighbours, especially its continental counterpart United States, thereby political autonomy in decision making will be hard to be realise (Dolan 1982). Therefore it is necessary here to illustrate the factors influencing the decision making process of Canada. According to Stairs (1994) "Canadian foreign policy literature in large measure reflects the Canadian preoccupation with Canada's Place in the world, a preoccupation with status, position, influence and power". The factors such as Canada's power, international location, the formal and informal actors and institutions involved in the decision making process and the extent of economic and strategic dependency and the interdependence would be helpful to understand the role of politics of intellectual property rights in formation and functioning of the CAMR.

CAMR is a domestic law which is designed to ease the generic pharmaceutical manufacturing in order to ensure the access to medicine for the poorer countries. It is a domestic implementation of TRIPS flexibilities on compulsory licenses (CLs) offered in the Doha Declaration 2001 and its affirmation of 2003 WTO Ministerial Conference decision. Even though this legislation was made to ease the domestic generic pharmaceutical manufacture, the targeted beneficiary population are not the residents of Canada but the people of poorer countries who lack access to affordable essential medicine. It could be assumed that a domestic legislation is accompanied by foreign elements for the reason that, (1) this legislation did not emerge from the autonomous domestic jurisdiction of Canada, but from the flexibilities allowed by the

WTO General Council decision (August 30 Decision); (2) presence of international actors in this decision making process.

According to Canada's Intellectual Property Office's (WIPO) website information the purpose of the legislation is:

> "[the] use of patents for international humanitarian purposes to address public health problems: Canada's Access to Medicine Regime (CAMR) authorises the export of patented medicines in order to make it easier to provide pharmaceutical products to developing nations facing crises such as HIV/AIDS, malaria and tuberculosis" (CIPO 2015).

This shows the humanitarian objectives of Canada and its international commitments in making CAMR. As mentioned earlier the functioning of CAMR is in a highly complex intellectual property regime. Moreover CAMR has complied with the international IP laws too. It has been placed in a highly complex relationship of actors and institutions and some extra-legal relationships in the form of bi-lateral and regional agreement beyond the bounds of existing international IP legal agreements – TRIPS. While implementing its humanitarian policy objectives, it is important to be precautious about the 'effective losers' who comes under the pretext of the policy.

The CAMR enables the government to grant compulsory licence on patented medicines to any eligible third party without the consent of the original patent holder (Lalitha 2005: 1357). The research-based pharmaceutical industries with supporting the humanitarian provisions in Canada's foreign IP policy forms a threat to the interests of profit based big players of the IP regime, and any changes threatening the status quo would invite peril to the political autonomy of Canada. In the particular context, factors like Canada's existing power equations, capabilities and the sphere of influences would become crucial in determining the prospect of CAMR. Although the targeted beneficiaries of the CAMR, the world's poor countries who do not have adequate pharmaceutical manufacturing capacity do have a global majority in number, they have retained a little influence in the international IP regime as well as in the Canadian political system in the post-TRIPS era (Watal 2003; Chandra 2010)

4.1. DETERMINANTS OF DECISION MAKING OF CANADA

The “governments conduct foreign policy in pursuit of preeminent long-range goals of economic well-being and political autonomy” (Dolan et al. 1982: 390). International system appears as an hierarchical one. The distribution of power among the actors in the international politics is not on the basis of sovereign equality but rather on their relative power and capabilities. Therefore the behaviour of the states’ are determined by this “structural asymmetries” existing in the system, which are reflected in its conduction of foreign policy and also in relationships with other state (Dolan et al 1982: 390 – 391). The “membership in the British empire” and the subordination to the American hegemony after the decline of British Empire curtailed the scope of political autonomy of Canada in their foreign affairs (Nossal 1997). John Hutcheson argued that “because of the economic, ideological and cultural linkages between Canada and United States, which had been a consistent feature of life on the North American continent, the country was pulled into an emerging, even informal, American empire” (Nossal 1997). Allan Gotlieb (2004) hold the view that in order to analyse Canadian foreign policy it is necessary to assess Canada’s relationship to its “superpower neighbour” and it remains a “central factor” of Canada’s foreign policy. While assessing Canada’s power, international location and the behaviour of actors involved in the decision making process, the influence and presence of United States becomes so very evident.

4.1.1. Canada’s Power

Power is an important subject matter in foreign policy analysis. The relative share of possession within the international power distribution in turn determines the “power of choice” in the foreign policy decision making process (Stairs 1994/2995). The determinants such as location, economic structure, actor’s and institution’s behaviour and the capabilities do have a potential impact on the state’s power on international setting (Nossal 1997). It is a widely held view that, Canada has been considered as a “middle power” (Nossal 1997; Gotlieb 2004; Stairs 1994/1995; Therein and Noel 1994; Shawki 2008). In terms of its military, economy or in population strength, Canada was never a 'big power' like the 'USSR' or the US. At the same time it cannot categorise Canada as a small power like the least-developed countries.

In 1944 the former Prime Minister of Canada William Lyon Mackenzie King propounded the idea of middle-power of "in between states" to designate Canada's power status (Nossal 1997: 55). The post-war role of Canada in international politics in maintaining peace and security and in propagating multilateralism through United Nations was instrumental in acknowledging Canada's "middlepowernmanship" as a credible international actor (Gotlieb 2004; Nossal 1997). Canada focussed on "functionalism and multilateralism" in order to express the role of non-big powers in international politics rather than the pursuit of realist might (Kirton 2009; Nossal 1997). Canada applied its diplomatic skills instead of military capabilities in maintaining world's peace order (Therein and Noel 1994:532). For example, in settling the deadlocks in the Suez Canal Crisis in 1954, resolving Cuban Missile Crisis in 1962, initiating the treaties on non-nuclear proliferation and in 'n' number of peace keeping operations, Canada has successfully applied their diplomatic skills (Nossal 1997: 58-62). Moreover when the Uruguay round of trade negotiation was being dragged into a deadlock, especially on the matters of incorporation of intellectual property rights, Canada applied its power of diplomacy and negotiation by introducing a new draft of idea on the negotiating table in order to overcome that deadlock (Watal 2003) Therefore we cannot fix Canada's power status as a middle power with mere "in between state" in the hierarchy of international system, "but rather with the power of a particular style of foreign policy" (Nossal 1997).

It cannot be assumed that Canada's middle power status was an image of international recognition rather it was something self-asserted. It is a Canadian dream of independent political entity rather than a subordinate follower of super powers forced Canada to adopt alternative ways with a "particular style of foreign policy" or a new "brand of diplomacy" (Stair 1994: 12-18; Nossal 1997: 56-57). Unlike the big-power politics, Canada demonstrates "innovative methods of diplomatic skills" in pursuit of its national interest (Gotlieb 2004). Canada exposes itself as a responsible international actor to prove it's independency in international politics as well as to remove its successive images of imperial ally or a 'subordinate' state of the Empire in the pre-independence era and later of the imperial neighbour United States (Stair 1994/1995: 18; Nossal 1997: 53-57; Dolan et al. 1982).

Apart from the self-assertion of independent identity, the conditions of power or the real context compels Canada to behave in a particular manner. Therefore the middle-power diplomacy and the principles of functionalism and multilateralism are the products of these conditions of Canada's Power (Nossal 1997; Kirton 2007). Canada maintains this particular kind of foreign policy under almost every political leadership Canada had. Even though Trudeau's was a realist as well as nationalist tenure and he even rejected the traditional role of middle-power diplomacy, he couldn't blindly undermine the role as a 'middle power' in his entire tenure (Nossal 1997: 58-59). The National Energy Programme and the Great constitutional Debates were some examples of this tendency (Panitch 1981: 27-28; Nossal 1997: 81).

Canada focuses on multilateralism and functionalism as prime objectives in their perusal of foreign policy. It is believed that these two principles are the realistic manifestation of Canada's power. Since the power possession of Canada in the international system was not 'optimal', it will barely identify its national interests by means of a realist approach to foreign policy. At the same time as a trading country, free trade environments will necessary for its "resource-based economy" at a larger extent (Hart 2002: 12). The early staple exports, 70s oil production and the service sectors of Canada need to have a peaceful and free environment abroad. The possible implications of this dependency will be sufficient to answer Canada's foreign policy behaviour as a search for a highly predictable "rule based" world order (Hart 2002: 5-8). This dependency outside the domestic market determines Canada's power of choice in nationalism or protectionism in order to promote the domestic production (Hart 2002: 12).

Canada's rich natural resources such as staple products, oil, water, natural gas and uranium give them an important power status in international relations. But its "branch plant"[35] nature of industrialisation especially as a fraction of US multinationals made them dependent on the foreign capital, technologies and expertise (Panitch 1981). This again distorts Canada's natural power in dependency.

[35]Branch plant industries are considered as the foreign owned and controlled domestic companies of a particular country. American companies have built its branch plants or franchisees in Canadian soil in order to reap the Canadian market. This branch plant nature of Canadian manufacturing made them reliant on United States.

One of the parameter to assess countries' strategic power is the defence spending. Evidences shows that Canada's military and defence spending has been poor. Stockholm International Peace Research institute estimate shows that Canada ranks 14th in terms of its military spending: 22.5 $ Billion in 2012 (Roser 2015). At the same time its super power neighbour spends 682.5$ billion in the same year (Roser 2015). A World Bank source shows that military expenditure share of GDP of Canada was 1.2% in 2011; 1.1% in 2012; and 1.0% in 2013 against Unites States where it was 4.7%, 4.2% and 3.8% in the respective years (World Bank 2015). The same data shows that Canada's share of military expenditure was very little compared to other poorer countries of the world. Even though Canada is the world's second largest country geographically constituting a potential natural resource and has been a prosperous country in terms of wealth and economy, Canada's defence capability has been very poor and always depended on its allies especially on the US.

Therefore in order to study the decision making on CAMR this power analysis approach would be useful to understand how Canada behaves in this power context.

4.1.2. Geography

A larger part of Canada's foreign policy is determined by its geography. Its geographical location determines its "limited neighbourhood" as well as the strategic location and drags it to a closer ally of the West, especially with the United States (Nossal 1997: 29). Nossal (1997) argued that the post-war big power rivalry altered Canada's geo strategic position as like the "sandwiched" position between USSR and US. The emergence of the nuclear tensions and the innovations on the long-range delivery systems made Canada re-think about its strategic interests to be consistent with the United States (Nossal 1997; Kirton 2009) At the same time the Washington government considered Canada as a vital space for their defence and to ease their space attacks over the Soviet Union (Nossal 1997) and the same also determines Canada's decision to join NATO and the decision to sign North American Air Defence with United States (Nossal 1997; Paquin 2008). This North-American security matters then decides Canada's co-operation with US in various matters such as border security, anti-terrorism measures, illegal immigration, piracy of intellectual property, intelligence sharing etc. (Paquin 2008: 105).

Geographically Canada has been endowed with different varieties of natural resources such as fisheries, fur, timber, uranium, renewable water, petroleum etc. The British colonial government as well as the succeeded national governments had given an important place to the natural resources. According to the government reports, "natural resources are [the] important part of the fabric of Canada's economy" as well as the major source behind the growth and new opportunities of the country (GoC 2013). As per the 2013 budget sources (Economic Action Plan) natural resources accounts for half of Canada's total exports and 15% of the GDP (Ministry of Finance 2013: 136)

The political economists hold the view that the development of Canada and its relations abroad emerged from the exploitation of these natural resources. A Canadian Marxian political economist Harold Innis argued that the early development of bourgeoisie capitalism and the state activities has been derived from the production of staple:

> "The economic history of Canada has been dominated by the discrepancy between the centre and the margin of the western civilisation… agriculture, industry, transportation, trade, finance and governmental activities tend to become subordinate to the production of the staple for a more highly specialised manufacturing community" (Innis 1956: 385).

The synonymous development of branch plant economy with the staple production determines the industrial dependency in the early development of capitalism in Canada (Panitch 198: 9-10). Naylor argued that "the maximisation of mercantile surplus will minimise the industrial surplus" of Canada (Naylor in Panitch 1981). Watkins (2006: 76) identified that Canada's industrialisation had happened later, behind capitalism's transformation "from a competitive to a monopoly mode" as a consequence of deep-rooted large-scale-multinational corporations. This supremacy of non-indigenous industrial base has made the "weak path of dependent industrialisation" in Canada (Watkins 2006: 76). Moreover the asymmetrical relations with the super power neighbour and the consequential imbalanced alliance have frozen Canadian dream of indigenous industrialisation into a cold storage (Dolan et al. 1982; Watkins 2006: 77).Even though on the one side Canada could increase its domestic control since the 70s, the inability of Canada to build a base in "global capital" as well as in the markets made Canadian dependency continued, and on the

other side the dependency on trade replaced the decreased dependency on foreign capital (Watkins 2006: 79).

4.1.3. Economic Structure

Canada's economic history has been largely about the staple production and export and the consequent extension into the socio-political development. This determined the economic structure and Canada's status in the "North Atlantic Triangle[36]" (Brebner1948; Nossal 1997). Nossal (1997: 29) argued that Canada's economic history was a search for benefits and advantage from this triangular relation "first from the Britain directly and then from the United States via indirect investment in branch plants located in Canada". This branch plant nature invited dependency of Canada (Innis 1999).

"The Staple theory @ 50: Reflections on the Lasting Significance of Mel Watkins' A Staple Theory of Economic Growth"; an edited volume of work by Jim Stanford (2014) argues that Innis' and Watkins' tradition of political economy analysis is still relevant for Canada. Stanford (2014: 5) holds that "Market driven approaches, reinforced by the rules of free trade deals… predictably leave us with a skewed, polarised, fragile, and unsustainable resource-addicted economy". In that volume, Thomas Gunton (2014) argues that old staples are replaced by new, such as oil and natural gas and have contributed a good share in economy. But the dependency has been still persisting in two ways: (1) almost the entire oil produced has been exported in unprocessed 'crude' form, rather than refined one causing a potential loss in Canadian economy; (2) the oil industry is highly reliant on the US supplies: almost all of its oil and gas produced is dependent on the US market (Gunton 2014).

In 2013, Canada was the biggest export market for the United States and second biggest supplier of goods (USTR 2015). Nearly one third of Canada's Gross Domestic Product is generated from export and among which a total of 80% is accounted to the US' (Nossal 1997: 29). But that has been comparatively a lower import share in

[36]This denotes the trade as well as security relations between Canada, United States and Britain. This had great share in the international trade. In case of Canada, their economy and security was largely dependent on this triangular relation. In the post war era its importance declined relationally with the decline of the Great Britain in international politics. But corresponding to this trade between US-Canada increased. The history of the relation among these nations would be important to analyze Canada's economic structure, power and dependency.

United States: around 14.6% of total US import (USTR 2015). During the pre-war period Great Britain was the largest exporting destination of Canada. In 1930s Canada's export share with Britain was around 40%; US accounted for only 30% (Nossal 1997: 30). It was gradually transformed into export dependency on US. In 1990s Canadian export to the entire Europe including Britain accounted to be below 10% (Nossal 1997: 30). Today Canada and the US are largest trading partners globally comprising a value of $1.6 billion cross-border goods transactions per day (GoC 2013: 131). United States is the biggest foreign investor of Canada "holding 54.5% of Canada's total inward investment stock in 2010" (GoC 2013a). The post-NAFTA period manifest one of the significant trends in Canada's regional trade, especially the US-Canada Trade. Canadian Export to United States increased by a 308% from the pre-NAFTA period (USTR 2015).

Moreover in 2013, Canada was the biggest export market for the United States and second biggest supplier of goods (USTR 2015). In terms of the Merchandise Export the United States accounts to 74.4 % (376 $bn of 492 $bn) of the total and 54.3% (278 $bn of 512 $bn) of the total Merchandise imports. The share of the rest of the major countries is shown in Table-1. This shows the Canada's dependency on a single market 'US'. Concentration on a single market destination rather than diversification of trade has continued throughout the entire economic history of Canada.

Table 4.1: Merchandise imports and exports between "Canada" and Other Major Countries, by Harmonized System section, customs basis, 2014 summary

Destination	Domestic exports	Imports
	CAN$ (Millions)	
Total Merchandise Trade	492,113	511,523
US	376,185 (77.4%)	277,987 (54.3%)
China	18,898	58,660
United Kingdom	14,312	9,175
Mexico	5,195	28,831
Germany	2,801	15,962
France	3,083	5,921
India	3,160	3,181
Brazil	2,068	3,466
Russian Federation	1,155	726

Source: Statistics Canada

One of the largest economic sectors which is manufacturing, still remained under dependency on foreign control. Asset wise it accounts to 50.3% in 2011 and 49.7% in 2012; revenue wise it accounts to 47.2% in 2011 and 48.7% in 2012 and operating profit wise it accounts to 42.5% and 45.8% in 2012 of the total manufacturing sector (Statistics Canada 2014). The Data shows that the share of natural oil and gas sector was also not optimal. A major share still remains under the foreign control (Statistics Canada 2014). Table 3 shows that United States is the largest foreign country that controls Canada. US controlled about 49.1% of the Assets, 53.8% of the operating revenues and 58.4% of the operating profits of the total foreign control of Canada in 2012 (Statistics: Canada 2014). The concentrated single nation foreign investment scenario of Canada against diversified investments points towards the high level of dependency existing in Canada's foreign trade policies.

Table 4.2: Assets, Operating Revenues and Operating Profits under Foreign Control Industry wise

	2011 – Under foreign control			2012 – Under foreign control		
	Assets	Operating Revenues	Operating Profits	Assets	Operating Revenues	Operating Profits
Manufacturing	50.3 %	47.2 %	42.5 %	49.7 %	48.7 %	45.8 %
Oil and gas extraction and support activities	38.5 %	55.0 %	41.7 %	36.7 %	48.6 %	30.7 %

Source: CANSIM table 179-0004 (Table 1) from Statistics Canada (Date Modified: 2014-12-09)

Table 4.3: Total Assets, Operating Revenues, and Operating Profits under Foreign Control by Major Country of Control, All Industries

	Assets		Operating Revenues		Operating Profits	
	2011	2012	2011	2012	2011	2012
	% Under Foreign Control					
United States	49.2	49.1	55.6	53.8	58.3	58.4
United Kingdom	13.2	13.2	8.5	8.0	8.0	7.7
Germany	4.5	5.2	4.2	4.3	4.9	4.2
France	3.3	3.2	3.3	3.3	4.0	5.3
Netherlands	7.9	5.7	6.8	6.9	2.7	1.8
Japan	3.7	4.0	5.6	6.3	2.9	3.6
All other foreign countries	18.2	19.6	16.0	17.3	19.3	19.0

Source: CANSIM Table 179-0004 (Table 2) from Statistics Canada (Date Modified 2014-12-09)

Today the Oil industry of Canada is one of the leading manufacturing sectors of Canada accounting to around a 5% share of the total GDP of Canada (Mendleson 2012). But the country is still depending on the crude oil trade rather than the refined. Some scholars argued this is an example for Canada's on-going nature of staple economy. Even though its oil export has grown tenfold from 1980- 2010, the refining capacity have been stagnant or have even declined. (Mendleson 2012). In 2007 around 97% of its total oil exports went to the US market. Moreover most of Canada's oil (crude) industry is owned by Americans. Number of domestic refineries has fallen to 17 from 40 (Mendleson 2012). Fred Wilson, (Communication, Energy and Paper workers Union of Canada) holds the view that branch plants are the major reason for the lack in capacity in refining crude oil: "they [may] ready to build refining capacity elsewhere, rather than in Canada" (Mendleson 2012).

Table 4.4: Leading Pharmaceutical Companies in Canada

Rank	Leading Companies	Parent country	Total Sales ($ billions)	Market Share (%)
1	Johnson & Johnson	United States	2.13	9.6
2	Pfizer	United States	1.45	6.5
3	Apotex	Canada	1.19	5.4
4	Merck	United States	1.17	5.3
5	Novartis	Switzerland	1.13	5.1
6	Teva	Canada	0.97	4.4
7	GlaxoSmithKline	Britain	0.91	4.1
8	Roche	Switzerland	0.80	3.6
9	Pharmascience	Canada	0.77	3.5
10	AstraZeneca	Britain	0.77	3.4

Source: IMS Health Pharmafocus 2018 from *Canadian Pharmaceutical Industry Profile* (2014), Industry Canada: https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01703.html

Foreign direct investment has been very visible regarding the pharmaceutical sector. Out of the 10 leading pharmaceutical companies in Canada, only three are owned Canadian nationals (See Table 4.4) and out of the top 20, not so surprisingly only four are Canada based. Most of the companies are branches of multinational corporations among which US multinationals are the leading producers in Canada (See Table 4.4). About the international intellectual property decision making these multinational corporations has been enjoying a leading role. Moreover the generic-branded disparity in sale is very high in Canada: the branded medicine accounted around 76% than the

remaining generic sale (GoC 2014). A new global trend is also reflecting in the branded pharmaceutical sales in Canada. The share of branded sale has been slightly declining. It is a consequence of "patent expiries". The TRIPS concluded its 20 years and simultaneously the first generation post-TRIPS patents life is expiring (GOC 2014). This trend would affect Canadian as well as global branded-medicine's market in the immediate coming days. This trend would be useful in predicting the future intellectual property policy changes in both Canadian as well as global pharmaceutical regimes.

Table 4.5: Domestic spending on research and development (GERD)

Year	Domestic spending on research and development	Gross domestic product	Domestic spending on research and development/Gross domestic product
	$ millions		%
2002	23,534	1,152,905	2.04
2003	24,693	1,213,175	2.04
2004	26,680	1,290,906	2.07
2005	28,022	1,373,845	2.04
2006	29,079	1,450,405	2.00
2007	30,038	1,529,589	1.96
2008	30,751	1,603,418	1.92
2009	30,129	1,528,985	1.97
2010	30,555	1,624,608	1.88
2011	31,486	1,720,748	1.83

Sources: Statistics Canada, CANSIM, Table 358-0001 and 380-0017; Catalogue nos. 88-001-XIE and 88f0006XIE; Date Modifies 17-10-2014.

Table 4.6: Patent Application and grants for the top 15 country of 2013 origin

Patents Applied				**Patents Granted**		
1	China	734,147		1	Japan	340,364
2	USA	501,903		2	USA	244,228
3	Japan	473,259		3	China	154,505
4	Republic of Korea	223,530		4	Republic of Korea	123,817
5	Germany	184,843		5	Germany	81,788
6	France	71,285		6	France	43,163
7	United Kingdom	51,424		7	Russia	23,507
8	Switserland	45,171		8	United Kingdom	21,017
9	Rissia	34,420		9	Swtizerland	20,166
10	Netherlands	33,777		10	Italy	19,378
11	Italy	28,988		11	Netherlands	16,745
12	Canada	26,360		12	Canada	13,418
13	Sweeden	22,684		13	Sweeden	12,293
14	India	20,941		14	D.P.R Korea	6,528
15	Austria	13,392		15	Belgium	6,323

Source: WIPO Staistics Data Base October 2014

Knowledge production is an important indicator of the industrial development for every country. The data shows that Canada's performance in the production of knowledge is very meagre. Regarding the share of spending in Research and Developments (R&D), Canada's share is poor and has been declining. Table-5 shows that Canada's spending in terms of money has increased but share of GDP has declined. According to Statista (2015), Canada is placed outside the top ten producers in the world with reference to the share of global pharmaceutical production. At the same time United States who is Canada's largest trading partner ranks first and accounts 32% of the total production in 2009. The global performance indicators show that Canada ranks 12th in terms of patent filing and granting. Canada's Patent application accounts to 26,684 and granted patents accounts to 13,418, in 2013. But its share of the total is very pitiable and distanced far from its largest trading partner, United States.

Many foreign policy analyses have argued that the dependent nature of Canada's economic structure has significant implications on Canada's foreign policy (Nossal 1997: 30). Canada's economic structure is still reliant on the trading of un-processed manufacturing goods (Stanford 2014). Therefore the countries such as Canada need a highly predictable as well as stable international system (Nossal 1997: 30). In international anarchy it is hardly possible for such countries to maintain their trade and economy. Canada considered "Peace while pursuing its foreign policy" (Ignatieff 2013). It can be assumed that it was derived from the realistic understanding of its domestic conditions that Canada is living in. Canada has necessitated "international peace and order" in order to extent its trade interest. This can be facilitated by a world of democracy or good governments alone. The extended level of this "democratic peace theory" as well as the "liberal internationalism", clarifies the implications of Canada's initiatives on peace keeping, human right diplomacy, human security and so on (Kirton 2007; Nossal 1997). For maintaining stable international order, Canada pursued multilateralism as well as rule based international institutionalism (Nossal 1997; Kirton 2007). This will provide a minimum predictability in international relations and transactions. Therefore Canada assumes this will be the best possible way of international order and stability (Nossal 1997; Kirton 2007).

Trudeau's period witnessed the biggest initiation for economic self-reliance nationalisation and trade diversification (Nossal 1997). He introduced some new doctrines of policy, such as "Third Option" in 1972 and indigenous entrepreneurship development and nationalisation of key industries through take-overs in order to reduce dependency and to enhance domestic industry (Kirton 2007: 129; Marsden 1997) Moreover a diversification of Canada's international trade was intended through Diversified bi-lateral agreements with countries other than the conventional partners. Canada Development Corporation and Canada Energy Programme were some examples of the initiative to implement industrial nationalisation (Marsden 1997). But this initiative invited US reprisals. Marsden argued that the NEP style domestic capitalism was sabotaged by the antagonistic United States interests and the foreign multinationals of Canada (Marsden 20077:129-132). Finally the diversification of trade remains a matter of future task of priority in Canada's foreign policy objectives. US remains Canada's largest trading partner accounting for more than a third of trade and accounting to around 80% of total export.

4.2. DEPENDENCY

From the above analysis on Canada's power and economic structure it can be seen that all the determinants discussed in the chapter are mutually dependent and determined. In turn dependency influences the behaviour of Canadian state in decision- making in domestic and foreign affairs, as well as the nature of relations with rest of the states.

Canada's dependency is an exceptional one compared to the dependency of the third world. Even though Canada achieves high economic growth and good conditions of human life, it could not revive itself from the shadows of imperialism. Harold Innis (2004: 115), a political economic historian wrote, "Canada has had no alternative but to serve an instrument of British imperialism and then American imperialism". Though Canada's colonial past became a history, the nature of staple-based economy as well as industrial structure successively dragged them into dependency especially on its neighbour, United States (Innis 1997: 40-41).

> Canada, "has never been self-sufficient, and her existence has depended primarily upon trade with other countries… [a]s a result …Canadian economic history must be approached from the stand point of trade with the other countries" (Innis 1999: 40).

These words' of Harold Innis has been ample for forecasting Canada's behaviour in the international politics - choosing the national interest priorities, adjusting with the interests of United states, liberal internationalism, functionalism, institutionalism, democratisation, peacekeeping, middle-power diplomacy, multilateralism, regionalism and so on (Nossal 1997, Marsden 2007). This view is supported by Watkins (2006: 79), who argues that since Canada couldn't transcend its "staple-biased, semi-industrial status" as well as the "Americanisation", dependency consequently spill over onto whole sections of the system: social, economic, cultural and military. Moreover Innis (1997) holds that, this particular nature of economic dependency invites foreign industrial investment from the United States, that in turn determined the dependent industrial structure in Canada.

The implications of this dependency have been very disturbing for Canada. On the one side Canada supports almost every international regional as well as bi-lateral trade agreements (GATT, WTO, NAFTA, CUFTA, TPP, etc.), even though such agreements have reduced the scope of other sectors than trade and on the other side the country is losing its political autonomy in decision making. Moreover it can be assumed that Canada's membership in various multilateral organisations and alliances is in the same manner. Briefly, we analysed Canada's behaviour in this political economy approach.

4.3. MAKING A DECISION: DOMESTIC ACTORS AND INSTITUTIONS

A countries' Decision Making is primarily a governmental activity. But various actors and institutions; both governmental and non-governmental are involved in it. The former section has examined Canada's domestic settings of decision making, such as power, capabilities, economic structure, geographical setting, and dependency. This section would be an identification of actors and institutions who has been involved in the decision making process of Canada. More over this section would be an examination of the role of major actors and institutions specifically in the IP decision making process, rather than an overall analysis. Therefore this would be helpful to analyse the politics involved in the IP decisions especially in the making and functioning of the Canada's Access to Medicine Regime.

In matters such as CAMR legislation and its amendment, the parliament is the final authority in the decision making process. The responsible actors are Houses, Senate and House of Commons and the Parliament Committees. Most of the Bill has been introduced by the concerned ministers in the parliament. But every members of the parliament has the right to introduce a bill in the concerned houses. For example, even though it was defeated by a narrow margin, amendment bill (C-398) on CAMR was introduced by the opposition member Helene Laverdire (Parliament Canada 2010). In the bills where highly Intellectual property matters are incorporated the role of Standing Committee on Industry, Science, Technology and Development are important. They hear the responses from various sections of interests, and recommended suggestions to make the final draft. Moreover the Bills in which external elements (international intellectual property laws, international trade, violations of foreign trade agreements etc.) are involved, like CAMR, the Department of International trade and External Affairs and the concerned portfolios are important. Regarding the functioning of intellectual property laws, the Canadian Intellectual Property Office (CIPO) is of utmost primacy. Overall the head of the executive branch of Federal Government and the leader of parliament, the Prime Minister of Canada has an important role in the decision making Process.

Other than the governmental actors and institutions, the role of the non-governmental institutions which have potential influence on the executive, bureaucratic as well as legislative branches has to be addressed in order to analyse the decision making process. In the legislation of CAMR, its review as well as the amendments of these actors has been directly and indirectly involved in the decision making process. The Standing Committees hears and receives the responses of NGO representatives and from both the Generic as well as Branded pharmaceutical companies'. Apart from that these NGOs and Pharmaceutical companies lobbies with the political parties, parliamentarians and ministers via press releases, publications, protest demonstrations and so on.

Chapter 5

ANALYSIS AT DIFFERENT LEVELS: CUTTING ACROSS CONCEPTUAL AXES OF UTILITY, HUMANITY AND DEPENDENCY ON CANADA'S ACCESS TO MEDICINES REGIME

The aim of this chapter is to explore the determinacy of the three factors utility, humanity and dependency, in the formation, reform and the functioning of the Canada's Access to Medicines Regime (CAMR). Literatures suggest that concepts such as utility, Humanity and dependency and its variants would find reflections in the legislative process of CAMR. Therefore this chapter used as a theoretical framework of *Utilitarianism*, *Humanitarianism*, and *Dependency* to study its impact on the legislative process of CAMR and on the behaviour of actors at different levels.

While the second chapter studied the utilitarian philosophical underpinnings of Intellectual property, the third chapter analysed the relevance of the humanitarian perspective on Canada's access to medicine regime using secondary literature. Following on this line, the fourth chapter clearly brought forth the '*dependency*' of Canada using secondary literature, this chapter proposes to analyse primary data sources such as parliamentary debates, committee hearings, patent law and so on to understand the failure of Canada's Access to Medicines Regime .

The novelty that this chapter proposes to offer is that while prior research studied the regime on the basis of its functioning, this chapter goes into the very heart of the legislative process by looking at various legislative artefacts. The research in this area although sparse has only covered the 2004 version of this bill, five year before the actual amendment process commenced. The focus of this chapter would be on the legislative processes that accompanied the review process of the bill that commenced in 2009 and ended in 2012 and subsequently the two amendments that were proposed to this act since 2012.

In order to do that, this chapter would analyse the roles played by *utility*, *humanity* and *dependency* at three levels; international-level, state-level and non-state actor level .The study is delimited to legal texts and the transcriptions of parliamentary procedures and also few variants.

To this end, this chapter will be divided in to three major sections: analyses of international system level, state level and non-state actor level. Before turning in to the major three analysing sections of the chapter it is necessary that a brief understanding about the reconciliation different priorities of interest in the making of CAMR. This would be helpful to understand the relationship between the legalities and the functioning of CAMR.

5.i. Three theories and reconciliation

As mentioned in the third chapter, there is a balance of interests behind the formation of Canada's Access to Medicines Regime. The government of Canada itself indicated that, "the regime" (Canada's Access to Medicines the Regime) "balances Canada's trade and intellectual property obligations with humanitarian objective of WTO decision" (GoC 2008). This balances politics of *utility* and *humanity* in the intellectual property decision making of Canada. Canada provided a negotiation table to the actors before making, reviewing and amending the CAMR and received policy inputs form various sections of interest such as NGOs like Medicines Sans Frontiers (MSF), Canadian HIV/AIDS Legal Network; Generic Pharmaceutical industry representatives, Research Based Pharmaceutical Industry representatives, health care activists, legal experts and so on (GoC 2008; GoC 2008a). Ministry of industry stated that:

> "[i]n developing the framework for CAMR, Canada faced the unique challenge of fashioning an unprecedented compulsory licensing for export regime which would advance the …humanitarian objectives, while respecting the international trade rules and maintaining the integrity of the domestic patent system" (Industry Canada 2007).

This balance of interests is dependent on international trade environment which limited the scope of CAMR, and ended up breaking up its "one and only experiment[37]"- the Apotex's Rwandan experience. The upcoming three sections will analyses this failure of balance or reconciliation.

5.ii. Three levels of analysis

This multi-level analysis chapter uses three levels to analyse the issue at hand: international system level, state level and non-state actor level. In the international system level multilateral and regional intellectual property agreements will be studied,

[37] It was discussed in the Third Chapter in detail

such as TRIPS, Doha Declaration Text, WTO August 30, Decision implementing Paragraph 6 of the Doha Declaration, NAFTA. In the international system analysis, the impact of international legal documents on Canadian Patent Laws, especially on CAMR will be examined qualitatively. The analysis will be based on a theoretical frame work of three theories: Utilitarianism, Humanitarianism and Dependency as a tool of analysing the impact.

The second and the third levels will use mixed methods of analysis, (i.e.) both the qualitative and the quantitative method will be used. The non-state actor level will involve the different interests and politics involved in the Decision making process on CAMR. The Review Committee submissions, Industry Committee Hearings will be utilised to reveal the non-state actor level politics involved in the working and of amendment (Bill C-393) of the CAMR. The response of dominant interested parties of CAMR such as NGOs, academia, research-based pharmaceutical industry, industry associations conveyed in the Review, and Hearings will be examined in this level.

In the state actor level the study delimits the interested actors in to the parliamentarians and concerned government departments; those are directly involved in the decision making on CAMR. The Department level responses will be available as Industry Committee Siting transcriptions on the Bill C-393. In the Parliament level, the transcriptions of MPs parliament speeches and responses delivered in the parliament debate on Bill C-393 and Bill C-398 will be examined. The Parliamentarians responses are divided into party level: Conservative Party, Liberal Party, New Democratic Party, and Bloc Quebecois. This chapter will examine the impact and replications of the different interest in the decision making process, which culminated in the defeat of the Bill C-398.

5.iii. Theoretical Perspectives

As mentioned earlier, the case of how utility, humanity, and dependency affected CAMR will be assessed at the three levels. This necessitates the use of the three theories: Utilitarianism, Humanitarianism and Dependency. The arguments in the parliamentary debates Review Committee submissions and Industry Committee Hearings on the Bill C-393 and Bill C-398 are categorized under the different themes of utility, dependency and humanity. It will be useful to examine the behaviours of

actors involved in the different camps. This categorization makes it possible to quantify the responses alongside its qualitative analysis. The coded themes of arguments and responses are as follows.

5.iii.i. Utilitarian

- #[38]Utility of IP (intellectual property): in this (head) the actors mentioned the necessity of securing exclusive market rights on intellectual property. Such kind of high level protection will encourage innovation and development. Any such actions limiting the intellectual property right will endanger the research and development environment in that countries and the resultant development. Therefore the "utility" will be the ultimatum of every government in order to ensure the overall development of the society. This argument expressed indirectly stating that even though it is humanitarian, the flexibilities of the CAMR possibly affect the status quo of intellectual property protection of Canada. Any such threats discourage the pharmaceutical companies to conduct R&D in Canada; in turn it will imperil the development of new drugs, and creating job opportunities and the overall development.
- #Diversion and #Anti Diversion: this argument indicates the probable violations or missuses of the regime. If the CAMR has amended the possibility of diverting the medicine from destination market to other markets there are possibilities that it may return to the Canadian market itself. This diversion of low cost medicines to other market threatens the IP rights of the patentees. It is expected to distort the influence of the high-priced branded medicines. Most of the times this argument come from the utilitarian camp those who are not in favour of or scared of generic competition and the consequent reduction in price.
- #Status quo on CAMR: in this head the actors argue that the CAMR is working. If the generic manufacturers consider it is unworkable, it is not the problem of the existing laws and regulations. It is the other factors that discourage the developing countries to choose generic products under CAMR. They are getting cheaper generic products from other developing countries (India, Brazil and China) those

[38] The # symbol will be used to identify the coded themes of responses and arguments

are capable in generic pharmaceutical production. Competitiveness of Canadian generic is minimal. Therefore the logic of amending the CAMR has been to oppose.

- #Non-competency of Canadian Generics: as mentioned in the #status quo there is a debate about the competency of Canadian generics in the international market due to the low-cost generic medicines from Indian, Brazilian and Chinese generic manufacturers.
- #IP Obligations: this will be discussed under the dependency. It is ultimately an utilitarian argument. But, for a dependent county IP obligations will be a prior concern.
- #Compliance with the TRIPS/trade agreement: the Actors who favour to maintain the status quo on CAMR argue, if the regime is amended it will affect the regimes compliance with the trips guidelines.

5.iii.ii. Humanitarian

- #Extension of flexibility… to ensure humanitarian commitment of CAMR in order to ensure (access to medicine): the CAMR should be amended and should make the CL process more flexible in order to fulfil Canada's Humanitarian commitment towards access to affordable medicines.
- #Contextualizing the world Health condition: the actors substantiating the need to amend the CAMR for more flexibility in the regime by referring the worst health conditions of the world especially the health crises of sub-Saharan Africa. They mentioned facts and statistics of the diseases and epidemics and the stories of people who are struggling with these diseases without or inadequate medicine access due to the un-affordable prices of the medicine.
- #Reduction of IP barriers: this argument considers that the strong intellectual property protection is the major threat to the global access to medicine. In order to deal with the health crisis of the world, the IP regime should be made flexible and it should also address the health crisis of the world.
- #A2M (Access to Medicine) via generic competition/#Generic Competition: it is argued for the necessity of more flexibility for CLs under the regime, in order to encourage the generic competition and for the subsequent reduction in price of the medicine in the market.

- #Canadian Generic Medicine is Competent: rejects the argument the incompetency of the Canadian generic product. Apotex, a Canadian generic manufacturer has send two shipment of generic medicine under CAMR with the same price of the similar Indian generic medicine. This has proven that the Canadian generic products are competitive. Moreover Canada is capable to produce second and third line therapy of HIV/AIDS medicines, the others are not or less capable.
- #Over-compliance of CAMR: this was mentioned to argue the over-compliance of the CAMR with the guidelines given by the Doha Declaration and August 30 Decision on CLs. This is beyond the Requirements of the TRIPS flexibilities. The complexities of the regime and the reason for the dis-functioning of the regime is emerge from this unnecessary clause.
- #Complied with the trade agreements/TRIPS: the actors in favour of the amendment argued that the regime is complied with the TRIPS and other international IP guidelines. Nothing will affect to the compliance if the regime amended or bill (C-393 and C-398) has passed.

5.iii.iii. Humanitarian but less / non-Harmful to Utilitarian Interest

- #Assistance and funding: this argument favours voluntary funding and assistance to health programmes to help the people suffering from diseases. This argument considers it is to be alternative to CAMR to fulfil Canada's humanitarian commitment as well as it is harmless to the interests of the patent holders and the branded medicine companies. Need for Canada's contribution to international collaborations, global health alliances, technical assistance, aid programmes, and other multilateral initiatives to help those countries suffering from health issues are coming under this head.
- #CSR (Corporate Social Responsibility)/Charity as an alternative: this was a similar argument like the "assistance and funding". The actors who are in favour of this argument considered the CSR or charity activities to be better alternative than amending the CAMR. This is also less or non-harmful to the interests of utilitarian camp.

5.iii.ix. Dependency

- #Trade Obligations: it is argued that the proposed bill violates the international trade obligations of Canada. For a county like Canada; its economy has been highly dependent on international trade and maintaining status of credible international player is highly important for Canada. As discussed in the fourth chapter any displeasure from its trade partners especially from the US may damage Canadian economic interests. Therefore the Canadian decision makers generally consider compliance with the trade obligations as a prime concern while taking any decisions.
- #IP (intellectual property) obligations: for a country that is highly dependent on the international regimes rule based governance of the international system, international obligations are considered as a prime concern while making a decision. Since a domestic law such as CAMR, which is considered highly related with both formal and informal international IP obligations and within dependency, such factors have a potential impact on Canadian decision making.

5.1. INTERNATIONAL SYSTEM LEVEL ANALYSIS

In the international level this study is focussed on the implications of utilitarian defences and humanitarian concerns in the patent laws of Canada, especially on the CAMR. In doing that the study has to cross-verify the international legal documents such as TRIPS, Doha Declaration 2001 and WTO 2003 August 30 Decision with the CAMR. The literatures indicated the relationships between Canada's dependency on international trade and the need for a more predictable rule-based international trade regime; and that have implications on Canada's domestic politics (Nossal 1997: 30; Hart 2002: 5-8).

5.1.1. Agreement on Trade Related aspects of Intellectual Property rights (TRIPS)

In its implementation level, TRIPS was discussed in the third and fourth chapters. This Chapter is analysing the legal text and the reflections of utilitarian and humanitarian politics in its lines of texts and clauses. These reflections will be useful

to analyse the state level intellectual property regimes such as CAMR. The preamble of Agreement on the TRIPS in 1994 declared that:

> "Members, [d]esiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade" (WTO 1994).

Moreover in the preamble the member states recognised the need for a new "multilateral framework of principles rules and disciplines" to deal with the international trade, intellectual property rights and counterfeit goods (WTO 1994). The section (e) of the preamble clearly indicates the utility of a rule-based international intellectual property rights agreement and states that,

> "[The members] recognizing that intellectual property rights are private rights; …underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objective…" (WTO 1994).

These texts revealed utilitarian defences of TRIPS agreement. According to Jeremy Bentham (1823) since the principle of utility provides a greatest happiness to a greatest number of the society, that principle will be the ultimatum of every "actions of both the individuals and the state"; indeed the prime force behind the "reason and law". Utilitarianism argues that (IPRs incentivises the innovation) and accordingly ensures the developmental and technological objectives of the society (Sterckx 2004; Chandra 2010). This would ensure an "overall happiness" to the society (Sterckx 2004). The TRIPS agreement reaffirms the utilitarian principle, by offering enhanced incentives to innovation and development via a (1) universal application of intellectual property rights (2) a rule-based "enforcement" mechanism for the same (3) and a highly predictable world trade organisation (WTO 1994).

Article 7: the "Objectives" is giving a more comprehensive account of utilitarianism in the TRIPS agreement.

> "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology to mutual advantage of procedures and users of technological knowledge and in a manner conductive to social and economic welfare, and to a balance of rights and obligations" (WTO 1994).

The objectives points out a hypothetical mutual advantage, through an improved technological development and transfer as being a part of this agreement. Indeed these technological developments will incentivise the socio-economic welfare in member countries. Section-5 of the Agreement deals with the patents. The patent rights enforcement deal with the question ("how" of utilitarianism); i.e., how patents makes utility or greatest happiness to a greatest number in the society. The Part II, Section 5, article 28 provides the patent owners an "exclusive market rights" and "transfer rights" (WTO 1994). Utilitarianism believes, an absence of exclusive market rights, makes people's actions irrational (Chandra 2010). In order to stimulate the inventions the inventors should have exclusive rights on their creations (Sterckx 2004). Moreover, the acknowledgement of such rights incentivises the advancement of useful knowledge (Richards 2002). This requirement for making utility has acknowledged in the Article 28 of the TRIPS Agreement by providing exclusive market rights to inventors (WTO 1994). The Part III of the TRIPS agreement deals the "Enforcement of Intellectual Property Rights", as a necessary requirement to enhance the utility of intellectual property rights (WTO 1994). Articles 41 to 61 of the Part-III mandated the member states to ensure the protection of intellectual property rights via making some specified institutional structure and providing the right to the IP holders to go for both civil and criminal judicial proceedings against the infringement of intellectual property (WTO 1994).

5.1.2. North American Free Trade Agreement, 1994

Canada is a one of three members of North American Free Trade Agreement (NAFTA). It is important to analyse the NAFTA, because of the geographical location, and regional dependency of Canada. As discussed in the fourth chapter it is the worlds' largest trading regime and is governed by NAFTA now[39]. Among that, Canada-US trade accounts a potential share of the worlds' total share[40]. The NAFTA will be an important obligations for Canada because, US is the largest trading partner of Canada, and accounts more than one third of total international trade of the country (GoC 2013).

[39] See the discussions of Chapter 4
[40] *Op. cit.*

It could be seen that NAFTA has many similarities with TRIPS Agreement while going through the lines of the Agreement. Similar to World Trade organisation, NAFTA also incorporates one chapter of the governing principles on intellectual property. The Chapter -17 of NAFTA deals with intellectual property (NAFTA 1994). The first Article of the Chapter 17 (1701) obligates the Members "to provide in its territory to the nationals of another party adequate and effective protection and intellectual property rights" in order to ensure the "legitimate trade" (NAFTA 1994). The Article 1703, instructed the member states to provide national treatment to the intellectual property rights of the foreign nationals (NAFTA 1994). Both the Articles points out the need for IP protection beyond the boundaries of the national territories. It is a necessity because in a globalised world and an era of free trade, a single state cannot "incentivise innovation and development" by providing intellectual property rights in its territory alone. The scope of infringement is also extending, with the extending scope of intellectual property beyond the national borders.

Regarding the compulsory licensing, Article 1709 of NAFTA (1994: 1709.08 and 09) also allows the members to grant the CLs –"use without the authorisation of the right holder". But such licences shall be "non-exclusive"; "non-assignable; and "predominantly for the supply of Party's domestic market" (NAFTA 1994: 1709.10.d, e, f). Moreover the "right holder shall be paid adequate remuneration taking in to account the economic value of the authorisation" (NAFTA 1994: 1709.10.g). Another important obligation of the NAFTA IP Chapter is the extension of patent life. NAFTA mandated the Members to provide"20 year duration of patent protection from the date of filing" the application or "17 years from the date of grant" (NAFTA 1994: 1709.12). Similar to the TRIPS, NAFTA-IP Chapter mandated the Members to setup adequate intellectual property rights enforcement mechanisms including administrative, provisional and legal (civil and criminal) proceedings (NAFTA 1994: #1714-1718).

5.1.3. Doha Declaration, 2001

While coming into the Doha Ministerial Conference 2001, the international political situation has turned into the public health crises and on the issues of access to medicine. As is discussed earlier, the politics of legal battles by the global research based pharmaceutical industry with the support of USTR united the global south as

the other side in the international trade regime on matters of intellectual property rights successfully (Lexchin 2013; 't Hoen 2009; Weber and Mills 2012; Williams and Lofgren 2013; Chandra 2010). The global South along with some concerned (INGO)s set forth a *humanitarian* politics on the issues of global access to medicine in this context (Chandra 2010; Lexchin 2013). Their efforts culminated in WTO's Doha Ministerial Conference 2001, and resulted in the "Declaration on the TRIPS Agreement and Public Health" (WTO 1994). The Declaration has comprised of seven main paragraphs of proposal and four sub paragraphs. It is clearly evident that the humanitarian objectives are reflected in each and every paragraphs of declaration while observing it. The declaration has acknowledged the developing and developed countries demand for creating a human face to the world's intellectual property regime and to interpret the TRIPS in a manner that recognized the public health needs of access to medicine. The Paragraph 1 dealing the issue declared that,

> "We recognize the gravity of the public health problem afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis malaria and other epidemics" (WTO 2001).

In the Paragraph 2, the Declaration stresses the need for reinterpreting the TRIPS in order to address the public health problems and making them part of the "national and international actions" to resolve these problems (WTO 2001). The Paragraph 4 providing a wider implication of the public health and access to medicine demand, which declared:

> "We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. …[and] affirm that the [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines to all" (WTO 2001).

The Paragraph 5 has given the full right to the Member states to interpret the public international law, TRIPS in order to fulfil the aforementioned objectives and purposes of the Declaration (WTO 2001). The sub-paragraph (b) gives the right to the Member states to grant compulsory licences (CLs) and gives the full right to interpret the "grounds upon which such licences are granted (WTO 2001). Furthermore the next sub-paragraph (c) clarifies the Article 30 of the original TRIPS agreement, by providing "right to determine what constitute national emergency and the

circumstances of the extreme urgency in a manner with respect to the public health crises of the Member states (WTO 1994; WTO 2001).

The paragraph 6 of the Declaration extends the scope of CLs under TRIPS; i.e., the Article 31(f) original TRIPS agreement. According to 31(f), the right to issue CLs was limited for the "supply of domestic market" (WTO 1994). The Paragraph 6 leads to the extension of the scope of CLs from domestic supply to 'export' purposes too.

> "We recognize that the WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of the compulsory licensing under the TRIPS Agreement" (WTO 2001).

Moreover the Declaration instructs the TRIPS Council "to find expeditious solution to this problem and to report to the General Council" (WTO 2001).(Later this led to the WTO "August 30 decision" 2003 and called by) "Implementation of Paragraph 6 of The Doha Declaration" (WTO 2003). The last paragraph (7) also reaffirms the humanitarian commitment of the TRIPS Agreement Article 66 (2), regarding the measures to overcome the technological incapability of least-developed countries and instructed the Developed country Members to encourage "technology transfer" to the least-developed countries (WTO 1994; WTO 2001).

Six out of seven paragraphs of the Doha Declaration deal with humanitarian requirements to improve the global access to medicine and technological transfer in order to meet the public health crises in the poor countries. Paragraph 3 only acknowledges the utility of the intellectual property by recognising the IP protection "for the development of new medicines". At the same time in the same paragraph the declaration expressed its worrying "concerns about its [IP's] effect on prices" of medicine (WTO 2001).

5.1.4. August 30 Decision, 2003: Implementation of Paragraph 6 of the Doha Declaration on TRIPS Agreement and Public Health

The politics of implementing of the objective priorities of the Doha Declaration becomes an important factor, while looking at the August 30 Decision. A reading of the August 30 decision clearly brings to fore the point that the principle of utility has finally broken its silence when compared with the earlier Doha Declaration. The Decision was taken by WTO General Council in 30th August 2003 and it comprises of

a Preamble, 11 Paragraphs and an Annex (WTO 2003). While the Doha Declaration deals how to make the TRIPS Agreement effective to meet the public health crises of the developing and least-developed countries, when coming in to its Implementation many parts of the August 30 Decision deals the question how to impede the "diversions" of generic pharmaceuticals while granting CLs for export (WTO 2001; WTO 2003). It is true that the Decision reaffirms the objectives of the declaration, especially the right to grant CLs for export (Paragraph 1) (WTO 2003), but the decision now provided an *opportunity to interpret* the provisions in a negative manner. The conditions and restrictions set out in the Decision, confirms the need for protecting intellectual property and its exclusivity to a larger extent.

The Paragraph 2 of the Decision provides a waiver to the Article 31(f) of the TRIPS agreement by allowing the developed country Members to grant CLs for export purposes, rather than "use… authorised predominantly for the supply of domestic market" (WTO 1994; WTO 2003) The Paragraph 1 of the decision allows the countries to grant export-oriented compulsory licence (CL) on any pharmaceutical product; that defines:

> "pharmaceutical product means any patented product or product manufactured through a patented process… needed to address the public health problems as recognised in the paragraph 1 of the [Doha] Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included…" (WTO 2003).

This gives a wider scope to the Member countries to import and export the medicine with the Waiver allowed in the Paragraph 2 (WTO 2003). Moreover the decision do not mention about any particular restriction on the duration or quantity of supply of the medicine in anywhere in the legal text. It mentions about quantity, but that is "only the amount necessary to meet the needs of eligible importing member" rather than a predesigned amount of supply (WTO 2003: #2.b.i). The Paragraph 7 mentions about the need for technology transfer and assistance to pharmaceutical manufacturing capacity building in order to overcome the problems faced by the developing and least developed countries.

However coming in to the rest of clauses especially the 3, 4, 5 paragraphs and its sub-paragraphs, it can be seen as a dilution of the flexible approach towards the humanitarian generic pharmaceutical supply. The sub-Paragraphs 2(a) (i) & (ii)

required a notification from the eligible importer regarding their demand of medicine, especially the name of the medicine and specified quantity of demand (WTO 2003). Paragraph 2 (b) (ii) required special packing/(colouring/colouring)/marking/labelling of the generic pharmaceutical product in order to distinguish such product (WTO 2003). More over the supplier pharmaceutical company should publish the details of the supply in their website (WTO 2003: #2.a.iii). Paragraph 3 mandated "adequate remuneration" to the right holder "taking in to account the economic value to the importing member of use" (WTO 2003: #3). Paragraph 4 mandated the importing Member to take reasonable measures to avoid the "trade diversion" and "re-exportation" of such product produced under these flexibilities (WTO 2003). The Paragraph 5 also instructed the members to provide "legal means to prevent the diversion" (WTO 2003).

It is true that the August 30 Decision reaffirms the Doha Declaration and allows the countries to grant export oriented compulsory licences, but a thorough observation highlights the reflections of prejudices on the compulsory licences and the export of the same. The Decision provides larger scope of interpretation of the clauses. Given the hierarchical nature of the international trade regime, it is difficult to interpret the Decision in a manner to address the public health crises in the developing and least-developed countries. The working of CAMR has to be examined, in this context.

5.1.5. Implications of International IP System on Canadian IP Regime

The same forces behind the construction of international IP laws are also influential in the Canadian intellectual property regime. Canadian IP regime acknowledged the utility principle as a justification of intellectual property protection. The chief governing body of intellectual property rights in Canada, Canadian Intellectual Property Office (CIPO) reaffirms the principle of utility in their governing guidelines. According to CIPO (2015a) Canada has been dependent on the intellectual property protection especially on patents for their scientific and technological advancement as well as for the economic growth of the country.

> "By giving inventors monopolies on their creations for a specific time period, patents protect investments and allow inventors to profit financially from their creativity. This in turn provides an attractive incentive for research and development, ultimately benefiting all Canadians. Without the possibility of patent protection, many people

> might not take the risk of investing time or money necessary to create or perfect new products, without which our economy would suffer" (WIPO 2015a).

Along with the Negotiations on Canada-US Free Trade Agreement and the Uruguay Round of Trade Negotiations Canada gradually changed its patent laws by reflecting the international discourses and the subsequent changes in the international Laws. In 1987, Canada significantly changed its patent law (Bill C-22, Patent Law Amendment) and made it more a rigid one (Parliament of Canada 2008). The Amendment allows an exclusive market rights (Article 42) to the inventions of the inventors including "privilege and liberty of making, constructing and using the inventions and selling it to others to be used" (GoC 2015a). Moreover the Amendment guaranteed security to the Patented Medicines from the compulsory licenses by giving a certain period of protection (Parliament of Canada 2008). That guaranteed a ten year import protection and 7 years' manufacturing protection against the CLs (Parliament of Canada 2008). Moreover the Bill C-22 Amendment provided a "twenty year" patent protection from 1989 (Parliament of Canada 2008). Prior to the TRIPS Agreement and NAFTA come in to force Canada has amended its Patent Act (Bill C-91) by comply with those Agreements. Critics frequently argued it is an over-compliance in some extent. The Bill tightened the patent protection on the pharmaceutical products by introducing a new "product patent regime" and eliminating its historically progressive compulsory licencing system (Parliament of Canada 2008).

> "The bill eliminated compulsory licences for the pharmaceutical products through compulsory licences in existence before 20 December 1991 in effect, subject to seven and ten year limitations established in Bill C-22. Compulsory licenses granted after 20 December 1991 but before the day the act came in to force were terminated when Act became effective" (Parliament of Canada 2008a).

Canada retrieved its humanitarian commitment of progressive as well as flexible compulsory licensing policies by pursuing the Doha Health Declaration 2001 and its affirmation in August 30 Decision 2003. In 2004 the Canadian Parliament passed the Bill C-9, *An Act to Amend the Food and Drugs Act,* and thereby became the first country to implement the flexibilities allowed by the Doha Declaration and which came in to force by implementing "Canada's Access to Medicines Regime" (Parliament of Canada 2008a; GoC 2015a). The Act aims to "facilitate access to safe and effective pharmaceuticals and eliminate barrier to of cheaper generic versions of

patented drugs to developing countries unable to manufacture generic locally" (Parliament of Canada 2008).

As mentioned earlier the complexity of legal language as used in the WTO August 30 Decision, i.e., the implementation of Doha Declaration, provide a wider scope of interpretation to the member countries. The construction of Decision has focused on the reduction of damages on the patented medicine causes by the Doha flexibilities. While going through the clauses of the amended law the complexities of the regime will be visible. The Critiques argue that the CAMR was sometimes over complied with the obligations given by the August 30 Decision. This was one of the most debated subject matter in the revision and amendment (Bill C-393 and Bill C398) and its Industry Committee sitting.

International legal text is an important source of the country's domestic laws. The above mentioned discussions could reveal the reflections of international legal guidelines in the Canadian Patent Laws and the Canada's Access to Medicines Regime. Since the international legal documents are a product of the international discourses, it acts as a medium of influence of the international level of politics to the shaping of domestic laws of a country. The 1980s North-South dialogues on exclusivity, intellectual property and the late millennium discourses on humanitarian supply of medicines are thus reflected in the development of Patent Laws of Canada (Watal 2003; Esmail 2010). It was shown in Canada's amendment of its patent laws in 1993 (Bill C-22) by giving priority to the utility of the patent from the theoretical perspectives of this study. Therefore it was a domestic translation of the changes in the international patent regime in order to ensure the utility by protecting IP from the violations abroad.

The litigation against Africa spurred the international attention towards the issue of IP barriers against access to medicine and which lead to the creation of humanitarian IP guidelines for access to medicine within the world IP regime. This global development again altered the Canadian Patent regime and the CAMR was established. But this translation of international humanitarian commitment towards global access to medicine failed to fulfil its purpose and promises (Esmail 2010; Kohler 2010). The dependent nature of domestic economic structure and the power capabilities made it dysfunctional except the "one and only" Apotex supply of

HIV/AIDS medicine to Rwanda. The following section will discuss how this balanced reconciliation of stakeholder's interests of IP protection and Canada's humanitarian commitment to ensure access to affordable essential medicine has turn into imbalance.

5.2. NON-STATE ACTOR LEVEL

Non-state actors are holding a vital position in influencing the decision making of Canada. They usually creates public opinion by using their propagandas like demonstrations, circulating pamphlets, sending letters to the concerned authorities, news conferences and lobbying in order to influence the decision making in Canada. The reflections of non-state actor's influence were noticeable in the decision making on CAMR too. The Web page of CAMR itself confirms the role of the non-state actors especially the NGO's in the framing of CAMR:

> "The government of Canada regards non-governmental organisations (NGOs) as valuable resources and actively consulted with them in designing Canada's Access to Medicines Regime" (GoC 2009a).

Immediate response to the August 30 Decision, Stephen Lewis, United Nations Secretary General's Special Envoy on HIV/AIDS urged the government to make a regime to increase the supply and the access to affordable medicine to the developing and least developed countries (Gatto 2011: 22). Simultaneously the public attention turned in to the issue because of the NGO and Media Campaigns. The efforts of NGOS especially, Medicines Sans Frontiers, Canadian HIV/AIDS Legal Network, Global Treatment Action Group and Oxfam Canada were considerable in the making of an access to medicine regime in Canada (Gatto 2011). In 2003, an article written by Richard Elliot was published in the *Global Mail* newspaper urging the Canadian government to remove patent barriers on generic export (Gatto 2001: 22). This brought a high momentum in Canada with respect to the creation of a regime for compulsory licenses and culminated in the amendment of patent law of Canada (Bill C-22), *The Jean Chretien Pledge to Africa* and established Canada's Access to Medicines Regime (GoC 2008).

5.2.i. Analysis: Non-State Actors and Decision making on CAMR

This section has analysed the extent of non-state actor's emphasis on particular arguments in the Consultation Papers they submitted in the Statutory Review of Canada's Access to Medicine Regime (2006-2007) and in the Evidence Hearings in the Standing Committee of Industry, Science and Technology. This non-state actor's role has potential influence in the real decision makers, i.e., the behaviour of the Members of Parliament (MPs) in the Parliament of Canada. In presenting this analysis, this study categorised the core interests of actors involved in the submissions and hearings.

5.2.1. Review Submissions on CAMR

In November 2006 Government of Canada released a consultation paper and called for the responses from the "interested parties" as a part of "statutory review of Canada's Access to Medicines Regime" (CAMR 2007). In February 2007, the Health Canada and Industry Canada had received 32 responses from various sources (CAMR 20007). The first part of the analysis on the non-state actors behaviour in the decision making process has been based on this submissions. For the convenience of the analysis the major repeated arguments and opinions are categorized, and analysed on the basis of the categorized responses.

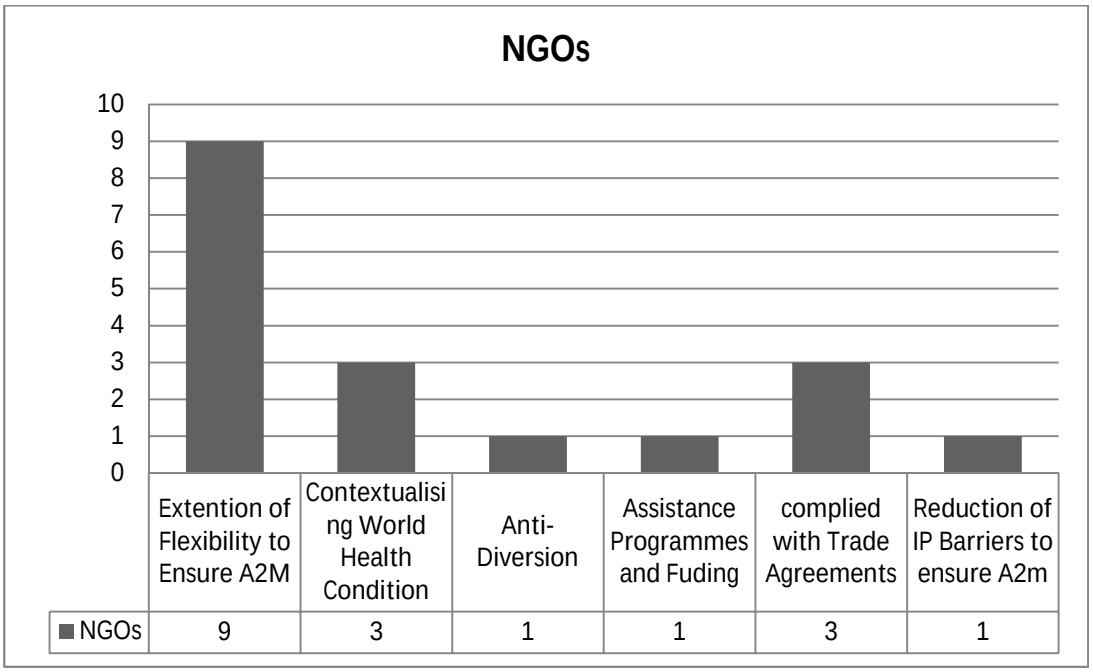
The analysis on the CAMR submissions has divided in to four sections based on the nature of organisations involved in the Review submission. They are: (1) NGOs (2) Generic Pharmaceutical Industry/Industry Associations (3) Research Based Pharmaceutical Industry and Research Based Pharmaceutical Industry Association (Rx & D) (4) Industry Associations including dominant global Pharmaceutical Industry association. A primary reading on the literatures shows that the first two favours for a flexible compulsory licensing regime in order to fulfil Canada's humanitarian commitments towards access to medicine; and the rest of two favours the utility of the intellectual property and a high-level protection of IP. The analysis follows:

5.2.1.1. Non-Governmental Organisations

The Figure 5.1 showing the responces of the non-governmental orgnisations those have submitted their openion in the Review. A total seven NGOs submitted their opinin on the review of CAMR (GoC 2007). The responces show the attention on humanitarianism of the NGOs. The NGOs favoured the revision of CAMR to #extent the flexibility in order to ensure the humanitarian committement of Canada towards access to medicine (GoC 2007). In their seven submissions the #extention of flexibility of CAMR for granting CL repeated 9 times. (Three times repeated the references of the #context wolrd health conditions to emphasise the need for CAMR amendment (GoC 2007)). The results shows they favoured for a minimal IP protection in order to ensure access to medicine in a humanitarian basis. It has a larger influence on the opposition parties (NDP, Liberals and Bloc) attention especially their arguments in the parliament and as reflected in their parliament speeches as well.

Figure 5.1

Responses and Arguments in CAMR Review Submission: NGOs



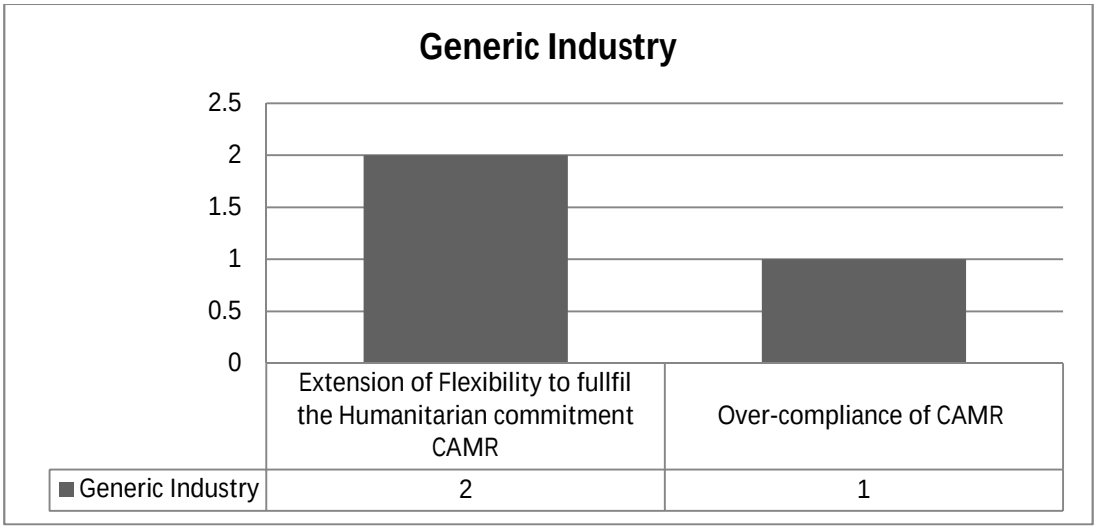
Source: The figures representing the responses and arguments of the actors are made on the basis of analysis of the themes which discussed in the *theoretical perspectives*. The numbers and figures are representing the actors focus on the above discussed theoretical perspectives. The data source was the Review Committee submissions and the transcripts of Industry Committee sittings and Parliament Debates and speeches on Bill C-393 and Bill C-398. It is same for all the figures.

5.2.1.2. Generic Industry

In the CAMR review submissions only two submissions represents the generic industy: Apotex and Canadian Generic Pharmaceutical Association (CGPA) (GoC 2007). The results (Figure 5.2) indicates that, among the two, their opinion favoured the amendement of CAMR (#Extention of flexibility) to ensure medicine supply to the suffering countries (GoC 2007;Apotex 2007; CGPA 2007). Moreover they expressed their worry about the #over compliance of CAMR with the TRIPS flexibilities (GoC 2007;Apotex 2007; CGPA 2007).

Figure 5.2

Responses and Arguments in CAMR Review Submission: Generic Industry

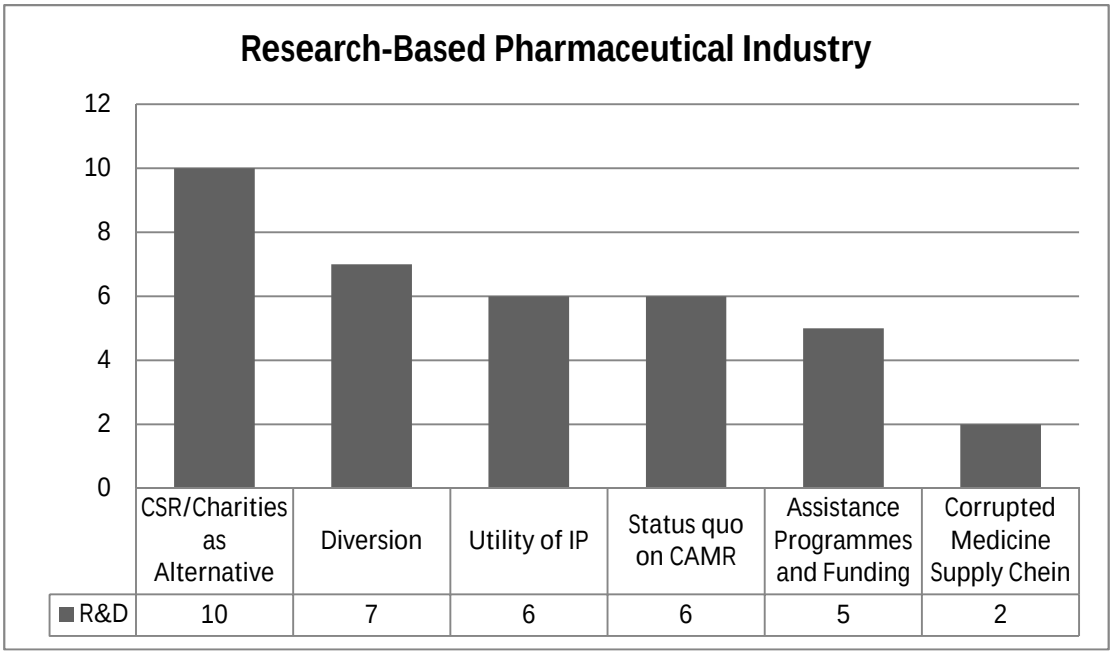


5.2.1.3. Research-Based Pharmaceutical Industry

The results of the analysis shows that the research based pharmaceutical industries are higly dependent on the intellectual property rights and opposed the amendment of CAMR - #status quo on CAMR (GoC 2007). They suggested less harmful measures (to the patent protection), to ensure canada's commitment towards the the global access to mediciine. They proposed voluntary mesures like #corporate social responsibility/charity (10 time repetation) and Financial #Assistance or contributions to multilateral initiatives (5 times) as an alternative to the CAMR amendement (Figure 5.2). Most of the companies explained their CSR activities in the submission (GOC 2007). One of the worlds largest pharmaceutical corporation Merck not only propose CSR as an alternative but also attached their CSR report to substanciate their argument (Merck 2007). The majority of industry argued with a utilitarian line (#utility of IP) and pointed out the need for IP protection (6times). Moreover they mentioned the chances of #diversion (7 times) of generic medicine if the CAMR amended in favour of CLs (GoC 2007). It can be concluded that the research-based pharmaceutical industry argued with utilitarian justification of IPRs and proposed less harmfull measures on intellectual property to ensure the humanitarian committements.

Figure 5.3

Responses and Arguments in CAMR Review Submission:Research Based Pharmaceutical Industry/ Rx&D

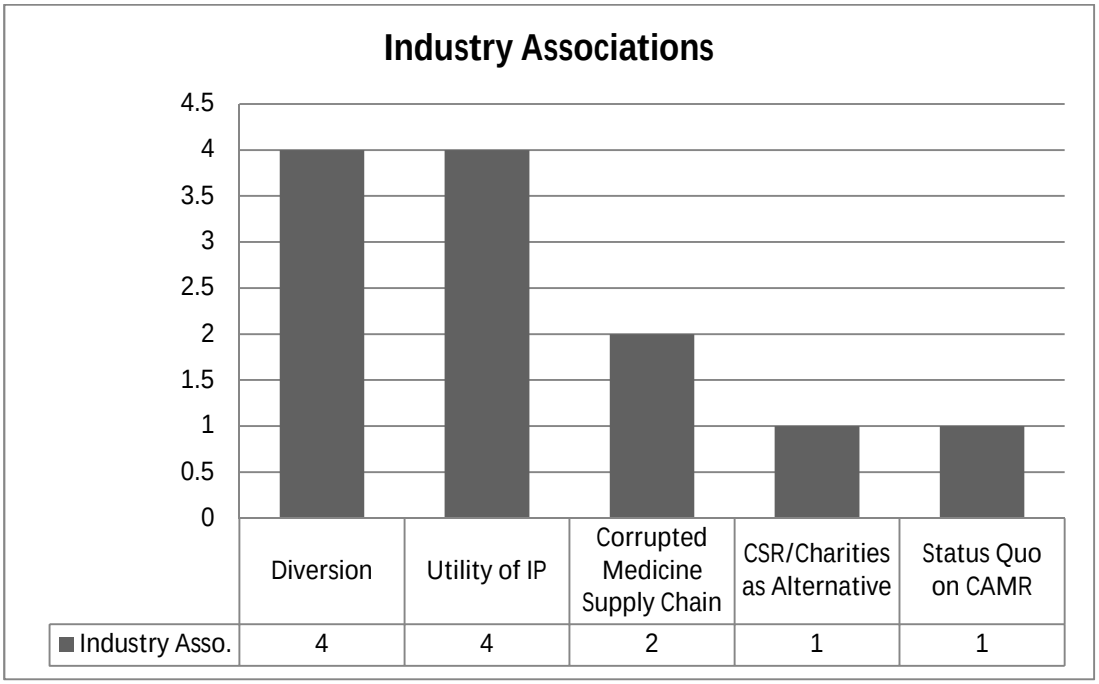


5.2.1.4. Industry Associations

The Review received seven submissions from the industry assciations - Biotec Canada, Canda's Research Based Pharmaceutical Companies (Rx&D), Canadian Generic Pharmaceutical Association (CGPA),Irish Pharmaceutical Helath Care Association (IPHA), International Federation of Pharmaceutical Manufactures & Association, European Federation Pharmaceutical Industy and Association, (GoC 2007). Two Submissions were not incorporated in this part of analysis. Rx&D was counted with the analysis of research-based pharmaceutical industry (5.2.1.3.) and the CGPA was counted with the analysis on generic industry (5.2.1.2.) The rest of five have been analysed in this section.

Figure 5.4

Responses and Arguments in CAMR Review Submission: Industry Associations



The results indicated that, similar to the Research based Pharmaceutical industry's opinions the Industry Associations are also focussed on the #utility of IP and #diversion. For example the International Federation of Pharmaceutical Manufactures and Association pointed out:

> "[s]ince undermining IP rights creates a powerfull disincentive to future of innovation, the CAMR review must carefully consider whether any additional measures aimed at enhancing access to medicines at the expence of IP rights… without reasonable and effective IP protection, the medicines and vaccines of the

> future will be delayed, or may not be developed, to the determent of those patients who are most volunreble to desease conditions" (IFPMA 2007).

They are generally supporting the CAMR in its present form without any changes or amendement on the status quo (GoC 2007). The problems in the global access to medicine is not about the CAMR amendment but the "corruption of the pharmaceutical supply chain" (IFPMA 2007; IPHA 2007). Both the opinoions of the Industry Associations and the research-based pharmaceutical industries' are influanced or even replicated in the parliament debates and standing committee hearings, especially in the speaches of the Conservative members. This reflections will be analysed in the following analysis.

5.2.2. Analysis: Industry Committee Sittings

In the 40th Parliament (2009) New Democratic Party (NDP) Member Judy Wasylycia-Lies introduced a private member Bill - C-393, "An Act Amend the Patent Act (Drugs for International Humanitarian Purposes) to Make Consequential Amendment to Another Act" (Parliament Canada 2011). The Committee was held in total five days (in 2010, October 7th, 21st, 26th, 28th and November 1st) and each days the committee heard the responses of representatives of various groups, associations and institutions and individuals. It summarised the purpose of the amendment bill as follows:

> "[t]his enactment amends the Patent Act and Food and Drugs Act to make it easier to manufacture and export pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, Malaria and other epidemics" (Parliament Canada 2011).

From the abovementioned summary of the purpose, it can be seen as the humanitarian nature of the bill (Parliament Canada 2011). It was reflection of NGO's arguments in the early debates on CAMR (#Extension of Flexibility to ensure humanitarian commitment of CAMR) and in the Review of CAMR.

This section of analysis divides the responses of the non-state actors in to two groups. Different from the above analysis this section group all human rights based groups under one head and the rest of Research based industries and institutions and association those supporting a high-level IP protection into the second. This grouping is based on the responses of the actors in the above analysis on the CAMR review:

those who supported humanitarian medicine supply through flexible CL policy and those who opposed a liberal CL policy and argued on the basis of utility (GoC 2007). The first group is composed of the generic pharmaceutical industry and human rights based groups including NGOs and Academia and the second group is composed of research based pharmaceutical industries and its supporting institutions and associations.

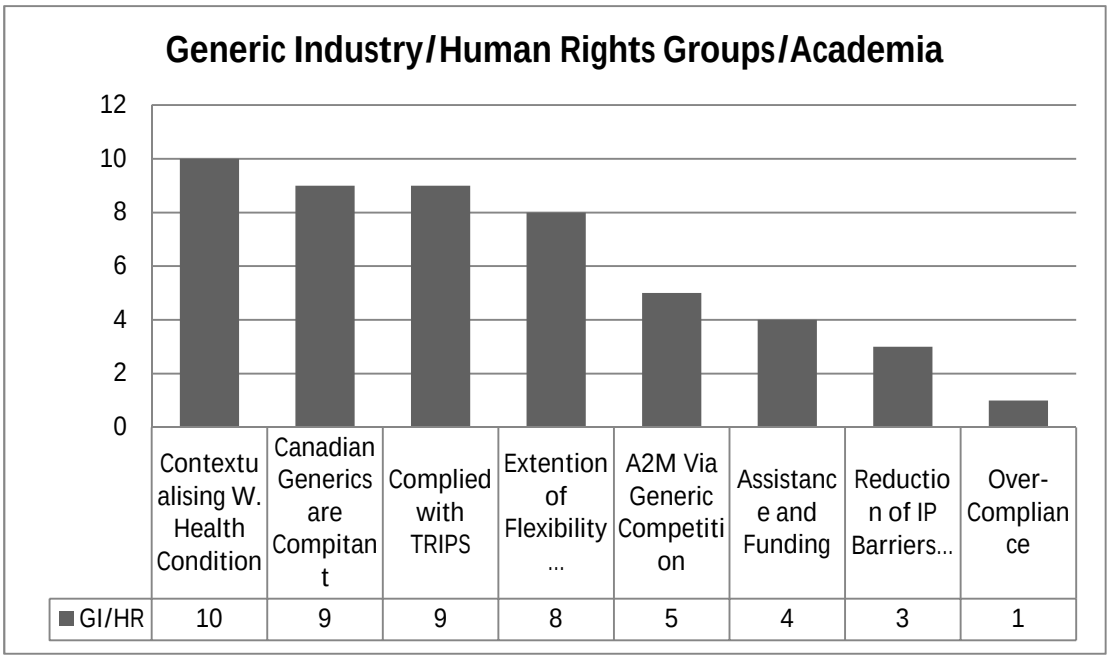
5.2.2.1. Analysis: Generic Pharmaceutical Industry and other NGO Responses in the Industry Committee Hearings

This section has analysed the hearing responses of 9 representatives from different humanitarian based organisations, that held in the Industry Committee on October 26th 2010 (9 out of total 18). The figure 5.4 is representing the responses of Generic Industry and NGOs. The analysis result indicated that the groups, associations and institutions that composed in this section had argued on a humanitarian ground. Figure 5.4 show that most of them had referred the #context of world's health crisis (10 times) in order to contextualise the need for the CAMR amendment. Moreover they explicitly expressed (8 out of 9 representations) their worry about the CAMR in its present un-working form and pointed out the need for the amendment (Bill C-393) to ensure the humanitarian commitment of Canada towards access to medicine (Parliament Canada 2010b). The Director of Campaign for A2M, Doctors without Borders (US), Emilou MacLean's response was a remarkable one; he pointed out the need for the amendment by contextualising Canada's commitment on their international leadership role and other facts related to the issues of access to medicine (Parliament Canada 2010b). According to him,

> "Canada is in a position to really take on a leadership role, demonstrate what can be done, demonstrate what the most effective language would look like in an August 30 decision that could work. This is a critical need and an increasingly critical need, as India's generic market under threat because of TRIPS …so Canada is in a position to take a very strong leadership role. It's not the only solution, and other countries hopefully would come forward as well. But there is a real need, and Canada can be the real player in this…" (Parliament Canada 2010b).

Figure 5.5

Responses and Arguments in Industry Committee: Generic Pharmaceutical Industry /Human Rights Groups for Access to Medicine/Academia



The organisations repudiate the question of non-competence of the Canadian generic medicine #Canadian generics are Competent. For example they noted that Apotex sent two shipment of Apo TriAvir with the same price of Indian medicine of (that time) (Parliament Canada 2010b). Moreover, regarding the second and third-line therapy, Indian or Brazilian generic industries are unlikely to produce Parliament Canada 2010b. Industry committee debated on the TRIPS-compliance issue of the amendment bill very rigorously. The research-based pharmaceuticals argued, the bill violate the provisions of TRIPS and other international IP obligations, if it passed (Parliament Canada 2010b). Therefore the bill should not pass according to them. Majority of those supported the bill claimed, the bill does not violate the international IP obligations regarding the export of generics by compulsory licencing (#complied with TRIPS) that outlined in August 30 Decision (Parliament Canada 2010b).

The analysis reveals and indicates the humanitarian defences of the NGOs, generic industry, Human Rights Groups and Academia. They favoured to amend the CAMR to fulfil the humanitarian promises of the regime and ensure affordable pharmaceutical supply for the poor countries those suffering with HIV/AIDS, tuberculosis, malaria etc. without or a minimal access to medicines (Parliament

Canada 2010b). They rejected the utilitarian defences of the R&D industry and pointed out: it is nothing, a greatest happiness of the society by protecting the IP holder's rights without addressing the public health crises of the world (Parliament Canada 2010b). Furthermore, they criticised the #Assistance and Funding argument and the #incompetency of Canadian generics arguments of the R&D industry. Paula Akugizibwe, Advocacy Coordinator, AIDS and Rights Alliance for South Africa pointed out:

> "Currently the global funding situation for HIV is looking dire. The recent replenishment of the global fund has left deep-seated anxiety in many people… In this time of financial austerity, it's really crucial that we take every measure possible to reduce the cost associated with HIV programmes… I guess ...the role of Canada in the generic field is even more crucial than it was in 2004" (Parliament Canada 2010b).

Replications and influences of the above mentioned arguments can be seen in the responses of the state-level actors such as Members of Parliament (rest of Conservatives). The following analysis would focus on the state-level actors.

5.2.2.2. Analysis: R&D Industry and other Supported Institutions in Industry Committee Hearing.

In this section, the study has analysed responses of 8 organisations including research based pharmaceutical corporations (Glaxo SmithKline – GSK), Research Based Pharmaceutical Companies (Rx & D, industry association), Gowlings, National Micro Biology Laboratory, Biotechnology Patents Committee, IFPMA, and some other individual who supporting a high-level IP protection (Parliament Canada 2010b). The results indicated that, the behaviour and the preferences of the respondents are highly favourable to exclusive market rights of IP (Parliament Canada 2010b). They argued with a utilitarian defence of IP, and criticized the initiative for making the CAMR more flexible (Parliament Canada 2010b). According to them such initiatives violates Canada's international trade and intellectual property obligations and consequently such efforts adversely affect the innovative and developmental activities of the country (Parliament Canada 2010b). On this ground the Bill C-393 cannot be passed.

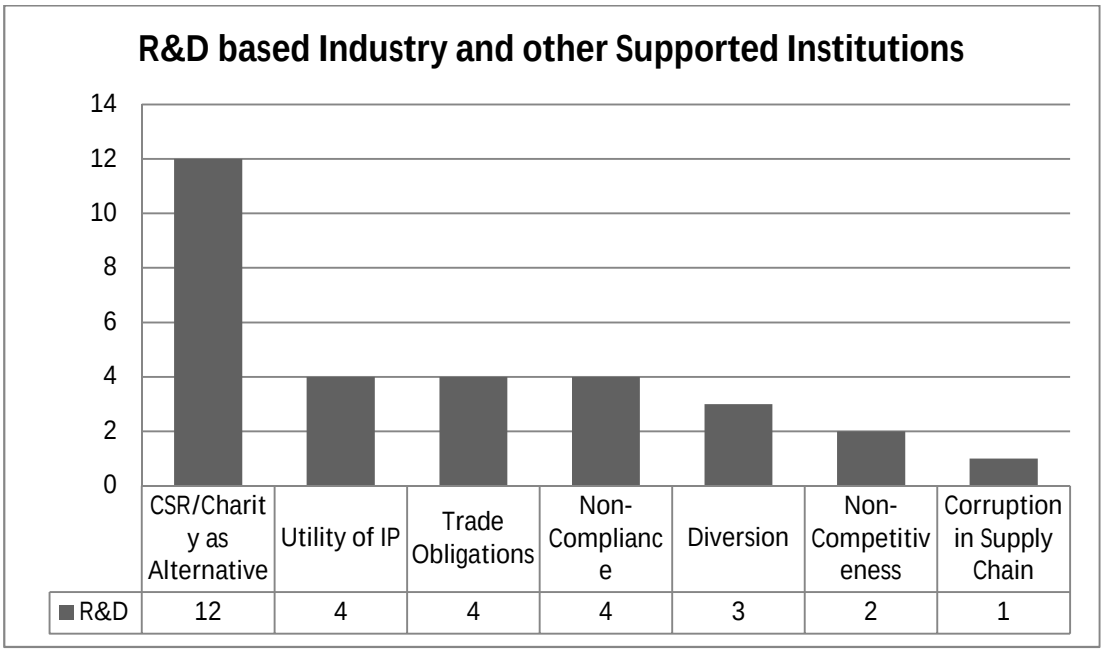
The results are shown in the Figure 5.5. It shows that the R&D industry had not supported the amendment Bill C-393 (parliament Canada 2010). They argued it would be harmful to Canada's interests on research and development if the bill was passed in the name of humanitarian purposes (Parliament Canada 2010b). But the same was

possible by encouraging CSR activities/ charities. Russell Williams, the President of Rx & D argued that the voluntary initiative taken by the R&D industry has proven efficient than compulsory licensing or other similar measures. He stated:

> "… [j]ust very briefly, what we said was that we are voluntarily, collaborating internationally, and absolutely with generics, and that has proven to be more effective. That partnership is the solution, but it's voluntary. We're very proud of the donations we make and we've made them on a voluntary basis …I hope we can continue to work every day on this – is that if we push the voluntary collaboration…" (Parliament Canada 2010b).

Figure 5.6

Responses and Arguments in Industry Committee: Research Based Pharmaceutical Industry and Supported Institutions



The Table 5.5 shows the R&D industry repeated 12 times #CSR/Charity as an alternative to the CAMR in the hearing. This indicates the possibility that CSR activities are less harmful to the interests of research based industry. They substantiated their argument against CAMR by indicating #diversion, Canada's #trade obligations and #non-compliance issues with the TRIPS and other international IP obligations (Figure 5.5)

Richard Dearden, the Gowlings representative brought out that Canada's dependency restricts any changes in CAMR, since the country has been a party of NAFTA noted:

> "…[a]nd you should know that Canada and the U.S. entered a memorandum of understanding that suspended the compulsory license obligations you find in NAFTA article 1709 (10) (f), which was identical to the TRIPS compulsory licensing obligation. That suspension is only valid with respect to the compulsory license issued in accordance with the WTO General Council Decision. So if the Bill C-393 system were allowed, it would be violating NAFTA …because it allows for any drug, in unlimited quantities, for unlimited term, for export to 140 countries" (Parliament Canada 2010b).

A significant number in this grouping justified their arguments with the #utility of intellectual property (IP) (Figure 5.5). Angus Livingstone (Managing Director of University-Industry Liaison Office, University of British Columbia) indicated the risk of drug development in the venture capital and biotech industries if the compulsory licensing liberalized (Parliament Canada 2010b). Moreover if the Bill has passed, this "would reduce the R and D investment potentially funded by pharmaceuticals in Canada" (Parliament Canada 2010b). David Schwartz, the Chair of Biotechnology Patents Committee of IPIC, had taken a rigid stand by opposing the Bill C-393. He argued the Bill reverse the balance of competing policy priorities (Parliament Canada 2010b). Moreover he argued,

> "It's accepted that innovation is important to the economic and social well-being of our country. Patent legislation is a key element of any country's innovation system, and this legislation must achieve a fine balance between competing policy goals and must confirm with a number of international treaties" (Parliament Canada 2010b).

In the following words of his speech, he revealed his dogma on IP. He said, TRIPS is the minimum IP standard, the members can move beyond the requirements (Parliament Canada 2010b). But unfortunately the members are "not permitted to establish laws that provides less protection than required under the TRIPS" (Parliament Canada 2010b). Grant Perry, representative of GSK (a global giant pharmaceutical corporation) was supporting Livingstone's argument; he pointed out:

> "While CAMR [original version] includes important safeguards and transparency requirements that help encourage R and D investment and support new drug discoveries, we must refrain from using CAMR as a means to re-open the intellectual property debate in Canada"(Parliament Canada 2010b).

While the GSK appreciating the existing structure of the CAMR, it is an interesting fact that it was the same company that denied voluntary licensing application of Apotex for Apo TriAvir under the same CAMR.

It can be concluded that the analysis affirm that with R&D industries "utility first" policy. They have acknowledged the humanitarian commitment of Canada and

world's health crisis, at the same time denied the amendment Bill as a solution to this issue (Parliament Canada 2010b). The Bill C-393 is not the solution, but it is our voluntary measures. It can be seen replications of the above arguments, while examining the responses of the state-level actors such as the government departments (Industry Canada, CIDA, and DFAIT) and the Members of Parliament (rest of Conservatives). That would be follows on the next section of analysis.

5.3. STATE-LEVEL ANALYSIS

The analysis on the state level actor's behaviour is divided into two sections. The first section will be the government institutions those have significant role in the decision making on CAMR. The government institutions like Department of Industry, Department of Foreign Affairs and International Trade (DFAIT), and Canadian International Development Agency (CIDA) will be examined in this section of analysis. The second section will be an analysis on the behaviour of Members of Parliaments from the parliament debates on Bill C-393 and Bill C-398. The analysis expected to provide the reflections of different interests in the parliament debate. Such reflections are important to study the dominant interests which are reflected in the dominant numbers of the parliament and thereby resulting to the defeat of the amendment bill C-398 in the parliament in 2012.

5.3.1. Analysis: Government Institutions

The government institutions played a significant role in the making and working of CAMR. They provide a consistency in the decision making as well as significant inputs to the decision making. Because of the permanent nature of the bureaucracy, the institutions are well aware of the legal as well as administrative circumstances of the decision making. Apart from the broader policy perspectives and the policy preferences given by the political decision makers, the personnel of concerned departments are drafting the real output legislations. Therefore the opinions of the concerned departments are very valuable in the legislation and its implementation for the political elites of the country.

This study observed the behaviour of three government departments/agencies in the legislative process of CAMR. Those are Department of Industry, Department of Foreign Affairs and International Trade (DFAIT), and Canadian International

Development Agency (CIDA). These departments are directly involved in the decision making process and the implementation of Canada's Access to Medicines Regime. The responses of the representatives of these institutions were taken in the Industry Committee held on 7th October, 28th October and 1st November 2010.

5.3.1.1. Department of Industry

Since it is dealing with industrial sector and its production, the intellectual property which facilitated the exclusive market rights for the industrial patent holders has been an important subject matter for Department of Industry. The analysis result confirms the above statement. A total 8 occasions the representatives of Department of Industry defended the IP protection with the #Utility of IP (Parliament Canada 2010; 2010c; 2010d). Colette Downie, Director General of Market Place Framework Policy Branch, Department of Industry pointed out the utility of the patent very clearly (Parliament Canada 2010d). According to Him,

> "…patent system is set up to reward investment, particularly in the area of medicines, were the investment can be huge to develop new medicines and bring them to production" (Parliament Canada 2010d).

Moreover the CAMR is little different from this fact, for ensuring humanitarian medicine supply for the poor, without making costly damages to the utility of the patent (Parliament Canada 2010d). Downie stated it is a balance of interests, and states that:

> "[t]hat's the reason why… preserving that incentive for investment is the reason why CAMR is delineated in the way that it is. The restrictions are designed to make sure that the definition is very clear while the same time preserving incentive to continue to develop products and sell them in Canada" (Parliament Canada 2010d).

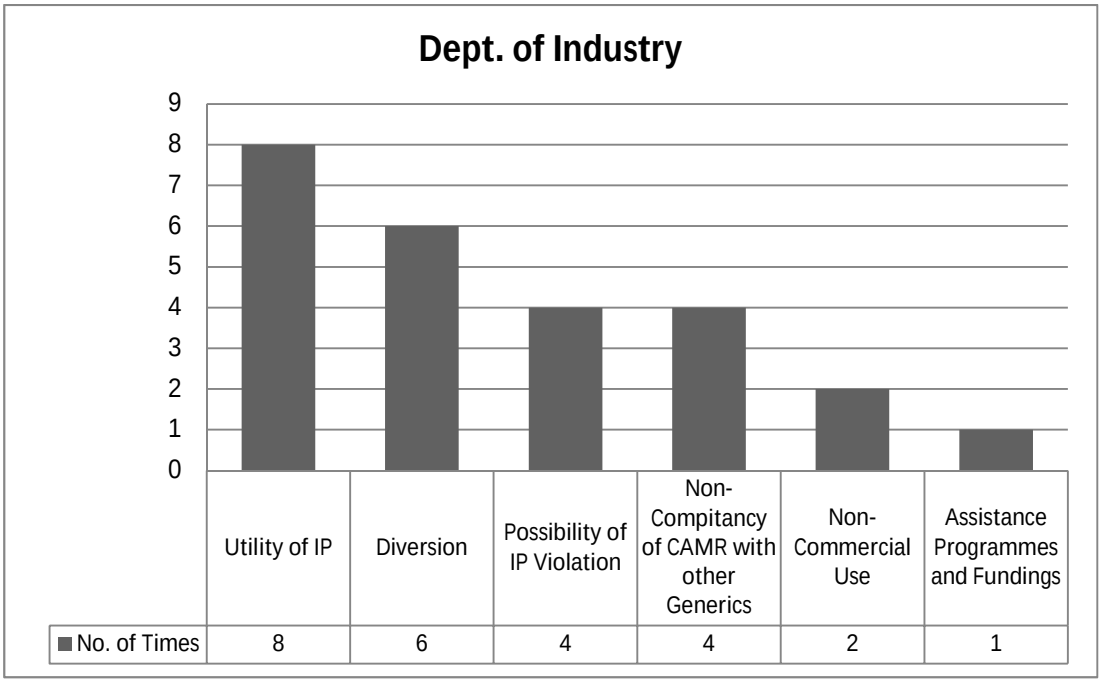
Donnie's statement was very clear about the Departments interests on the Bill, i.e., they are unlikely to support any changes that are creating costly damages to the interests of the patent holder (Parliament Canada 2010d). From this it becomes clear that the Department's major concern is the #utility of the patents. The major arguments were raised in the parliament is those which ensuring #utility of IP (8 times). The #diversion (6 times), #possibility of IP violations (4 times), #non-commercial use (2 times) are considered the factors of infringement of IP and of making damages on the interests of the intellectual property holders (Parliament

Canada 2010; 2010c; 2010d). Moreover Colette Downie gestures the dependency of Canada on international trade and domestic investments. He says:

> "Research and development-focused pharmaceutical companies have global reach, they have global perspective, they have flexibility about where they invest their R and D dollars, and they naturally favour jurisdictions that provide strong and predictable IP regimes. We are concerned that reducing the safeguards provided in CAMR will result in pharmaceutical companies' hesitating to invest in Canada for lack of certainty about the protection of their investments…" (Parliament Canada 2010).

Figure 5.7

Responses and Arguments in Industry Committee: Department of Industry



One of another key argument raised in the Industry Committee hearing was the #non-competency of the Canadian generics (4 times). This argument indicated that the non-working of the CAMR is not the matter of flexibility or amendment but the availability of low priced medicines from other destinies (Parliament Canada 2010; 2010c; 2010d). Colette Downie, Director General of Market Place Framework Policy Branch, Department of Industry substantiated this argument:

> "I think, though, when Canadian manufacturers face competition, when developing countries can get cheaper medicines from other countries such as China and India… [t]hey may be aware of CAMR and a mechanism by which to get them from Canada, but they would have no reason to use it when they can get cheaper medicines from elsewhere" (Parliament Canada 2010).

It can be concluded from the the analysis on behaviour of Department of Industry that represented the "utility first" polity. The following analysis will examine the impact of this utilitarian defences in the parliament debate.

5.3.1.2. Canadian International Development Agency (CIDA)

Canadian International Development Agency is a state level government organization to govern the international financial assistance programmes and foreign aid programmes of Canada. According to Louise Clement of CIDA, "[t]hough Canada is working with global community to address health needs of developing countries, [CIDA] committed to doing so effectively and accountably" (Parliament Canada 2010). Since it is dealing with the aforementioned subject matters, it is an important organization in dealing Canada's humanitarian low-cost medicine supply to the poor countries under CAMR. Along with the DFAIT, Department of Canada, and Health Canada, CIDA were also requested to express their opinions and suggestions in the Industry Committee held on October 7th, 2010. On behalf of CIDA Louise Clement, Senior Director, Regional and Geographic Programs –South and Eastern Africa and Christine Reissmann, Director of AIDS, TB Programming and Health Initiatives, Multilateral and Global Programs Branch attended the sitting (Parliament Canada 2010).

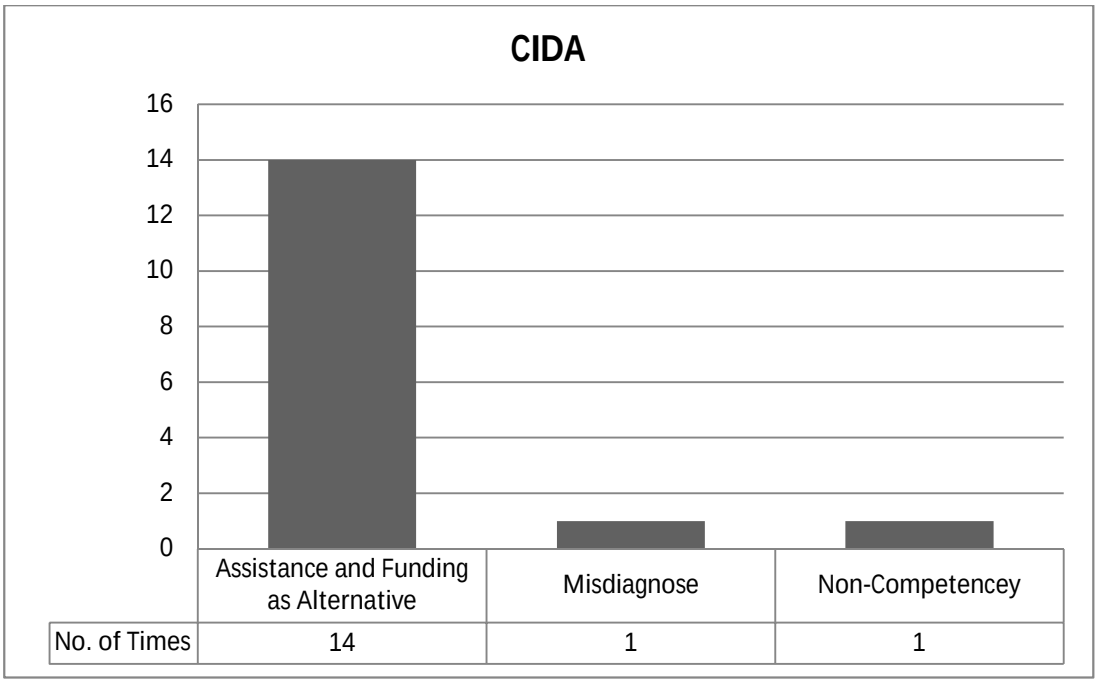
The analysis indicates that, while supporting the original version of CAMR, they expressed their disagreement with the liberal CL clauses of the private bill amendment – Bill C-393 (Parliament Canada 2010). Reissmann pointed out, it (flexibility) may be good for the humanitarian drug supply, but the gaps in the diagnostics (#misdiagnose) in such countries reverse the purpose of the regime (Parliament Canada 2010).

> "There are also issues or gaps in laboratory and diagnostic services. In some countries, people are misdiagnosed – quite badly misdiagnosed – for a long period of time while their real illness flourishes. Distribution and delivery networks are in some cases non-existent. In the end …we have experienced situations in which large shipments languish somewhere and expire and create another problem of disposing those products when they have expired" (Parliament Canada 2010).

His statement was indirectly indicating CIDA's disagreement with the Bill-C393, because it was supposed to liberalise the compulsory licensing to the generic medicine supply to the poor countries (Parliament Canada 2010).

Figure 5.7

Responses and Arguments in Industry Committee: CIDA



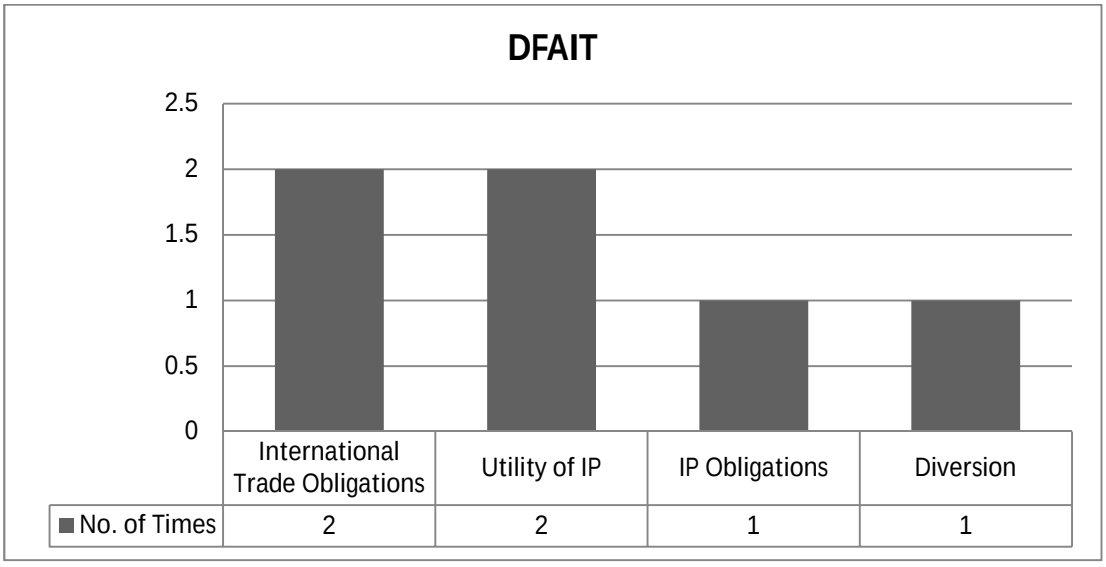
CIDA's frequently repeated argument can be placed in this context. CIDA mentions the international #assistance and funding 14 times (Figure 5.7) as the appropriate means to fulfil Canada's commitment towards global access to medicine (Parliament Canada 2010). It was the same argument focussed in the research based pharmaceutical industry (see above analyses). These replications of the statements are indirectly indicating CIDA's disinterest to make the regime harmful to the interests of the dominant pharmaceutical industry. Due to the branch plant nature of the Canadian industry (and)a significant share of the industry has been appropriated by the global pharmaceutical giants (Johnson & Johnson 9.6%, Pfizer 6.5%, Merck 5.3%, Novartis 5.1%, GSK 4.1%, Roche 3.6%, AstraZeneca 3.4% etc.)[41]. Because of the dependency it was difficult for Canada to make the regime flexible. Moreover, similar to Department of Industry and the research-based pharmaceutical industry CIDA also argued the #non-competency of the Canadian generics as the reason for the non-working of the regime rather than inflexibility (Parliament Canada 2010).

[41] IMS Health Pharmafocus 2018 from *Canadian Pharmaceutical Industry Profile* (2014), Industry Canada, for further details see Chapter - 4

5.3.1.3. Department of Foreign Affairs and International Trade (DFAIT)

Since it has been dealing with the external affairs and the international trade of Canada, the rules and obligations' that governs the international system is very important for DFAIT. The department is very much concerned about the political economic and trade developments in the international system. As Canada is an export dependent staple economy and because of branch-plant nature, it has been highly dependent on a predictable as well as rule based international system (Innis 1956; Hart 2002; Nossal 1997; Kirton: 385 Panitch 1981). This is the same reason why Canada is supporting international multilateral as well as bi-lateral agreements and complying with the international obligations (Nossal 1997). In this context any domestic laws and governmental actions which are linked to Canada's international obligations such as CAMR, has been an important concern of DFAIT. While the CAMR allows flexibility in the intellectual property obligations but constraining aspect is the role of DFAIT has to make sure its conformity with Canada's credibility in the international system; and should not harm the dominant interests in the international system (Parliament Canada 2010).

Figure 5.9
Responses and Arguments in Industry Committee: DFAIT



The hearing of DFAIT representative was held on 7th October 2010 in the Industry Committee on Bill C-393 (Parliament Canada 2010). The Chief Air Navigator, Robert Ready was the representative on behalf of the DFAIT in the Hearing. The results indicate that, DFAIT focused on four arguments in the Industry Committee hearings,

that is: #international trade obligations, #IP obligations of Canada, #utility of IP, and #diversion. The first two are mutually related and indicate Canada's international obligations; the third one indicates the benefits of pursuing those aforementioned obligations; and the last one indicates the possibility of the violations of those obligations and the resulting consequences on Canada's credibility as a responsible international actor and on the developmental as well as economic interests of Canada (Parliament Canada 2010). Robert Ready's speech was indirectly expressing the dependency of Canada in taking a decision domestically, while it is related to various formal and informal international obligations. He mentioned some other impediments to make the regime flexible, beyond the question of whether the bill complied with the WTO August 30 Decision or not, "I think there are other impediments, other structural issues outside the WTO system, that are perhaps more important" (Parliament Canada 2010).

5.3.2. Members of Parliament

In a parliamentary democracy, the elected representatives of the parliament have significant role in the decision making of the country. The final decision on the legislative (product) is taken by the parliamentarians. Every discourse on a particular bill culminates in the parliament and the parliament decides whether the bill has to pass or not. Above analysis related to the the international, non-state actor level and state level bureaucratic level discourses on CAMR and its amendment (Bill C-393 and Bill C-398). Those level discourses are considered to be a potential determinate on the behaviour of the parliamentarians.

The analysis aims to examine the parliament debates on CAMR amendment, the Bill C-393 (An Act to Amend the Patent Act (Drugs for International Humanitarian Purposes) and to make consequential amendment to another Act and the Bill C-398 (An Act to Amend the Patent Act (Drugs for International Humanitarian Purposes) (Parliament Canada 2011; 2012). Both the Bills are drafted for the same purposes, i.e., to amend the CAMR, in order to make flexible the compulsory licensing to fulfil its promises. The first Bill was introduced in 40th parliament by a NDP member; Judy Wasylycia-Lies in 2009 and which passed in a majority in the House of Commons, but did not become a law because of the parliament was dissolved for general election in March 2011 (Parliament Canada 2011). The Bill was introduced again in the 41st

parliament by another NDP member Helene Laverdire, but it was defeated with a narrow margin of seven votes (Parliament Canada 2010).

Table 5.1
Party Wise Composition of House of Commons during the Parliament Debate

	Number of MPs (HoC)	
	March 2011	**Nov 2012**
	Bill C-393 (End of 40th Parliament)	Bill C-398 (While the Bill C-398 Defeated)
Conservative Party	143	165
NDP	36	101
Liberal Party	77	35
Bloc Quebecois	47	4
Others/Vacant	5	3
Total	308	308

Source: Library of Parliament, Parliament of Canada, Party setting (1967 to date) in the House of Commons.

The party-wise composition of the parliament is an important factor in analysing prospects of the Bill. The Table 5.1 represents the party wise composition of the parliament. While dissolving the 40th parliament in which the Bill C-393 was introduced, Conservatives are the ruling party of a minority government. They had 143 members in the House of Commons out of total 308. The major opposition, the Liberals had 77 representations; the Bloc Quebecois had 47; and the New Democratic Party had 36 representatives (Library of Parliament 2015). Subsequently in the 41st parliament, the composition has changed dramatically and the Conservatives formed a majority government with a clear majority of 165 seats out of 308 (Library of Parliament 2015). The NDP improved its position from 36 of the 40th Parliament to 101 in the 41st Parliament (Library of Parliament 2015). The liberals lost their strength dramatically from 77 to 35. The Bloc, they too lost heavily from the 47 seats in the end of 40th parliament and shrunk in to a mere 4 in 41st (Library of Parliament 2015).

The Parliament composition in the 40th and 41st parliament to a considerable extent determines the status of the Bills. The literatures indicated that the conservatives were opposed to both amendment Bills (Parliament Canada 2011; 2012). Albeit the Conservatives opposed the Bill C-393, it was passed by a considerable majority (143/127) (Parliament of Canada 2009). It was referred to the further parliamentary proceeding (but did not become a law due to the parliament being dissolved)

(Parliament of Canada 2012; 2012b). The situation changed under the 41st parliament majority government. The Conservative majority defeated the bill with a narrow majority of 7 votes (148/141) (Parliament of Canada 2012b). The Table 5.2 shows that even though the conservatives opposed the bill some back bench conservatives supported the amendment. Similarly in the liberal camp, even though the party favoured the amendment, some members voted against.

Table 5.2
Voting Composition in House of Commons, Bill C-393 and Bill C-398

	Bill C-393		Bill C-398	
	support	Against	support	Against
Conservative Party	12	115	7	147
Liberal Party	58	11	31	0
NDP	34	0	98	0
Bloc Quebecois	39	0	3	0
Green Party	0	0	1	0
independent	0	1	1	0
Total (270/308)	143	127	141	148

Source: Parliament of Canada, Vote Details, Bill C-393 and Bill C-398.

Ultimately in the parliamentary democracies the party composition and the preferences of the parties decide the status of every bill while voting. But the party behaviour in the parliament may influence several factors. It is considered the culmination of every influences and preferences. The following analysis will be done party wise and analysed on the basis of party wise behaviour of Members of Parliament separately (Conservatives, Liberals, Bloc and NDP), with the theoretical framework; based on the arguments from the different levels replicated in the parliament speeches is being presented.

Table 5.3

Party-wise Chance to Speak About the Amendment in Parliament

	Bill C-393	Bill C-398
NDP	10	27
Liberals	6	20
Bloc	3	0
Conservative	8	16

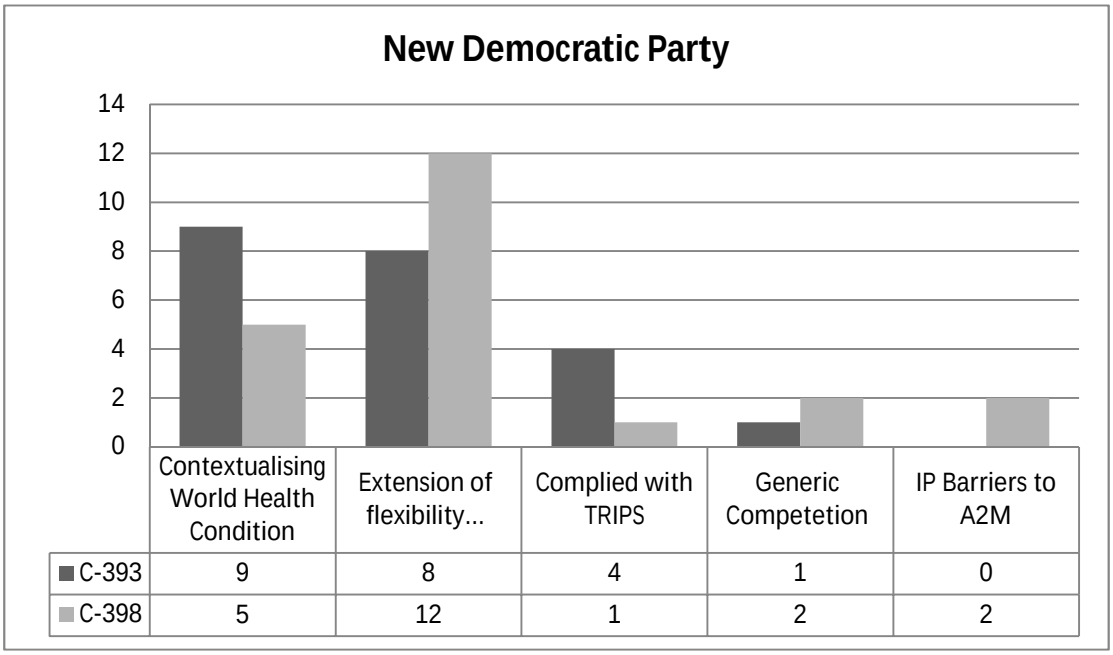
5.3.2.1. National Democratic Party

The Bill C-393 and C398 was introduced in the parliament by a National Democratic Party Member, Judy Wasylycia-Lies. The literatures indicated that, from the beginning issue on CAMR, they have been demanding the simplification of the compulsory licencing under the regime. The members of the party have been working with NGOs and other human rights activists in order to simplify the regime, especially Grand Mothers Association, Canadian HIV/AIDS Legal Network, and Oxfam Canada etc. (Parliament Canada 2010). In the drafting of the bill some noted NGOs and academia associated with them (Parliament Canada 2011). That is the reason why, the "one licence solution" which was originally introduced by Canadian HIV/AIDS Legal Network was incorporated as a priority item in the amendment bills (Canadian HIV/AIDS Legal Network 2011; Esmail 2010). Moreover throughout the speeches of the NDP members in parliament, they referred the arguments of those NGOs and academia and acknowledged their efforts for making CAMR workable (Parliament Canada 2011). The Most referred NGOs are the Grand Mothers Association and Canadian HIV/AIDS Legal Network in the parliament in the NDP member's speeches (Parliament Canada 2011). Not only the NDP members, but also almost all the Party representatives mentioned these names.

The result shows that (Figure 5.9), most of the arguments and claims of the NDP representatives were the replications of the NGOs and Generic Industry[42]. Similar to them NGO representative's arguments in the Industry Committee hearing the NDP members also #contextualised worrying world health condition frequently (14 (9+5) times) in order to substantiate the necessity of simplifying the compulsory licencing and the humanitarian generic supply under CAMR (Parliament Canada 2011). They urged the parliament members to pass the amendment to #extent the flexibility of the regime (20 (8+12) times) in order to fulfil the purpose and promises for the humanitarian generic medicine supply to the countries those suffering with HIV/AIDS, malaria, tuberculosis and other epidemics (Parliament Canada 2011).

[42] See the above analysis on the NGOs and generic pharmaceutical industry

Figure 5.10
Responses and Arguments in Parliament on Bill C-393 & C-398: NDP



In several times the debate turned to emotional ways, while the members talking about the humanity and the need for humanitarian medicine assistance to the people who are struggling without medicine (Parliament Canada 2012). Jasbir Sandhu NDP member form Surrey North, BC spoke once about this as:

> "Bill C-398 is one tool at our disposal to ensure that affordable treatment reaches as many of the world's poor as possible… [i]t is my sincere hope that members from all parties will support this legislation. This is a moral imperative. It is a matter of conscience. It is a matter of compassion. It is basic humanity…" (Parliament Canada 2012).

Furthermore, he continued:

> "This need is dire. CAMR is broken and it is failing to meet its goal. In five years, CAMR has been used only once to supply a single order…, but this one instance required years of efforts and was so complicated that CAMR has not been used since then. This needs to be fixed …solution that we already have in place… We can provide those drugs to those nations…" (Parliament Canada 2012).

The NDP members pointed out the need for #generic competition to reduce the price of the medicine in the global market (Parliament Canada 2011; 2012). The #intellectual property has been creating obstacle to access to medicine because of the lack of #generic competition in the post-TRIPS era by introducing product patent regime (Parliament Canada 2011; 2012). Since the world's health security has threatened by enormous spread of diseases and epidemics, it is an injustice to explore

the readily available opportunity given by the Doha Declaration to rescue the generic alternatives in the global market of medicine (Parliament Canada 2011; 2012). Moreover the NDP members denied the charges against the bill regarding the non-compliance of the bill with the TRIPS guidelines. A NDP member Brain Masse Criticised R&D industries non-compliance charges against the bill and the utility defences; he argued:

> "[t]here is no other excuse. The Bill is WTO and TRIPS complaint… they were not verified. At the very least we could try with this bill… the drug industry has blatantly said that if we do this it is going to cost us research and development… Despite the dangerous corporate tax cuts, despite all the grants and subsidiaries the industry is getting for research and development and all other incentives that have been thrown in the mix, the industry would throw the county under the bus just because a bill could pass that would, ironically, give the industry money" (Parliament Canada 2011).

The analysis has reflected the attributes of humanitarian or moral defences of NDP argument in the parliamentary debate (Table 5.9). It was indirectly indicated that, the utility can be justified if and only the millions of people gets essential medicine at a fair and affordable price. More over the analysis revealed a close relationship of NDP with the NGOs, generic industry and the human rights groups. The replications of the statements and arguments confirmed this alliance.

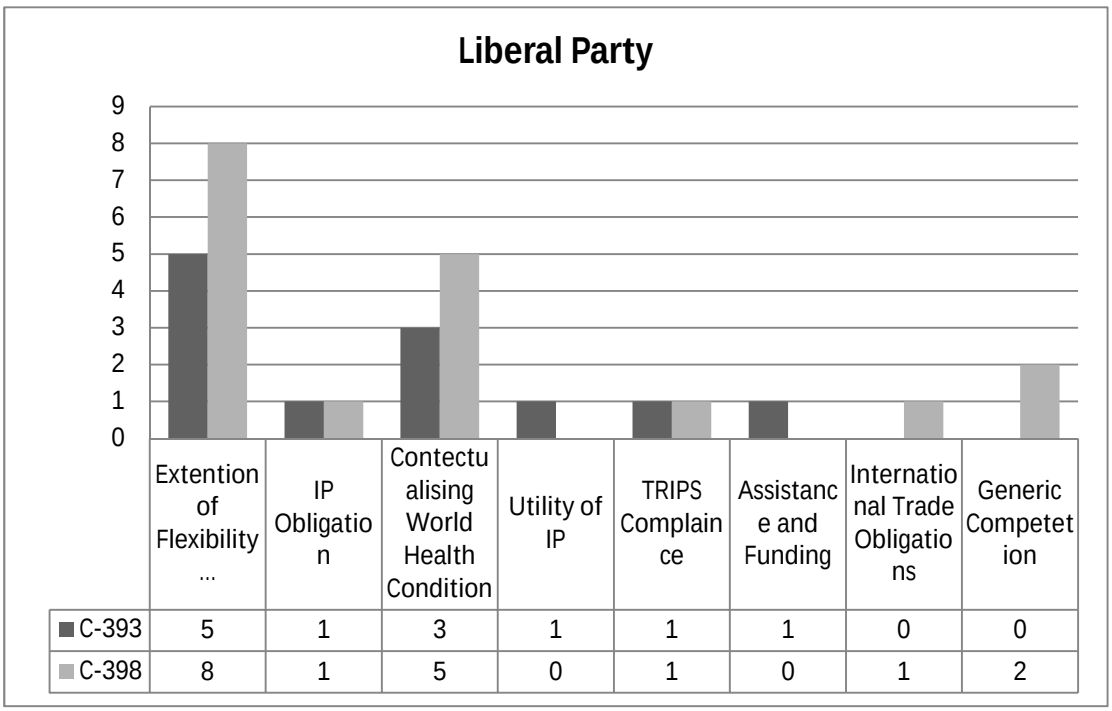
5.3.2.2. Liberal Party of Canada

The CAMR was originally introduced during a Liberal government in 2004. The literatures suggested that the Liberal Party has been in support the regime from its introduction. It has ruled Canada for the longest period. But they lost the electoral support since the end of the 20th century (Library of Parliament 2015). Their representation declined significantly in the 41st parliament and shrunk to 35 in house of commons from 77 in the 40th parliament (Library of Parliament 2015). Throughout the parliament debate and the in the Industry committee hearings most of the members of the party supported introduction of "one-license solution" to make the regime flexible (Parliament Canada 2011; 2012; 2010). But paradoxically some members defied the party whip and voted against the one-licence solution by defending the utility argument of the IP (Parliament Canada 2011). Moreover the result shows that, many of their arguments are the replications of the NGO arguments; apart from that many among them mentioned the Grand Mothers Association,

HIV/IDS Legal Network and other human right groups in their speeches (Parliament Canada 2011; 2012).

Figure 5.11

Responses and Arguments in Parliament on Bill C-393 & C-398: Liberals



	Extention of Flexibility ...	IP Obligation	Contectualising World Health Condition	Utility of IP	TRIPS Compliance	Assistance and Funding	International Trade Obligations	Generic Competetion
C-393	5	1	3	1	1	1	0	0
C-398	8	1	5	0	1	0	1	2

Most of the liberal speeches #contextualised the upsetting world's health condition in order to validate the need for amending the CAMR (Parliament Canada 2011; 2012). They placed the "one license solution" in this context. For example, a Liberal member Frank Valeriote argued that the regime had proved non-feasible in the present form, and it should be amended:

> Many of the recipients in greatest need cannot wait much longer. Most of the recent statistics estimate that 34 million people are suffering from HIV/Aids, 50% are women, 3.4 million are children and 22.5 million are in sub-Saharan Africa, among some of the world's poorest, least stable countries. Without effective access to medicine, the numbers keep growing …we have come far enough, scientifically and medicinally, to have avoided" (Parliament Canada 2012).

They urged the need for #extension of flexibility of the regime by passing the Bill by referring the similar #context referred by NGOs (Parliament Canada 2011; 2012). The party members in general support the bill on a humanitarian ground. But a few members argued for #TRIPS compliance and mentioned the importance of conformity with the # international trade obligations to avoid the adverse impacts and retaliations

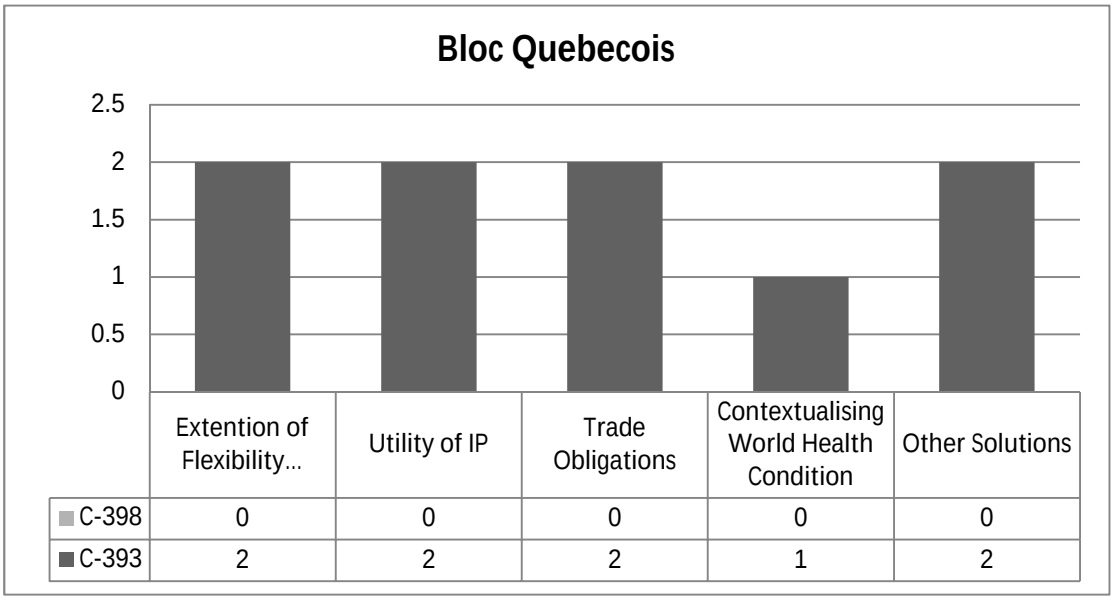
(Parliament Canada 2011; 2012). A few corners of the liberal camp defended the utility of patents. It was reflected in the voting pattern also, i.e. 11 Liberal MPs out of 69 (Table 5.2) voted against the bill (C-393) in the 40th parliament (Parliament Canada 2011).

5.3.2.3. Bloc Quebecois

Bloc was comparatively a smaller party than the others. It had 47 representatives in the House of Commons while the Bill C-393 was debated (Library of Parliament 2015). But when coming into the 41st Parliament, met after election Block lost its presence in the House dramatically with a mere 4 MPs (Library of Parliament 2015). This is the reason why the Bloc was not included in the analysis of the Bill C-398. No one from the total four delivered their speeches or opinions about the Bill C-398 in the 41st parliament (Parliament Canada 2012).

Figure 5.11

Responses and Arguments in Parliament on Bill C-393: Bloc Quebecois



The analysis result shows that Block (3 representatives out of 47) has been supporting the initiatives to make the regime flexible (#extension of flexibility…) in order to fulfil the commitment of the CAMR (Parliament Canada 2011). But they took a middle way of humanitarian and utilitarian camps. On the one hand they argued in favour of #extension of flexibility under the regime, on the other hand argued with the #utilitarian defences. The Table 5.11 shows, out of 3 representations they mentioned

the need for #extension of flexibility… two times and defended #utility of IP 2 times (Parliament Canada 2011). Bloc mentioned #international trade negotiations 2 times as well; it was indirectly indicating the dependency of Canada on international trade (Parliament Canada 2011). The Bloc's mass base was located in Quebec. This middle way of Bloc can be linked with the industrial as well as pharmaceutical capital security requirements of the Quebec. More over the Bloc has suggested finding some #other solutions other than the amendment or more soften stands regarding Canada's commitments towards access to medicine (Parliament Canada 2011).

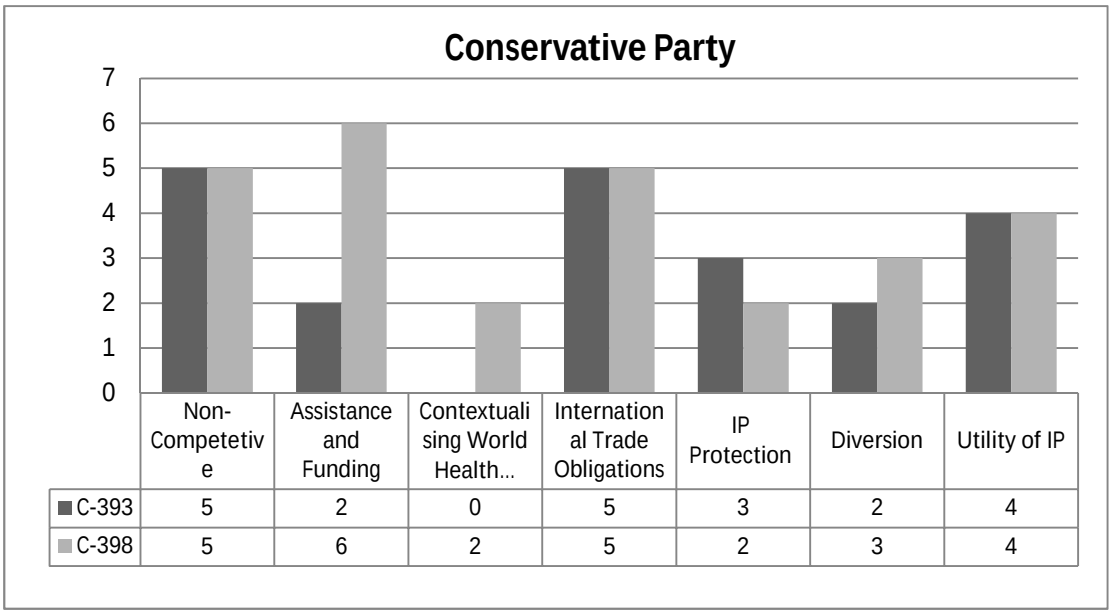
5.3.2.4. Conservative Party of Canada

The Conservative majority of Canada was the ultimate determining factor of the destiny of the amendment on CAMR. Even though the three major parties in the parliament voted in favour of the Bill, Conservative majority defeated the Bill C-398 in a narrow margin (141 against 148) (Parliament Canada 2012b). The literatures indicated that, from the beginning, the Conservative government took a negative approach towards making a dramatic change from the present form of the regime. The governments stand had been reflected in the Conservative members in the parliament as well as in the Industry Committee Hearings (Parliament Canada 2011; 2012; 2010; 2010a; 2010b; 2010c; 2010d).

The conservatives completely rejected both the Bills – C-393 and C-398; by defending the #utility of Intellectual property and #International trade and #intellectual property obligations. Their major arguments such as #international trade obligations; #utility of IP; #non-competitiveness of the regime with other generic regimes; #IP protection; #assistance and funding; #diversion was clearly replicated with the arguments of research-based pharmaceutical industry and with the Government institutions like CIDA, DFAIT, and Department of Industry (Parliament Canada 2011; 2012; 2010; 2010c; 2010d)

Figure 5.13

Responses and Arguments in Parliament on Bill C-393 & Bill C-398: Conservatives



Mike Lake, a Conservative Member from Alberta, and the Parliamentary Secretary to the Minister of Industry as well as the Chair of Industry Committee Sittings on Bill C-393 detailed the Governments view on the amendment (Parliament Canada 2011) as:

> "Our government's concerns with the Bill C-393's proposal to water down Canadian patent laws… At the conclusion of the review …Committee Members voted to substantially amend the Bill C-393. These amendments were considered necessary by some members of the committee to ensure that the bill would both respect Canada's international trade obligations and maintain the integrity of Canada's framework for encouraging innovation and access to medicine for Canadians" (Parliament Canada 2011)

He was very clear about the utility of the patents. The people of Canada needed a better access to medicine (Parliament Canada 2011). Innovation facilitated only if Canada encourages the Pharmaceutical research by providing adequate security to the inventions (Parliament Canada 2011). He had indirectly indicating that, if the Bill is passed, the patent laws would be diluted, the entry of new medicines in to Canada will be endangered accordingly (Parliament Canada 2011). He continued,

> "However, I still have reservations with the amended Bill C-393, which is why I cannot support it. In particular, I am concerned that, unlike the existing Access to Medicines Regime, the amended Bill C-393 does not include sufficient safeguards to ensure that drugs authorized for export are used for humanitarian purposes only and cannot be sold on the black market" (Parliament Canada 2011).

Mike Wallace, another Conservative member reaffirms his party's utilitarian defence. He argued, the Bill should ensure an "international drug procurement framework and

trade obligations" in order to "encouraging innovation and to ensure access to medicine for Canadians" (Parliament Canada 2011). In the second round speech (Bill C-393), Mike Lake pointed out that, the one license solution "could have serious negative implications for continued pharmaceutical investment and growth in Canada" (Parliament Canada 2011). It was a repetition of another Conservative member, Dave Van Kesteren's argument during debate on Bill C-393, without any changes in any words which delivered in the House four months before (Parliament Canada 2011).

In the 41st Parliament also (Bill C-398) the Conservatives continued their former arguments such as #utility of IP, #international trade obligations, #IP protection #diversion and so on (Parliament Canada 2012). Chris Warkentin pointed out:

> Intellectual property protection provides incentives for companies to invest in research and development into new and innovative drugs and medical devises. This research and development benefits all Canadians by improving our knowledge, generating research infrastructure, creating more highly paid, skilled jobs in Canada and leading to innovations that will help people live longer healthier and more productive lives" (Parliament Canada 2012).

From this utilitarian ground he rejected Bill C-398. According to him the "the Bill C-398 would interfere in the balanced approach of Canada's access to medical regime, and make Canada a less stable, less reliable and less welcoming place for those who want to invest and innovate" (Parliament Canada 2012). Therefore it could be assumed why the conservatives recommended #assistance and funding as an alternative to the amendment. As a trade dependent country and with its branch plant nature, it is difficult for a ruling party to make the regime harmful to country's trading partners and the investors.

The above analysis and the results showed the influence of the research based pharmaceutical industries and of the interests of trading partners to protect their 'nationals' investment abroad. Thus the utility became the defence of conservatives and the dependency became the invisible force behind their behaviour in the legislation.

5.4. CONCLUSION

The purpose of this Chapter was to analyses the three levels of influences of the determining factors and on Canada's Access to Medicines Regime (CAMR). This chapter has examined the involvement politics of the international system level, non-state actor level and state level in the making, working and amending of CAMR. The first section has identified the impact of international legal texts on Canada's patent law. The international IP politics based on utilitarian defenses and humanitarian critics has significantly reflected in the patent laws of Canada especially in the post-TRIPS era. The creation of CAMR was facilitated by the humanitarian trends in the international IP politics. But, the analysis has shown that the embedded dependency of Canadian polity and economy has made the regime complex.

In the non-state actor level the analysis has identified two camps of actors based on the two justifications and defences, i.e., the utilitarians and humanitarians. The NGOs, generic pharmaceutical industries and some noted academia stands in favour of humanitarian medicine supply by making the CAMR flexible via amendment (Bill C-393 and Bill C-398). The counterpart research-based pharmaceutical industries and industry associations stand in defence of intellectual property protection. They opposed the amendment bill by arguing utility of the patent, i.e., if the bill is passed it will adversely affect the research and development environment of Canada and in turn which will reverse the developmental interests of Canada.

The last section of the analysis examined the behaviour of the state actors. In that the responses of the MPs and government departments are examined. The study has identified the utilitarian IP defences of the government departments against the CAMR amendment. The bill ultimately failed in the parliament because of the opposition from the ruling party and its significant majority in the parliament. But how this behaviour was moulded has been identified in this chapter. The liberals, NDP and Bloc were voted in favour of the bill. Among, the first two argued in the same line as the humanitarian camp has argued. Even though the Blocs voted for the bill, but they pursued a tactical mid-way. The conservatives have replicated the arguments of the utilitarian camp. And finally the bill failed with the conservative majority those who opposed the bill in the 41st parliament of Canada in 2012.

Chapter 6

CONCLUSION

This dissertation was intended to explore the influence of three factors; utility, humanity and dependency, in determining the formation, reform and the functioning of the Canada's Access to Medicines Regime (CAMR). The study has revealed the politics of various gamut on intellectual property interests involved in the functioning of a humanitarian access to medicine regime at the three levels of analysis; (1) international system level; (2) state level; (3) and non-state actor level. Taking forwards from the hypothesis proposed to initiate the study; it is now possible to state that: "the politics of intellectual property rights determines the domestic and international direction of Canada's humanitarian commitments on access to medicine". Utilitarianism humanitarianism and dependency were the three domains used in the study; and these factors clearly come out to be imperative in determining the future of the regime. The former two 'designed' the interests of distinct camps of concerned actors in the discourse on access to medicine regime and intellectual property regime; and later one has constructed the political-economy in which the CAMR made up of.

The discourses on intellectual property and access to medicine have brought about different changes in the intellectual property regime over a period of time of which one among the most important was the Doha Declaration. It has challenged the dominant utilitarian defence of the intellectual property regime, and attached some humanitarian clauses on to the regime. It was in the Doha Declaration and its WTO General Council affirmation which removed the barriers on humanitarian medicine supply. The new provision in the Declaration allowed the courtiers with adequate pharmaceutical manufacturing capacity to grant compulsory licenses for 'exporting' medicine to the countries struggling with public health crises (WTO 2001; WTO 2003). The re-structured compulsory licensing facilitated the WTO members to amend their patent laws in a humanitarian manner in order to address the world's public health crises (ibid).

A number of Countries amended their patent laws according to the Doha public health guidelines, in different ways relating it to the domestic contexts (Parliament Canada

2010). Canada (CAMR) is the only WTO member, which elaborately framed laws by amendment proper (Bill C-9) and was able to send shipments of generic medicines successfully using the provisions of Doha guidelines (ibid). But, that was the "one and only" experience of Canada under Canada's Access to Medicines Regime (Elliot 2013). The regime failed in delivering its humanitarian promises in its future (Esmail 2010; Gatto 2011).

This particular study has examined the forces behind the failure of the CAMR. It was the politics of intellectual property right which decided the fate of CAMR. That politics was dominated by 'utilitarian' defences and 'humanitarian' critics of intellectual property rights. Moreover, Canada's Domestic structures of dependency also facilitated the dominant actors to maintain the regime as un-workable. The chapterisation of this Dissertation was structured accordingly. The dissertation contains six chapters including introduction and conclusion. The first three review chapters (Chapter 2, 3 and 4) were framed on the basis of aforementioned theoretical framework: utility, humanitarianism and dependency and were based on analytical literature review of webs based literatures and documents available in the archives and fundamental books on theories.

Chapter Two dealt with the philosophical discourses on IP and focussed on the utilitarian defences of intellectual property. The first session of the chapter provided a brief review on the development of intellectual property laws, which also provided some insights on simultaneous development of the intellectual property philosophies. The development of the modern capitalist state system employed philosophical justifications of both property and intellectual property for the development of distinct territories and for legitimising their activities (Richards 2002). It provided an understanding about the conversion of the philosophies on property and it affected in extension of property from tangible to intangible. The first major justification of intellectual property was derived from John Lock's (1698) "self-ownership" theory. Later the utilitarian defences emerged. The states and individual were suggested to follow utility as a force behind their reasoning and in formation of laws (Bentham 1823). The utilitarian reasoning incentivising individual labour was later applied to intellectual property. The utilitarians highlighted the necessity of a system of motivation for protecting the rights of the inventors, for a better innovative incubation

and innovation discloses (Sterckx 2004). As per them, this will facilitate the overall development of the society (ibid). The last section of the chapter described the critics of intellectual property. Critics questioned the philosophical justifications of IP with the very nature of the intellectual creations (Perelman 2003a). The ideas and creations are not a product of a single person; it has been derived from an intergenerational process and drawn upon multiple sources (Perlman 2003; 2003a). Moreover they criticised the utilitarian logic of "incentive-to-invent-and-innovate" (Sterckx (2004). The "winner takes all" logic creates an "all-out competition"; and prevents the fellow competitors to innovate socially useful creations (Chang 2001; Perelman 2003). So the 'utility' or the 'usefulness' of the IPRs has been challenged (Perlman 2003)

Third Chapter was contextualised to bring out the worrying concerns world's health conditions. The chapter has been designed with the humanitarian and utilitarian discourses on intellectual property and access to medicine and to evaluate, how these discourses reflected in the international IP regimes. It exposed the poor health conditions of the developing and least-developed countries, particularly those living in the sub-Saharan Africa (UN 2012: 61; 7: Kohler 2010; 't Hoen; WHO 2004; Thomas 2002) This access to medicine discourse has brought about the demand for flexibility in the TRIPS document in order to meet the public health crises (Esmail 2010; Gatto 2011; 't Hoen 2009). The discourses have culminated into the Doha Public Health Declaration and based on the Declaration, Canada's Access to Medicines Regime emerged (WTO 2001; ibid). The last section of the chapter discussed the functioning of Canada's Access to Medicines Regime and the internal complexities of the regime which lead to the non-working of the regime were also brought out.

The fourth chapter has examined the domestic determinants of Canadian foreign policy and how Dependency has been the prominent factor of the decision making process. An analysis of Canada's power structure, capabilities, geography and natural resources and economic structure facilitated an understanding of the nature of Canadian dependency and how it affects the decision making behaviour of Canada. The chapter has discussed the Harold Innis (1999; 2004) traditions of Canadian dependency; its historical roots; and its implications on the overall policy framework of Canada. Finally the chapter has provided a statistical review of contemporary

Canada; which revealed the continuations of Canadian dependency on international trade especially on the US-Canada Trade and the persisting of the branch-plant character of Canadian industrialisation.

Chapter five examined the influence of three theoretical perspectives on Canada's Access to Medicine Regime at three levels: international system level, non-state actor level and the state level. The chapter has identified a reconciliation of utilitarian and humanitarian interests at the international system level in the implementation of the paragraph 6 of the Doha Declaration (WTO 2003). Canada implemented the Doha mandates domestically by establishing the CAMR (Esmail 2010; Gatto 2011; Kohler 2010). But the study has revealed that Canada failed to exploit the original essence of the Doha Declaration at the implementation level. Even though, original purpose of CAMR was a humanitarian generic medicine supply, a predominance of protection of the rights of patent holders reflected in the regime, such as the anti-diversion; limits on duration, quantity and supply; and restrictions of varieties of medicines made the regime unfeasible. The second and third section has analysed the actors' behaviour in the amendment of CAMR (Bill C-393 and Bill C-398) at non-state actor level and state level, both quantitatively and qualitatively, and the study identified two camps of interests: utilitarian and humanitarian. The utilitarian camp (including research-based pharmaceutical industry, industry associations, conservative party members and so on) defended to maintain the unfeasible status quo of CAMR (GoC 2007; Parliament Canada 2010; 2010a; 2010b; 2010c; 2010d; 2011; 2012). The humanitarian counter camp (generic industry, NGOs, Human Rights groups, New Democratic Party, Liberal Party and so on) argued in favour of the amendment "in order to make [the CAMR] easier to manufacture and export pharmaceutical products to address the public health problems afflicting many developing and least-developed countries" (ibid). The replicated utilitarian arguments finally succeeded to defeat the amendment bill with the Conservative majority in the parliament. Moreover the analysis has shown the influence of Canadian dependency in the arguments of state-level actors.

Key Findings

The study has identified reconciliation or a balance of different interests in the making of Canada's Access to Medicines Regime. The patent laws of Canada are the reflections of the structures of international patent regime, which in turn was resulted

from the global discourse of humanitarian and utilitarian perspectives which amalgamated to the international patent regime. CAMR is a part of Canada's Patent Law that, all the mandates of CAMR are within the purview of Patent Act of Canada. The Bill C-9 of the Parliament of Canada provided the amendment for exporting generic essential drugs using compulsory licencing and a scope of humanitarian perspective to address the access to medicine needs of the developing and least developed countries.

The provision under CAMR was utilised for a single time for exporting drugs for AIDS therapy in Rwanda which was facilitated by the largest generic producer in the country Apotex. The 'one and only' experience under the regime revealed the complexities, both bureaucratic and legal, and it was found that, the particular humanitarian provision was 'impractical' in different aspects. The experience brought about different discourses within Parliament of Canada, to loosen certain mandates within the regime so as the provisioning through the Bill can be proceeded in the future. The varying interests of the representatives which were debated within and the attempts for reconciliation failed. There were attempts to cushion the stringent abiding laws within CAMR by different segments within the parliament and it was vehemently opposed especially by the ruling the party within the parliament. The ultimate win over was of the utilitarian defences over the humanitarian critiques and within the particular dichotomy of philosophical perceptions of utility and humanitarianism; the upper hand of the utilitarian interests were augmented by the dependency of the capitalist country Canada on other 'influential' global players like US.

The geopolitical and diplomatic manoeuvrings of Canada as a developed nation but not as a superpower influences deeply in its foreign policy. Even though its foreign policy track record provides us many visible hints of 'positive' initiatives like CAMR, those were not culminated to the expected outcomes. There are historical and contemporary reasons for these failed policy initiatives. It is evident that Canada has yet to recover its historical imperial dependency. In a post liberalised era this dependency is being manifested in the multi-lateral and bi-lateral agreements in which the nation is a part of. In the current globalised world order, where the liberalised economies are highly integrated and interdependent, it is almost impossible for a

country like Canada to push for an alternative policy challenging the existing power relations.

REFERENCES

Primary Sources

Apotex (2007), "Apotex CAMR Submission" , *Review of Canada's Access to Medicines Regime*, Government of Canada, [Online Web] Accessed: 17/07/2015, URL: http://www.camr-rcam.gc.ca/review-reviser/camr_rcam_apotex_18-eng.pdf.

CETA (2014), *Consolidated CETA Text*, Canada EU Free Trade Agreement, Published in 26th September 2014.

CIPO (2015) Canada's Access to Medicine regime, Canadian Intellectual Property Office, Government of Canada, Date Modified 2015-06-1 URL: https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr00116.html.

CIPO (2015a), *A Guide to Patents*, Canadian Intellectual Property Office, Government of Canada, [Online Web] Accessed: 01/06/2015, URL: http://www.cipo.ic.gc.ca/eic/site/cipoInternet-Internetopic.nsf/eng/h_wr03652.html.

Constitution of US (1776), *U.S. Constitution*, Washington: Government of United States.

GATT (1986), "Ministerial Declaration on Uruguay Round", General Agreement on Trade and Tariffs, Punta Del Este, December 20, 1987, Annexed in Watal, Jayasree, *Intellectual Property Rights in the WTO and Developing Countries* (New Delhi: Oxford University Press).

GoC (2008), *Canada's Access to Medicines Regime: Background*. Government of Canada, Date Modified: 13-03-2008, [Online Web] Accessed 29-06-2015, URL: http://www.camr-rcam.gc.ca/intro/context-eng.php.

GoC (2008a), *Canada's Access to Medicines Regime: Features of the Regime*, Government of Canada, Date Modified: 13-03-2008, [Online Web] Accessed 29-06-2015, URL: http://www.camr-rcam.gc.ca/intro/regime-eng.php.

GoC (2009), *Canada's Access to Medicines Regime: Countries*, Government of Canada, Date Modified: 14-09-2009, [Online Web] Accessed 29-06-2015, URL: http://www.camr-rcam.gc.ca/countr-pays/index-eng.php

GoC (2013), *Canada's Economic Action Plan*, Overview, Government of Canada: Ottawa, URL: http://actionplan.gc.ca/en/page/r2d-dr2/overview.

GoC (2013a) Bi-Lateral Relations: "Canada-U.S. Trade and Investment", *Canada's hjyEconomic Action Plan* [Online Web] Accessed 23, June 2015, URL: http://actionplan.gc.ca/en/page/bbg-tpf/bilateral-relations-canada-us-trade-and-investment.

GoC (2014), *Canada's Pharmaceutical Industry and Prospects*, Industry Canada, [Online Web] Date Modified: 2014-04-08, URL: https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/hn01768.html.

GoC (2015), *Canada's Access to Medicines Regime*, Government of Canada, Date Modified: 09-04-2015, [Online Web] Accessed 29-06-2015, URL: http://www.camr-rcam.gc.ca/index-eng.php.

GoC (2015a), *Patent Act*, Government of Canada, Justice Laws Website [Online Web] Accessed: 7/15/2015, URL: http://www.laws-lois.justice.gc.ca/eng/acts/P-4/FullText.html.

IFPMA (2007), "Review of Canada' Access to Medicines Regime" *Review of Canada's Access to Medicines Regime*, Government of Canada, [Online Web] Accessed: 17/07/2015, URL: http://www.camr-rcam.gc.ca/review-reviser/camr_rcam_ifpma_03-eng.pdf.

Industry Canada (2007), "Report on the Statutory Review of Sections 21.01 to 21.19 of the Patent Act", Government of Canada, Cat. No. Iu4-118/2007, URL: http://www.camr-rcam.gc.ca/doc/camr_rcam_report_rapport-eng.pdf.

IPHA (2007) "Review of Canada' Access to Medicines Regime" *Review of Canada's Access to Medicines Regime*, Government of Canada, [Online Web] Accessed: 17/07/2015, URL: http://www.camr-rcam.gc.ca/review-reviser/camr_rcam_ipha_28-eng.pdf.

Library of Parliament (2015), *Party Settings (1967 to Date) in the House of Commons*, Parliament of Canada, [Online Wed] Accessed: 12/07/2015, URL:

http://www.parl.gc.ca/Parlinfo/lists/PartyStandingsHistoric.aspx?Menu=SEN-Politic&Section=03d93c58-f843-49b3-9653-84275c23f3fb.

Merck (2007), "Merck CAMR Submission", *Review of Canada's Access to Medicines Regime*, Government of Canada, [Online Web] Accessed: 17/07/2015, URL: http://www.camr-rcam.gc.ca/review-reviser/camr_rcam_merck_25-eng.pdf.

Ministry of Finance (2013), Government of Canada, Ministry of Finance, 'Jobs Growth and Long Term Prosperity', *Economic Action Plan 2013*, March 21, 2013, URL: http://www.budget.gc.ca/2013/doc/plan/budget2013-eng.pdf.

MSF (2012), Medicines Sans Frontiers, *Trading Away Health: How the US's Intellectual Property Demands for the Trans-Pacific Partnership Agreement Threaten Access to Medicine*, Issue Brief, August 2012, Accessed in 01/06/2015, URL: http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/Access_Briefing_TPP_ENG_2012_update.pdf.

NAFTA (1994), *North American Free Trade Agreement*, NAFTA Secretariat.

Parliament Canada (2010), Industry Committee on Oct. 7th, 2010, Evidence Meeting #37 for Industry Science and Technology in the 40th Parliament, 3rd Session, Openparliament.ca, [Online Web] Accessed: 17/07/2015, URL: https://openparliament.ca/committees/industry/40-3/37/?singlepage=1.

Parliament Canada (2010a), Industry Committee on Oct. 21st, 2010, Evidence Meeting #39 for Industry Science and Technology in the 40th Parliament, 3rd Session, Openparliament.ca, [Online Web] Accessed: 17/07/2015, URL: https://openparliament.ca/committees/industry/40-3/39/?singlepage=1.

Parliament Canada (2010b), Industry Committee on Oct. 26th, 2010, Evidence Meeting #40 for Industry Science and Technology in the 40th Parliament, 3rd Session, Openparliament.ca, [Online Web] Accessed: 17/07/2015, URL: https://openparliament.ca/committees/industry/40-3/40/?singlepage=1.

Parliament Canada (2010c), Industry Committee on Oct. 28th, 2010, Evidence Meeting #41 for Industry Science and Technology in the 40th Parliament, 3rd Session, Openparliament.ca, [Online Web] Accessed: 17/07/2015, URL: https://openparliament.ca/committees/industry/40-3/41/?singlepage=1.

Parliament Canada (2010d), Industry Committee on Nov. 1st, 2010, Evidence Meeting #42 for Industry Science and Technology in the 40th Parliament, 3rd Session, Openparliament.ca, [Online Web] Accessed: 17/07/2015, URL: https://openparliament.ca/committees/industry/40-3/42/?singlepage=1.

Parliament Canada (2011) *Bill C-393 (Historical)*, An Act to Amend the Patent Act (Drugs for International Humanitarian Purposes) and to make a Consequential amendment to Another Act, Parliament Speeches, Openparliament.ca, [Online Web] Accessed: 17/07/2015, URL: https://openparliament.ca/bills/40-3/C-393/?singlepage=1.

Parliament Canada (2012) *Bill C-398 (Historical)*, An Act to Amend the Patent Act (Drugs for International Humanitarian Purposes), Parliament Speeches, Openparliament.ca, [Online Web] Accessed: 17/07/2015, URL: https://openparliament.ca/bills/41-1/C-398/.

Parliament of Canada (2004), Bill C-9: "An Act to Amend the Patent Act and the Food and Drugs Act", Legislative Summery, Library of Canada, Government of Canada, [Online Web] Accessed: 29/06/2015, URL: http://www.parl.gc.ca/About/Parliament/LegislativeSummaries/bills_ls.asp?ls=C9&Parl=37&Ses=3.

Parliament of Canada (2008) *Patent Protection for Pharmaceutical Products in Canada – Chronology of Significant Events*, Government of Canada [Online Web] Accessed: 01/06/2015, URL: http://www.parl.gc.ca/Content/LOP/ResearchPublications/prb9946-e.htm.

Parliament of Canada (2009), *Vote Details*, Bill C-393, Vote No. 142, Sitting No. 122, Parliament of Canada, [Online Web] Accessed: 12/07/2015, URL: http://www.parl.gc.ca/HouseChamberBusiness/ChamberVoteDetail.aspx?FltrParl=40&FltrSes=2&Vote=142&Language=E&Mode=1.

Parliament of Canada (2012), *Bill C-398: An Act to Amend the Patent Act (Drugs for International Humanitarian Purposes)*, Legislative info, Government of Canada, [Online Web] Accessed: 15-03-2015, URL: http://www.parl.gc.ca/LegisInfo/BillDetails.aspx?Language=E&billId=5349039&Mode=1&view=1.

Parliament of Canada (2012a), *Bill C-398*, First Session, 41st Parliament, 60-61 Elizabeth II, 2011-2012, House of Commons, and Government of Canada [Online Web] Accessed: 07/04/2015, URL:

http://www.parl.gc.ca/HousePublications/Publication.aspx?Language=E&Mode=1&DocId=5391829&File=4.

Parliament of Canada (2012b), *Vote Details*, Bill C-398, Vote No. 515, Sitting No. 187, Chamber Business, Parliament of Canada, [Online Web] Accessed: 12/07/2015, URL: http://www.parl.gc.ca/HouseChamberBusiness/ChamberVoteDetail.aspx?FltrParl=41&FltrSes=1&Vote=515&Language=E&Mode=1.

Patent Act (1923), Patent Act, R.S.C. 1923, c.23 ("Patent Act (1923)", s. 40(a), cited in Zischaka, Matthew et al (2009), "Watch Out! Compulsory Licensing Lurks around Global Corners (The View from Canada)", *Smart and Bigger*, Alpha Mid-Winter Meeting, Jan 2009, Accessed 29-09-2015, URL: http://www.smart-biggar.ca/files/AIPLA_final-Jan12.pdf.

Statista (2015), "Percentage of Selected Countries in Global Pharmaceutical Production in 1990 and 2009", The Statistics Portal [Online Web] Accessed: 25/06/2015, URL: http://www.statista.com/statistics/266124/percentage-of-selected-countries-in-pharmaceutical-production/.

Statistics Canada (2014), "Foreign Control in the Canadian Economy, 2012", Government of Canada, Date Modified 2014-12-09 [Online Web] URL: http://www.statcan.gc.ca/daily-quotidien/141209/dq141209a-eng.htm.

Statistics Canada (2015), *Canadian International Trade Merchandize,* Government of Canada, "Merchandise Imports and Exports between Canada and World, by Harmonised System Selection, Customs Basis, April 2015 [Online Web] Accessed 23 June 2015, URL: http://www5.statcan.gc.ca/cimt-cicm/section-section?lang=eng&dataTransformation=0&refYr=2015&refMonth=4&freq=6&countryId=9&usaState=0&provId=1&retrieve=Retrieve&save=null&trade=null.

Statistics Canada (2015a), *Canadian International Trade Merchandize,* Government of Canada, "Merchandise Imports and Exports between Canada and United Sates, by Harmonised System Selection, Customs Basis, April 2015" [Online Web] Accessed 23 June 2015, URL: http://www5.statcan.gc.ca/cimt-cicm/section-section?lang=eng&dataTransformation=0&refYr=2015&refMonth=4&freq=6&countryId=9&usaState=0&provId=1&retrieve=Retrieve&save=null&trade=null.

UN (2012), "The Global Partnership for Developing: Making Rhetoric a Reality", *MDG Gap Task Force Report 2012*, New York: United Nations.

USTR (2015), Office of the United States Trade Representatives, "U.S.-Canada Trade Facts", [Online Web] Accessed 23 June 2015, URL: https://ustr.gov/countries-regions/americas/canada.

WHO (2005), *Access to Medicine*, WHO Drug Information, 19 (03):236-241.

World Bank (2015), "Military Expenditure (% of GDP)", *World Bank Development Indicators*, Data, URL: http://data.worldbank.org/indicator/MS.MIL.XPND.GD.ZS.

WTO (1994) *Trade Related Aspects of Intellectual Property Rights*, Annex 1C of Marrakesh Agreement on Establishing World Trade Organisation Signed in Marrakesh, Morocco on 15 April 1994, Accessed in 04/06/2015, URL: https://www.wto.org/english/docs_e/legal_e/27-trips.pdf

WTO (2001), "Declaration in the TRIPS Agreement and Public Health" Doha WTO Ministerial: TRIPS, WT/MIN(01)/DEC/2, Accessed 03/06/2015, URL: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm .

WTO (2003), General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 and Corr.1, 1 September 2003, Accessed in 03/06/2015, URL: https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

Secondary Sources

't Hoen, Ellen F.M. (2009), *The Global Politics of Pharmaceutical Monopoly Power*, Diemen – Netherlands: AMB Publishers (MSF Open Access) Accessed: 12-06-2015, URL: http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf.

A.T. Kearney (2010), "Merges and Acquisitions in the Health Care Industry", *A.T. Kearney Case Studies*, PDF: ATK610139, [Online Web] Accessed 23/07/2015, URL: https://www.atkearney.com/paper/-

/asset_publisher/dVxv4Hz2h8bS/content/mergers-and-acquisitions-in-the-healthcare-industry/10192.

Abbott, Frederick M (2007), "Introductory Note to World Trade Organization: Canada First Notice to Manufacture Generic Drug for Export", *International Legal Materials: American Society of International La*w, 46(6): 1127-1129, Accessed: 16/10/2014, URL: http://www.jstor.org/stable/20695769.

Apotex (2008) "Canadian-Made Life Saving HIV/AIDS Drug Heading to Africa Under Canada's Access to Medicines Regime (CAMR)", cited in, Esmail, Laura Caroline (2010), *The Politics of Canada's Access to Medicine Regime: the Dogs that Didn't Bark*, PhD Thesis, University of Toronto.

Apotex Group (2008) "Canadian Company Receives Final Tender Approval from Rwanda for vital AIDS Drug", Press release, Cited in Kohler, Jillian Clare et al (2010), "Canada's Access to Medicines Regime: Promise or Failure of Humanitarian Effort?" *Health Policy*, 5(3): 40-48.

Bellanthyne, Zoe (2004), *IPR Handbook*, Sanger Institute, UK: Welcome Trust [Online Web] Accessed: 12/06/2012, URL: http://www.iprhandbook.org/handbook/authors/A4/.

Bentham, Jeremy (1823), *Principles of Morals and Legislation*, Warehouse: Oxford University Press.

Bhargava, Rajeev and Acharya, Ashok (2008), *Political Theory: An Introduction*, New Delhi: Dorling Kindersley (India) Pvt. Ltd.

Boyce, David E., Huw, CWL Williams (2015), *Forecasting Urban Travel: Past Present and Future*, United Kingdom: Edward Elgar Publishing.

Brebner, Bartlet J. (1948), "A Changing North Atlantic Triangle", *International Journal*, 3(4): 309-319, URL: http://www.jstor.org/stable/40197451.

Brooks, Mick (2005), Intellectual Property Rights – The Modern Day Enclosure of the Commons, In Defence Of Marxism Series, *International Marxist Tendency*, Marxist.Com, Accessed in 22/05/2015, URL: http://www.marxist.com/intellectual-property-rights221105.htm .

Bruce, Lehman (2003), "The Pharmaceutical Industry and the Patent System", Discussion Paper at Wake Forest University, North Carolina, Accessed on 01/06/2015, URL:http://users.wfu.edu/mcfallta/DIR0/pharma_patents.pdf

Bubela, Tania & Morin, Jean-Frederic (2010), "Lost in Translation: The Canadian Access to Medicines Regime from Transnational Activism to Domestic Implementation", *Health Law Review Journal*, 18: 113-158.

Bucci, Christina (2013) "Responsible Patent Protections: Preserving Public Health Objectives in Trans-Pacific Partnership Agreement" Global Business & Development Law Journal, 26: 213-234, Accessed in 01/06/2015, URL: http://www.mcgeorge.edu/Documents/Publications/261_9BucciFix.pdf.

Burger, Roland (2013), "Global Pharmaceutical Industry is in a Strategic Crisis – Business Models Must be Adjusted" Press Release on 6 January 2013, Munich Accessed on 01/06/2015, URL:http://www.rolandberger.com/press_releases/513-press_archive2013_sc_content/Pharmaceutical_industry_in_a_strategic_crisis.html.

Canadian HIV/AIDS Legal Network (2011), "Fixing Canada's Access to Medicines Regime: Bill C-393 Up for Final Vote in House of Commons in Early March", *Release,* Canadian HIV/AIDS Legal Network, February 2015.

CGPA (2007), "Canadian Generic Pharmaceutical Association's CAMR Submission" *Review of Canada's Access to Medicines Regime,* Government of Canada, [Online Web] Accessed: 17/07/2015, URL: http://www.camr-rcam.gc.ca/review-reviser/camr_rcam_cgpa_01_e.pdf.

Chandra, Rajshree (2010), *Knowledge as Property: Issues in the Moral Grounding of Intellectual Property Right,* New Delhi: Oxford University Press.

Chang, Ha-joon (2001), "Intellectual Property Rights and Economic Development – Historical Lessons and Emerging Issues" *Third World Network Intellectual Property Rights Series*: 3.

Christopher, Divya and Arishma, Miss (2013), "Pharmaceutical Mergers and Acquisitions", *International Journal of Advanced Research,* 1(05): 119-130, Accessed on 1/06/2015, URL:file:///C:/Users/AJI/Downloads/2013-07-31_192125_802.pdf.

Cohen, G.A. (1995) *Self Ownership, Freedom and Equality*, Cambridge: Cambridge University Press, Cited in Chandra, Rajshree (2010), *Knowledge as Property: Issues in the Moral Grounding of Intellectual Property Right,* New Delhi: Oxford University Press.

Correa, Carlos and Matthews Duncan (2011), *The Doha Declaration Ten Years on and Its Impact on Access to Medicine and Right to Health*, Discussion Paper, Bureau for Development Policy, United Nations Development Programme, 20 December 2011.

Dhar, Biswajit and Rao, C. Niranjan (1994), "The Dunkal Draft on TRIPs: An Assessment", in Nair, KRG and Kumar, Ashok (eds.), *Intellectual Property Rights,* New Delhi: Allied Publishers Limited.

Dolan, Michael B. et al. (1982), "Asymmetrical Dyads and Foreign Policy: Canada-U.S. Relations 1963-1972", *The Journal of Conflict Resolution*, 26(3): 387-422, URL: http://www.jstor.org/stable/173755

Elliot, Richard (2012), *Fixing Canada's Access to Medicines Regime – Bill C 398*, Intellectual Property Watch, [Online Web] Accessed: 29-06-2012, URL: http://www.ip-watch.org/2012/11/18/fixing-canadas-access-to-medicines-regime-bill-c-398/.

Elliot, Richard (2013), "Government of Canada Misleads Parliament and Public, Kills bill on Access to Medicines for Developing Countries", Newsletters, *Equilibri*, Published: 06-03-2013 [Online Web] Accessed 10-23-2014 URL: …….

Esmail and Kohler (2012), N/A.

Esmail, Laura Caroline (2010), *The Politics of Canada's Access to Medicine Regime: the Dogs that Didn't Bark*, PhD Thesis, University of Toronto.

Fassin, D (2007) "Humanitarianism as a Politics of Life", *Public Culture*, 19(3): 499-520.

Galloway, Gloria (2011), "Tony Clement urges Senators to Block Generic-Drug Legislation", *The Global Mail*, [24/03/2011].

Gatto, Stephanie (2011), *Unpacking the Senate of Canada Debate on Bill S232 – An Act to Amend the Patent Act: Inconsistencies and Implications for Global Public Health*, PhD Thesis, British Columbia: Simon Fraser University.

GoC (2007), *Review of Canada's Access to Medicines Regime*, Government of Canada, Last updated: 15/02/2007 [Online Web] Accessed: 16/07/2015, URL: http://www.camr-rcam.gc.ca/review-reviser/index_e.html.

GoC (2009a) *Canada's Access to Medicines Regime: Role of Non-Governmental Organisations*, Government of Canada, Date Modified: 14-09-2009, [Online Web] Accessed: 07-06-2015, URL: http://www.camr-rcam.gc.ca/countr-pays/ngo-ong/index-eng.php.

Gotlieb, Allan (2004), "Romanticism and Realism in Canada's Foreign Policy", Lecture Delivered on 3 April 2004, C.D. Howe Institute: Toronto.

Gunton, Thomas (2014), "Staple Theory and the New Staple Boom", in Stanford, Jim (Ed.), *The Staple Theory @ 50: Reflections on Lasting Significance of Mel Watkins' "A Staple Theory of Economic Growth*, Ottawa: Canadian Centre for Policy Alternative.

Hart, Michael. A (2002), *A Trading Nation: Canadian Trade Policy From Colonisation To Globalisation*, Vancouver: UBC Press.

Hegel, G.W.F. (2001), *Philosophy of Rights*, Translated by Dyde, S.W, Kitchener, Ontario: Batoche Books.

Hegel, Georg Wilhelm Friedrich (2008), *Outlines of the Philosophy of Right*, Oxford: Oxford University Press.

Heywood, Andrew (2012), *Global Politics*, New Delhi: Palgrave MacMillan.

Himelfarb, Jenna (2015), "The Limitations of Canada's Access to Medicines Regime: Lessons from Apotex's Export of Essential Medicines to Rwanda", *Queen Mary Journal of Intellectual Property*, Posted: March 22, 2015, [Online Web] Accessed: 07/01/2015, URL: https://qmjip.wordpress.com/2015/03/22/.

HRWA (2007), "Canada's Access to Medicine Regime" A Consultation Submitted by The Human Right Working Group on HIV/AIDS and Public Health, Faculty of Law: McGill University.

HRWA (2007), "Canada's Access to Medicine Regime" A Consultation Submitted by The Human Right Working Group on HIV/AIDS and Public Health, Faculty of Law: McGill University.

Hughes, Justin (1988), "The Philosophy of Intellectual Property Rights", *Georgetown Law Journal*, 77.

Huth, Carly L. (2010), "The Best of Intentions: Why Proposed Changes to the Canadian Access to Medicine regime should not be Implemented", *CYBARIS, An Intellectual Property Rights Review*, 1(124): 124-153.

Ignatieff Michael (2013), "Peace Order and Good Government: A Foreign Policy Agenda for Canada", *O. D. Skelton Lectures*, Foreign Affairs, Trade and Development Canada, Government of Canada, [Online Web] Date Modified: 25-04-2013, URL: http://www.international.gc.ca/odskelton/ignatieff.aspx?lang=eng&_ga=1.243 11802.133140727.1434103552.

Innis Harold (1999) *The Fur Trade in Canada*, Revised Edition, Toronto: University of Toronto Press.

Innis, Harold A. (2004), *Changing Concepts of Time*, United States of America, Maryland: Rowman & Littlefield Publishers.

Kalo, Zoltan et al. (2011), *International Comparison of Pharmaceutical Expenditure in Middle Income Countries: Methodological Questions*, Research Report, [Online Web] Accessed : 21/12/2014, URL: http://www.ispor.org/research_pdfs/40/pdffiles/php44.pdf.

Kearney, A.T. (2010), "Merges and Acquisitions in the Health Care Industry", *A.T. Kearney Case Studies*, PDF:ATK610139, URL: file:///C:/Users/AJI/Desktop/MA_in_Healthcare.pdf.

Kirton, John j. (2007), *Canadian Foreign Policy in a Changing World*, Toronto: Thomson Nelson.

Kohler, Jullian Clare et al (2010), "Canada's Access to Medicine Regime: Promises or Failure of Humanitarian Effort?" *Health Care Policy*, 5(3): 40-48.

Lalitha, N. (2005), "Review of the Pharmaceutical Industry of Canada", *Economic and Political Weakly*, 40(13): 1355-1362.

Laverdiere, Helene (2012), *Defeat of Bill C-39*, an Open Letter Written by Helene Laverdiere, MP in House of Commons, House of Commons, 03/12/2012, Ottawa.

Lexchin, Joel (2003), *Intellectual Property Rights and the Canadian Market Place: Where do We Go from here?* ISBN: 0-88627-348-X, Ottawa: Canadian Centre for Policy Alternatives.

Lexchin, Joel (2013), "Canada and Access to Medicines in Developing Countries: Intellectual Property Rights First", *Globalisation and Health*, 9: 42.

Leys, Colin (2010), "Health, Health Care and Capitalism", in Panitch, Leo and Leys, Colin (eds.), *Socialist Register 2010: Morbid Symptoms: Health under Capitalism*, New Delhi: Leftward Books.

Locke, John (1698), *Two Treatises of Government*, At the University Press, From Google Books.

Lois Boland (2002) Cited in Thomas, Caroline, "The Policy and Politics of Access to Drugs", *Third World Quarterly*, 23 (02): 251 -264.

Manell, Peter S. (1999), "Intellectual Property: General Theories" *N/A, 129-188, URL: http://levine.sscnet.ucla.edu/archive/ittheory.pdf.*

Marcellin, Sherry S. (2010), *The Political Economy of Pharmaceutical Patents: US Sectional Interests and the African Group at the WTO*, United Kingdom: Ashgate Publishing, Ltd.

Marsden, Guy (1997), *The Liberal Third Option: A Study of Policy Development*, Thesis, Saskatchewan: University of Regina.

McNally, David (1981), "Staple Theory as Commodity Fetishism: Marx, Innis and Canadian Political Economy" *Studies in Political Economy*, 6: 35-63, URL: http://spe.library.utoronto.ca/index.php/spe/article/view/13582/10459.

Mendleson, Rachel (2012), "Why aren't We Building Refineries in Canada? Because it's too Late, Experts Say", *Huffington Post*, Business Canada, 24/05/2012 (Updated: 06/01/2013) URL: http://www.huffingtonpost.ca/2012/05/23/canada-oil-refineries_n_1539701.html

Nair, KRG and Kumar, Ashok (ed.) (1994), *Intellectual Property Rights*, New Delhi: Allied Publishers Limited.

Nossal, Kim Richard. (1997), *The politics of Canadian foreign policy*. Canada: Prentice Hall of Canada Ltd.

Nozick, Robert (1974), *Anarchy State and Utopia*, Oxford UK: Blackwell Publishers Ltd.

Okediji, Ruth L. (2014), "The Role of WIPO in Access to Medicines", in Dreyluss, Rochelle C. and Rodriguez- Garavito, *Balancing Health and Wealth: the Battle over Intellectual Property Rights and Access to Medicine in Latin America*, United Kingdom: Oxford University Press.

Panitch, Leo (1981), "Dependency and Class in Canadian Political Economy", *Studies in Political Economy*, 6:7-33.

Panitch, Leo and Leys, Colin (2010), *Socialist Register 2010: Morbid Symptoms: Health under Capitalism*, New Delhi: Leftward Books.

Paquin, Jonathan (2008), "Canadian Foreign policy and Security Policy: Reaching a Balance between Autonomy and North American Harmony in the Twenty-First Century, *Canadian Foreign Policy*, 15: 99-108, URL: http://www3.carleton.ca/cfpj/Without%20subscription/15-2Paquin.pdf.

Perelman Michael (2003 a), "The Political Economy of Intellectual Property", *Monthly Review*, 54(8), [Online web] Accessed: 24/05/2015 URL: http://monthlyreview.org/2003/01/01/the-political-economy-of-intellectual-property/.

Perelman Michael (2003), "Intellectual Property Rights and the Commodity Form: New Dimensions in Legislated Transfer of Surplus Value", *Review of Radical Political Economies*, 35:3, 304 – 311, Accessed in 24/05/2015, URL: http://fido.rockymedia.net/anthro/newdimensionlegislative.pdf.

Raduntz, Helen (2006), "Trends Towards the Privatisation of Intellectual Property; A Marxian Progress Report for Educators and Educational Researchers", A Paper presented on 26-30 November at the International Education Research Conference, Australian Association for Research in Education: Adelaide, South Australia, Code – RAD06109.

Rao, M.B & Guru, Manjula (2003), *Understanding TRIPS: Managing Knowledge in Developing Countries* (New Delhi: Response Books).

Richards, Donald G. (2002), "The Ideology of Intellectual Property Rights in the International Political Economy", *Review of Social Economy,* 60(4):521 – 541, Accessed: 05/05/2015, URL: http://www.jstor.org/stable/29770180.

Roser, Max (2015), "Military Spending" *Our World in Data*, URL: http://ourworldindata.org/data/war-peace/military-spending/#note-6.

Sell, Susan and May, Christopher (2001), "Moments in Law: Contestation and Settlement in the History of Intellectual Property", *Review of International Political Economy*, 8(3): 467-500, Accessed 05 May 2015, URL: http://www.jstor.org/stable/4177394.

Shawki, Noha (2008), Civil Society, "Middle Powers and R2P: An Analysis of Canada's Response to the Crisis in Darfur", *Peace Research*, 40(1): 24-54, URL: http://www.jstor.org/stable/23607695.

So, Antony D. and Rachel Sachs (2012) "Making Intellectual Property Work for Global Health" *Harvard International Law Journal*, Volume 53: 153 - 180.

Stairs, Denis (Winter 1994/1995), "Will and Circumstances and the Postwar Study of Canada's Foreign Policy" *International Journal*, 50(1): 9-39, URL: http://www.jstor.org/stable/40202995.

Stanford, Jim (2014), "The Staple Theory @ 50: Reflections on Lasting Significance of Mel Watkins' "A Staple Theory of Economic Growth", Canadian Centre for Policy Alternative, ISBN 978-1-77125-114-3, URL: https://www.policyalternatives.ca/sites/default/files/uploads/publications/National%20Office/2014/03/Staple_Theory_at_50.pdf.

Stengel, Daniel (2004), Intellectual Property in Philosophy, Archives for Philosophy of Law and Social Philosophy, 90(1): 20-50, Accessed 05/05/2015, URL: http://www.jstor.org/stable/23681627.

Sterckx, Sigrid (2004), "Patents and Access to Drugs in Developing countries: An Ethical Analysis", *Developing World Bioethics*, 4(1): 58-75.

Stone, Graig and Solomon, Binayam (2005), "Canadian Defence Policy and Spending", *Defence and Peace Economics*, 16(3): 145-169, URL: file:///C:/Users/AJI/Desktop/canadian_defence_policy.pdf.

Sunder, Madhavi (2006), "IP^{3}", *Stanford Law Review, 59(02): 257-332 Accessed in 05/05 2015, URL:* http://www.jstor.org/stable/40040300.

Symonds, Alexandra (2014), "The Tragedy of Commons" UK: Intellectual Property Office, Posted in 10 January 2014, URL: http://www.ipo.gov.uk/blogs/ipofacto/tag/tragedy-of-the-commons/.

Therein, Jean-Philippe and Noel Alain (1994), "Welfare Institutions and Foreign Aid: Domesstic Foundations of Canadian Foreign Policy" *anadian Journal of Political Science*, 27(3): 529-558, URL: http://www.jstor.org/stable/3229357.

Thomas, Caroline (2002) "The Policy and Politics of Access to Drugs", *Third World Quarterly*, 23 (02): 251-264.

Waltz, Kenneth W (1959), *Man the State and War: A Theoretical Analysis* (Los Angeles)

Watal, Jayasree (2003), *Intellectual Property Rights in the WTO and Developing Countries* (New Delhi: Oxford University Press).

Watkins, Mel, Grant, Hugh Murray and Wolfe, David (2006), *Staples and Beyond: Selected Writings of Mel Watkins*, No. 210, Canada: McGill-Queen's Press.

Weber, Ashley & Mills, Lisa (2010), "A One-Time-Only Combination: Emergency Medicine Exports under Canada's Access to Medicines Regime", *Health and Human Rights*, 12(1): 109-122.

Williams, Owain David and Lofgren, Hans (2013), *The New Political Economy of Pharmaceuticals: Conformity and Resistance in the Global Health*, USA: Palgrave Macmillan.

Zischaka, Matthew et al (2009), "Watch Out! Compulsory Licensing Lurks around Global Corners (The View from Canada)", *Smart and Bigger*, Alpha Mid-Winter Meeting, Jan 2009, Accessed 29-09-2015, URL: http://www.smart-biggar.ca/files/AIPLA_final-Jan12.pdf.