



FACULTY OF LAW  
Lund University

Ulysses Moreira Formiga

Developments and Obstacles to  
the Right of Access to Medicines:  
A Study of Human Rights,  
International Trade and  
Pharmaceutical Business

Master thesis  
20 credits (30 ECTS)

Supervisor:  
Asbjørn Eide

Masters Programme in Human Rights and Intellectual Property  
Rights Law  
Autumn Semester  
2007

*Para vovó  
(In Memoriam)*

# Contents

<b>SUMMARY</b>	<b>6</b>
<b>ACKNOWLEDGEMENTS</b>	<b>7</b>
<b>ABBREVIATIONS</b>	<b>8</b>
<b>1 INTRODUCTION</b>	<b>9</b>
1.1 Background: Access to Medicines in World Politics	9
1.2 Objectives	10
1.3 Delimitation	11
1.4 Method	12
<b>2 THE RIGHT OF ACCESS TO MEDICINES AND CORRESPONDING OBLIGATIONS: SOURCES IN INTERNATIONAL LAW AND THEIR INTERPRETATION</b>	<b>14</b>
2.1 The Right to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health	15
2.1.1 <i>Legal Sources</i>	15
2.1.2 <i>Interpreters</i>	18
2.1.3 <i>Definition and Normative Content</i>	19
2.1.4 <i>General Obligations of State parties</i>	21
2.1.5 <i>Minimum Core Obligations</i>	22
2.1.6 <i>International Obligations</i>	25
2.1.7 <i>Violations</i>	28
2.1.8 <i>Other concerns and specific developments on the right to                 health</i>	29
2.2 The Right to Enjoy the Benefits of Scientific Progress and its Applications	30
2.2.1 <i>Legal Sources and Interpretation</i>	30
2.2.2 <i>The Right to the Benefits of Science and Other Science-Related                 Rights</i>	32
2.2.3 <i>The Definition and Nature of the Right to the Benefits of                 Science: a Right of Access</i>	35
2.2.4 <i>General Obligations and Violations</i>	37
2.2.5 <i>The Importance of the Right of Access to Medicines to the                 Definition of the Right of Access to the Benefits of Science</i>	40
2.3 The Right of Access to Medicines as a specific right	41
2.3.1 <i>Definition and Normative Content</i>	41
2.3.2 <i>General Obligations, immediate Obligations and Violations</i>	43

2.4	Conclusion	46
<b>3</b>	<b>THE PHARMACEUTICAL PATENT PROTECTION REGIME</b>	<b>48</b>
3.1	Overview	48
3.2	Intellectual Property Rights and Patents. Definitions and Justifications	49
3.3	The International Protection of Patents	51
3.3.1	<i>Historical Evolution of the Patent Protection Regime</i>	51
3.3.2	<i>The Forum-Shifting</i>	55
3.3.3	<i>The TRIPS Agreement</i>	56
3.3.4	<i>The Doha Declaration on the TRIPS Agreement and Public Health</i>	60
3.4	Are Pharmaceutical Patents a Human Right?	67
3.4.1	Overview	67
3.4.2	<i>The inclusion of IPR in the Human Rights Framework: Controversies and historical differences</i>	68
3.4.3	<i>General Comment No. 17: Establishing Criteria to distinguish IPR and Human Rights</i>	70
3.4.4	<i>Applying the Criteria to Pharmaceutical Patent Protection</i>	74
<b>4</b>	<b>THE BALANCE BETWEEN ACCESS TO MEDICINES AND PHARMACEUTICAL PATENT PROTECTION</b>	<b>77</b>
4.1	Conflicts of Norms in International Law. Traditional and Broader Definition	77
4.2	Is There a Legal Conflict Between Access to Medicines and Pharmaceutical Patent Protection?	80
4.2.1	<i>The ICESCR Requisites for Limitations to Economic, Social and Cultural Rights</i>	80
4.2.2	<i>Applying the Broad Definition of Conflict to the Relationship Between Access to Medicines and the Pharmaceutical Patent Protection</i>	83
4.2.3	<i>The Legal Consequences of the Established Conflict</i>	85
4.3	International Law Tools for Addressing Conflicts of International Norms. The Vienna Convention on the Law of Treaties	86
4.4	The WTO and Conflicts Between Trade and Human Rights: The WTO Dispute Settlement System	91
4.4.1	Overview	91
4.4.2	<i>The Principles that Counterbalance the Factual Precedence of the WTO Regime. Towards an Acceptance of the Precedence of Human Rights Over Trade Obligations?</i>	93
4.4.3	<i>Applying Human Rights in Practice Within the WTO Framework</i>	96
4.5	Conclusion: The Insufficiency of International Law Guidelines to Promote the Fair Balance and to Affect States' Practice	98

<b>5</b>	<b>ACCESS TO MEDICINES AND THE PHARMACEUTICAL INDUSTRY: TOWARDS CORPORATE SOCIAL RESPONSIBILITY</b>	<b>102</b>
5.1	The Effect of the Legal Evolution of the Intellectual Property Protection on the Pharmaceutical Industry's Reputation	103
5.2	Corporate Social Responsibility. What is it?	104
5.3	The Implementation of CSR in the pharmaceutical sector.	108
5.4	The Draft Human Rights Guidelines for Pharmaceutical Companies	113
5.5	Conclusion	116
<b>6</b>	<b>CONCLUSION</b>	<b>118</b>
	<b>APPENDIX: DRAFT HUMAN RIGHTS GUIDELINES FOR PHARMACEUTICAL COMPANIES IN RELATION TO ACCESS TO MEDICINES</b>	<b>136</b>

# Summary

The right of access to medicines has challenged the common perception that economic, social and cultural rights, due to their progressive character, are aspirations rather than a legal set of obligations. It has received strong and sustainable global support and has achieved a remarkably detailed legal definition within the UN human rights system, including the provision of access to essential medicines as an immediate obligation, not subjected to resource constraints. Meanwhile, the protection for pharmaceutical patents has achieved unprecedented strength, while definitely excluded from the human rights protection system.

This thesis details what the right of access to medicines exactly entails and investigates how it applies outside the boundaries of the human rights system and outside the general field of State obligations. It concludes that although the right of access to medicines has found recognition on international trade law, the obligations it sets to States do not resonate strongly enough in this field in order to prevent a legal conflict between the right of access to medicines and pharmaceutical patent protection. Furthermore, the global perception of an unbalanced relationship between these rights put States and pharmaceutical companies in a direct conflict, preventing the development of partnerships and pressuring for a rushed and incomplete development of Corporate Social Responsibility in the pharmaceutical sector. Hence, international law is failing to provide clear, safe and effective guidance for States to freely and democratically determine their health policies, particularly in the case they are unable to fulfil their obligations under different fields of law. Simultaneously, it creates an unstable economic environment for the further development of the pharmaceutical industry.

# Acknowledgements

This Master Thesis is the final product of a wonderful academic and life experience, one that I had always dreamed of having and I will always be grateful for...

The Raoul Wallenberg Institute of Human Rights and Humanitarian Law staff members, especially to the precise, exemplary and expert supervision of Asbjørn Eide.

The support from the Brazilian Northeastern Bank, which leased me to fulfil my dream.

The unconditional love of my family. *Mãinha, paínho, Becu, Ana, primos, primas, tios e tias*, how can I deserve it?

My friends from Brazil, being present even if so apart, all the time. I cannot wait to see you all again.

Finally, my fellow classmates and new friends, for being inspirational, fun and just plain amazing. You do not know how much you mean to me.

“Oh, if the trip and the plan come apart in your hand,  
you look contorted on yourself your ridiculous prop.  
You forgot what you meant when you read what you said,  
and you always knew you were tired, but then,  
where are your friends tonight?  
If I could see all my friends tonight”

James Murphy

# Abbreviations

BIRPI	United International Bureaux for the Protection of Intellectual Property
CESCR	Committee on Economic, Social and Cultural Rights
CEDAW	Committee on the Elimination of Discrimination Against Women
CSR	Corporate Social Responsibility
Doha Declaration	2001 Declaration on the TRIPS Agreement and Public Health
DSU	World Trade Organization Dispute Settlement Understanding
ETS	European Treaty Series (Council of Europe)
GA	United Nations General Assembly
GAOR	Official Records of the UN General Assembly
GATT	General Agreement on Tariffs and Trade System
GC	General Comment
ICCPR	1966 Covenant on Civil and Political Rights
ICESCR	1966 Covenant on Economic, Social and Cultural Rights
ILO	International Labour Organisation
IPR	Intellectual Property Rights
ISO	International Organisation for Standardisation
NGO	Non-Governmental Organization
OAS	Organisation of American States
OECD	Organisation for Economic Cooperation and Development
Paris Convention	1883 Paris Convention for the Protection of Industrial Property
PCT	Patent Cooperation Treaty
TRIPS Agreement	1994 Agreement on Trade-Related Aspects of Intellectual Property Rights
UDHR	1948 Universal Declaration on Human Rights
UN	United Nations
UNCTAD	United Nations Conference for Trade and Development
UNESCO	United Nations Educational, Science and Cultural Organization
UNTS	United Nations Treaty Series
USA	United States of America
VCLT	Vienna Convention on the Law of Treaties
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

# 1 Introduction

## 1.1 Background: Access to Medicines in World Politics

Access to medicines was without doubt one of the most crucial subjects in world politics in the last decades. It has been a focal point within not only Human Rights bodies, but also in non-Human Rights International Organisations. The need for its inclusion in economic policies, international trade agreements, States and International Institution's behaviour was unprecedented. Nowadays, a general debate over economics, trade development, intellectual property, progress of science or international finances cannot progress without some concern over its impacts on access to medicines.

Particularly, the debate about the impact of the intellectual property protection over the access to medicines in developing countries was a crucial one. Since the conclusion of the TRIPS Agreement and the establishment of the World Trade Organization, it has only been deepened. Indeed, access to medicines became not only an ordinary subject within WTO, but also a source of criticism that has challenged the legitimacy of the organization.

The HIV/AIDS pandemic is one of the main responsible for such change in the dynamics of the world economic, political and financial agenda. Its dimension and catastrophic consequences defy the international community. States, International Institutions and even private multinational corporations cannot ignore the pandemic. International politics, finances and trade policies are now scrutinized also according to its impact over the pandemic.

This political context has led to an interesting point: the right of access to medicines, which is not even a specifically defined right in any of the most

relevant human rights international agreements,<sup>1</sup> can potentially become the defining economic, social and cultural right. The future decisions regarding access to medicines will most probably influence the progress, justiciability and general strength of all rights enshrined in the International Covenant of Economic, Social and Cultural Rights.

Even at the present times, the right of access to medicines has a more specific legal definition than most of other economic, social and cultural rights. Additionally, it is justiciable in several States' Constitutions. Finally, international experts and international organisations – notably the World Health Organization – have identified specific immediate obligations regarding the right of access to medicines, facing the conceptual problem of the progress realization of the economic, social and cultural rights.

## **1.2 Objectives**

This thesis looks toward access to medicines in a broad way. Its ultimately goal is to present the right of access to medicines as a properly defined economic, social and economic right, in order to address how the international legal community has dealt with the obligations set by it. In this sense, every chapter provides a description of international norms – hard and soft law - that relate to the right of access to medicines and offers a critical analysis over its implementation and impact on the access to medicines.

Chapter 2 aims at defining the right of access to medicines as a specific right within the economic, social and cultural rights. Chapter 3 objectives to present the intellectual property regime and to define the nature of its relationship with the right of access to medicines. Chapter 4, consequently, attempts to analyse the relationship between IPR and the right of access to medicines, in order to answer (a) if there is a legal conflict between the rights, and (b) what the international community has provided to prevent or

---

<sup>1</sup> There is not a specific article defining the right of access to medicines in the ICESCR and in the UDHR.

solve such conflict. Chapter 5 tries to describe how the right of access to medicines has challenged the pharmaceutical industry and how this private sector has answered to the societal claims for a higher contribution to the fulfilment of the right of access to medicines. In this regard, it provides an analysis of the implementation of Corporate Social Responsibility principles in the pharmaceutical sector. Finally, chapter 6 presents a conclusion about the present relevance of the international regarding the right of access to medicines.

### 1.3 Delimitation

The right of access to medicines is one of the key elements of the right to the enjoyment of the highest attainable standard of physical and mental health in the UN framework of the economic, social and cultural rights.<sup>2</sup> As such, it is at the core of international Human Rights Law and it is characterized by a profound interconnection with economics, private entrepreneurship, public governance and world politics.

This interdisciplinary aspect, together with the sheer size and variety of obstacles for providing access to medicines to people in need can be dispersive and misleading. It can lead to a lack of precise legal definition and of practical implementation of the right. In fact, one of the biggest challenges for the study and practice of the right of access to medicines is to navigate between its numerous, complex and vital issues, in order to arrive at practical achievable recommendations.<sup>3</sup> This challenge is exasperated by the fact that the rights within the ICESCR are mainly of progressive realization,<sup>4</sup> which contributes to a general lack of precision and to the

---

<sup>2</sup> The UN Committee on Economic, Social and Cultural Rights, General Comment No. 14. on the Right to the Highest Attainable Standard of Health, E/C.12/2000.4, paragraph 43.d, p.12

<sup>3</sup> Hunt, Paul, Report of the Special Rapporteur on the Right to Health, submitted in accordance with Commission Regulations 2002/31, E/CN.4/2003/58, 13 February 2003, p.23.

<sup>4</sup> International Covenant of Economic, Social and Cultural Rights, G.A: res. 2200A (XXI), 21 U.N.GAOR Supp. (No. 16) at 49, U.N. Doc. A/6316 (1966), 993 U.N.T.S. 3, *entered into force* Jan. 3, 1976, article 2. (hereinafter ICESCR)

problems regarding the implementation and evaluation of economic, social and cultural rights.<sup>5</sup>

Acknowledging the problems above, this thesis focuses on the legal definition, the legal interconnections and the positive obligations set by the right of access to medicines. Therefore, it does not provide an in-depth discussion of some important related topics regarding the right of access to medicines. For instance, negative obligations, such as non-discrimination, will not be dealt with herein. The same applies to the underlying conditions to the right to health, poverty reduction policies and the problem of neglected diseases.

Additionally, the sources of the right of access to medicines<sup>6</sup> are presented only to the extent necessary to define the specific right of access to medicines. The same occurs to the intellectual property protection regime and to corporate social responsibility principles, whose presentations are limited to the points where it intersects with or are interesting to the right of access to medicines.

Finally, the thesis discusses the right of access to medicines broadly in its approach. Its analysis is not limited to a specific medicine or a specific disease or pandemic, nor is it limited to the obligations held by States.

## 1.4 Method

The thesis uses traditional and comparative legal methods to analyse the intricacies of the right of access to medicines. International norms are described and analysed through legal principles of interpretation set out by the norms themselves or by the Vienna Convention on the Law of Treaties. Specifically, when addressing the interconnections between two different

---

<sup>5</sup> A. R. Chapman, and R. Sage, *Core Obligation: building a Framework for Economic, Social and Cultural Rights*, (Intersentia Publishers, Schoten – Belgium, 2002) p.4

<sup>6</sup> These sources are especially the right to the enjoyment of the highest standard of physical and mental health and the right to benefit from the advancements of science.

bodies of international law, the thesis uses the integrative method of legal interpretation. Nevertheless, the right of access to medicines, by its own nature, possesses an undeniable emotional, ethical and moral significance. This aspect adds importance and urgency to the right to health and cannot be completely unaddressed. They are, indeed, part of the right. Hence, when necessary, the thesis uses legal-political methods and legal-philosophical methods in order to investigate the subject.

Herein, there is a description and an analysis of the main international norms that establish, contain or affect the right of access to medicines, be them Hard-law or soft-law. Arguments by scholars, experts and advocates are presented and emphasized accordingly to their legal base. Meanwhile, divergent opinions are also exposed. The work of relevant International Organisations are addressed according to their relevance, with emphasis to the contributions from International Human Rights Committees, the Special Rapporteur for the Right to Health, the World Health Organization and the World Trade Organization, which will be extensive objects of study.

## 2 The Right of Access to Medicines and Corresponding Obligations: Sources in International Law and their Interpretation

The right of access to medicines is not defined in a specific article in any of the main human rights conventions, not even the International Covenant on Economic, Social and Cultural Rights. Nevertheless, it is undoubtedly a core obligation within the framework of the right to highest attainable standard of health.<sup>7</sup>

In fact, the right of access to medicines represents a convergence of human rights. It is a prime example of the interdependence of human rights and of international law in general. Its respect, protection and fulfilment reverberate in several other human rights. For instance, the Human Rights Committee's General Comment (GC) No.6, regarding the right to life<sup>8</sup> defined the role of States in protecting human life as to include obligations to undertake measures for the elimination of epidemics, which implies the fulfilment of the right of access to medicines.<sup>9</sup> Furthermore, neglecting of the right of access to medicines can amount to torture, cruel or inhuman treatment.<sup>10</sup>

Admittedly, the definition of the right of access to medicines benefited from the development of other human rights. For instance, the right to life, the

---

<sup>7</sup> CESCR General Comment 14, *supra* note 2, para. 43.

<sup>8</sup> International Covenant on Civil and Political Rights, Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966, entry into force 23 March 1976, UN GAOR, 21<sup>st</sup> Sess., Supp. No. 16, Art. 47, UN Doc. A/6316, article 6 (hereinafter ICCPR)

<sup>9</sup> The UN Human Rights Committee, General Comment No. 6, on The Right to Life, UN Doc A/37/40, paragraph 5.

<sup>10</sup> ICCPR, *supra* note 8, article 7.

prohibition to torture, cruel or inhuman treatment,<sup>11</sup> the prohibition of discrimination,<sup>12</sup> the right to food<sup>13</sup> and the right to an adequate standard of living.<sup>14</sup> However, the main and most obvious sources of the right to access to medicines are the right to the enjoyment of the highest attainable standard of physical and mental health<sup>15</sup> and the right to enjoy the benefits of scientific progress and its applications.<sup>16</sup> The convergence of these rights ultimately defines the right of access to medicines.

This chapter separately describes the developments of the two main sources of the right of access to medicines, including the problems faced by each one of them. In the end, the right of access to medicines is defined taking into account the contributions of its two most important sources.

## **2.1 The Right to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health**

### **2.1.1 Legal Sources**

The 1946 WHO Constitution<sup>17</sup> was the first explicit international legal setting of the right to the enjoyment of the highest attainable standard of physical and mental health (hereinafter called right to health).<sup>18</sup> Its preamble affirms, “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.”<sup>19</sup>

---

<sup>11</sup> *Ibid.*

<sup>12</sup> ICCPR, *supra* note 8, article 2. *Also*, ICESCR, *supra* note 4, article 2.2.

<sup>13</sup> ICESCR, *supra* note 4, article 11.2.

<sup>14</sup> ICESCR, *supra* note 4, article 11.1.

<sup>15</sup> ICESCR, *supra* note 4, article 12.

<sup>16</sup> ICESCR, *supra* note 4, article 15(b).

<sup>17</sup> The World Health Organization has 193 member States. *See* World Health Organization. Available at <[www.who.int/countries/en](http://www.who.int/countries/en)>, last visited on 10 January 2008.

<sup>18</sup> B. Toebes, The right to health, in *Economic, Social and Cultural Rights*, A. Eide, C. Krause and A. Rosas (eds.), Kluwer law, Martinus Nijhoff Publishers, Dordrecht, The Netherlands, 2001, pg 170.

<sup>19</sup> Constitution of the World Health Organization, signed at New York on 22 July 1946 and entered into force on 7 April 1948, preamble.

Article 25.1 of the Universal Declaration of Human Rights legally established the right to health. It affirmed that

“Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.”<sup>20</sup>

Additionally, article 12 of the ICESCR affirmed that “[t]he States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”<sup>21</sup> Notably, the ICESCR went a step further than the UDHR, by establishing that

“The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:

- (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
- (b) The improvement of all aspects of environmental and industrial hygiene;
- (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
- (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.”<sup>22</sup>

The UDHR and the ICESCR are the main international legal sources of the right to health, the second one being binding on States, as they are the most referred by the international community<sup>23</sup> and adopted by the vast majority of States in the World.<sup>24</sup> Nevertheless, they are far from being the only legal sources of the right to health. In fact, they inspired the inclusion of the right to health in a myriad of international human rights agreements, especially in agreements addressing particularly vulnerable groups. For instance, the

---

<sup>20</sup> Universal Declaration of Human Rights, G.A. Res. 217, U.N. GAOR, 3d Sess., U.N. A7810 (1948), article 25(1).

<sup>21</sup> ICESCR, *supra* note 4, article 12.1.

<sup>22</sup> ICESCR, *supra* note 4, article 12.2.

<sup>23</sup> Together, the UDHR, the ICESCR and the ICCPR form the International Bill of Rights. The ICESCR and the ICCPR are binding human rights treaties.

<sup>24</sup> The ICESCR has 157 States parties. *See* Office of the United Nations High Commissioner for Human Rights, available at [www.ohchr.org/english/bodies/ratification/3.htm](http://www.ohchr.org/english/bodies/ratification/3.htm), last visited at 10 January 2008.

Convention of the Rights of the Child,<sup>25</sup> the Convention on the Elimination of All Forms of Discrimination Against Women,<sup>26</sup> and the International Convention on the Elimination of All Forms of Racial Discrimination.<sup>27</sup>

Furthermore, the right to health is enshrined in several important international Declarations, for instance, the Declaration on the Right to Development,<sup>28</sup> the Declaration on the Rights of Mentally Retarded Persons,<sup>29</sup> the Declaration on Social Progress and Development<sup>30</sup> and the Declaration on the Protection of Women and Children in Emergency and Armed Conflict.<sup>31</sup>

Finally, the right to health is enshrined in several regional human rights instruments, for instance, the European Social Charter,<sup>32</sup> the African Charter on Human and Peoples' Rights,<sup>33</sup> and the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights.<sup>34</sup>

---

<sup>25</sup> Convention on the Rights of the Child, G.A. res. 44/25, annex, 44 U.N. GAOR Supp. (No. 49) at 167, U.N. Doc. A/44/49 (1989), *entered into force* Sept. 2, 1990., art. 24

<sup>26</sup> Convention on the Elimination of All Forms of Discrimination Against Women, G.A. res. 34/180, 34 U.N. GAOR Supp. (No. 46) at 193, U.N. Doc. A/34/46, *entered into force* Sept. 3, 1981., articles 10 and 12.

<sup>27</sup> International Covenant on the Elimination of All Forms of Racial Discrimination, 660 U.N.T.S. 195, *entered into force* Jan. 4, 1969, art. 5(e)(iv).

<sup>28</sup> Declaration on the Right to Development, GA. res. 41/128, annex, 41 U.N. GA OR Supp. (No. 53) at 186, U.N. Doc. A/41/53, (1986), article 11.

<sup>29</sup> Declaration on the Rights of Mentally Retarded Persons, proclaimed by the General Assembly resolution 2856 (XXVI), 20 December 1971, article 2.

<sup>30</sup> Declaration on Social Progress and Development, GA res. 2542 (XXIV) 24 UN GAOR Supp. (No. 30) at 49 UN Doc. A/7630, 11 December 1969, articles 10(d) and 11(a, b, and c).

<sup>31</sup> Declaration on the Protection of Women and Children in Emergency and Armed Conflict, GA res. 3318 (XXIX), 29 U.N. GAOR Supp. (No. 31) at 146, U.N. Doc. A/9631, (1974), para. 6.

<sup>32</sup> European Social Charter (revised), CETS No.: 163, opened for signatures on 3 May 1996 and *entered into force* 1 January 1999, articles 3 and 11. *See also* European Social Charter, CETS No.: 035, opened for signatures on 18 October 1961 and *entered into force* on 26 February 1965, articles 3 and 11.

<sup>33</sup> African Charter on Human and Peoples' Rights, OAU Doc. CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982), adopted June 27, 1981, *entered into force* Oct. 21, 1986, article 16.

<sup>34</sup> Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights, O.A.S. Treaty Series No. 69 (1988), *reprinted in* Basic Documents Pertaining to Human Rights in the Inter-American System, OEA/Ser.L.V/II.82 doc.6 rev.1 at 67 (1992), art. 9, (1988), article 10.

## 2.1.2 Interpreters

In spite of its widespread international recognition and reiteration over half a century, the international legal meaning of the right to health remained relatively obscured until very recent.<sup>35</sup> Most of the international and regional human rights instruments signed after 1966 indeed acknowledged the right to health, but did not go beyond the broad definition set in the ICESCR. Certainly, these agreements do not contain a specification of what article 12 of the ICESCR entails in practice.<sup>36</sup>

In fact, the necessarily broad definition of the right to health provokes much controversy about its precise content. This fact, combined with the progressive realization character of economic, social and cultural rights, definitely weakens the right to health in practice.

It was only in 2000 that the UN Committee on Economic, Social and Cultural Rights (CESCR) published General Comment No. 14 on *Substantives Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights*.<sup>37</sup> The General Comment is the work that most closely resembles an authoritative interpretation<sup>38</sup> of the right to health. It clarifies the normative content of the article 12 of ICESCR. It more precisely defines the States parties' obligations, including their core obligations.<sup>39</sup> It also illustrates the possible

---

<sup>35</sup> Nevertheless, there had been significant attempts to make the right to health more tangible, for instance, the Declaration of Alma-Ata. See WHO *Primary Health care: Report of the International Conference on Primary Health Care*, Alma-Ata, USSR, 6-12 September 1978, Health for All Series No. 1, 1978, paras. 1-10.

<sup>36</sup> An exception is article 24 of the 1990 Convention on the Rights of the Child, which expressed in better details what was included in the right to health, for the purposes of the Convention. Also shall be mentioned the General Recommendation No.: 24, on article 12 - Woman and Health, by the Committee on the Elimination of Discrimination Against Women, CEDAW/C/1999/I/WG.II/WP.2/rev.1.

<sup>37</sup> See CESCR General Comment 14, *supra* note 2.

<sup>38</sup> It is not a *proper* authoritative interpretation because it is not the product of an explicit agreement between all States members to the ICESCR.

<sup>39</sup> See also The Limburg Principles on the Implementation of the International Covenant on Economic, Social and Cultural Rights, E/CN.4/1987/17

violations<sup>40</sup> of the right to health and instructs States on their framework legislation. Finally, it addresses the obligations of non-state actors and third parties.<sup>41</sup>

Subsequently, in 2002, the UN Commission on Human Rights appointed a Special Rapporteur on the Right to Health,<sup>42</sup> whose three-year mandate was prolonged for the same period in 2005.<sup>43</sup>

It is the combination of General Comment No. 14 by the CESCR and the reports by the Special Rapporteur on the Right to Health that provide the decisive enhancements of the definition of the content of the right to health and, consequently, of the right of access to medicines.

### **2.1.3 Definition and Normative Content**

According to the CESCR, the right to health is a right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health.<sup>44</sup> It is an inclusive right that requests the participation of the population in all the health-related decision-making processes.<sup>45</sup> It contains freedoms and entitlements<sup>46</sup> extending not only to timely and appropriate health care, but also to

---

<sup>40</sup> See also The Maastricht Guidelines on Violations of Economic, Social and Cultural Rights. This document was done in celebration of the 10th Anniversary of the Limburg Principles, between 22 and 26 January 1997.

<sup>41</sup> See CESCR General Comment 14, *supra* note 2.

<sup>42</sup> Commission on Human Rights Resolution 2002/31, on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, E/CN.4.RES.2002.31, 58<sup>th</sup> Sess., February 10, 2003, para. 4. Also available at <<http://www.unhchr.ch/Huridocda/Huridoca.nsf/TestFrame/5f07e25ce34edd01c1256ba60056deff?Opendocument>>, last visited on January 10, 2008.

<sup>43</sup> Commission on Human Rights Resolution 2005/24, on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, E/CN.4/2005.L.10Add.10, para. 19, 15 April 2005. Also available at [http://ap.ohchr.org/documents/E/CHR/resolutions/E-CN\\_4-RES-2005-24.doc](http://ap.ohchr.org/documents/E/CHR/resolutions/E-CN_4-RES-2005-24.doc), last visited on January 10, 2008.

<sup>44</sup> CESCR General Comment 14, *supra* note 2, para. 9

<sup>45</sup> CESCR General Comment 14, *supra* note 2, para. 11.

<sup>46</sup> CESCR General Comment 14, *supra* note 2, para. 8.

underlying determinants of health<sup>47</sup> that are seen as the two separate categories of the right to health.<sup>48</sup>

The Committee defines the normative content of the right to the health using the elements of *availability*, *accessibility*, *acceptability* and *quality*. According to this criteria, the right to health means:

- Sufficient quantity of working public health and related health-care facilities, goods and services, as well as health programmes. Sufficient underlying determinants of health, such as potable water, sanitation facilities, hospitals, trained medical personnel and essential drugs as defined by the WHO Action Programme on Essential Drugs.<sup>49</sup>
- Accessible health facilities, goods, services and underlying determinants of health.<sup>50</sup> Accessibility has four dimensions:
  - Non-discrimination, especially considering marginalized or vulnerable groups;
  - Physical accessibility, especially considering the need of rural areas and persons with disabilities;
  - Economic accessibility – affordability;
  - Access to information, including to seek, receive and impart health-related information, respecting the right of confidentiality.
- Health facilities, goods and services that are respectful, culturally accepted<sup>51</sup> by individuals, minorities, peoples and communities, with sensibility to gender, life-cycle requirements and confidentiality.<sup>52</sup>

---

<sup>47</sup> CESCR General Comment 14, *supra* note 2, para. 11.

<sup>48</sup> B. Toebes, *Supra* note 18, p. 174.

<sup>49</sup> CESCR General Comment 14, *supra* note 2, para. 12(a)

<sup>50</sup> CESCR General Comment 14, *supra* note 2, para. 12(b) 1-4.

<sup>51</sup> An exception to the dimension of acceptability is the need to adopt effective measures to abolish traditional practices affecting the health of children, particularly girls, including early marriage, female genital mutilation, preferential feeding and care of male children.

*See* CESCR General Comment No. 14, *supra* note 2, para. 22.

<sup>52</sup> CESCR General Comment 14, *supra* note 2, para. 12(c).

- Good quality, scientifically and medically appropriate facilities, goods, services and underlying determinants of health.<sup>53</sup>

## 2.1.4 General Obligations of State parties

The normative content described above gives precision to the human right to highest attainable standard of health. Even so, a clear definition of an economic, social and cultural right lacks practical effect if it is not accompanied by a set of obligations towards the State parties of the Covenant.

Hence, the Committee defines the obligations of the State parties for the right to health following the same tripartite typology used in General Comment No. 12 on the right to food.<sup>54</sup> The obligations, are consequently divided into obligations to *respect*, *protect* and *fulfil*, while the obligation of *fulfil* was split into obligations to *facilitate*, *provide* and *promote*.<sup>55</sup>

The obligation to respect is the States' negative obligation relating to the right to health. States shall refrain from interfering on the equal access to available health services. They shall refrain from limiting access to contraceptives and other means of reproductive health. Ultimately, States shall abstain from acts that negatively affect people's health, such as unlawful pollution of air, water and soil.<sup>56</sup>

The obligation to protect is the States' positive obligation to take legislative and other measures to protect people's rights to health from the actions of

<sup>53</sup> CESCR General Comment 14, *supra* note 2, para. 12(d).

<sup>54</sup> The UN Committee on Economic, Social and Cultural Rights, General Comment No. 12. E/C.12/1999/5, 12 May 1999, para. 15. This subdivision was first cited by Henry Shue. See Shue, Henry, *Basic Rights, Subsistence, Affluence and U.S. Foreign Policy*, Princeton University Press, 2<sup>nd</sup> sub edition, USA, (1996), and it was further developed and implemented for the first time in the UN System by Asbjørn. Eide. See A. Eide, Report of the Special Rapporteur to the Right to Food, Final Report presented to the Human Rights Commission, 39<sup>th</sup> Sess., UN Doc. E/CN.4/Sub.2/1987/23 (1987). See also B. Toebes, Towards an Improved Understanding of the International Human Right to Health, 21.3 *Human Rights Quarterly* (1999), p.677.

<sup>55</sup> CESCR General Comment 14, *supra* note 2, para. 37.

<sup>56</sup> CESCR General Comment 14, *supra* note 2, para. 34.

third parties. States shall specifically protect equal access to health services in case where third parties provide them. They shall also ensure that third parties do not limit people's access to health-related information and services. Furthermore, the obligation to protect includes the control or regulation of medicine marketing and commerce, in case where third parties provide them.<sup>57</sup>

Finally, the obligation to fulfil is the State's direct obligation towards the fulfilment of the right to health. It means that States shall give sufficient recognition to the right in their political and legal systems, particularly by adopting a national health policy.<sup>58</sup> As already mentioned, the obligation to fulfil is subdivided into obligations to facilitate, provide and promote.

The obligation to facilitate is a direct obligation to take positive measures to enable and assist individuals and communities to enjoy the right to health. The obligation to provide means to directly grant specific health-related goods and services to groups that are unable to realise the right to health by themselves. The obligation to promote commits State parties to undertake actions that create, maintain and restore the health of the population, for instance, supporting people in making informed choices about their health.<sup>59</sup>

## 2.1.5 Minimum Core Obligations

Another important aspect of the right to health is the differentiation between the obligations of progressive realisation from immediate obligations. This distinction is achieved through the identification of the *minimum core obligations* regarding the right to health, following a strategy set by General Comment No. 3 on the nature of State parties' obligations.<sup>60</sup>

---

<sup>57</sup> CESCR General Comment 14, *supra* note 2, para. 35.

<sup>58</sup> CESCR General Comment 14, *supra* note 2, para. 36.

<sup>59</sup> CESCR General Comment 14, *supra* note 2, paragraph 37.

<sup>60</sup> The UN Committee on Economic, Social and Cultural Rights, General Comment No. 3. E/1991/23, 14 December 1990, para. 10. Here the Committee defined the existence of a "minimum core content" regarding the rights enshrined in the ICESCR, which are of immediate realization. However, the Committee did not define the scope of the minimum

Progressive realization means that States have a specific and continuous obligation to move as expeditiously as possible towards the full realization of the right to health.<sup>61</sup> Rephrased, it means that “a State is required to be doing better in five years time than it is doing today”.<sup>62</sup> The reason for progressive realisation lies in the inequality of resources available among States. It is because of the inequality of available resources that the required highest attainable standard of health varies between developed and developing countries.<sup>63</sup>

Even if not free from criticism,<sup>64</sup> the distinction between obligations of progressive realization and immediate obligations is of extreme importance. While the obligations of progressive realization are conditioned to resource constraints, the immediate obligations – the minimum core content - apply irrespective of availability of resources or any other factors.<sup>65</sup> As a result, States cannot excuse the implementation of the minimum core obligations by lack of resources justification.<sup>66</sup>

The setting of the minimum core obligations represents a clear step towards a more enforceable right to health, especially because the list includes more than simply negative obligations. In fact, the Committee includes positive obligations of respect and fulfilment as minimum core obligations. The complete list, due to its importance, is fully reproduced below:

---

core content for each specific right in the Covenant here, giving only few examples of such content.

<sup>61</sup> Hunt, Paul, Report of the Special Rapporteur on the Right to Health, Mission to the world Trade Organization, E/CN.4/2004/49, 01 March 2004, p.8

<sup>62</sup> Hunt, Paul, Report of the Special Rapporteur on the Right to Health to the general Assembly, A/61/338, 13 September 2006, p.14

<sup>63</sup> *Ibid.*

<sup>64</sup> A. R. Chapman and S. Russel, *supra* note 5, pp. 8-11.

<sup>65</sup> CESCR General Comment 14, *supra* note 2, para. 47.

<sup>66</sup> The CESCR General Comment 14 represented an advance, but also a change in comparison to GC 3, in which the Committee still accepted the resources restraint as an excuse for the lack of implementation of the minimum core obligations. In the words of GC 3, “In order for a State party to be able to attribute its failure to meet at least its minimum core obligations to a lack of available resources it must demonstrate that every effort has been made to use all resources that are at its disposition in an effort to satisfy, as a matter of priority, those minimum obligations.” See CESCR General Comment No.: 3, *supra* note 60, para. 10.

- (a) To ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalized groups;
- (b) To ensure access to the minimum essential food which is nutritionally adequate and safe, to ensure freedom from hunger to everyone;
- (c) To ensure access to basic shelter, housing and sanitation, and an adequate supply of safe and potable water;
- (d) To provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs;
- (e) To ensure equitable distribution of all health facilities, goods and services;
- (f) To adopt and implement a national public health strategy and plan of action, on the basis of epidemiological evidence, addressing the health concerns of the whole population; the strategy and plan of action shall be devised, and periodically reviewed, on the basis of a participatory and transparent process; they shall include methods, such as right to health indicators and benchmarks, by which progress can be closely monitored; the process by which the strategy and plan of action are devised, as well as their content, shall give particular attention to all vulnerable or marginalized groups.<sup>67</sup>

In addition, the Committee also defines obligations of comparable priority to the minimum content. They are:

- (a) To ensure reproductive, maternal (pre-natal as well as post-natal) and child health care;
- (b) To provide immunization against the major infectious diseases occurring in the community;
- (c) To take measures to prevent, treat and control epidemic and endemic diseases;

---

<sup>67</sup> CESCR General Comment 14, *supra* note 2, para. 43.

- (d) To provide education and access to information concerning the main health problems in the community, including methods of preventing and controlling them;
- (e) To provide appropriate training for health personnel, including education on health and human rights.<sup>68</sup>

The description above demonstrates the extensiveness of the right to health minimum core obligations. It means that, despite the relative lack of enforceability of the right to health,<sup>69</sup> the wording of the ICESCR sets a wide variety of positive obligations that States are to fulfil in order not to violate the Convention.

## 2.1.6 International Obligations

The comprehensive character of the minimum core obligations shown above raises questions as to its reasonableness. Certainly, many of the developing countries – and definitely the least developed countries – do not have the financial and technical means to fulfil their immediate obligations, even when truly willing to. For this reason, the CESCR emphasises that the obligation of international assistance and cooperation, especially economic and technical, immediately after setting the minimum core obligations.<sup>70</sup>

The obligation of international assistance and cooperation goes back to the combination of articles 56 and 55(c) of the United Nations Charter (UN Charter).<sup>71</sup> The ICESCR also expresses the same obligation in its articles

---

<sup>68</sup> *Ibid.*

<sup>69</sup> The relative lack of enforceability is a general characteristic of economic, social and cultural rights as they stand today, as a consequence to their lack of international justiciability.

<sup>70</sup> CESCR General Comment 14, *supra* note 2, para. 45.

<sup>71</sup> Charter of the United Nations, open for signature on 26 June 1945 and *entered into force* on 24 October 1945, article 56. It affirms: “All Members pledge themselves to take joint and separate action in co-operation with the Organisation for the achievement of the purposes set forth in Article 55”. Article 55 (c) of the charter affirms: “With a view to the creation of conditions of stability and well-being which are necessary for peaceful and friendly relations among nations based on respect for the principle of equal rights and self-determination of peoples, the United Nations shall promote: (c) universal respect for, and observance of, human rights and fundamental freedoms for all without distinction as to race, sex, language, or religion.

2(1) and 22<sup>72</sup>. It has been also mentioned in several General Comments by the CESCR, particularly in General Comment No. 3<sup>73</sup> on the nature of State parties obligations and in General Comment No. 2, which deals specifically with international technical assistance measures.<sup>74</sup>

In General Comment No. 14, the obligation of international assistance and cooperation is very broad. Therefore, according to the CESCR, State parties shall:

- Respect the enjoyment of the right to health in other countries, and to prevent third parties from violating the right in other countries, if they are able to influence these third parties by way of legal or political means, in accordance with the UN Charter and applicable international law;<sup>75</sup>
- Facilitate access to essential health facilities, goods and services in other countries, wherever possible and provide the necessary aid when required;<sup>76</sup>
- Ensure that the right to health is given due attention in international agreements;<sup>77</sup>
- Ensure that their actions as members of international organisations take due account of the right to health;<sup>78</sup>
- Cooperate in providing disaster relief and humanitarian assistance in times of emergency, including assistance to refugees and internally displaced persons, prioritising the provision of international medical aid, distribution and management of resources, such as safe and potable water, food and medical supplies, and financial aid should be

---

<sup>72</sup> ICESCR, *supra* note 4, article 2(1).

<sup>73</sup> CESCR General Comment 3, *supra* note 60, paragraph 14.

<sup>74</sup> The UN Committee on Economic, Social and Cultural Rights, General Comment No. 2. E/1990/23, 2 February 1990.

<sup>75</sup> CESCR General Comment 14, *supra* note 2, paragraph 39.

<sup>76</sup> *Ibid.*

<sup>77</sup> *Ibid.*

<sup>78</sup> *Ibid.*

given to the most vulnerable or marginalised groups of the population;<sup>79</sup>

- Refrain at all times from imposing embargoes or similar measures restricting the supply of another State with adequate medicines and medical equipment;<sup>80</sup>
- State parties which are members of international financial institutions, notably the International Monetary Fund, the World Bank, and regional development banks, should pay greater attention to the protection of the right to health when influencing the lending policies, credit agreements and international measures of these institutions.<sup>81</sup>

One criticism regarding General Comment 14 is that the Committee did not clearly define which obligations of international assistance and cooperation are immediate obligations and which are of progressive nature. Even when considering this lack of clarification, the importance of this set of international obligations cannot be overestimated. After all, the gravest problems regarding access to health are localised or more urgent in developing countries and in the least developed countries, which rely on international assistance and cooperation. Additionally, the emphasis on the actions of State members of powerful international organisations, especially the World Bank, the International Monetary Fund and the World Trade Organization, is key to the development of coherent international policies by these organs.

---

<sup>79</sup> CESCR General Comment 14, *supra* note 2, para. 40.

<sup>80</sup> CESCR General Comment 14, *supra* note 2, para. 41. *See Also*, The UN Committee on Economic, Social and Cultural Rights, General Comment No. 8, on the relationship between economic sanctions and respect for economic, social and cultural rights, E/C.12/1997/8, 12 December 1997.

<sup>81</sup> CESCR General Comment 14, *supra* note 2, para. 39.

## 2.1.7 Violations

The violations to the right to health derive directly from the obligations – to respect, protect and fulfil – already mentioned.<sup>82</sup> They can occur both through acts of commission,<sup>83</sup> and through acts of omission.<sup>84</sup> Moreover, in determining which actions or omissions amount to a violation of the right to health, a distinction between inability and unwillingness of a State party to comply with its obligations under article 12 shall be made.

The violations of the obligation to respect are State actions, policies or laws that disobey the standards set out in article 12 of the ICESCR. As the obligation to respect is generally a negative obligation, the violations normally arise through acts of commission; for instance, by discriminatory laws or policies that result in the denial of access to health facilities and goods to a vulnerable group. Of particular importance to the changing of State behaviour are the violations of the obligation to respect when a State disregards its ICESCR obligations while entering into bilateral or multilateral agreements with other States, international organisations and other entities, such as multinational corporations.<sup>85</sup>

The violations of the obligation to protect occur when a State fails to safeguard the right to health of its people from third party infringements. The obligation can be violated through omission to regulate the activities of individuals, groups or corporations to prevent them from violating the right to health of others. It mostly concerns the underlying determinants of health, although not exclusively. Examples of violations of the obligation to protect are failure to protect consumers and workers rights and failure to discourage production, marketing and consumption of tobacco, narcotics and other harmful substances.<sup>86</sup> Violations of the obligation to protect can also occur

---

<sup>82</sup> In the CESCR General Comment 14, the Committee defined the violations to the right to health in a scale of detail until unseen in other economic, social and cultural rights.

<sup>83</sup> CESCR General Comment 14, *supra* note 2, para. 48.

<sup>84</sup> CESCR General Comment 14, *supra* note 2, para. 49.

<sup>85</sup> CESCR General Comment 14, *supra* note 2, para. 50.

<sup>86</sup> CESCR General Comment 14, *supra* note 2, para. 52.

through international relationships; for instance, when a State fails to control the environmental impact of transnational corporations.

The violations of the obligation to fulfil are the result of a State direct failure to comply with its immediate and progressively realised obligations regarding the right to health.<sup>87</sup> They occur mostly through omission or incomplete or incompetent action. For example, the failure to adopt a national policy with a detailed plan for realising its minimum core obligations; insufficient expenditure or misallocation of public resources resulting in a lower standard of enjoyment of the right to health; failure to provide people in need with health facilities or failure to provide the population with free or affordable medicines.

As most of the obligations included in the minimum core obligations are obligations to fulfil, States shall not excuse themselves by claiming resource constraints. In addition, the violations of the obligation to fulfil<sup>88</sup> occur even if the State correctly allocates and uses all national resources; and even if the State is willing to fulfil such obligation.

### **2.1.8 Other concerns and specific developments on the right to health**

The recent development of the right to health has brought a more practical approach to the challenges faced by economic, social and cultural rights. As such, specific problems received more detailed attention by the CESCR, the Special Rapporteur on the Right to Health, the WHO and non-governmental organisations.

Examples of these important topics are:

- Definition of indicators and benchmarks for the analysis and accountability of the progressive realization of the right to health;

---

<sup>87</sup> CESCR General Comment 14, *supra* note 2, para. 53.

<sup>88</sup> This refers to both obligation of progressive nature and to the minimum core obligations.

- Implementation of gender-concerned policies regarding the right to health, including women health-status, reproductive rights, discriminatory cultural practices and family planning services;
- People with disabilities;
- Right to mental health;
- Training and availability of health professionals;
- Neglected diseases in the developing world;
- Poverty-reduction policies;
- Political and economic embargos and its impact on health;
- Prevention of violence and health.

Several of these topics received individual attention in reports from the Special Rapporteur on the Right to Health. Human rights and non-human rights institutions have also discussed some of them. Even if they are not going to be examined herein, their existence is mentioned in order to acknowledge the advanced state of evolution of the right to health. It is because of this conceptual and practical evolution that a specific right of access to medicines can be delineated, since they all apply, to a certain extent, to the definition of the right of access to medicines.

## **2.2 The Right to Enjoy the Benefits of Scientific Progress and its Applications**

### **2.2.1 Legal Sources and Interpretation**

The realisation of the right to enjoy the benefits of scientific progress and its applications is, in comparison with the right to health, in the far distance. As the right to health, the right to enjoy the benefits of scientific progress and its applications (herein called the right to the benefits of science) is enshrined in both the UDHR and the ICESCR. In both instruments, it is

defined together with cultural rights<sup>89</sup>. In the UDHR, it is included in article 27(1), which affirms, “[e]veryone has the right to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.”<sup>90</sup> In the ICESCR, the right to the benefits of science is stated in article 15.1(b), which expresses that the State parties to the Covenant shall recognize the right “to enjoy the benefits of scientific progress and its applications.”<sup>91</sup>

Nevertheless, the right to the benefits of science - together with cultural rights - is one of the most neglected rights enshrined in the ICESCR and in the whole International Bill of Rights. The literature about the article 15.1(b) is even sparser than most of the other rights defined in the ICESCR<sup>92</sup> Even when the specialised human rights literature discusses article 15.1(b), it is mostly a generic and brief debate. Additional to the minimum attention it receives by the international community, the CESCR has not published any General Comment on the right to the benefits of science and there is no Special Rapporteur assigned to this right.

As consequence, the interpretation and enforcement of the right to the benefits of science is severely weaker and less clear than the right to health. In reality, the problems that economic, social and cultural rights face are even graver when it comes to the right to the benefits of science.

---

<sup>89</sup> Prior to its inclusion in the UDHR and ICESCR, the right to the benefits of science was discussed in 1945 in the Inter-American conference on the Problems of War and Peace and also included in the American Declaration of the Right and Duties of Man, adopted by the Ninth International Conference of American States, in Bogotá - Colombia, 1948. Available at <<http://www.cidh.org/Basicos/English/Basic2.American%20Declaration.htm>>, last visited on 10 January 2007.

<sup>90</sup> UDHR, *supra* note 20, article 27.

<sup>91</sup> ICESCR, *supra* note 4, article 15.1(b).

<sup>92</sup> Chapman, Audrey R., A Human Rights Perspective on Intellectual Property, Scientific Progress, and Access to the Benefits of Science, *in* Intellectual Property and Human Rights, A Panel Discussion to Commemorate the 50<sup>th</sup> Anniversary of the Universal Declaration of Human Rights, organised by WIPO and UN High Commissioner for Human Rights, Geneva, November 9, 1998, p.84.

## 2.2.2 The Right to the Benefits of Science and Other Science-Related Rights

There is a great confusion about the definition of the right to the benefits of science. Authors consider the right to the benefits of science as a binary provision that includes several rights relating to the scientific activity.<sup>93</sup> On the one hand, the right to the benefits of science is said to protect the rights of scientists, on the other, to protect the right of everyone to benefit from the results of science applications.

Indeed, article 15 of the ICESCR is a proclamation of an ample set of rights. It contains:

- The right to take part in cultural life;<sup>94</sup>
- The right to enjoy the benefits of science and its applications;<sup>95</sup>
- The intellectual property rights of authors;<sup>96</sup>
- Other rights relating to science and science policy: the right to the conservation, development and diffusion of science culture;<sup>97</sup> the right to the freedom indispensable for scientific research and creative activity;<sup>98</sup> the encouragement and development of international contacts and co-operation in the scientific and cultural fields.<sup>99</sup>

The union of these important subjects in the same article, however, does not mean that they are different faces of the same right. In fact, they are different rights, giving way to different sets of obligations. Their interdependence is not different from the interdependence that characterises all economic, social and cultural rights. Additionally, the discussion of such

---

<sup>93</sup> Claude, Richard Pierre, 'Scientists' Rights and the Human Right to the Benefits of Science', in A. R. Chapman and S. Russell, (eds.), *Core Obligation: building a Framework for Economic, Social and Cultural Rights*, Intersentia Publishers, Schoten – Belgium, 2002, p.251.

<sup>94</sup> ICESCR, *supra* note 4, article 15.1(a).

<sup>95</sup> ICESCR, *supra* note 4, article 15.1(b).

<sup>96</sup> ICESCR, *supra* note 4, article 15.1(c).

<sup>97</sup> ICESCR, *supra* note 4, article 15.2.

<sup>98</sup> ICESCR, *supra* note 4, article 15.3.

<sup>99</sup> ICESCR, *supra* note 4, article 15.4.

broad rights under the same heading does not help to define the specific obligations that derive from each of them. It actually contributes to the lack of clarification and implementation of the right to the benefits of science.

This confusion, though, is also present in the work of the CESCR. In the Revised Guidelines Regarding the Form and Contents of Reports to Be Submitted by States Parties under Articles 16 and 17 of the ICESCR, the CESCR affirms - regarding article 15 of the Covenant - that when judging States fulfilment of the right it would consider the following factors:<sup>100</sup>

- (a) Measures taken to ensure the application of scientific progress for the benefit of everyone, including measures aimed at the preservation of mankind's natural heritage and at promoting a healthy and pure environment and information on the institutional infrastructures established for that purpose;
- (b) Measures taken to promote the diffusion of information on scientific progress;
- (c) Measures taken to prevent the use of scientific and technical progress for purposes which are contrary to the enjoyment of all human rights, including the rights to life, health, personal freedom, privacy and the like;
- (d) Any restrictions which are placed upon the exercise of this right, with details of the legal provisions prescribing such restrictions;

Among these factors, there is not any specific guideline for article 15.1(b) of the Covenant. All the guidelines aim to either prevent harmful uses of science or illegal State limitations to its practice. No guideline explicitly orientates States on how to make the *benefits of science and its applications* more enjoyable to *everyone*. In fact, even in the first guideline - which is the one more closely connected to article 15.1(b) – the Committee simply

---

<sup>100</sup> Revised Guidelines Regarding the Forms and Contents of Reports to Be Submitted by States Parties under Articles 16 and 17 of the International Covenant on Economic and Social Rights, *article 15 of the Covenant*. E/C/1991/1, 17 June 1991. Also available at <<http://humanrights.law.monash.edu.au/esc/revisedguidelines1991.html>>, last visited in 10 January 1990.

repeats the text of the article, while formulating examples that in truth relate to the prevention of possible harmful effects that can be caused by scientific activities.

In fact, the discussion of other science-related rights in the context of the right to the benefits of science generally results in the neglect of the definition of obligations that derive directly from article 15.1(b). Indeed, it is not only the CESCR that fails to provide detailed guidelines to the enjoyment of the right to the benefits of science, the United Nations Educational, Science and Cultural Organization (UNESCO), which should also provide specific guidelines for the accomplishment of the right to the benefits of science, also fails to do so. Actually, regarding the role of UNESCO, it is interesting to note that, while the right to health is seen as final goal to the WHO, the right to the benefits of science is seen as a mean to a higher end, as stated in the article I of the Constitution of UNESCO.<sup>101</sup>

Obviously, there can be no accomplishment of the right to the benefits of science when rights such as the freedom of opinion and expression;<sup>102</sup> freedom of peaceful assembly and association;<sup>103</sup> the right to education;<sup>104</sup> and the right to work<sup>105</sup> are not respected, protected and fulfilled. These rights are basic conditions for scientific activity. Without them, there would probably be no scientific benefits for everyone to enjoy. Yet again, this is only another proof of the interconnection of human rights.

It seems necessary to discuss the right to the benefits of science separately from other science-related rights, especially when defining the legal obligation deriving from article 15.1(b) of the ICESCR, in order to avoid neglecting the definition of the positive obligations that derive from the right to the benefits of science. It is necessary to discuss it separately from,

---

<sup>101</sup> Constitution of UNESCO signed on 16 November 1945 and *entered into force* on 4 November 1946.

<sup>102</sup> UDHR, *supra* note 20, article 19.

<sup>103</sup> UDHR, *supra* note 20, article 20.

<sup>104</sup> UDHR, *supra* note 20, article 26.

<sup>105</sup> ICESCR, *supra* note 4, articles 6 and 7.

for example, the right to democratic participation in science policy; the right to knowledge resource; the right to enhanced participation on science; the right to science education; and the right to assessing harmful impact and promoting accountability on science.<sup>106</sup> They all constitute antecedents to the right to the benefits of science, but not its core.

In fact, a separate discussion of one of the different rights of article 15 of the ICESCR is not only a possibility. It has been done by the CESCR in General Comment 17 on the right to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author, as defined in article 15.1(c).<sup>107</sup>

### **2.2.3 The Definition and Nature of the Right to the Benefits of Science: a Right of Access**

According to the Oxford Dictionary of English, *science* is the knowledge acquired by study, acquaintance with or mastery of any department of learning.<sup>108</sup> The same dictionary defines *benefits* as a thing well done; a good or noble deed; a kind deed, a kindness, a favour, a gift,<sup>109</sup> while in legal terms, *benefits* are an advantage, profit, fruit, gain or interest.<sup>110</sup> Therefore, in general terms, *benefits of science* are the fruits acquired by study, acquaintance with or mastery of any department of learning. They are, in a few words, the products of scientific activities.

Bearing this in mind, the significance of the right to *enjoy the benefits of scientific progress and its applications*, as proclaimed by the ICESCR, emerges in a very clear way. It is a universal human right to be practically

---

<sup>106</sup> For a discussion of these rights, see R. P. Claude, *supra* note 93, p.263 - 270.

<sup>107</sup> The UN Committee on Economic, Social and Cultural Rights, General Comment No. 17, on the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author, E/C. 12/GC/17.

<sup>108</sup> Oxford English Dictionary Online. Available at <[www.oed.com](http://www.oed.com)>, last visited on 10 January 2008.

<sup>109</sup> *Ibid*

<sup>110</sup> Black's Law Dictionary with Pronunciations, sixth edition, West Publishing CO, St. Paul, Minnesota, 1990, pg. 158.

and advantageously affected by the fruits of scientific activity; it is a right to use the achievements of the scientific endeavours. This definition is even more evident when considering the evolution from the UDHR, which used the term “share in scientific advancement and its benefits,” to the ICESCR that more directly uses the term “to enjoy” the benefits of scientific progress and its applications. Furthermore, it is both a collective and an individual right, as it is proclaimed to *everyone* in both UDHR and ICESCR.

Without a doubt, the right to the benefits of science represents an important achievement in International Law. However, as already mentioned, the interpretation of such a broad right did not receive much attention over the years. The result is a gap between what the ICESCR says and the practice of States, international organisations and private science entrepreneurs. Indeed, the right to the benefits of science, as defined by the ICESCR article 15(b), strongly needs specific definitions, such as the ones provided by the CESCR General Comment No. 17 on article 15(c) of the ICESCR.

Even in the absence of an authoritative general definition of what constitute the right to the benefits of science in practice, the human rights specialised literature quotes some examples of practical *rights* to the benefits of science. For instance, the right to overcome discrimination in science developments;<sup>111</sup> the right of access to computers and the internet;<sup>112</sup> the right of access to better food;<sup>113</sup> the right of access to new media technologies;<sup>114</sup> the right of access to new health treatments;<sup>115</sup> and the right of access to medicines, which will be detailed in the end of this chapter.

---

<sup>111</sup> R. P. Claude, *supra* note 93, pg 268.

<sup>112</sup> Adalsteinsson, ragnar & Thórhallsson, ‘Article 27’, in *The Universal Declaration of Human Rights, A Common Standard of Achievement*, Alfredsson, Gudmundur and Eide, Asbjørn, Martinus Nijhoff Publishers, The Hague, 1999, p.593.

<sup>113</sup> *Ibid.*

<sup>114</sup> *Ibid.*

<sup>115</sup> Eide, Asbjørn, *Economic, Social and Cultural Rights, A Textbook*, Eide, Asbjørn, Krause, Catarina & Rosas, Alan (eds.), 2<sup>nd</sup> edition, Martinus Nijhoff Publishers, London – UK, 2001, p.296.

The definition presented above, together with these examples of practical rights, is a strong indication that the right to the benefits of science is a *right of access* in its essence. Therefore, its interpretation can and shall take advantage from the developments of other rights of access, such as the right to education, the right to adequate housing, the right to food, the right to health and, particularly, the right of access to medicines.

## 2.2.4 General Obligations and Violations

As an economic, social and cultural right of access, the right to the benefits of science implies duties on States to respect protect and fulfil the realisation of the right. Indeed, the CESCR published several general comments regarding other rights of access, such as the right to food,<sup>116</sup> the right to education,<sup>117</sup> the right to health<sup>118</sup> and the right to water.<sup>119</sup> Their observations on these rights of access can be used to better define the meaning of article 15.1(b), which, as a right to access, is comparable in nature.

The duty to respect implies a negative obligation of States concerning the right to the benefits of science. It obliges States to ensure that their policies – not exclusively the ones directly related to science - do not discriminate against women, minorities and other disadvantaged groups concerning equal enjoyment to the benefits of science. For instance, States shall refrain from denying access to disposable syringes to drug users. Additionally, they have to consider the right to the benefits of science when signing international agreements.

The duty to protect requires States to ensure that third parties do not impede the enjoyment of the benefits of science by everyone. It is a positive

---

<sup>116</sup> CESCR, General Comment 12, *supra* note 54.

<sup>117</sup> The UN Committee on Economic, Social and Cultural Rights, General Comment No. 13 on the Right to Education, E/C. 12/1999/10.

<sup>118</sup> CESCR General Comment 14, *supra* note 2.

<sup>119</sup> The UN Committee on Economic, Social and Cultural Rights, General Comment No. 15 on the Right to Water, E/C.12/2002/11.

obligation requiring States to take effective measures to protect the enjoyment of the right, including legislative measures. Therefore, States shall ensure that the privatisation of the scientific research does not hinder the enjoyment of the benefits of science. For instance, States have to address the problem of neglected diseases.

In fact, the relationship between private scientific research and public advantage from its benefits and applications is a key point to the practical implementation of the right to the benefits of science and to the right of access to medicines. Economic globalisation and economic liberalism dramatically increased the role of private companies in the scientific progress.<sup>120</sup> Until recently, at least in the most developed countries, the right to the benefits of science relied heavily on the States' strong financial support for scientific studies.<sup>121</sup> Nowadays, even the most developed countries are finding increasingly difficult to maintain the rate of growth that public science has enjoyed over the past half century.<sup>122</sup> Therefore, these countries increasingly stimulate private scientific research. This is specifically the case in the US after the entering into force of the US Bayh-Dole Act,<sup>123</sup> which gave American universities the ownership for their inventions even if they were under federally funded research.<sup>124</sup> The Act was enacted in the expectation that they would be more effective in the patenting and commercialisation of the findings of their research.<sup>125</sup>

One of the consequences of this privatisation of scientific research is that it is increasingly difficult for States to protect the right to the benefits of

---

<sup>120</sup> Chapman, Audrey R. *Supra* note 92, pg 84.

<sup>121</sup> US National Research Council Committee on Issues in the Transborder Flow of Scientific Data, *Bits of Power: Issues in Global Access to Scientific Data*, Washington D.C. – USA, National Academy Press, (1997), pg 133.

<sup>122</sup> *Ibid.*

<sup>123</sup> US Bayh-Dole Act, 35 U.S.C.A. para. 200 to 212. PL 96-517.

<sup>124</sup> Technology Transfer Office, *What is Bayh-Dole and Why it is So Important to Technology Transfer?* Available < [www.csurf.org/eneews/bayhdole\\_403.html](http://www.csurf.org/eneews/bayhdole_403.html) >, last visited in 10 January 2008.

<sup>125</sup> M. Jellinek, and S. Markham, Industry-University IP Relations: Integrating Perspectives and Policy Solutions, 54:2 *IEEE Transactions on Engineering Management*, (May 2007), p. 1.

science, due to the strong emphasis to intellectual property protection.<sup>126</sup> Nevertheless, States still have to achieve a balance between the protection of intellectual property law and the rights of access to health, to the benefits of science and to medicines. This balance is the essence of the duty to protect deriving from the right of access to the benefits of science.

The duty to fulfil requires States to give sufficient recognition to the right to the benefits of science in their political and legal systems. Beyond this, it obliges States to take positive actions to make the right a reality, by facilitating, providing and promoting the right to the benefits of science. For instance, concerning the access to computers and to the internet, States shall facilitate their enjoyment through policies that reduce the price of such commodities. Additionally, they shall provide computers and access to the internet to people without sufficient economic means to provide for those commodities themselves. Moreover, they shall promote the right through actions that prod the population to exercise their right.

Finally, as the definition of the obligations deriving from article 15.1(b), the definitions of the violations to the right to the benefits of science also suffer from confusion with scientists' rights already presented.<sup>127</sup> However, the definition of the violations is achievable using the same analogy to the other rights of access of the ICESCR, including the right to health. They are a direct consequence of the lack of accomplishment of the obligations to respect, protect and fulfil the right to the benefits of science, both through acts of commission and omission. For instance, States violate the duty to respect when they have policies that discriminate vulnerable groups of the population to enjoy the benefits of science. They violate the duty to protect when they provide unbalanced protection to intellectual property in detriment of the right to the benefits of science. And they violate the duty to

---

<sup>126</sup> Other important consequence to this change is the introduction of market consideration in the conducts of science, which brings negative effects to the right to health, particularly to the neglected diseases, whose possible medicines might not be profitable. *See* Hunt, Paul, *supra* note 3, pp. 18-19. *See also* Hunt, Paul, *supra* note 61, pp. 19-20.

<sup>127</sup> *See* Claude, Richard Pierre. *Supra* note 93, p.271-277.

fulfil when they fail to provide the most essential benefits of science – such as medicines – to people in need.

### **2.2.5 The Importance of the Right of Access to Medicines to the Definition of the Right of Access to the Benefits of Science**

The discussion above proves the underdevelopment of the right to the benefits of science. In fact, it is a right that finds very little practical meaning nowadays, especially because it is not specific enough to orientate State policies. Bearing this fact in mind, the recent developments of the right of access to medicines are of crucial importance to the definition of the obligation to fulfil the right to the benefits of science. Indeed, medicines are the scientific application regarding which the international community has developed the most complex set of obligations in order to facilitate, provide and promote its access to everyone. Additionally, the right of access to essential medicines, as they defined by each State, following the models set by the WHO,<sup>128</sup> is the single benefit of science<sup>129</sup> whose access is an immediate obligation for States to provide for everyone.<sup>130</sup> In this sense, it is expected that today's legal developments regarding the access to medicines might reverberate in the more neglected general right to the benefits of science.

In conclusion, the right of access to medicines finds an important part of its legal source in the right to the benefits of science, as established by the ICESCR article 15(b). However, it is the more detailed definition and application of the right of access to medicines that will ultimately define what the right to the benefits of science means in practice.

---

<sup>128</sup> WHO Model List of Essential Medicines, 15<sup>th</sup> List, March 2007, available at <[www.who.int/medicines/publications/EML15.pdf](http://www.who.int/medicines/publications/EML15.pdf)>, last visited on 10 January 2008. See also the WHO Model List of Essential Medicines for Children, first List, October 2007, available at <[www.who.int/medicines/publications/essentialmedicines/en/index.html](http://www.who.int/medicines/publications/essentialmedicines/en/index.html)>, last visited on 10 January 2008.

<sup>129</sup> This statement considers only the benefits of science that heavily rely on expensive research.

<sup>130</sup> Hunt, Paul, *supra* note 62, pp. 14-15.

## 2.3 The Right of Access to Medicines as a specific right

### 2.3.1 Definition and Normative Content

The right of access to medicines emerges from the convergence between the right to health and the right to the benefits of science. Moreover, as affirmed above, it receives contributions from other human rights, such as the right to life, the right to food and the right to the highest standard of living.

Nevertheless, even if the right of access to medicines is the perfect example of the interdependence among human rights, it is also a very detailed and well defined right, unlike most other economic, social and cultural rights. This fact is extremely important, since one of the weaknesses of the economic, social and cultural rights framework is its *umbrella* aspect, meaning that the rights are sometimes too broad to be effectively enforced in practice.

Therefore, based on the sources provided throughout this chapter, and taking into account the four dimensions of the concept of accessibility,<sup>131</sup> the right of access to medicines has found a very clear definition. It is the right of everyone to be able to physically find, to economically afford, to non-discriminatorily use and to receive information about the medicines necessary to achieve his or her highest standard of physical and mental health.

The normative content of the right of access to medicines follows the same parameters as the right to health, meaning that States shall ensure that medicines are *available, accessible, culturally acceptable and of good quality*.

---

<sup>131</sup> See sub-chapter 2.1.3.

The availability means that States shall take effective measures to promote the development of new drugs and vaccines.<sup>132</sup> The requirement of cultural acceptability obliges States to provide medicines that are accepted by its people and respectful of medical ethics. For instance, there shall be incentives for the use of traditional medicines.<sup>133</sup> The normative content of good quality obliges States to establish a regulatory system to check medicine safety and quality.<sup>134</sup> Finally, the four dimensions of the concept of *accessibility* oblige States to ensure that:

- Medicines are accessible in all parts of its territory, including the rural areas. For such, States shall establish medicine supply systems;<sup>135</sup>
- Medicines are affordable for all the States' population, including the ones living in poverty;<sup>136</sup>
- Medicines are accessible without discrimination. In order to guarantee this, States might need to take measure to ensure equality of access for all individuals, especially disadvantaged minorities;<sup>137</sup>
- Medicines are taken after having been able to make well-informed individual decisions. For such, States shall provide reliable information about medicines to patients and health professionals.<sup>138</sup>

Amongst the obligations that derive from the normative content described above, probably the most complex one is the requisite of *affordability*.

---

<sup>132</sup> Regarding the normative context of availability, it has to be remembered that developed States, following their obligations of international assistance, are required to seek the development of drugs and vaccines for the diseases that affect mainly developing countries as well.

<sup>133</sup> Hunt, Paul, *supra* note 62, p. 13.

<sup>134</sup> Hunt, Paul, *supra* note 62, p. 14. *See also* page 17 of the same document, in which the Special Rapporteur to the right to health points out that “one third of the States have either no medicine regulatory authority or inadequate capacity to regulate the medicines market. The absence of such authority is clearly inconsistent with the right to the highest attainable standard of health.”

<sup>135</sup> Hunt, Paul, *supra* note 62, p. 13.

<sup>136</sup> *Ibid.*

<sup>137</sup> *Ibid.*

<sup>138</sup> *Ibid.*

Indeed, the provision of affordable medicines for a State's population has implications on several complex subjects. For instance:

- Funding of medicines, as the price of medicines shall vary depending if the research was public or privately funded;
- Tax policies, as the State might need to import medicines from other countries and the import taxes might make those medicines unaffordable for the majority of the population;
- Intellectual Property Protection, as the payment of royalties for patent holders is one of the main factors on the pricing of newly developed medicines;
- International politics and the establishment of international and regional trade-agreements, as their provisions shall have a decisive influence on the pricing of medicines.

The above factors epitomise the current debate relating to the access of medicines. While some of them (funding of medicines and tax policies) constitute internal State decisions, others (IP protection and international agreements that interfere in the pricing of medicines) are mostly beyond the sphere of competence of a single State. Particularly, developing States sometimes do not possess the necessary power to pursue their interests in the international arena effectively.

### **2.3.2 General Obligations, immediate Obligations and Violations**

The States' obligations towards access to medicines are generally the same as towards other economic, social and cultural rights. Hence, States have the duty to respect, protect and fulfil the right of access to medicines.<sup>139</sup> Additionally, they are also divided between progressive and immediate obligations.

---

<sup>139</sup> See subchapter 2.1.4. See also subchapter 2.2.4.

As previously mentioned, the right to access to essential medicines is a core obligation within the right to health.<sup>140</sup> This means that the access to essential medicines is an individual entitlement. Therefore, States are required to establish a national list of essential medicines that shall be made available and accessible throughout its jurisdiction. In the absence of a national list, the WHO Action Programme on Essential Drugs shall be used as reference for essential medicines.<sup>141</sup>

The most important factor of the definition above is that the State's obligation to provide access to essential medicines towards its entire population is not submitted to resource constraints. This implies a serious struggle to fulfil the right of access to essential medicines, particularly in developing countries. The impact of such obligation in the State's policy cannot be overestimated. Indeed, all State policies have to bear this obligation in mind, in order not to violate the right of access to medicines.

Therefore, even if a State proves it has given the necessary priority to the right of access to medicines and pursued international assistance, the CESCR can still find violations to the right of access to medicines. In this case, however, the Committee shall acknowledge the State's effort and conclude that the responsibility for the violation rests within the international community, based on the obligation of international assistance and on the obligation not to prevent States, through excessive IP protection or in other ways, from fulfilling their primary obligations.

Additionally, concerning non-essential medicines, States still have an obligation to progressively make them accessible to all their population, including the ones living in poverty. This means that, in the words of the Paul Hunt, "a State is required to be doing better in five years time than it is doing today; while resource constraint means that what is required of a

---

<sup>140</sup> See subchapter 2.1.6.

<sup>141</sup> WHO Model List of Essential Medicines and WHO Model List of Essential Medicines for Children, *supra* note 128.

developed States is of a higher standard than what is required of a developing State.”<sup>142</sup>

Furthermore, the violations to the right of access to medicines are analogous to other economic, social and cultural rights, especially the right to health.<sup>143</sup> Therefore, a State violates the right of access to medicines when it fails to respect, protect and fulfil it. Nevertheless, due to the interdependency that permeates the right of access to medicines, in order not to violate that right, a State has to acknowledge its influence in most of its spheres of competence. As it will be discussed later, this has severe implications regarding intellectual property and trade policies.

Finally, although this thesis focuses in the right of access to medicines in international law, it is essential to mention that the right of access to medicines is enforceable through domestic courts in some States. A recent Study about the domestic justiciability of the right of access to medicines reached the following finding:

“In 59 cases, access to medicines as a part of the fulfilment of the right to health could indeed be enforced through the courts, with most coming from Central and Latin America. Success was mainly linked to constitutional provisions on the right to health, supported by human rights treaties. Other success factors were a link between the right to health and the right to life, and support by public-interest non-government organisations. Individual cases have generated entitlements across a population group, the right to health was not restricted by limitations in social security coverage, and government policies have successfully been challenged in court.”<sup>144</sup>

---

<sup>142</sup> Hunt, Paul, *supra* note 62, p.14.

<sup>143</sup> See subchapter 2.1.7. See also subchapter 2.2.4.

<sup>144</sup> H. V. Hogerzeil, M. Samson, J. V. Casanovas and L. Rahmani-Ocara, ‘Is Access to Essential Medicines as part of the Fulfilment of the Right to Health Enforceable Through the Courts?’, 368 *Lancet (British Edition)* (2006) pp. 305-311.

## 2.4 Conclusion

The international human rights law establishes the right of access to medicines as a convergence of different economic, social and cultural rights. Particularly, it is clearly one of the core obligations within the right to health. In fact, nowadays the right of access to medicines is one of the better-established rights within the economic, social and cultural rights.

Furthermore, the human rights system, especially the ICESCR interpreted by the CESCR and the Special Rapporteur for the right to health, provide clear guidelines to States in order to fulfil their obligations and implement effective policies in day-to-day political and economic practice.

As a well-established right, the right of access to medicines can potentially become a cornerstone of the economic, social and cultural rights, due to its strong influence in politics, economics and State practice. Additionally, it is one of the few economic, social and cultural rights that is enforceable through domestic courts in some States.

In conclusion, although the right of access to medicines does not have a strong enforceable mechanism in international law, it sets clear positive obligations to States that have ratified any of the main international human rights treaties. These obligations necessarily reverberate in governmental departments that are not directly involved with the protection of human rights. In other words, the right of access to medicines demands governments to consider it in all activities that might affect the access to medicines. Additionally, it implies that international organisations and private entrepreneurs, especially pharmaceutical companies, also have to acknowledge this well-established right.

Indeed, the interdisciplinary aspect of the right of access to medicines puts it in a focal position in today's world politics. Specifically, the debates about trade and intellectual property protection cannot proceed without

consideration for the right of access to medicines. The next chapters will investigate exactly how the right of access to medicines reciprocally influences and is influenced by the subjects of intellectual property and international trade.

# 3 The Pharmaceutical Patent Protection Regime

## 3.1 Overview

The existence of a relationship between pharmaceutical patents and access to medicines is rather obvious. As explained in the last chapter, the right of access to medicines obliges States to provide access in four dimensions, including *physical accessibility* and *affordability*. Pharmaceutical patent rights, on the other hand, with the long-term intention of promoting innovation, have the primary goal to restrict the non-authorised use of new inventions, affecting the affordability of medicines.

Indeed, “patent protection is the category of intellectual property rights that has been considered the most problematic in the relation to human rights.”<sup>145</sup> While the ICESCR emphasizes universal access as crucial for the realization of human rights, the TRIPS Agreement limits the same access by the conditions set by the patent holder.<sup>146</sup> The relationship between these provisions, therefore, can amount to a legal conflict of international laws. The quantity of resolutions, declarations, statements and studies from the most varied sources that address the relationship between patents and access to medicines is nothing short of overwhelming and proves this statement.<sup>147</sup>

Nevertheless, the conflicting tendency does not automatically lead to the conclusion that there is indeed a legal conflict between the right of access to medicines and pharmaceutical patent rights. It is common for legal provisions with different objectives to look conflicting if read in isolation or if applied in disregard to one another, especially in the international arena, which lacks the same structure of domestic legal systems. Ultimately, the

---

<sup>145</sup> H. M. Haugen, ‘Patent Rights and Human Rights: Exploring their Relationship’, *The Journal of World Intellectual Property* (2007) Vol. 10, no. 2, p. 97.

<sup>146</sup> *Ibid*, p.102.

<sup>147</sup> The CESCR General Comment 14 on the right to health, for instance, was published in this period.

existence of conflict lies on the balance between the different rights, its objectives and its practical enforcement.

This Chapter focuses on the analysis of the pharmaceutical patent protection. It presents the legal evolution of its protection both within and outside the human rights framework, arriving at the TRIPS Agreement. Furthermore, it analyses the consequences of the pharmaceutical patent protection on the right of access to medicines, which led to the Doha Declaration on the TRIPS Agreement and the Right to Health. Finally, it concludes in what basis the relationship between the right of access to medicines and the pharmaceutical patent protection is to be understood.

## **3.2 Intellectual Property Rights and Patents. Definitions and Justifications**

There is no satisfactory definition for the term “intellectual property right” that is capable of covering its whole meaning today.<sup>148</sup> The term has been used for almost one hundred and fifty years to refer to the general area of law that encompasses copyright, patents, design, and trademarks, as well as a host of related rights.<sup>149</sup> IPR are, in fact, an umbrella phrase regarding the protection of various rights that may be invoked to prevent imitations.<sup>150</sup> The key factor that unites these distinct rights into the term IPR is that they commonly establish property protection over intangible things such as ideas, inventions, signs and information.<sup>151</sup>

As an umbrella phrase, it is difficult – and possibly without practical purpose - to define a general justification for IPR. In fact, each branch of IPR – copyrights, patents and trademarks, for instance – have had different

---

<sup>148</sup> W. Cornish and D. Llewellyn, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, Sweet & Maxwell Limited, London – UK, 6<sup>th</sup> edition, (2007), p.3.

<sup>149</sup> L. Bently, and B. Sherman, *Intellectual Property Law*, Oxford University Press, Oxford – UK, (2002), p.1

<sup>150</sup> R. Jacob, D. Alexander and L. Jane, *A Guidebook to Intellectual Property. Patents, Trade Marks, Copyrights and Designs*, Sweet and Maxwell, London – UK, 5<sup>th</sup> edition, (2004), p.3.

<sup>151</sup> L. Bently, and B. Sherman, *supra* note 149, p1.

evolutions and historically developed its moral and ethical justifications with some degree of independence. In spite of this, most of the philosophical justifications for all IPR branches have found ground on natural law or distributive justice theories. For instance, copyright protection has been morally and ethically justified as a right of artists to have the fruits of their labour – which are immaterial – to be protected by law.<sup>152</sup> Additionally, apart from philosophical justifications, intellectual property law is a highly politicised field of law nowadays, a fact that comes from the last decade's developments and general view of the considerable economic and social importance of IPR.<sup>153</sup>

Patents are one of the branches under the umbrella of intellectual property protection. They are documents emitted by a government organ that grant a monopoly, among other exclusive rights, for a limited time on the use and development of an invention.<sup>154</sup> They are also defined as the limited monopolies themselves, granted in return for the disclosure of technical information.<sup>155</sup> This monopoly means that the applicant of the patent has the exclusive right to control the exploitation of the invention in a very extensive way, covering most of its commercial uses.<sup>156</sup> In simple words, “a patent is granted to protect a product that is essentially better in some way than what was made before, or for a better way of making it.”<sup>157</sup>

The justification for patent protection has varied over time, but it has been generally commonly based in three grounds: (1) a natural right; (2) a distributive justice measure; and (3) a utilitarian/economic reason.<sup>158</sup> As a natural right, patents are a societal obligation to reward any man's ideas.<sup>159</sup>

---

<sup>152</sup> G. Daves, *Modern Legal Studies. Copyright and the Public Interest*, Sweet & Maxwell Limited, London – UK, (2002), p. 15.

<sup>153</sup> L. Bently, and B. Sherman, *supra* note 149, p.3.

<sup>154</sup> E. Stephen, and R. Stim, *Patent, Copyright and trademark. An Intellectual Property Right Reference*, Nolo and Richard Stim, 7<sup>th</sup> edition, Berkeley – USA, (2004), p. 226.

<sup>155</sup> L. Bently, and B. Sherman, *supra* note 149, p309.

<sup>156</sup> L. Bently, and B. Sherman, *supra* note 149, p309.

<sup>157</sup> R. Jacob, D. Alexander and L. Jane, *supra* note 150, pg 18.

<sup>158</sup> S. Sterckx, 'Patents and Access to Drugs in Developing Countries: An Ethical Analysis', *Developing World Bioethics* ISSN 1471-8731, Volume 4, Number 1, (2004), p. 62.

<sup>159</sup> *Ibid*, p.62

As a distributive right, it is a reward for the inventors' contribution to society.<sup>160</sup> Finally, as a matter of utilitarian/economic reason, patents are justified as a tool to provide an incentive for the production of new inventions, meaning that investors will be more willing to fund research and development due to the granted monopoly over the inventions. It "induces or encourages desirable behaviour" from society in the search for technical innovations.<sup>161</sup>

Nowadays, even if the ideas of patents as a natural right or a distributive reward remain attractive and are by no means exhausted,<sup>162</sup> the utilitarian economic justification is by far the strongest ground for the patent international protection, especially as the discussions over patents in the last decades have been mostly centred in the economic arena. Patents are justified now as the cornerstone factor without which there would be far less technical innovations achievements. In spite of this, questions such as how patents promote innovation and how far the IP system acts as an effective disseminator of knowledge<sup>163</sup> are subject of severe controversy and it is very difficult to assess the contribution of patents for the production of innovation.<sup>164</sup> On the other hand, it is almost indefensible that some sort of incentive for inventiveness and creativity shall be given by society.

### **3.3 The International Protection of Patents**

#### **3.3.1 Historical Evolution of the Patent Protection Regime**

A set of rights of exclusive use resembling the modern conception of patents were given by Roman Law as early as 1200 A.D. for the use of mines and

---

<sup>160</sup> L. Bently, and B. Sherman, *supra* note 149, p309.

<sup>161</sup> L. Bently, and B. Sherman, *supra* note 149, p.309-310.

<sup>162</sup> W. Cornish and D. Llewellyn, *supra* note 148, p.36. Additionally, the debate about the protection of indigenous intellectual property rights has enhanced the discussion about the natural rights and distributive justice justification of patents.

<sup>163</sup> A. Webster and P. Katryn, *Innovation and the Intellectual Property System*, Kluwer Law International, The Hague – The Netherlands, (1996), p.14.

<sup>164</sup> W. Cornish and D. Llewellyn, *supra* note 148, p.134.

natural resources.<sup>165</sup> In the Middle Ages, with the expansion of commerce, the Italian cities of Florence and Venice conceded patents as the general set of exclusive and temporary rights given to an inventor for its work.<sup>166</sup> From there,<sup>167</sup> the institution of patents gradually spread in the north direction, often being distorted by absolutist governments that transformed the so-called “privileges” into a “royal reward for favourites.”<sup>168</sup> The practice became so corrupted that in 1623 the English Parliament passed the Statute of Monopolies with the intent to control such distortions and to make patents add to the public wealth.<sup>169</sup>

Later, the French revolution, with its appraisal of individual rights, together with the further development of commerce and the industrial revolution, marked the establishment of patents as liberal “right”, instead of a “privilege”.<sup>170</sup> It was appropriate, then, that the first multilateral treaty regarding patents was the 1883 Paris Convention for the Protection of Industrial Property.<sup>171</sup> It established a union for the protection of industrial property,<sup>172</sup> under which an application for patent in one of the contracting countries gave a period in which to pursue an application in any of the others.<sup>173</sup> The system became known as the “union system” or “convention system.”<sup>174</sup>

---

<sup>165</sup> Ryan, Michael P., *Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property*, the Brookings Institution Press, Washington D.C. – USA, (1998), p.22.

<sup>166</sup> Bugbee, Bruce W, *Genesis of American Patent and Copyright Law*, Public Affairs press, Washington D.C. – USA, (1967), p.21.

<sup>167</sup> Venice claims to be the nest of the industrial invention’s protection, but the most ancient privilege seems to have been conceded in Bordeaux – France, in 1236. *See* Basso, Maristela, *O Direito da Propriedade Intelectual*, Editora Livraria do Advogado, Porto Alegre – Brazil, (2000), p.67.

<sup>168</sup> Ryan, Michael P., *supra* note 165, p.24.

<sup>169</sup> Kaufer, Erich, *The Economics of the patent System*, Harwood Academic Publishers, Chur – Switzerland, (1989), p.6.

<sup>170</sup> Bassos, Maristela, *supra* note 167, p.73.

<sup>171</sup> Paris Convention for the Protection of Industrial Property, signed on 20 March 1883, and revised at Brussels on 14 December 1900, at Washington on 2 June 1911, at the Hague on 6 November 1925, at London on 2 June 1934, at Lisbon on 31 October 1958, and at Stockholm on 14 July 1967, and as amended on September 28, 1979.

<sup>172</sup> *Ibid*, article 1, paragraph 1

<sup>173</sup> *Ibid*, article 4, Section C, paragraph 2

<sup>174</sup> W. Cornish and D. Llewellyn, *supra* note 148, p.120.

The Paris Convention created an International Secretariat to administrate the union, which became known as the “Union of Paris.” Subsequently, the Union of Paris was combined with the “Union of Berne,” that administrated the 1886 Berne Convention for the Protection of Literary and Artistic Works. In fact, both Berne and Paris Conventions adopted the same basic principles, including the principle of “national treatment,”<sup>175</sup> which was in the root of the union system.

Together, they became the Unified International Bureaux for the Protection of Intellectual Property (BIRPI),<sup>176</sup> under the supervision of the Swiss government.<sup>177</sup> Finally, in the 1967 Stockholm revision of the Paris Convention,<sup>178</sup> the BIRPI was extinct and replaced the World Intellectual Property Organization – WIPO.<sup>179</sup>

Meanwhile, the Universal Declaration of Human Rights and the International Covenant on Economic, Social and Cultural Rights were proclaimed and dedicated provisions to intellectual property rights. The UDHR article 27 (2) established that “everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.”<sup>180</sup> And the ICESCR article 15(c) affirmed that everyone have the right “to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.”<sup>181</sup>

Although the inclusion of IPR among human rights is at least controversial, as it is shown below, WIPO became an UN Specialised Agency by an

---

<sup>175</sup> L. Bently, and B. Sherman, *supra* note 149, p5.

<sup>176</sup> The abbreviation BIRPI refers to the French-language version of the name.

<sup>177</sup> WIPO Intellectual Property Handbook: Policy, Law and Use, WIPO Publishing, Geneva – Switzerland, 2<sup>nd</sup> edition, 2004, p.4.

<sup>178</sup> See Bastos, Maristela, *supra* note 167, p. 74.

<sup>179</sup> Convention Establishing the World Intellectual Property Organization, signed at Stockholm on 14 July 1967 and amended on 28 September 1979.

<sup>180</sup> UDHR, *supra* note 20, article 27(2).

<sup>181</sup> ICESCR, *supra* note 8, article 15(c).

agreement that entered into force in December 17, 1974.<sup>182</sup> This transformation was not simply structural. In fact, by the 1974 agreement,<sup>183</sup> WIPO was transformed from a “club of patent-wealthy, industrialised countries” into a more global intergovernmental organisation that included many developing countries that needed considerable help establishing patent systems.<sup>184</sup>

WIPO became, in truth, the world forum for all IPR branches, including patents. In was under the auspices of WIPO that the Patent Cooperation Treaty (PCT) was celebrated, with a clear objective to rationalise and improve the application for patent protection in several countries.<sup>185</sup> Additionally, as the patents debate became universal and included more and more developing countries, the influence of other United Nations organs became more decisive. The United Nations Conference for Trade and Development (UNCTAD) and UNESCO debated and implemented patents law as well, but with a focus on access to technology and development.<sup>186</sup>

The studies of UNCTAD and UNESCO, indeed, contributed to the ideological division between developed and underdeveloped countries that gained force in the 1970s and remains until today. To developing States, IPR are a matter of public law and are only justified if they generate economic and social development; on the other hand, to developed States, IPR are a private right that necessarily create economic development and shall be protected similarly to tangible properties.<sup>187</sup> During the 1970s and 1980s, while the debate over patents was ongoing in WIPO and other UN organs, little was advanced in the worldwide enforcement of patent.

---

<sup>182</sup> Agreement Between the United Nations and the World Intellectual Property Organization, GA Res. 3346 (XXIX), 2323<sup>rd</sup> plenary meeting, 17 December, 1974.

<sup>183</sup> *Ibid.*

<sup>184</sup> Ryan, Michael P., *supra* note 165, p.14.

<sup>185</sup> WIPO Intellectual Property Handbook: Policy, Law and Use, *supra* note 177, p.277.

<sup>186</sup> According to UNCTAD, in the decade of 1970, 84% of the patents registered in developing countries belonged to the USA, Germany, France, Switzerland and England. See UNCTAD, *The Role of the Patent System in the Transfer of Technology to Developing Countries*, U.N. Dept of Economy And Social Affairs, UNCTAD Secretariat, UN Doc. TD/B/AC.11/19 (1974).

<sup>187</sup> Basso, Maristela, *supra* note 167, p.148.

### 3.3.2 The Forum-Shifting

The lock on the negotiations over patents obviously did not please States that are strong providers of IPR. As a consequence, the United States, Europe and Japan, as gross producers of intellectual property goods, began to advocate for higher levels of intellectual property protection worldwide through more aggressive strategies and trade retaliations.<sup>188</sup> For instance, the USA 1984 Trade Act,<sup>189</sup> gave the U.S. Trade Representative's Office power to eliminate commercial practices that were considered unjustifiable through retaliations and restrictions to exportation to the American market.<sup>190</sup> The 1984 Trade Act was even amplified by the 1988 Omnibus Trade and Competitiveness Act,<sup>191</sup> which is still used by the USA to pressure States to enforce IPR.<sup>192</sup>

Additionally, these States advocated the inclusion of IPR into the General Agreement on Tariffs and Trade System (GATT),<sup>193</sup> in which they succeeded. This forum-shifting from WIPO, UNESCO and UNCTAD to GATT was a water divisor in the protection and enforcement of the patents and, consequently, in the balance between IPR and human rights. The main reasons for this forum-shifting strategy were three:

- Developed States considered WIPO's policies and remedies against piracy a failure. The trading of counterfeiting good was considered unjustifiable and needed an urgent solution within trade law;<sup>194</sup>
- It introduced IPR in a broader arena, in which the enforcement of stronger patent protection could be negotiated together with different

---

<sup>188</sup> L. Bently, and B. Sherman, *supra* note 149, p.6.

<sup>189</sup> USA Trade and tariff Act of 1984, 19 USC 1654 note.

<sup>190</sup> Basso, Maristela, *supra* note 167, p.151

<sup>191</sup> The USA Omnibus Trade and Competitiveness Act of 1988, 19 USC 2901 note.

<sup>192</sup> Basso, Maristela, *supra* note 167, p. 152.

<sup>193</sup> General Agreement on Trade and Tariffs – GATT – first signed in 1947.

<sup>194</sup> D. Gervais, *The TRIPS Agreement: Drafting History and Analysis*, Sweet and Maxwell Limited of, London – UK, (2003), p.10.

provisions, such as the transference of technology to developing countries;<sup>195</sup>

- The negotiations in GATT were more streamlined, since NGO's were excluded from the treaty process.<sup>196</sup>

In 1994 it was signed the Agreement on Trade Related Aspects of Intellectual Property Rights<sup>197</sup> and the created the World Trade Organization, by an Agreement signed in Marrakech.<sup>198</sup> From there on, even if WIPO still administrates several intellectual property agreements<sup>199</sup> the debate over IPR is divided with the WTO.

### 3.3.3 The TRIPS Agreement

The TRIPS Agreement is the most comprehensive intellectual property law ever produced. Important scholars even affirmed that it covered all areas of intellectual property.<sup>200</sup> In its preamble, the objective of the Agreement to “curb trade of illicit goods”<sup>201</sup> is rather clear:

“*Desiring* 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;”<sup>202</sup>

---

<sup>195</sup> L. Bently, and B. Sherman, *supra* note 149, p.7.

<sup>196</sup> L. Bently, and B. Sherman, *supra* note 149, p.7

<sup>197</sup> The Agreement on Trade Related Aspects of Intellectual Property – TRIPS -, as included as Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh – Morocco, on 15 April, 1994.

<sup>198</sup> Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh – Morocco, on 15 April, 1994.

<sup>199</sup> The intellectual property treaties administrated by WIPO nowadays are the [Berne Convention](#), the [Brussels Convention](#), the [Film Register Treaty](#), the [Madrid Agreement \(Indications of Source\)](#), the [Nairobi Treaty](#), the [Paris Convention](#), the [Patent Law Treaty](#), the [Phonograms Convention](#), the [Rome Convention](#), the [Singapore Treaty on the Law of Trademarks](#), the [Trademark Law Treaty](#), the [Washington Treaty](#), the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty. Available at < [www.wipo.int/treaties/en/](http://www.wipo.int/treaties/en/) >, last visited on 10 January 2008.

<sup>200</sup> L. Bently, and B. Sherman, *supra* note 149, p.7. This affirmation is, however, controversial. For instance, the protection of traditional knowledge was not included on TRIPS and is still not well protected internationally.

<sup>201</sup> D. Gervais, *supra* note 194, p.12.

<sup>202</sup> TRIPS Agreement, *supra* note 197, preamble. Note: Article 7 of the Agreement is labelled “objectives” but it actually states the objectives of “the protection and enforcement

The TRIPS Agreement obliges States members to comply with the protection of the intellectual property, with few provided flexibilities. The minimum international IPR standards it established<sup>203</sup> obliged some countries, notably developing countries, to expand their protection. Concerning medicines, before TRIPS the decision whether to grant protection for pharmaceutical processes and products was within the discretion of the States. Indeed, before TRIPS more than forty States did not apply patents for medicines, while others only patented drug processes, or applied shorter terms of protection.<sup>204</sup>

Nevertheless, within the scope of the agreement, not only were all countries obliged to protect them, but moreover the protection was identical for both developed and developing countries.

Patents are treated in the Section 5 of TRIPS. Article 28 confers patent holders the rights to:

- (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;<sup>205</sup>
- (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of

---

of intellectual property rights” and not of the Agreement *per se*. It says: “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 the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”

<sup>203</sup> TRIPS Agreement, *supra* note 197, article 27.

<sup>204</sup> L. Forman, ‘Trade Rules, Intellectual Property, and the Right to Health’, *Ethics & International Affairs*, Vol. 21, Issue 3, (2007), Blackwell Publishing, p.339. *See also* WHO Policy Perspectives on Medicines, No. 03, (2001) – Globalization, TRIPS and Access to Medicines, WHO MD; 2001; pp. 1-6.

<sup>205</sup> These rights, like all other rights conferred under TRIPS in respect of the use, sale, importation or other distribution of goods, is subject to the exhaustion provisions of Article 6.

using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.<sup>206</sup>

These rights of patent holders were also granted with procedures and remedies to guarantee their effective enforcement.<sup>207</sup> It established that the patent protection should not end before the expiration of a period of twenty years counted from the filing date.<sup>208</sup> Indeed, the Agreement overcame the criticism and resistance for such high IPR level of enforcement by developing countries and was considered a resounding victory for the defence of the IPR-heavy industries from developed States, particularly the pharmaceutical industry.

In summary, TRIPS established twenty years patent for pharmaceuticals products in all WTO-member States,<sup>209</sup> awarding exclusive rights to the patent holders, with national and international tools of enforcement, including the WTO's formal mechanism for dispute settling.<sup>210</sup>

The Agreement addressed the human right to the highest attainable standard of health, but in clearly weaker wording. Article 7 affirms the protection and enforcement of the intellectual property shall be implemented in a manner *conducive to social and economical welfare, and to a balance of rights and obligations.*<sup>211</sup> Additionally, it affirms that members may, *in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.*<sup>212</sup>

---

<sup>206</sup> TRIPS Agreement, *supra* note 197, article 28.

<sup>207</sup> TRIPS Agreement, *supra* note 197, part III.

<sup>208</sup> TRIPS Agreement, *supra* note 197, article 33.

<sup>209</sup> The Least Developed Countries, however, are not obliged to implement TRIPS until 1 January 2016.

<sup>210</sup> L Forman, *supra* note 204, p.339.

<sup>211</sup> TRIPS Agreement, *supra* note 197, article 7.

<sup>212</sup> TRIPS Agreement, *supra* note 197, article 8(1).

The public health concern is also mentioned in articles 30 and 31, which respectively provide for exceptions to the rights conferred by TRIPS<sup>213</sup> and other uses without authorization of the right holder.<sup>214</sup> Rather implicitly, these articles touch the subjects of *compulsory licensing* and *parallel import*, which are the main exceptions to the exclusive rights of patent holders under TRIPS.

These articles allow some freedom for the State members to formulate their public health policies. Nevertheless, the TRIPS Agreement clearly weakened the capacity of developing countries to implement the right to health of their populations. In fact, few States have made use of these flexibilities and the ones who did use the flexibilities contained in articles 30 and 31 faced threats of trade sanctions from developed States and time consuming corporate litigations against pharmaceutical companies,<sup>215</sup> which were unavoidably costly, both in terms of finances and of personnel.<sup>216</sup> Thailand, Mexico, Chile, Brazil, Indonesia, Indonesia, Bolivia, Colombia, Ecuador, Peru, Venezuela and South Korea are examples of States that faced such difficulties in implementing the exceptions to the patent regime under TRIPS Agreement.<sup>217</sup>

The *South-Africa case*, however, is the prime example of such difficulties for developing countries. The government of South Africa enacted a law granting the Minister of Health the power to take measures in order to provide consumers with more affordable medicines by authorising the parallel import of generic drugs and also by limiting exclusive rights of the right holder via compulsory license. Against this law, a coalition of forty-two pharmaceutical companies sued the Government of South Africa,

---

<sup>213</sup> TRIPS Agreement, *supra* note 197, article 30.

<sup>214</sup> TRIPS Agreement, *supra* note 197, article 31.

<sup>215</sup> L Forman, *supra* note 204, p.342.

<sup>216</sup> F. M. Abbot, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lightning a Dark Corner at the WTO', *Journal of International Economic Law*, June issue (2002), p.2

<sup>217</sup> L Forman, *supra* note 204, p.342.

arguing that the TRIPS patents provision could not be limited by a decision of the Minister of Health.<sup>218</sup>

The case attracted immense international attention and several non-governmental organisations joined the Government of South Africa in defending its policies. This pressure against the pharmaceutical coalition was in fact successful and on 19 April 2001, the pharmaceutical companies withdrew the action. Despite the successful conclusion, this case illustrates how weak the position of developing countries is in addressing their health problems after the adoption of the TRIPS Agreement. However, the South African example explicitly encouraged African countries to press for amendments and clarifications of the TRIPS Agreement.<sup>219</sup> They were commonly referred at the future WTO negotiations at Doha as the “African Group”.

Indeed, after its entry into force, pressure against TRIPS from society and non-governmental organisations in the most important institutions of the international legal system only increased both in the developing and developed countries,<sup>220</sup> with some level of success, as the South-Africa case portrays. In academia, even scholars that devoted studies to explain the gains achieved by developing countries in the TRIPS Agreement<sup>221</sup> stress that it reflects the bigger bargaining power of the industrialized countries.

### 3.3.4 The Doha Declaration on the TRIPS

---

<sup>218</sup> *Treatment Action Campaign et al. V. Minister of Health et al*, High Court of South Africa, Transvaal Provincial Division, Case No. 21182/2001.

<sup>219</sup> S. J. Haakonsson, and A. Richey, ‘TRIPS and Public Health: The Doha Declaration and Africa’, *Development and policy review*, issue 25, Blackwell Publishing, Oxford – UK, (2007), pp. 75-76.

<sup>220</sup> Some scholars argue that the NGO protesters threats to disrupt the political campaign of Vice President Gore eased the opposition of the USA in regards to the Doha Declaration. See F. M. Abbott, ‘The TRIPS-legality of Measures Taken to Address Public Health Crises: Responding to USTR-State-Industry Positions that Undermine the WTO’, in D. L. M. Kennedy and J. D. Southwick (eds.) *The Political Economy of International trade Law: Essays in Honor of Robert E. Hudec*, Cambridge University Press, Cambridge – UK, (2002), p. 311.

<sup>221</sup> A. Panagariya, *Developing Countries at Doha, a Political Economy Analysis*, *The World Economy*, volume 25, issue 9, September, (2002) p. 1221.

## Agreement and Public Health

The pressure from developing States and organised groups from civil society worldwide<sup>222</sup> led to the Doha Declaration on the TRIPS Agreement and the Right to Health, adopted at the WTO Ministerial Conference in November 14, 2001, in the city of Doha. The Declaration attempted to clarify the relationship between patent rights and the public health concern and therefore better harmonise the TRIPS Agreement with the UN Human Rights framework. Indeed, even if the Doha Declaration is a short document of seven paragraphs, it represented an important step for trade and business towards the right to health.

The Declaration starts by clearly defining the problem it tries to overcome. Paragraph one recognizes *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.*<sup>223</sup>

The interpretation of the first paragraph is very important to define the amplitude of the scope of the Doha Declaration. The developed countries, especially the United States and Switzerland, tried to limit the scope of the Declaration by limiting the epidemics it could apply to.<sup>224</sup> Their proposal, however, was defeated and paragraph one reflects a victory of developing countries in the sense that the Declaration regards the public health concern in general, without limitation to certain diseases.<sup>225</sup>

---

<sup>222</sup> Two specific situations can also be credited as reasons for the Doha Declaration: (1) The “anthrax crisis” that made the United States and Canada face a situation in which they needed immediate and widespread access to products still on patent and in which the right-holder seemed unable or unwilling to offer enough supplies to meet the immediate demand; and (2) the threat of non-governmental organisations to stop the support for the at time Vice President of the United States, Al Gore, in his attempt to win the election for president. Although it is doubtful that the connection between these events and the conclusion of the Doha Declaration probably will remain unknown, it is not only unreasonable, but mostly probable. See F. M. Abbott, *supra* note 216, p. 479.

<sup>223</sup> The Doha Declaration on the TRIPS Agreement and the Right to Health, WT/MIN(01)/DEC/W/2, signed on 14 November 2001, paragraph .

<sup>224</sup> For a discussion on the subject see Hoen, Ellen T, TRIPS, Pharmaceutical Patents and Access to Essential Medicines: A Long Way from Seattle to Doha. *Chicago Journal of International Law*, vol.3, no.1, spring, (2002), pp. 41-75

<sup>225</sup> C. M. Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, Publications of the World Health Organization Geneva – Switzerland, (2002), pg 5.

Paragraph 2 and 3 of the Doha Declaration are a implicit but necessary self-criticism on the WTO and the TRIPS Agreement for its insufficient concern to the public health. Paragraph 2 acknowledges the need of the WTO and TRIPS *to be part of the wider national and international action to address these problems.*<sup>226</sup> Paragraph 3, while re-stressing the importance of intellectual property protection for the development of new medicines, recognizes *the concerns about its effects on prices* of medications.<sup>227</sup>

These paragraphs, not only present an auto-criticism to the WTO and TRIPS, but simultaneously give strength to the argument that intellectual property rights are one of the main obstacles regarding the access to drugs in developing countries. It is, therefore, a contra argument to the pharmaceutical lobbies, which try to disassociate the public health concern and intellectual property protection.<sup>228</sup>

Paragraph 4 of the Doha Declaration is maybe its most important one. It contains three essential statements:

The TRIPS Agreement does not and should not prevent members from taking measures to protect public health;

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;

A Reaffirmation of the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.<sup>229</sup>

This paragraph represents a stronger acknowledgement of the States' rights to create policies for their public health problems than article 8(1) of the

---

This work, although not being an official document, is of particular importance to the comprehension and interpretation of the Doha Declaration, since it was made as an express request by the World Health Organization and the Department of Essential Drugs and Medicines Polices of the WHO.

<sup>226</sup> The Doha Declaration, *supra* note 223, para. 2.

<sup>227</sup> The Doha Declaration, *supra* note 223, para. 3.

<sup>228</sup> See Lehman, Fabrice, *The Trade Debate Needs the Voice of Business*, International Trade Forum, 2006, ABI/INFORM Global, pg 13.

<sup>229</sup> The Doha Declaration, *supra* note 223, para. 4.

TRIPS Agreement. Through this paragraph, developing countries achieved a declaration – even if not explicit - from the WTO, recognizing their right to implement the still legally controversial policies of compulsory license and parallel import.<sup>230</sup>

Compulsory licensing is a State sovereign decision to license to a company, government agency or other party the right to use a patent without the title holder's consent. According to the scholar Carlos Correa, “a compulsory license must be granted by a competent authority to a designated person, who should generally compensate the title-holder through payment of remuneration.”<sup>231</sup>

Parallel import, “is the import and resale in a country without the consent of the patent holder of a patented product that has been legitimately put on the market of the exporting country. This means that drugs sold at a lower price in one country can be imported into another country where the same drug is sold at a higher price.”<sup>232</sup>

Paragraph 5 of the Doha Declaration also provides a deeper and better understanding of articles 7 and 8 of the TRIPS Agreement (objectives and purposes). It specifies more clearly the flexibilities of the Agreement to address problems of public health.

Within the TRIPS Agreement, the most important flexibility is, without doubt, the issuing of compulsory licenses. However, the TRIPS Agreement itself did not even contain such an expression.<sup>233</sup> Paragraph 5 of the Doha Declaration, on the other hand, specifically uses the term and affirms, “each

---

<sup>230</sup> The right to parallel import was clarified later in the Council Decision of 30 of August of 2003. However, the legal basis for its latter approach is to be found in paragraph 4 of the Doha Declaration, since it was there that the public health concern was raised to a higher level of awareness.

<sup>231</sup> C. M. Correa, *Integrating Public Health Concerns into patent legislation in developing countries*, South Centre Publication, Geneva – Switzerland, (2000), p. 109.

<sup>232</sup> J. Wise, ‘Access to AIDS medicines stumbles on trade rules’, *Bulletin of the World Health Organization*, volume 84, number 5, may, (2006), p. 343.

<sup>233</sup> Article 31 of the TRIPS Agreement uses the expression “other use without authorization of the right holder.” See also C. M. Correa, *supra* note 225, p. 15.

member has the right to grant compulsory license and the freedom to determine the ground upon which such licenses are granted.”<sup>234</sup>

The importance of such a statement in the Doha Declaration is that it clarifies article 31 of the TRIPS Agreement. Therefore, although the conditions for granting compulsory licenses are limited by article 31 of the TRIPS Agreement, the *grounds* on which such licenses are conceded are not limited by the same article. The grounds, in fact, are within the margin of discretion of each country to decide.

The most relevant ground for the concession of compulsory licenses – or at least the most debated one – is the occurrence of a *national emergency*. Paragraph 5(c) of the Doha Declaration starts by saying what actually should be the obvious: that “each member has the right to determine what constitutes national emergency or other circumstances of extreme urgency.”<sup>235</sup> The importance of this first part of the paragraph is easy to explain: not all countries, especially the least developed ones, are financially and administratively equipped to protect the most basic rights. Therefore, sometimes it is utterly necessary that their rights and freedom of necessary action to be defended through international institutions such as the WTO, through the explicit recognition of such principles as the one contained in article 5(c) above.<sup>236</sup>

The second part of article 5(c) is even more relevant. It affirms, “public health crises, including those related to HIV/AIDS, tuberculosis, malaria and other epidemics can represent a national emergency or other circumstances of extreme urgency.” This statement is supremely important for two reasons:

- It clarifies that public health crises can represent a national emergency or other circumstances of extreme urgency.

---

<sup>234</sup> The Doha Declaration, *supra* note 223, para. 5(b).

<sup>235</sup> The Doha Declaration, *supra* note 223, para. 5(c).

<sup>236</sup> L. Forman, *supra* note 204, p.339.

Therefore, the compulsory license can be provided for by national legislations, without prior negotiation with the patent owner;

- The reference to diseases such as HIV/AIDS indicates that a national emergency can be a long-lasting situation. Hence, the use of the TRIPS flexibilities might be maintained for as long as the situation is still considered grave by the State member.<sup>237</sup>

Furthermore, in paragraph 6, the Doha Declaration touches the difficult problem of the countries with insufficient or no manufacturing capacities. Under the TRIPS Agreement, the use of compulsory license is restricted to supplying only the market of the country authorising such use.<sup>238</sup> This condition, in practice, limits the use of the TRIPS' flexibilities for the great majority of developing countries, especially the least developed countries, which include most of the African States facing the most serious HIV/AIDS pandemic.

The problem involves the controversial subject of *parallel import*, which is the most foreseeable way<sup>239</sup> of addressing pandemics such as HIV/AIDS in countries which lack manufacturing capacities. Nevertheless, the Doha Declaration failed in providing a legal solution for this problem.

Concluding the Declaration, paragraph 7 reaffirms the commitment to technology transfer to be made by developed countries, their enterprises and institutions, pursuant to article 66.2 of the TRIPS Agreement; and the

---

<sup>237</sup> See C. M. Correa, *supra* note 225, pp. 16-17. This author presents three reasons for the importance of paragraph 5(c) of the Doha Declaration. In his opinion, the language of paragraph 5(c) also inverts the burden of proof, meaning that the complaining country or company is the one who has to prove that such emergency does not exist.

<sup>238</sup> TRIPS Agreement, *supra* note 197, article 31(f).

<sup>239</sup> Apart from philanthropic measures.

transition rules for the least developed countries are also reassured, in pursuant of article 66.1 of the TRIPS Agreement.<sup>240</sup>

Finally, it is necessary to acknowledge that the Doha Declaration on the TRIPS Agreement and Public Health is not binding law on the member States of the WTO. However, as a Ministerial Decision, it is an authoritative interpretation of the TRIPS Agreement and has legal effects on the work of the Dispute Settlement Body and the Council for TRIPS.<sup>241</sup> Hence, it decisively influences the State member's policies regarding one another and cannot be disregarded as a relevant step in the balance of the objectives set forth by the TRIPS Agreement.

After the Doha Declaration, two important political and legal decisions are worth mentioning: the General Council Decision of August 30, 2003; and the amendment of the TRIPS in 2005.

The General Council Decision of August 30, 2003, waived eligible importing countries from the obligations relating to the remuneration of right holders. Hence, generic drug producer countries now had a stronger legal base for manufacturing drugs not exclusively for the supply of their domestic markets. In other words, countries lacking manufacturing capacity could request other countries to produce drugs and export to them, under three conditions:

- Notification of the TRIPS Council;
- Proof of the incapacity to manufacture, which is presumed in the case of Least Developed Countries;
- The exporting country still has an obligation to pay the right holder. This is, of course, the most problematic and debated condition.

---

<sup>240</sup> The Doha Declaration, *supra* note 223, paragraph 7.

<sup>241</sup> Correa, Carlos M, *supra* note 225, pp. 44-45.

The amendment of TRIPS in 2005 has four parts and is basically a formal inclusion of the decisions the organisation took in recent years. The amending protocol was open until December 1, 2007 and will enter into force after two-thirds of the State members have notified their acceptance. Article 3bis will be included, reiterating the Doha Declaration and the Decision of General Council of August 30, 2003 and there will be a possibility to export compulsory licensed drugs within regional context facing the same health problem, by regional agreement.

Even acknowledging the improvements achieved with the Doha Declaration, the balance between pharmaceutical patents and the right of access to medicine remains a matter of strong controversy. Now, once presented the historical evolution of the patent protection and the grounds in which it stands today, the relationship between pharmaceutical patents and the right of access to medicines can be better discussed.

## **3.4 Are Pharmaceutical Patents a Human Right?**

### **3.4.1 Overview**

The relationship between pharmaceutical patent protection and the right of access to medicines can be theoretically approached by two different angles:<sup>242</sup> (1) a relationship between two human rights; or (2) a relationship between a human right and a trade-related right. Hence, it is the nature of the pharmaceutical patent protection that will define the correct angle of analysis.

In order to define the correct approach, the nature of the pharmaceutical patent protection has to be analysed. At last, the approach depends on the inclusion or not of pharmaceutical patent protection among the human rights framework. This is the objective of this section.

---

<sup>242</sup> H. M. Haugen, *supra* note 145, p. 98

### 3.4.2 The inclusion of IPR in the Human Rights Framework: Controversies and historical differences

As already presented, intellectual property rights were included in the international bill of rights by the UDHR, article 27 and ICESCR article 15(c). Nevertheless, the controversy over its inclusion among human rights was present throughout the drafting of both articles.<sup>243</sup> In fact, it is arguable that the inclusion of authors' rights in the UDHR came from the coincidence that the UDHR was a contemporary of the drafting of the American Declaration of the Rights and Duties of Man, which included a provision on the rights of authors,<sup>244</sup> and of the Berne International Copyright Convention.<sup>245</sup>

Already at that time, members of the Commission on Human Rights argued that authors' rights were not applicable to everyone, adding their feeling that "patents and copyrights could sometimes become an obstacle to the possibility for others to enjoy the benefits of scientific progress and its applications."<sup>246</sup> In fact, the proposal of authors' rights to be included in the UDHR was not made by the Commission on Human Rights. It was the Third Committee of the General Assembly who promoted the inclusion, by an amendment.<sup>247</sup> The main reason for it was that UDHR article 17 covered property rights, but not intellectual property rights. On the other hand, also

---

<sup>243</sup>3D (Trade, Human Rights, Equitable Economy) *Intellectual Property and Human Rights: Is the Distinction Clear Now? An Assessment of the Committee on Economic, Social and Cultural Rights' General Comment No. 17 (2005) on "The Right of Everyone to Benefit from the Protection of the Moral and Material Interest Resulting from Any Scientific, Literary or Artistic Production on Which He is the Author"* Policy Brief No. 3, October 2006, p.3. Also available at < <http://www.3dthree.org/en/pages.php?IDcat=5> >, last visited on 10 January 2008.

<sup>244</sup> The American Declaration of the Rights and Duties of Man, O.A.S. Res. XXX, adopted by the Ninth International Conference of American States (1948) reprinted in Basic Documents Pertaining to Human Rights in the Inter-American System, OEA/Ser.L.V./II.82 doc.6 rev.1 at 17 (1992), article XIII.

<sup>245</sup> 3D (Trade, Human Rights, Equitable Economy) *supra* note 243, p.2.

<sup>246</sup> A. Eide, Asbjorn, *supra* note 18, p.296.

<sup>247</sup> Interestingly, the USA and the UK opposed the inclusion of authors' rights in the UDHR, arguing that copyright and related rights were not fundamental human rights. *See* 3D (Trade, Human Rights, Equitable Economy) *supra* note 243, p3

in the Third Committee there was disagreement on whether copyright and related rights could be considered human rights.<sup>248</sup>

One of the consequences of the disagreement among the Universal Declaration legislators was that the Third Committee declined from including the transferral of authors' rights to their inheritors, defeating a proposal presented by the Delegate of Ecuador in this respect. Indeed, it is doubtful that the inclusion of author's rights in the UDHR and in the ICESCR has represented major contributions to the field, as intellectual property rights had already different international agreements for their protection.<sup>249</sup>

Despite all the controversies, it is undisputable that author's rights, as a representation of intellectual property protection, are human rights. However, as already portrayed, the definition of intellectual property right is rather unclear,<sup>250</sup> and this field of law developed in almost absolute independence from the human rights theory, especially considering the forum-shifting on the discussion and regulation of intellectual property which occurred in the second half of the twentieth century.<sup>251</sup>

For instance, neither the Paris Convention nor the TRIPS Agreement contains reference to patent rights as a human right. The TRIPS Agreement actually refers to intellectual property merely as "private rights."<sup>252</sup> In both treaties, the principal justification for these agreements lies not in the deontological claims about inalienable liberties, but rather in the economic and instrumental benefits that flow from protecting intellectual property products across national borders.<sup>253</sup>

---

<sup>248</sup> R. Adalsteisson and P. Thórballson, *supra* note 112, pp. 578-579.

<sup>249</sup> A. Eide, *supra* note 18, p.296

<sup>250</sup> See Chapter 3.2

<sup>251</sup> See Chapter 3.3.2

<sup>252</sup> TRIPS Agreement, *supra* note 197, preamble.

<sup>253</sup> L. R. Helfer, 'Human Rights and Intellectual Property: Conflict or Coexistence?' *Minnesota Intellectual Property Review* 47, Vol. 5, number 1, (2003), pp 49-51.

In fact, the historical evolution and the actual stage of protection of IPR are an indication that not all intellectual property rights are human rights. This difference is even more sensible in regards to patents. Indeed, the plausibility of the argument that the whole of IPR is included in the human rights framework is seriously undermined by the fact of the forum-shifting from UNESCO, UNCTAD and WIPO – with their comprehensive mandate where human rights are central – to GATT and WTO, where intellectual property is treated solely as material property subjected to trade principles.<sup>254</sup>

### **3.4.3 General Comment No. 17: Establishing Criteria to distinguish IPR and Human Rights**

The difference between IPR as conceptualized by human rights instruments and IPR as established by international trade law<sup>255</sup> is the object of the CESCR General Comment 17 on the article 15(c) of the ICESCR.<sup>256</sup> Indeed, it aims at clarifying the meaning of author's rights, as recognized by the Covenant. Its drafting was undertaken in close cooperation with WIPO and, interestingly, its structure is similar to General Comment No. 14, on the right to health.<sup>257</sup>

The first two paragraphs of the General Comment stress the inherent difference between the nature of human rights and IPR. The Committee affirms that “Human rights are fundamental, inalienable and universal entitlements belonging to individuals and, under certain circumstances,

---

<sup>254</sup> J. Braithwaire and P. Drahos, ‘Global Business Regulation’, in J. Dine (ed.), *Companies, International Trade and Human Rights*, Cambridge University Press, 2005, p. 202.

<sup>255</sup> A. R. Chapman, Audrey R., *The Human Rights Implications of Intellectual Property Protection*, Journal of International Economy Law, Oxford University Press, 2002, Vol. 5, Issue 4, (2002) p. 867.

<sup>256</sup> The General Comment No. 17 is a follow up from the *Day of Discussion on article 15(c)*, held in 26 November 2001, and the *Human Rights and Intellectual Property: Statement by the Committee on Economic, Social and Cultural Rights*, December 14<sup>th</sup>, 2001, E/C. 12/2001/15.

<sup>257</sup> Haugen, *supra* note 145, p. 56.

groups of individuals and communities.”<sup>258</sup> “In contrast ... intellectual property rights are generally of a temporary nature, and can be revoked, licensed or assigned to someone else.”<sup>259</sup> Additionally, the Committee says that “Intellectual property regimes primarily protect business and corporate interests and investments. Moreover, the scope of protection of the moral and material interests of the author provided for by article 15, paragraph 1 (c), does not necessarily coincide with what is referred to as intellectual property rights under national legislation or international agreements.”<sup>260</sup>

The conclusion of paragraph two is that “It is therefore important not to equate intellectual property rights with the human right recognized in article 15, paragraph 1 (c).”<sup>261</sup>

A Committee member even affirmed that “we have stated that a very clear difference, that (intellectual property rights and human rights) are two very different concepts, because human rights are not subject to any negotiation, while the other is economic.”<sup>262</sup> Meanwhile the Committee’s Vice-President highlighted the difference between IPR and human rights by referring to the “changeable IP regimes.”<sup>263</sup>

While the statements above can be counterbalanced by the fact that human rights, even if non-negotiable, are in practice submitted to political discussion about their implementation and also to progressive realization, there is no doubt that IPR are not always a human right. The provision of ICESCR article 15(c) not only not coincides or includes TRIPS, but it also includes intellectual property rights that are not covered in the TRIPS Agreement. In fact, paragraph 32 of General Comment 17 affirms that States should adopt measures to ensure the effective protection of the

---

<sup>258</sup> CESCR General Comment 17, *supra* note 107, para. 1.

<sup>259</sup> CESCR General Comment 17, *supra* note 107, para. 2.

<sup>260</sup> CESCR General Comment 17, *supra* note 107, Para. 2.

<sup>261</sup> CESCR General Comment 17, *supra* note 107, Para. 3.

<sup>262</sup> H. M. Haugen, ‘General Comment No. 17 on “Authors’ Right’s, in *The Journal of World Intellectual Property*, Vol. 10, no. 1, (2007), p.58.

<sup>263</sup> *Ibid*, p. 66.

interests of indigenous peoples relating to their productions, which are often expressions of their cultural heritage and traditional knowledge.<sup>264</sup> Meanwhile, the TRIPS Agreement provides no protection for traditional knowledge.

Helfer argues that the Committee adopted an antagonistic approach to TRIPS.<sup>265</sup> However, it did not exclude that the requirements of article 15, paragraph 1(c) can be met by the standard intellectual property legislation.<sup>266</sup> In fact, it did not introduce a clear principle to make the distinction between “those rights derived from the efforts of intellectual and creative workers that fall within the scope of human rights protection, on the one hand, and those efforts that qualify for the more general intellectual property rights protection.”<sup>267</sup> Therefore, the task of how to differentiate when the IPR is simultaneously a human right is not always easy. Some substantive and procedural measures discussed in General Comment 17, though, help to face this task.

Following General Comment No. 17, especially the chapter that defines “authors”, the inclusion of an intellectual property right within the scope of the human rights protection depends on three main criteria:

1. The existence of a personal link between the author and his creation;

Even if IPR can - and in some cases should<sup>268</sup> - apply to groups of individuals or to a whole community,<sup>269</sup> “under the existing international treaty protection regimes, legal entities are included among the holders of intellectual property rights. However, as noted above, their entitlements,

---

<sup>264</sup> CESCR General Comment 17, *supra* note 107, para. 32.

<sup>265</sup> L. R. Helfer, *supra* note 253, p55.

<sup>266</sup> H. M. Haugen, *supra* note 262, p.58.

<sup>267</sup> H. M. Haugen, *supra* note 262., p.65

<sup>268</sup> It is the case of traditional knowledge.

<sup>269</sup> CESCR General Comment 17, *supra* note 107, para. 8.

because of their different nature, are not protected at the level of human rights.”<sup>270</sup>

Therefore, the link author-creation is essential to determine if the intellectual property right in question is a human right or a “right that serves the business and corporate interest and investment.”<sup>271</sup>

2. The necessity to uphold the human dignity of the author.

This criterion is a direct consequence of the first one and demonstrates the interdependence of human rights. Simply put, it is because human rights are “embedded in human dignity.”<sup>272</sup> Therefore, the intellectual protection shall be a tool that allows authors to achieve an adequate standard of living in dignity, as envisaged in the Universal Declaration of Human Rights articles 1 and 25.

IPR, to fall within human rights, does not need to reflect the level and means of protection found in today’s copyright and patents regime.<sup>273</sup> For instance, paragraph 16 affirms:

“the term of protection of material interests under article 15, paragraph 1 (c), need not extend over the entire lifespan of an author. Rather, the purpose of enabling authors to enjoy an adequate standard of living can also be achieved through one-time payments or by vesting an author, for a limited period of time, with the exclusive right to exploit his scientific, literary or artistic production.”<sup>274</sup>

3. The acknowledgement of the need for protection of the other human rights and to balance authors’ rights with other human rights.

The enjoyment of IPR must not make it more difficult for others to enjoy their human rights as well. This criterion derives both from the

---

<sup>270</sup> CESCR General Comment 17, *supra* note 107, para. 7.

<sup>271</sup> H. M. Haugen, *supra* note 262, p.57.

<sup>272</sup> H. M. Haugen, *supra* note 262, pp.65-66.

<sup>273</sup> CESCR General Comment 17, *supra* note 107, para. 10.

<sup>274</sup> CESCR General Comment 17, *supra* note 107, para. 16.

interdependence of human rights, and also from the indivisibility of human rights. The right of authors to benefit from the protection of the moral and material interests resulting from their scientific, literary and artistic productions cannot be isolated from the other rights recognised in the Covenant.<sup>275</sup> In fact, IPR, if not balanced, can amount to a direct violation of other human rights. IPR is not a violation of such rights only if the level of protection does not “unjustifiably limit the enjoyment by others of their rights under the Covenant.”<sup>276</sup>

In order to be included among the human rights framework, the intellectual property protection shall simultaneously fulfill these three criteria.

### **3.4.4 Applying the Criteria to Pharmaceutical Patent Protection**

The criteria above, identified within General Comment No. 17, does not present a totally clear distinction between IPR and human rights. Specifically in the case of copyrights, they are not completely helpful in setting the distinction between the human rights protection and the traditional intellectual property protection.

Nevertheless, concerning today’s standards of pharmaceutical patent protection, the criteria is clear enough<sup>277</sup> to affirm without any doubt that, at the present times, they do not fall within the human rights framework.

Nowadays, in order to create a new pharmaceutical, a complex and expensive structure is demanded. This is the main justification for the pharmaceutical patent protection in general and it is an argument strongly pursued by pharmaceutical companies in defence of their interests and as a

---

<sup>275</sup> CESCR General Comment 17, *supra* note 107, para. 35.

<sup>276</sup> CESCR General Comment 17, *supra* note 107, para. 35.

<sup>277</sup> Against: The 3D Organization criticized the CG 17 by affirming that it “fails to look at the current reality of scientific inventions and literary products as being almost wholly owned by corporations.” See 3D (Trade, Human Rights, Equitable Economy) *supra* note 243, p.5

link between pharmaceutical patent protection and the incentive to innovation and research for new medicines. Indeed, the complex organisation demanded for the creation of new medicines nowadays includes multinational corporations, universities, public research institutions and financial investors, sometimes all interlinked.

The facts stated above are the main reason why pharmaceutical patent protection does not fall within the human rights framework. Because of such complex structure, the link between the author and his creation cannot be established in the pharmaceutical field. Therefore, today's pharmaceutical patents do not fulfil the first criterion in order to be included in the human rights framework. Indeed, the individual scientist, if identified as the author of the innovation, may have a claim on the corporation, which the State should protect under Article 15 (c) of the ICESCR, but the corporation as such cannot use human rights as a justification for its claims to have a monopoly right to market and set the price of the product.

Since the second criteria is a direct consequence of the first one, and bearing in mind the non-fulfilment of the first criterion by the pharmaceutical patent protection, it is logical that the pharmaceutical patent protection does not fulfil the second criterion as well. Indeed, also as a result of the multifaceted structure of the pharmaceutical field nowadays, the creation of a new medicine can involve hundreds, maybe thousands of people. These people's capacity to achieve their highest standard of living does not depend directly from the pharmaceutical patent protection, but rather from their salaries, like any other employees. Although the pharmaceutical patent protection might reflect on their employment and finances, this is not enough of a link to fulfil the second criterion presented above.

Finally, the analysis of the fulfilment of the third criterion is more intricate to approach than the first two. It concerns the indivisibility and the balance of human rights. According to the principle of the indivisibility, the enjoyment of one human right cannot impede the enjoyment of the other

human right. As affirmed before,<sup>278</sup> the question of the balance between pharmaceutical patent protection and access to medicines is the core point in identifying a conflict between them, regardless if the pharmaceutical patent protection is a human right or not. For that reason, in order to analyse the fulfilment of this criterion, it is necessary to confront the substance of the pharmaceutical patent protection with the substance of other human rights, especially the right of access to medicines. It is necessary, for instance, to analyse how influential the Doha Declaration was. Furthermore, the findings of this analysis are actually findings about the existence or inexistence of conflict between the pharmaceutical patent protection and the right of access to medicines. Indeed, this criterion is more useful to identify a violation to the human right framework than it is to distinguish IPR and human rights.

However, the analysis of the link between authors and their creations and the link between pharmaceutical patent protection and the human dignity of the authors is enough to prove that the pharmaceutical patent protection do not fall within the human rights framework.<sup>279</sup> Therefore, the analysis of the relationship between pharmaceutical patents and the right of access to medicines is an analysis of the relationship between a human right and a trade-related right. This will be the approach for the analysis below.

---

<sup>278</sup> See sub-chapter 3.1

<sup>279</sup> See also 3D (Trade, Human Rights, Equitable Economy) *supra* note 243, pp. 5-6.

## **4 The Balance between Access to Medicines and Pharmaceutical Patent Protection**

In the last chapter, the pharmaceutical patent protection was historically and substantively introduced; its basic relationship and the legal standards regarding the right of access to medicines was presented; and it was concluded that it does not fall within the human rights regime of protection. Therefore, the relationship between the right of access to medicines and pharmaceutical patent protection is a relationship between a human right and a trade-related right.

After both rights have been clearly presented, the relationship between access to medicines and pharmaceutical patent protection can be better analysed, in order to: first, identify if there is a legal conflict between these rights; second, to describe the measures provided by international law to avoid or resolve such conflict; third to draw conclusions if such measures in practice provide a fair balance between the right of access to medicines and pharmaceutical patent protection.

### **4.1 Conflicts of Norms in International Law. Traditional and Broader Definition**

The international community has given greater attention to the notion of conflict between norms in recent years.<sup>280</sup> This interest is greatly welcomed, as the conclusion about the existence of a legal conflict between the right of access to medicines and pharmaceutical patent protection relies heavily on the definition of the conflict of norms in international law.

---

<sup>280</sup> H. Hestermeyer, *Human Rights and the WTO: the Case of Patents and Access to Medicines*, Oxford University Press, Oxford – UK, (2007), p. 174.

In general, legal norms can either accumulate or conflict with each other. A conflict of international laws has two basic features: the first is the existence of an *overlap* between two legal provisions, meaning that the norms have to be concurrent in some way.<sup>281</sup> This overlapping shall be *ratione materiae* (same subject matter), *ratione personae* (same State parties) and *ratione temporis* (same time).<sup>282</sup> The second feature is a *contradiction*, meaning that the norms need to contradict each other in order to establish a conflict. Putting these two features together, the notion of a conflict arises as a matter of *incompatibility* between international norms.

The existence of overlaps between international norms is not difficult to observe. For instance, the TRIPS Agreement and the ICESCR regarding right of access to medicines have provisions that clearly overlap. Both treaties bind most States at the same time and they apply to the same subject - medicines.<sup>283</sup> It is the presence of *contradiction* between norms that leads to disagreements between scholars.

The traditional notion of conflict relies on a strict definition of contradiction. Traditionally, a conflict of norms arises when “it is impossible to comply with all requirements of two norms.”<sup>284</sup> This traditional definition of conflict focuses solely on the direct incompatibility between norms, meaning that there is a conflict only when one treaty prohibits *all* manners by which the other treaty can be performed.<sup>285</sup> This definition is blind to the occurrence of indirect incompatibilities between norms. According to it, the existence of exclusions or exceptions in one treaty that overlaps with another is enough to prevent a conflict between them.<sup>286</sup>

---

<sup>281</sup> *Ibid*, p. 174.

<sup>282</sup> H. M. Haugen, *supra* note 145, p.104.

<sup>283</sup> H. Hestermeyer, *supra* note 280, p. 175.

<sup>284</sup> S. A. Sadat-Akhavi, *Methods of Resolving Conflicts Between Treaties*, Martinus Nijhoff Publishers, Leiden – The Netherlands, (2003), p.5.

<sup>285</sup> *Ibid*, p. 43.

<sup>286</sup> H. M. Haugen, *supra* note 145, p.103.

The traditional definition of conflict, however, is being challenged and perceived as unduly narrow.<sup>287</sup> It seems to be obsolete in order to consider the complexity of today's different international legal regimes, especially after the creation of the WTO. In fact, in order to harmonise the complex legal obligations arising from the multitude of international treaties, it seems essential that the notion of conflict between international norms takes into account both direct and indirect incompatibility between treaties.

Hence, several scholars apply a broader definition of conflict. Hestermeyer argues that “a norm that contains a permission, i.e. an option to take a certain course of action or not, is in conflict with a norm that commands or prohibits that course of action.”<sup>288</sup> Haugen recognizes that one of the approaches to determine the existence of conflict is to identify “if the *ability* of the State to adopt the measures prescribed by one treaty is impeded as a result of the measures it has to adopt under another treaty.”<sup>289</sup> Pauwelyn devoted an entire book to the analysis of conflict of norms in public international law, in which the broader definition of conflict of norms is applied. According to him, “there is a conflict of norms in case one norm breached, has led or may lead to breach of another norm.”<sup>290</sup>

From a conceptual point of view, both definitions of conflict are correct and both are internationally accepted. However, it seems clear that the broader definition is the most *appropriate* to analyse the relationship between access to medicines and pharmaceutical patent protection in depth. Indeed, Hestermeyer points out that:

“the definition of the notion of conflict depends largely on the purpose for which the definition is needed. Are we trying to identify cases in which one of the two norms can survive *or are we trying to identify cases in which the interference of two norms might limit the scope of one or both of them to some extent, remaining within the bounds of an appropriate interpretation?*”<sup>291</sup> (Emphasis added)

---

<sup>287</sup> H. Hestermeyer, *supra* note 280, p. 175

<sup>288</sup> H. Hestermeyer, *supra* note 280, p. 175.

<sup>289</sup> H. M. Haugen, *supra* note 145, p.103.

<sup>290</sup> J. Pauwelyn, *Conflicts of Norms in Public International Law. How WTO Law Relates to Other Rules of International Law*, Cambridge University Press, Cambridge – UK, (2004), p. 489.

<sup>291</sup> H. Hestermeyer, *supra* note 280, p. 179.

It is evident that the ICESCR and the TRIPS Agreement will continue to coexist and apply in their respective fields. The overlap between them will not cease. Additionally, this study does not intend to establish if one of them is *illegal*, but to address the balance between these two international norms, a balance that lies on the appropriate interpretation of each treaty. Hence, in order to address this balance in depth, one has to analyse not only if one provision prohibits the fulfilment of the other, but also if the measures of both provisions are well balanced, allowing both rights to be achieved in practice. It is appropriate, for this purpose, to apply the broader definition of conflict.

## **4.2 Is There a Legal Conflict Between Access to Medicines and Pharmaceutical Patent Protection?**

### **4.2.1 The ICESCR Requisites for Limitations to Economic, Social and Cultural Rights**

As observed in the previous chapters, the ICESCR and the TRIPS Agreement include very different provisions, with different goals, wording and levels of enforcement. It is evident that the TRIPS Agreement contains far more prohibitions than the ICESCR, especially considering its strong enforcement of intellectual property rights. Also, while the ICESCR leaves the decision on how the Covenants' obligations will be fulfilled in each particular case up to the States, the TRIPS Agreement is more detail-oriented and directly guides States regarding how to fulfil the obligations it establishes.

Nevertheless, the ICESCR also contains general prohibitions on State behaviour. Its articles 1.2 and 4 together establish four concomitant requisites for the legality of any limitation set to an economic, social and cultural right. They are the following:

1. To be determined by law;
2. To be compatible with the nature of these rights;
3. To have the purpose of promoting the general welfare in a democratic society;<sup>292</sup>
4. In no case may a people be deprived of its own means of subsistence.<sup>293</sup>

These limitations apply to all obligations deriving from the ICESCR. However, their interpretation differs depending if the limitation in question applies to obligations of progressive realisation or if they affect a minimum core obligation. Indeed, obligations of progressive realisation are submitted to resource constraint and are therefore subjected to more limitations and even to retrogressive steps towards their realisation.<sup>294</sup> Meanwhile, the minimum core obligations,<sup>295</sup> as the name says, are the minimum standard of each right. Hence, they are not subjected to resource constraints and any limitation to them is less justifiable in practice. In other words, limitations to the minimum core obligations are most probably incompatible with the nature of the rights and will likely deprive people of its own means of subsistence.

Bringing the context of ICESCR articles 1.2 and 4 to the balance between TRIPS and the ICESCR, two characteristics of these provisions are essential:

In the ICESCR:

- The emphasis on access;

---

<sup>292</sup> ICESCR, *supra* note 4, article 4.

<sup>293</sup> ICESCR, *supra* note 4, article 1.2.

<sup>294</sup> See CESCR General Comment No. 3, *supra* note 60, para. 9: “It thus imposes an obligation to move as expeditiously and effectively as possible towards that goal. Moreover, any deliberately retrogressive measures in that regard would require the most careful consideration and would need to be fully justified by reference to the totality of the rights provided for in the Covenant and in the context of the full use of the maximum available resources.”

<sup>295</sup> For instance, the right of access to essential medicines, according to the WHO Model List. See WHO Model lists, *supra* note 128.

- The ample margin of discretion for States' actions.

In the TRIPS Agreement:

- The emphasis on the rights granted to the right holders
- The narrow margin of discretion for State's actions

Observing the characteristics above, it is clear that the TRIPS Agreement acts as limitation to the ICESCR. Firstly, it limits the access emphasised by the ICESCR, by making it possible only under the conditions set by the IPR holders;<sup>296</sup> secondly, it limits the margin of discretion of States to observe their obligations under the ICESCR.

The affirmations above are in agreement with the position taken by the UN High Commissioner for Human Rights, which regarding the analysis of the balance between the TRIPS Agreement and human rights, published a Report on the Impact of the TRIPS Agreement on Human Rights.<sup>297</sup> The conclusions of that Report were brilliantly summarised by Haugen. "First, in the TRIPS Agreement, the subject matter of human rights is expressed only in terms of *exceptions*. Second, in the TRIPS Agreement there is no guidance on how to *balance* rights with obligations. Third, the TRIPS Agreement *impedes* on the ability of States to decide their own development strategy. Fourth, the TRIPS Agreement protects the knowledge and technology relevant for, and in a *manner* appropriate for, industrialized States. Fifth, the TRIPS Agreement is *silent* on the protection of the heritage and technology of local communities and indigenous people."<sup>298</sup>

In conclusion, the TRIPS Agreement acts as a limitation to the ICESCR regarding the relationship between the right of access to medicines and the pharmaceutical patent protection. Hence, it shall comply with the requisites

---

<sup>296</sup> H. M. Haugen, *supra* note 145, p. 101.

<sup>297</sup> United Nations High Commissioner for Human Rights, Report on the Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights, E/CN.4/Sub.2/2001/13.

<sup>298</sup> H. M. Haugen, *supra* note 145, p.101.

of articles 1.2 and 4 of the Covenant. TRIPS can be interpreted in a way that satisfies such requisites,<sup>299</sup> since international trade can be considered as a way to promote general welfare. Nevertheless, this compliance depends on how TRIPS is implemented by States.<sup>300</sup>

#### **4.2.2 Applying the Broad Definition of Conflict to the Relationship Between Access to Medicines and the Pharmaceutical Patent Protection**

The Doha Declaration on the TRIPS Agreement and the Right to Health meant that the TRIPS Agreement should be implemented in the light of the public health needs of individual Members States. In practice, however, TRIPS provides only *exceptions* in order to allow States some margin of discretion in addressing their health policies, while still observing their TRIPS obligations. These exceptions are the *only* provided way for States to implement TRIPS obligations in agreement with the ICESCR requisites explained above.

The strong IPR protection established by TRIPS is one of the main reasons why the pricing of medicines dramatically exceeds their production cost.<sup>301</sup> Its implementation makes virtually impossible for developing States to simultaneously comply with their obligations under the right of access to medicines *unless* they make full use of the exceptions provided by TRIPS and interpreted in Doha. Sometimes even that is not enough for a State to meet its obligations under the ICESCR. This fact turns the *permission* conferred by TRIPS into *obligations* to States, in order for them not to violate the ICESCR while implementing TRIPS.

---

<sup>299</sup> Against: Haugen argues, “The introduction of the TRIPS-compatible legislation does not fulfil the requirements of article 4 of ICESCR in order to justify any limitations on the exercise of the recognized human rights. Nevertheless, he understands that this does not prove the conflict between these treaties. *See* H. M. Haugen, *supra* note 145, p.105.

<sup>300</sup> UN High Commissioner for Human Rights, *supra* note 297, para. 28. *See also*, H. M. Haugen, *supra* note 145, p.101.

<sup>301</sup> L. Forman, *supra* note 204, p.347.

Even scholars who vehemently advocate the inexistence of a general conflict between the WTO regime and the human rights framework acknowledge this change in the meaning of the TRIPS Agreement - that States are *obliged* to adopt the *permission* established by TRIPS in order to comply with the ICESCR.<sup>302</sup> Under the broader definition of conflict adopted by this study,<sup>303</sup> however, it demonstrates that there is a conflict between the rights of access to medicines and the pharmaceutical patent protection.

This conflict is even also evident taking into consideration the limited power of developing States' markets to effectively gain from the protection of patents, as their markets do not produce enough incentives to stimulate the production of new medicines adapted to their specific needs.<sup>304</sup> Consequently, pharmaceutical companies, regardless of patent protection, normally neglect diseases that affect predominantly developing States.<sup>305</sup> In this particular scenario, the patent protection does not fulfil the prerequisite of having the purpose of promoting the general welfare in a democratic society. Hence, it is in direct conflict with the right of access to medicines.

Furthermore, TRIPS obligations are provided with very strong enforcement measures, while the economic, social and cultural rights are particularly weak regarding their enforcement.<sup>306</sup> In fact, the WTO, which administrates the TRIPS Agreement, contains the most effective enforcement mechanism in international law.<sup>307</sup> Violations to the TRIPS Agreement can engender substantial financial losses to States. On the other hand, ICESCR violations bring few more consequences than general international disapproval. Additionally, under TRIPS, the intended beneficiaries are generally external

---

<sup>302</sup> E. Petersmann, Introduction, 8(2) *Journal of International Economic Law*, (2005) p.347.

<sup>303</sup> See H. Hestermeyer, *supra* note 280, p. 175. "A norm that contains a permission, i.e. an option to take a certain course of action or not, is in conflict with a norm that commands or prohibits that course of action."

<sup>304</sup> WHO Report of The Commission on Intellectual Property Rights, Innovation and Public Health, WHO Publications, Geneva – Switzerland, (2006) p. 34.

<sup>305</sup> See Hunt, Paul, Report of the Special Rapporteur on the Right to Health, A/58/427, 10 October 2003, p.20.

<sup>306</sup> H. Hestermeyer, *supra* note 280, p. 205.

<sup>307</sup> H. Hestermeyer, *supra* note 280, p. 199.

corporations backed up by their home states; regarding human rights, the intended beneficiaries are individuals or groups inside the State, often vulnerable and without the backing of powerful external states. This makes the enforcement machinery much weaker for the latter.

The divergent level of enforcement explained above occurs regardless of the fact that human rights are an end in themselves, while the WTO regime is solely of utilitarian nature. It puts States parties to both treaties in an uncomfortable position. Hence, it is not unreasonable to argue that it may lead to States not fulfilling their obligation under the ICESCR, preferring, or rather being pressured to fulfil their obligations under the TRIPS Agreement.

The analysis above demonstrates that there is a legal conflict between the right of access to medicines and the pharmaceutical patent protection. Firstly, because TRIPS exceptions are to be interpreted as obligations under human rights instruments; secondly, because the protection of pharmaceuticals via patents does not generate general welfare in weaker markets; thirdly, because the stronger enforcement mechanism of the pharmaceutical patent protection according to TRIPS may lead States not to fulfil their ICESCR obligations.

### **4.2.3 The Legal Consequences of the Established Conflict**

This conflict established above does not mean that any of the rights are illegal or unjustifiable. It means that in practice, there needs to be an extra emphasis by the international community on the implementation and the interpretation of these rights, in order to avoid the unduly, incorrect or exaggerated precedence of one norm over the other.

The implementation and interpretation of both ICESCR and the TRIPS Agreement together should result in clear guidance for the simultaneous

fulfilment of the right of access to medicines and the pharmaceutical patent protection. Furthermore, in the case when a State cannot achieve the ideal level of protection for both rights, the joint interpretation of the ICESCR and the TRIPS Agreement cannot restrict the States' margin of discretion to balance the fulfilment of each right.

Indeed, the General Comments published by the CESCR, the Reports by the Special Rapporteur for the Right to Health, the WHO studies and the Doha Declaration on the TRIPS Agreements and the Right to Health, suggest that the aforementioned balance is to be achieved through a prevalence of the right of access to medicines, especially for the access for essential medicines, as defined by the WHO.

Therefore, bearing in mind the stronger enforcement mechanism enjoyed by pharmaceutical patents, addressing the conflict means making sure that this stronger mechanism acknowledges and effectively applies the general precedence of the right of access to medicines over pharmaceutical patent protection when both rights cannot be simultaneously achieved, providing legal and political strength to States willing to apply the aforementioned precedence.

### **4.3 International Law Tools for Addressing Conflicts of International Norms. The Vienna Convention on the Law of Treaties**

A conflict of international laws should be resolved by the tools provided by the international law itself, especially the general principals of the contractual freedom of states, *pacta sunt servanda* and *pacta tertiis*.<sup>308</sup> In fact, conflicts are not an extraordinary occurrence within international law, due to the absence of a centralised international lawmaker.

---

<sup>308</sup> J. Pauwelyn, *supra* note 290, p. 490.

In domestic law, conflicts of norms are normally decided by a superior judicial body, which can rely on the competing sources of the norms to solve the conflict. In international law, the sources of the different international obligations cannot constitute a foundation for a theory on conflicts of norms, as every international obligations is essentially a norm based upon State consent, which is their ultimate source. Therefore, in principle all international laws have the same binding force. Even the higher standing of *jus cogens* is unrelated to its source.<sup>309</sup> The precedence of one international norm over another is determined by the substance of each norm and by the provisions that each norm contains addressing its relationship with other international obligations.

The 1969 Vienna Convention on the Law of Treaties (VCLT) is probably the most important international agreement regarding guidelines for the interpretation of international law. Its article 30 presents the rules for the Application of successive treaties relating to the same subject matter. It states that:

1. Subject to Article 103 of the Charter of the United Nations,<sup>310</sup> the rights and obligations of States Parties to successive treaties relating to the same subject matter shall be determined in accordance with the following paragraphs.
2. When a treaty specifies that it is subject to, or that it is not to be considered as incompatible with, an earlier or later treaty, the provisions of that other treaty prevail.
3. When all the parties to the earlier treaty are parties also to the later treaty but the earlier treaty is not terminated or suspended in operation under article 59, the earlier treaty applies only to the extent that its provisions are compatible with those of the later treaty.
4. When the parties to the later treaty do not include all the parties to the earlier one:
  - (a) as between States Parties to both treaties the same rule applies as in paragraph 3;

---

<sup>309</sup> J. Pauwelyn, *supra* note 290, p. 488.

<sup>310</sup> The UN Charter article 103 affirms that the obligations under the Charter prevail over any other international obligations of UN State members. This clear guideline, however, is of little help in addressing the aforementioned conflict, since even if human rights clearly take precedence over trade obligations within the UN framework, the UN Charter is not the specific UN legal instrument that defines the right of access to medicines.

(b) as between a State party to both treaties and a State party to only one of the treaties, the treaty to which both States are parties governs their mutual rights and obligations.

5. Paragraph 4 is without prejudice to article 41, or to any question of the termination or suspension of the operation of a treaty under article 60 or to any question of responsibility which may arise for a State from the conclusion or application of a treaty the provisions of which are incompatible with its obligations towards another State under another treaty.<sup>311</sup>

The guideline provided by paragraph two above, is not completely adequate regarding the conflict between trade obligations and human rights. The TRIPS Agreement, article 73 on security exceptions does not acknowledge that TRIPS is subjected to human rights provisions. However, the combination of TRIPS Agreement articles 73 and 27.2 and the Doha Declaration on the TRIPS Agreement and the Right to Health, suggests that, at least in the case of the aforementioned conflict, the VCLT article 30(2) guideline might be applicable for countries experiencing extreme human right threats.

Indeed, under article 73 the only exceptions to the fulfilment of TRIPS obligations are the cases below:

(a) to require a Member to furnish any information the disclosure of which it considers contrary to its essential security interests; or

(b) to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests;

(i) relating to fissionable materials or the materials from which they are derived;

(ii) relating to the traffic in arms, ammunition and implements of war and to such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment;

(iii) taken in time of war or other emergency in international relations; or

---

<sup>311</sup> The Vienna Convention on the Law of Treaties (VCLT), signed in Vienna on 23 May 1969, *entered into force* on 27 January 1980. United Nations, *Treaty Series*, vol. 1155, p. 331.

(c) to prevent a Member from taking any action in pursuance of its obligations under the United Nations Charter for the maintenance of international peace and security.<sup>312</sup>

More specifically to the protection of patents, TRIPS Agreement article 27.2 affirms:

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.<sup>313</sup>

According to Petersmann, the right of States to exclude inventions from patent protection in the TRIPS Agreement is a human rights obligation.<sup>314</sup> Indeed, article 27.2 acknowledges that human rights might be relevant in order to justify an exception to a trade obligation,<sup>315</sup> but only under the requirements of State security, morality and *ordre public*. Hence, unless these requirements are interpreted in a very broad way,<sup>316</sup> it cannot be concluded that the TRIPS Agreement is subjected to the ICESCR in general terms. Nevertheless, article 27.2 gives strength to the argument that pharmaceutical patent protection, specifically, is subjected to the fulfilment of the right of access to medicines, according to the guidelines of the VCLT article 30, paragraph 2.

The other guidelines provided by the VCLT article 30 are less important in the case under debate. Regarding article 30.3, it has to be noted that the parties of the ICESCR and the TRIPS Agreement are not necessarily the same. The right of access to medicines is also defined in several other human rights instruments. The pharmaceutical patent protection is also

---

<sup>312</sup> TRIPS Agreement, *supra* note 197, article 73.

<sup>313</sup> TRIPS Agreement, *supra* note 197, article 27.2.

<sup>314</sup> E. Petersmann, *supra* note 302, p.34, footnote 29. *See also* H. M. Haugen, *supra* note 145, p. 107.

<sup>315</sup> H. M. Haugen, *supra* note 145, p. 107.

<sup>316</sup> Hestermeyer suggests this as a solution for the conflict. *See* H Hestermeyer, *supra* note 280, p. 289.

established via multiple bilateral agreements. Hence, the rule of paragraph 3 does not adequately apply.

Furthermore, the rule established by paragraph 4 of the article 30 of the VCLT cannot apply to a conflict of international laws that includes human rights. Due to the fact that human rights are of a universal and indivisible nature, they cannot be interpreted differently between States that have entered in different agreements.

Applying the VCLT to the relationship between the TRIPS Agreement and the ICESCR, it cannot be concluded that, in general, one of the agreements shall be given precedence over the other. On the other hand, it can be inferred that pharmaceutical patent protection is subjected to the fulfilment of the right of access to medicines, at least in situations of an extreme threat to human rights.

Finally, beyond the rules addressing conflict of laws, the rules of the interpretation of treaties provided by article 31 of the VCLT fully apply to the conflict discussed here, especially the principle that both treaties shall be interpreted in good faith;<sup>317</sup> and that the interpretation of the treaties shall take account of any relevant rules of international law applicable in the relations between the parties.<sup>318</sup>

Other principles also derive from the combination of the VCLT and customary law. These principles which are referred to later also have the VCLT as its source. Scholars also point out specific principles that shall apply to the conflict between human rights and trade obligations. For instance, the principle of the most favourable provision in the field of human rights;<sup>319</sup> the principle of cumulative application of instruments on dispute settlement;<sup>320</sup> the maximum effectiveness in the field of private

---

<sup>317</sup> VCLT, *supra* note 311, article 31, para. 1.

<sup>318</sup> VCLT, *supra* note 311, article 31, para. 3(c).

<sup>319</sup> S. A. Sadat-Akhavi, *supra* note 284, pp. 213-231.

<sup>320</sup> S. A. Sadat-Akhavi, *supra* note 284, pp. 232-239.

law;<sup>321</sup> the priority of treaties relating to special matters;<sup>322</sup> the principle of fair interpretation of rules;<sup>323</sup> and the principle of honest implementation.<sup>324</sup> Finally, the Doha Declaration on the TRIPS Agreement and Public Health, as have been seen here, also provide for interpretation tools for addressing the aforementioned conflict.

In conclusion, the VCLT puts some light in the relationship between access to medicines and pharmaceutical patents. In case of the aforementioned conflict, it cannot be concluded that one norm prevails over the other. From the combination between the VCLT and the TRIPS provisions, it can only be concluded that human rights conventions shall be used to clarify and to interpret the WTO law,<sup>325</sup> but how exactly this must happen is rather unclear and sometimes disorienting. More specifically, although there is a clear indication that the right of access to medicines takes precedence over pharmaceutical patent protection, it is unclear how this precedence takes place in practice, as the same norm that affirms such precedence also dictates requisites that might nullify the same precedence.

## **4.4 The WTO and Conflicts Between Trade and Human Rights: The WTO Dispute Settlement System**

### **4.4.1 Overview**

As previously mentioned, pharmaceutical patents are enforced by a stronger enforcement mechanism than the right of access to medicines. This

---

<sup>321</sup> S. A. Sadat-Akhavi, *supra* note 284, pp. 238-239.

<sup>322</sup> S. A. Sadat-Akhavi, *supra* note 284, p. 244.

<sup>323</sup> R. Prabhash, 'International Trade and Human Rights: Conflicting Obligations', in T. Cottier, J. Pauwelyn and E. Bürgi (eds.) *Human Rights and International Trade*, Oxford University Press, Oxford – UK, (2005), p. 320.

<sup>324</sup> *Ibid*, p.320.

<sup>325</sup> R. Prabhash, *supra* note 323, p.319.

mechanism is the WTO integrated dispute settlement system, which is basically composed of the Dispute Settlement Body and the Appellate Body.

The integrated WTO dispute settlement system was established by the Understanding on Rules and Procedures Governing the Settlement of Dispute (DSU)<sup>326</sup> which composes the Annex 2 of the Agreement Establishing the World Trade Organization and is binding to all WTO members.<sup>327</sup> According to Petersmann, the DSU is definitely a broader jurisdiction than the previous GATT procedures.<sup>328</sup>

Although it cannot be positively affirmed that a definitive balance between access to medicines and pharmaceutical patent protection will be drawn by the DSU, its influence on the subject is undeniable and it is at least probable that it will decide on complaints regarding the subject. To say the least, its influence on the behaviour of States is unquestionable. The binding nature of its decisions, its short timeframe and its strengthened mechanism of surveillance and enforcement of WTO rulings decisively influence State's behaviour. Indeed, "one of the most notable developments since the establishment of the WTO has been the increased propensity for parties to reach mutually agreed solutions to disputes".<sup>329</sup>

Therefore, it is ultimately essential to analyse how human rights in general, and the right of access to medicines, in particular, is to be applied by the DSU.<sup>330</sup>

---

<sup>326</sup> Understanding on Rules and Procedures Governing the Settlement of Dispute (DSU), in The WTO Dispute Settlement Procedures: a Collection of Relevant Legal Texts, WTO Secretariat, Second Edition, Cambridge – UK, (2001), p. 1-32.

<sup>327</sup> Marrakesh Agreement, *supra* note 198, article II:2.

<sup>328</sup> E. Petersmann, *Studies in Transnational Economic Law, Volume 11: International Trade Law and the GATT/WTO Dispute Settlement System*, Kluwer Law International, London – UK (1999), p.55.

<sup>329</sup> P. Steger, Debra P. and S. M. Hainsworth, 'New Directions in International Trade Law: WTO Dispute Settlement', in J. Cameron, K. Campbell (eds.) *Dispute Resolution in the World Trade Organization*, Cameron May, London – UK, (1998), p. 33-34.

<sup>330</sup> It is not unanimous, however, that the WTO should apply human rights and draw the balance between human rights and trade. See Sol, Picciotto, *Private Rights Vs. Public Interests in the TRIPS Agreement: the Access to Medicines Dispute*, Presentation to the Annual Conference of the American Society of International Law, Washington DC, 2nd-5th April 2003, Panel on "Is the International Trade Régime Fair to Developing States?"

#### **4.4.2 The Principles that Counterbalance the Factual Precedence of the WTO Regime. Towards an Acceptance of the Precedence of Human Rights Over Trade Obligations?**

The establishment of the WTO regime is responsible for most of the recent international attention to the definition of conflict in international law. Its exceptional breadth puts it into a prominent position regarding conflicts of international norms.

In fact, there is hardly any regime with which the WTO might not potentially come into conflict with,<sup>331</sup> making the WTO regime extraordinarily vulnerable to conflict. Almost every trade regulation has the potential to affect other branches of international law, such as environmental law and human rights. The opposite is also true.<sup>332</sup>

Legally speaking, the WTO does not establish precedence over other international law. In fact, in contrast to the UN Charter, in the event of a conflict between WTO provisions and other international provisions, WTO law will not always prevail, even if the question is before a WTO panel.

---

Published in 97 ASIL Proc. 167 (2003), p.5. Also available at <http://www.lancs.ac.uk/staff/lwasp/asil2003.pdf>, last visited on 10 January 2008. Picciotto Sol argues, "Ultimately, how the balance is struck between different conflicting rights-claims must be decided by democratic deliberation. For a supra-national adjudicative body to evaluate the validity of regulations adopted by national democratic states, on the basis of its perception of the proper balance of private rights of individuals, gives insufficient emphasis to democratic decision-making. An important proposal has been made in this respect by Laurence Helfer, for the adoption of the principle of the 'margin of appreciation' in WTO practice and jurisprudence, especially in relation to the TRIPS.<sup>8</sup> This aims to restore a better balance between the local/national and global/international levels of governance. It is notable that although some of the WTO's trade-remedy rules articulate a standard of review which does provide leeway for national state judgements, this is not present in the TRIPS".

<sup>331</sup> Hestermeyer quotes several treaties with which the WTO might conflict. See H. Hestermeyer, *supra* note 280, p. 200.

<sup>332</sup> H. Hestermeyer, *supra* note 280, p. 200.

However, in the absence of a clearer hierarchy between international laws, the sheer power of the WTO enforcement mechanism puts the WTO regime in a factually superior position than most other legal regimes.

Hence, other rules of international law apply to the WTO not only in cases of conflict, but also as a mean of interpretation and limitation of WTO law itself. A conclusion otherwise would mean that, in practice, WTO rules are superior to any other international rules, simply due to its more effective enforcement mechanism. It would be the law of the strongest international regime, surpassing any harmonising or integrative principle of international law.

In contemporising the strength of the WTO regime, the principles of the presumption of continuity and the precedence of obligations of integral nature over obligations of reciprocal nature are key elements of harmonisation.

The principle of the presumption of the continuity of laws means that all new law must be seen in the context of pre-existing law. According to it, pre-existing norms apply to any new treaty unless the new treaty “contracts out” of it. The principle provides a tool of interpretation for the new law.<sup>333</sup> The principle of the precedence of obligations of integral nature over obligations of reciprocal nature, on the other hand, is a logical tool of interpretation, based on the substance of each norm.

It is following this principle that Pauwelyn concludes:

“It shows that in most cases conflict between, for example, human rights and environmental conventions (generally setting out obligations of “integral type”), on the one hand, and the WTO obligations (of the “reciprocal type”), on the other hand, WTO provisions will have to give way. This will be so either on the basis of the rules resolving “inherent

---

<sup>333</sup> J. Pauwelyn, *supra* note 290, p. 488.

normative conflict” (in particular, the fact that *inter se* deviations from integral obligations are “illegal”) or rules resolving “conflict in the applicable law.”<sup>334</sup>

Nevertheless, the conclusion above, which establishes a general prevalence of human rights over trade rights, is very controversial. In a response to it, Trachtman observed:

“It seems quite incorrect to say that WTO law is generally trumped by international environmental, human rights or labor agreements. Rather, in the general international legal system, we are stuck with the messy and often normatively incoherent rules of *lex posterior*, as reflected in Article 30 of the Vienna Convention, and questions about how multilateral treaties may be modified by custom or by other multilateral treaties with different membership under Articles 41 and 58 of the Vienna Convention.”<sup>335</sup>

In truth, before the TRIPS Agreement, the GATT article XX-b offered an attractive solution for conflicts between WTO and other regimes, by offering general exceptions to the GATT. If the other regime was among the exceptions listed by article XX, the GATT solved the conflict in favour of the non-trade regime.<sup>336</sup> In this sense, the GATT explicitly accounted for the possibility of non-trade values overriding GATT rules.<sup>337</sup> However, an analogous article is not to be found in the TRIPS Agreement.

The debate above demonstrates that despite the arguable moral superiority of human rights and the factual superiority of trade rights, it is not

---

<sup>334</sup> J. Pauwelyn, *supra* note 290, p. 491.

<sup>335</sup> J. P. Trachtman, ‘Reviewed work: Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law, by Joost Pauwelyn’, *The American Journal of International Law*, Vol. 98, No. 4, (2004), p. 860.

<sup>336</sup> See GATT, *Supra* note 193, article XX. It affirmed general exceptions to the trade regime. Article XX General Exceptions: “Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: (b) necessary to protect human, animal or plant life or health.”

<sup>337</sup> H. Hestermeyer, *supra* note 280, p. 201.

consensual that in cases of conflicts between human rights and trade obligations within WTO dispute settlement system, the first will receive prevalence as a rule. The conflicts between trade and any other international legal provisions will be decided following specific guidelines applying to each subject matter. For instance, in the conflict between access to medicines and pharmaceutical patent protection, the Doha Declaration on the TRIPS Agreement and the Right to Health can be such guidance.

#### **4.4.3 Applying Human Rights in Practice Within the WTO Framework**

Not only is the general precedence of human rights over trade obligations in the WTO regime very controversial, the mere use of human rights conventions within the WTO panels and appellate body is a controversial subject as well, as the jurisdiction of WTO panels and the Appellate Body are limited to claims exclusively under WTO covered agreements.<sup>338</sup> The DSU article 7.1 very clearly prohibits human rights to be used as a legal basis for claims within the WTO dispute settlement regime. Nevertheless, there is now a consensus about the use of human rights as a valid defence within the WTO adjudication regime.<sup>339</sup>

The application of human rights law within WTO Panels and the Appellate Body as a defence argument is accepted even by the opponents of a general precedence of human rights over trade-related rights. For instance, Trachtman, while fundamentally opposing Pauwelyn's conclusion about the relationship between WTO law and human rights, acknowledges that "the only law that WTO panels and the Appellate body are authorised to apply (directly) is WTO law."<sup>340</sup> In other words, he acknowledges that other branches of law might indirectly apply. Hence, it is not necessary to expand the mandate of the WTO for it to take account of other non-trade concerns.

---

<sup>338</sup> DSU, *supra* note 326, article 7.1.

<sup>339</sup> J. Pauwelyn, *supra* note 290,, p. 491.

<sup>340</sup> J. P. Trachtman, *supra* note 335, p.858.

Until this day, there is not a specific precedent from a WTO Panel or the Appellate Body effectively deciding that the right of access to medicines can indeed be used as a defence argument by a State under a claim of having breached the pharmaceutical patent protection. However, in the *Asbestos Case*, the Appellate Body decided that health concerns are a valid defence for the overruling of a WTO obligation.<sup>341</sup> More importantly, in this case the DSU made clear that WTO members are free to determine the level of health protection they want to attain.<sup>342</sup>

In conclusion, there is a consensus that human rights can be used by the WTO panels and Appellate Bodies, but exclusively as a defence argument for the breaching of WTO norms. This conclusion is in agreement with the tone of the Doha Declaration on the TRIPS Agreement and the Right to Health, which gives some precedence to the public health concern over the TRIPS Agreement.

It is possible that the WTO dispute settlement system might in specific cases brought to its attention decide in favour of access to medicines over pharmaceutical patent protection in borderline situations. The interpretational tools are provided by international law and should be used in the WTO context, even to promote a “stretched” interpretation of the TRIPS Agreement, allowing a more favourable approach to human rights in trade, in order to counterbalance the factual precedence enjoyed by trade obligations nowadays. The conflict can therefore be solved, at least legally.

---

<sup>341</sup> European Communities-Measures Affecting Asbestos and Asbestos-Containing Products. WT/DS135R, Panel Report, September, 18, 2000.

<sup>342</sup> *Ibid*, paragraph 168.

## **4.5 Conclusion: The Insufficiency of International Law Guidelines to Promote the Fair Balance and to Affect States' Practice**

As portrayed in this study, while it is undisputable that the pharmaceutical industry has a legitimate commercial interest in the medicine market, the protection of this legitimate right does not fall within the human rights protection and it in fact conflicts with the right of access to medicines.

The establishment of this conflict, far from resulting in the illegality of any treaty, presents a challenge to the international community and to the conduct of States. To the international community the challenge is to provide clear and effective legal guidance to States. To States the challenge is to fulfil their obligations under both sets of obligations in a balanced way, without this resulting in unjustifiable violations of trade or human rights obligations.

The CESCR General Comments, the Reports from the Special Rapporteur for the Right to Health, the WHO studies and the Doha Declaration give a clear precedence to the right of access to medicines, especially to essential medicines, over pharmaceutical patent protection. The application of the article 30(2) of the VCLT to the aforementioned conflict strengthens this conclusion.<sup>343</sup> This precedence might even prevail in the WTO dispute settlement system. Nevertheless, it cannot be argued in order to establish complaints in the DSU, but solely as a defence argument.

The conclusions above, however, are insufficient to provide a fair balance between access to medicines and pharmaceutical patent protection. Indeed, the TRIPS flexibilities do not acknowledge the political and economic difficulties that are inevitably involved in their use. The lack of implementation of the TRIPS flexibilities proves that this legal tools are

---

<sup>343</sup> See Chapter 3.

insufficient in order to solve the discussed conflict, even within the WTO framework. First, they do not decisively influence States' behaviour to apply the general precedence of access to medicines over pharmaceutical patent protection. Second, they do not protect States that desire to apply these flexibilities from the extra-legal factors that are intrinsically linked to this decision. The TRIPS Agreements, as demonstrated by the patent legislation evolution,<sup>344</sup> is a result of strong debate, bargain and, ultimately, political and economic power. The international community cannot pretend that these factors do not influence its application.

Indeed, in a recent interview, the Brazilian national director for STD and AIDS prevention, Ms. Mariângela Simão, did not refer to international law when pointing out the reasons for the success of the Brazilian AIDS Prevention Program. Instead, the reasons were the following:

- The State's precocious implementation of a free and universal distribution programme of cutting-edge, newly developed medicines for the treatment of HIV-AIDS;
- The universality of prevention campaigns, regardless of societal taboos;
- The Brazilian society pressure, bearing in mind that the HIV-AIDS pandemic started in Brazil as a disease of the middle-class, who are more able to pursue their rights.<sup>345</sup> (translated from the original in Portuguese)

Furthermore, when asked about the reasons and the effects of the Brazilian use of the TRIPS flexibilities,<sup>346</sup> again, there is no mention of international law:

---

<sup>344</sup> See Chapter 3.

<sup>345</sup> Folha de São Paulo, December 1st, 2007. Also at [www.folha.uol.com.br/folha/ciencia/ult306u350225.shtml](http://www.folha.uol.com.br/folha/ciencia/ult306u350225.shtml), last visited on 10 January 2008.

<sup>346</sup> *Ibid.* Brazil recently established the compulsory licence for the antiretroviral "efavirenz", produced by Merck and used for HIV-AIDS treatment. The State was paying US\$ 1,59 for each unit before the compulsory licence and the pharmaceutical company

“This is only possible because Brazil has negotiation power and a firm policy. Brazil is an important State marketwise. Proof of this is that *Merck*, even facing the compulsory license of Efavirenz, asked for the registry of another AIDS medicine in Brazil and another big pharmaceutical company, *Janssen Cilag*, introduced a new AIDS medicine in Brazil this year, *Darunavir*.”<sup>347</sup> (Translated from the original in Portuguese)

Obviously, the statements above do not carry the same relevance as a scientific work. Ultimately, it is a politician’s statement. Nevertheless, as mentioned before, politics play a decisive role in this subject and therefore cannot be overlooked. The statements are a clear indication that for countries that lack a big market or political power, the guidelines provided by international law nowadays might be not enough to balance the factual stronger enforcement, by political and economic pressure, of pharmaceutical patents, even if they are willing to do so.

In fact, pharmaceutical patent protection is now commonly included in Free Trade Agreements and in Bilateral Investment Treaties, often with even stronger terms than the ones provided in the TRIPS Agreement. These trade agreements are usually referred to as “TRIPS-plus”. They indicate that developed States, particularly the United States of America are shifting negotiations from the WTO to the bilateral and regional fora.<sup>348</sup> Indeed, since 2001 the USA has negotiated 11 bilateral and regional trade agreements with 23 States.<sup>349</sup> The European Union has also signed and is negotiating similar agreements.<sup>350</sup>

Analysing one of these agreements, the Special Rapporteur to the Right to Health also emphasised the influence of political and economic pressure over developing countries and recommended:

---

lowest offered was US\$ 1,56. After the compulsory license, Brazil is spending US\$ 0,44 per unity.

<sup>347</sup> *Ibid.*

<sup>348</sup> H. Hestermeyer, *supra* note 280, p. 289.

<sup>349</sup> C. M. Correa, ‘Public Health Review: Implications of Bilateral Free Trade Agreements on Access to Medicines’, *Bulletin of the World Health Organization (BLT)*, Volume 84, number 5, May, (2006), p.399.

<sup>350</sup> *Ibid.*, p.404, footnote c.

“The United States should not apply pressure on Peru to enter into commitments that are inconsistent with Peru’s constitutional and international human rights obligations, or by their nature are “WTO-plus”.<sup>351</sup>

Carlos Correa affirmed that these agreements represent a “drastic setback” and that they not only undermined the TRIPS flexibilities but “impose a number of additional obligations on states that can further restrict their access to medicines.”<sup>352</sup> He adds:

“Although the FTAs that have been discussed here are too recent to be able to assess fully their effects on public health, their higher standards of protection will, by their very nature, delay or restrict generic competition and thereby reduce access to medicines. Accepting those standards negates the letter and spirit of the Doha Declaration, and will limit the capacity of States to progressively realize the human right to health.”<sup>353</sup>

In conclusion, the legal measures discussed in the present charter to solve the conflict between access to medicines and the pharmaceutical patent protection fail in providing a clear legal guidance to decisively influence States’ practices and to ultimately provide a fair balance between the right of access to medicines and pharmaceutical patent protection.

There is still a very clear gap that needs to be interlinked between human right and trade. The difficulty is that, in the words of Paul Hunt, there is basic difference between trade law and human rights:

“while some trade and development theorists accept that there will be some “losers” in the process of trade liberalization and development, but this can be justified through the overall gains to welfare, a human rights approach focuses on protecting the rights of all, particularly the potential “losers”, and seeks to design policies accordingly.”<sup>354</sup>

---

<sup>351</sup> Hunt, Paul, Report Submitted by the Special Rapporteur on the right to health, Mission to Peru, E/CN.4/2005/51Add.3, February 4th, 2005, p. 15.

<sup>352</sup> C. M. Correa, *supra* note 349, p. 400.

<sup>353</sup> C. M. Correa, *supra* note 349, p. 404.

<sup>354</sup> Hunt, Paul, Report Submitted by the Special Rapporteur on the right to health , E/CN.4/2004/49Add.1, March 1<sup>st</sup>, 2004, p. 14.

## 5 Access to Medicines and the Pharmaceutical Industry: Towards Corporate Social Responsibility

The production of medicines could be properly characterised as an industry on the beginning of the 19<sup>th</sup> Century.<sup>355</sup> The pharmaceutical industry has grown to be one of the largest industries in the world today, becoming both politically and economically important, having a decisive influence over people's life and health. Recently, however, the pharmaceutical industry has been targeted by international organisations, NGOs, developing countries and even developed States for their lack of contribution to the achievement of the right of access to medicines.

This chapter presents how the conflict between the protection of intellectual property rights and the right to health has challenged the pharmaceutical industry in, representing a source of pressure and criticism. Furthermore, it explains what Corporate Social Responsibility (CSR) is. In addition, it presents a critical overview on how CSR is being applied by the pharmaceutical industry. Finally, it presents the recently released UN Special Rapporteur's Draft Human Rights Guidelines for Pharmaceutical Companies.

---

<sup>355</sup> J. K. Crellin, 'Pharmaceutical history and its sources in the Wellcome Collections. I. The growth of professionalism in nineteenth-century British pharmacy, *11(3) Medical History Journal*. (1967). Also available at: <http://www.pubmedcentral.nih.gov/pagerender.fcgi?artid=1033727&pageindex=1#page>, last visited on 10 January 2008..

## 5.1 The Effect of the Legal Evolution of the Intellectual Property Protection on the Pharmaceutical Industry's Reputation

The strengthening of the pharmaceutical patent protection via the TRIPS Agreement occurred while large parts of the world, especially developing countries, were facing the spread of the HIV-AIDS pandemic. This fact undeniably represented a major achievement for the pharmaceutical industry, a sector heavily based on the protection of patents. However, it also enhanced the perception of the TRIPS Agreement as a threat to programs aiming at controlling of the HIV-AIDS pandemic. Consequently, the pharmaceutical industry has also been perceived as a threat to the public health concern. Indeed, not only TRIPS, but also the pharmaceutical industry is strongly criticised by several developing countries, which argued that they were placed in an even weaker position in their struggle to fight against pandemics and to protect and fulfil the right of access to medicines.

Furthermore, the pharmaceutical industry reactions against successful and reference programs and health-concerned laws from Brazil and South Africa added to the widespread opinion that the industry lacked a minimum human-rights perspective. Specifically, by the end of the *South Africa case*,<sup>356</sup> even acknowledging the pharmaceutical industry withdrawal, the damage to the image of the industry was noteworthy. Rarely such a strong consensus against a particular industry has been seen in world history.

It was in this context that in November of 2001 the Doha Declaration on the TRIPS Agreement and the Right to Health was adopted. This Declaration clarified the powers each State has in pursuing their health policies. Almost simultaneously, on the UN forum, the CESCR General Comment No. 14 on the right to the highest attainable standard of health used an unprecedented

---

<sup>356</sup> *Treatment Action Campaign et al. V. Minister of Health et al*, High Court of South Africa, *supra* note 218.

stronger wording, claiming for the responsibility of all the international community, including non-States actors,<sup>357</sup> to act in coordinated efforts for the achievement of the right to health.<sup>358</sup>

Finally, in 2005, General Comment No. 17 from CESCR used an even stronger wording to express that intellectual property regimes primarily protect business and corporate interests and investments.<sup>359</sup> This is the only time the Committee has expressed what is not a human right until today.

As such, the pharmaceutical industry's firm position in strengthening its intellectual property rights was not without its costs. The industry has faced a crescent opposition, which received an ever-growing legitimisation by international institutions, human rights bodies and respected NGOs. As a result, although the international obligation of private entrepreneurs are not clearly defined or clarified in international law, the pharmaceutical industry felt the need to react to the general public opinion by implementing policies emphasising their awareness and their contribution to human rights, particularly to the right of access to medicines. There is, indeed, a clear effort by the industry to be seen as a socially responsible industry.

## 5.2 Corporate Social Responsibility. What is it?

There is still no precise definition of what CSR really means. It is generally acknowledged as a product of globalisation, although it has existed ever since large corporations appeared in the United States.<sup>360</sup> The Dow Jones Sustainability Index understands it as *a business approach that creates*

---

<sup>357</sup> CESCR General Comment 14, *supra* note 2, para. 63-65.

<sup>358</sup> T. Barret and A. Whiteside, *AIDS in the Twenty-First Century – Disease and Globalization*, Palgrave Macmillan, Hampshire, 2003, pg 282.

<sup>359</sup> CESCR General Comment 17, *supra* note 107, para. 2.

<sup>360</sup> R. Mares, *Corporate Responsibilities – Their Incremental Institutionalisation*, Martinus Nijhoff Publishers, Dordrecht - The Netherlands, forthcoming 2008, p 3.

*long-term shareholder value by embracing opportunities and managing risks deriving from economic, environmental and social developments.*<sup>361</sup>

Regardless of the lack of precise definition, CSR is undeniably a growing *movement* in the beginning of the 21<sup>st</sup> century. Many initiatives are aiming at establishing the bridge between profit-making and sustainable development.

The United Nations has contributed with its own CSR initiatives, adding credibility and legitimacy to the movement. The UN Global Compact is one of the pioneer actions in trying to bring companies together with UN agencies, labour organisations, and civil society to support human rights, the environment and social principles.<sup>362</sup> Its ten non-binding principles in areas of human rights, labour, the environment and anti-corruption represent at least a minimum consensus about business policies.<sup>363</sup>

Additionally, in 2003, the Sub-Commission on the Promotion and Protection of Human Rights produced the *UN Norms on the Responsibility of Transnational Corporations and Other Business Enterprises with Regard to Human Rights*,<sup>364</sup> and in 2005 the Secretary General appointed John Ruggie as *Special Representative on Human Rights and Transnational Corporations and Other Business Enterprises*. His mandate, which is still ongoing, includes, among other objectives, the definition of standards of corporate responsibility and business accountability with regard to human rights; the clarification of the role of States regarding regulation and CSR; the clarification of the implications for transnational corporations and other

---

<sup>361</sup> *Ibid*, p. 3.

<sup>362</sup> What is the UN Global Compact? Available at <http://www.unglobalcompact.org/AboutTheGC/index.html>, last visited on 10 January 2008.

<sup>363</sup> *Ibid* For instance, the principles regarding human rights ask companies to (1) support and respect the protection of internationally proclaimed human rights and (2) make sure that they are not complicit in human rights abuses. Also important is the anti-corruption principle, which demands business to work against corruption in all forms, including extortion and bribery.

<sup>364</sup> UN Norms on the Responsibility of Transnational Corporations and Other Business Enterprises with Regard to Human Rights, U.N. Doc. E/CN.4/Sub.2/2003/12/Rev2 (2003).

business enterprises on concepts such as “complicity” and “sphere of influence.”<sup>365</sup>

Another main “builder” of CSR is the Organization for Economic Cooperation and Development (OECD) which as far back as 1976 produced the *OECD Guidelines for Multinational Enterprises*.<sup>366</sup> The Guidelines were revised in 2000 and deal with a wide range of topics, such as disclosure regulation, environment, combating bribery, consumer interests, science and technology, competition and taxation.

These international institutions might be the most important, but are far from being alone in the attempt of injecting a socially, environmentally and human rights accountable reasoning into the business area. The International Labour Organization, for instance has its own standards. Other initiatives, such as the Fair Labour Organization, are also progressing well.<sup>367</sup> Furthermore, other important endeavours are under development, like the ISO 26000, which will be an international Standard for Social Responsibility.<sup>368</sup>

In a sense, CSR relates to business the same way that human rights-based development relates to States. They are both attempts to remind these public and private actors to consider their human rights obligations, not only in order to comply with the UDHR and the ICESCR, but also to be sustainable in terms of growth and profitability.

Bearing in mind these undeniably important initiatives and its predominant human rights background, it cannot be forgotten that, as pointed out by the Down Jones Sustainable Index, CSR is still a “business approach”. Hence,

---

<sup>365</sup> Office of the High Commissioner For Human Rights, Human Rights Resolution 2005/69 on Human Rights and Transnational Corporations and Other Business, U.N. Doc E/CN.4/2005/L.87 (2005).

<sup>366</sup> Organization for Economic Co-operation and Development (OECD), Guidelines For Multinational Enterprises, available at <http://www.oecd.org/dataoecd/56/36/1922428.pdf>, last visited on 10 January 2008.

<sup>367</sup> Information available at [www.fairlabor.org](http://www.fairlabor.org), last visited on 10 January 2008.

<sup>368</sup> Information available at <http://isotc.iso.org>, last visited on 10 January 2008.

in order to be effective it has also to be reasoned within the company law perspective.

At first, CSR faced severe opposition from more dogmatic business and economic theorists, the most famous being Milton Friedman, who considered the only social obligation of companies was to generate and maximize profit for shareholders. Since then, the Stakeholders Theory has tried to respond to this opposition, but the debate over the theoretical basis of CSR still remains in the business academia.

For the purposes of this thesis, however, what is essential is to understand that CSR is intrinsically related with the *duty of care* within the *managerial duty* of businesspersons. This duty of care includes four main elements, which collaborate to the independent business judgement:<sup>369</sup>

- Loyalty solely towards the interest/success of the company;
- Long-term perspective of business success;
- Inclusive view of the relationship with stakeholders;
- Sound processes for decision-making, allowing well-informed and fast decisions.

Hence, what CSR implies is the inclusion of social, environmental and human rights as key factors to the success of the company; to its long-term goals; to the relationship between the company and its stakeholders; and to the enhancement of the decision-making process. The inclusion of these factors occurs within a business approach. What CSR brings to company law are means to manage new risks that today's corporations have to acknowledge, especially due to the growing awareness and mobilisation of the global community regarding human rights and the environment. For instance, NGO's and the civil society are nowadays prompt to defame companies and to seek for informal sanctions due to neglecting of human rights, labour and environmental standards, which can undeniably affect the

---

<sup>369</sup> R. Mares, *supra note* 360, pg 63.

companies' profit. Businesspersons cannot neglect these factors anymore. It is, indeed, inside their *managerial duties*.

The management of the factors and risks described above, however, takes place without any enforcement mechanism. CSR has developed mostly through a combination of voluntarism and soft-law.

In this context, companies are pursuing recognition as socially responsible enterprises through a myriad of ways, some more effective than others. Distinguishing them is a difficult endeavour. Standard setting proposals like the Human Rights Compliance Assessment, elaborated by the Danish Institute of Human Rights<sup>370</sup> and the currently under development ISO 26000 can be a general guidance in approaching this confusion.<sup>371</sup> They might help as an orientation and as a parameter to distinguish socially responsible companies from others which simply aim at “surfing” in the CSR trend.

### **5.3 The Implementation of CSR in the pharmaceutical sector.**

In most regards, CSR applies to pharmaceutical industries in the same way it applies in other business' fields. All major pharmaceutical companies have long noticed the impact and the risks their bad reputation has brought to them. Hence, nowadays they struggle to present themselves as socially responsible companies.

A visit to the websites of the ten biggest pharmaceutical industries shows that all of them provide extensive information about their CSR policies. This information is normally placed in prime spots of each website. Indeed,

---

<sup>370</sup> Danish Institute for Human Rights, Human Rights Compliance Assessment, available at [http://www.humanrightsbusiness.org/040\\_hrca.htm](http://www.humanrightsbusiness.org/040_hrca.htm), last visited on 10 January 2008.

<sup>371</sup> Other examples of management and CSR assessment systems are the SIGMA guidelines and the FORGE guidance.

a strong emphasis is given to the CSR programmes and there are reiterated references to ethical research and development, patient assistance programs, caring for the community, corporate citizenship, care for animals, philanthropy, etc.<sup>372</sup>

However, the analysis of the pharmaceutical companies CSR programs can be an overwhelming and misleading experience if one forgets most of these programs were implemented at the same time as the companies were deeply involved in the less-than-human-rights-concerned developments on the international trade legislation. An article on *The Economist* magazine about CSR starts by affirming that “if you believe what they say about themselves, big companies have never been better citizens.”<sup>373</sup> It seems, then, that a hint of scepticism is welcomed when analysing such programs.

In truth, the relationship between CSR and the pharmaceutical industry is very complex, especially when it concerns access to medicines. Applying business reasoning, the challenge faced by the pharmaceutical industry resembles a dilemma: how to keep the progressively more expensive and risky processes of developing new drugs and, simultaneously, make these drugs more accessible to people? This question remains complex from a CSR perspective: how to facilitate the access to medicines, making way for the effective observation of the right to health and improving the industry’s

---

<sup>372</sup> Source of the ranking: <http://www.pharmaceuticalsales.org/pharmaceutical-resources.php#top20>, last visited on 10 January 2008.

The top 10 pharmaceutical companies websites according to the 2004 sales, all last visited at ( ), 2007:

- Pfizer: <http://www.pfizer.com/pfizer/main.jsp>
- Johnson and Johnson: <http://www.jnj.com/home.htm>
- GlaxoSmithKline: <http://www.gsk.com/>
- Novartis: <http://www.novartis.com/>
- Hoffman LaRoche: <http://www.roche.com/home.html>
- Merck: <http://www.merck.com/>
- AstraZeneca: <http://www.astrazeneca-us.com/>
- Sanofi-Aventis: <http://www.sanofi-aventis.us/live/us/en/index.jsp>
- Abbot : <http://www.abbott.com/>
- Bristol-Meyers Squibb: <http://www.bristolmyerssquibb.com/landing/data/index.html>.

<sup>373</sup> *In Search of the Good Company: The Social Debate About the Social Responsibilities of Companies if Heating Up Again*, *The Economist* magazine, September 6<sup>th</sup>, 2007, New York – USA.

reputation while still maintaining the industry's necessary profitability? These questions expose once again the conflict between the pharmaceutical industry and the right of access to medicines. Although difficult, the answers should be pursued by both States and industries.

The international legal regime provides incentives to all parties to collaborate in the balance between corporate profit interests and the public interest for the access to medicines. In fact, even if there is no mechanism to enforce CSR in the pharmaceutical sector, the exceptions to TRIPS – compulsory license and parallel import – represent a serious financial risk to the pharmaceutical industry. In a context where the companies do not have any public support, this risk is enhanced. It undeniably provides for a strong incentive for the introduction of social responsible reasoning among the managerial duties of the pharmaceutical businesspersons.

Hence, in dealing with the complex decision-making of developing, marketing, pricing and distributing medicines, pharmaceutical businessmen should be concerned with the States' financial capacity to pay for these medicines and also to the global need for the same drugs. In doing so, from a company law perspective, they are minimising the risk of revenue losses due to the breaking of a pharmaceutical patent. It is, therefore, an exercise of the duty of care.

If on the one hand, the TRIPS Agreement offers an "incentive" to CSR implementation in the pharmaceutical sector, on the other hand it established an open conflict between the two main actors for a more human rights-based approach to business: States and private companies. In this scenario, the establishment of public-private partnerships, which is one of the most successful and sustainable ways of promoting CSR,<sup>374</sup> is not intelligently stimulated.

---

<sup>374</sup> See UN Millennium Development Goals, available at <[www.un.org/millenniumgoals/](http://www.un.org/millenniumgoals/)> last visited on 10 January 2008. The establishment of public-private partnerships was included in the UN Millennium Development Goals No. 8, which affirms: "In cooperation

As a result, public-private partnerships initiatives are still not a rule in the pharmaceutical sector,<sup>375</sup> although some initiatives are successful, as the Gilead Access Program.<sup>376</sup> Additionally, agreements on regional level, regional pricing tiers and networks for antiretrovirals show that there are creative ways to make drugs available while still supporting innovation.<sup>377</sup>

Furthermore, the implementation of CSR in the pharmaceutical industry has also shown specific problems. It has not been holistically implemented in the companies. Even if all major pharmaceutical companies advertise their corporate social responsible activities, the Special Rapporteur to the right to health points out that “few make specific references in their corporate mission statements to human rights in general or the right to health in particular. Even fewer appear to have carefully examined their policies through the lens of the right to the highest attainable standard of health.”<sup>378</sup>

Also serious is the confusion between CSR and philanthropy in the pharmaceutical sector. Most of the CSR initiatives in the pharmaceutical sector are not more than philanthropic initiatives, which create only limited expectations.<sup>379</sup> This is because first, there are no guarantees regarding the sustainability of such philanthropic programmes; second, these philanthropic actions can be easily used as another pressure tool for States not to use all the exceptions provided by TRIPS and clarified by the Doha Declaration. Indeed, pharmaceutical philanthropic programs might be simple acts of reluctant compromise made by pharmaceutical companies to

---

with the pharmaceutical companies, provide access to affordable essential drugs in developing countries.”

<sup>375</sup> G. Atul, *Pharmaceutical Companies Should 'Broaden' Efforts To Provide Access to Antiretrovirals, Other Drugs in Developing Countries*. News from the Kaiser Network. Available at [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?DR\\_ID=44966](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=44966) last visited on 10 January 2008.

<sup>376</sup> Information available at <http://www.gileadaccess.org/wt/page/welcome>, last visited on 10 January 2008.

<sup>377</sup> G. Atul, *supra* note 375.

<sup>378</sup> Hunt, Paul, *supra* note 62, p.20.

<sup>379</sup> B. Freeman, *To What Extent Can Voluntarism Provide Answers?*, Wilton Park Conference on Business and Human Rights, 11 October 2005. [www.reports-and-materials.org/Bennett-Freeman-Wilton-Park-11-Oct-2005.doc](http://www.reports-and-materials.org/Bennett-Freeman-Wilton-Park-11-Oct-2005.doc), last visited on 10 January 2008.

avoid negative State measures towards their monopolies and profit. More importantly, there might be compromises which can prevent evolutions on the international law regarding access to medicines, by avoiding new binding legal limitations on their monopolies and activities,

In reality, the pharmaceutical industry has the largest lobby before the American Congress.<sup>380</sup> Such power of political pressure on the largest global economy is an indicator of the power the industry has over less developed States. Therefore, unless CSR is implemented in the whole industry – not just by a single department in each company - it is definitely not certain that these philanthropic programmes might not be used as an instrument of additional pressure against States, undermining their position once again.

The facts above are the main reasons for the mixed perception CSR programmes in the pharmaceutical industry have received from human-rights advocates and scholars. For instance, according to Celine Chaveriat, Oxfam's Make Trade Fair Director, philanthropic programmes, although welcomed, are not "a sustainable way of providing medicines." She concludes that "corporate philanthropy has its place, but generic competition is the proven way of keeping drug prices affordable".<sup>381</sup> Furthermore, also according to Oxfam, "compulsory licensing almost never occurs because developing countries face pressure from rich governments acting on behalf of their drug companies."<sup>382</sup>

---

<sup>380</sup> Aaron C, Lincoln T. *The other drug war 2003: Drug companies deploy an army of 675 lobbyists to protect profits*. Washington (DC): Public Citizen Congress Watch; June 2003. Available at [www.citizen.org/documents/Other\\_Drug\\_War2003.pdf](http://www.citizen.org/documents/Other_Drug_War2003.pdf), last visited on 10 January 2008.

<sup>381</sup> See Oxfam website, available at [http://www.oxfam.org.uk/applications/blogs/pressoffice/2007/01/novartis\\_lawsuit\\_threatens\\_acc.html?searchterm=access+to+medicine](http://www.oxfam.org.uk/applications/blogs/pressoffice/2007/01/novartis_lawsuit_threatens_acc.html?searchterm=access+to+medicine), last visited on 10 January 2008.

<sup>382</sup> Klapper, Bradley's, Associated Press: WHO Presses Development of Cheap Drugs, available at <http://www.forbes.com/feeds/ap/2007/05/23/ap3752158.html>, last visited on 10 January 2008.

The Special Rapporteur to the right to health expressed hope, but also concern about the present of CSR in the pharmaceutical sector. In a 2006 Report he affirmed:

“States and other have criticized the pharmaceutical sector setting prices too high, erratic drug donations, imbalanced research and development, lobbying for TRIPS-plus standards, inappropriate drug promotion, problematic clinical trials, and other practices that are seen to obstruct the State’s ability to discharge its right to health responsibilities. However, States and other have also commended some significant progress in recent years, such as the more widespread use of differential pricing, predictable and sustainable drug donations, and a renewal commitment to research and development into neglected diseases.”<sup>383</sup>

In the scenario presented above, CSR can either strengthen or weaken the effective achievement of the right of access to medicines. The importance of its proper implementation cannot be overestimated. Without a doubt, it will be one of the most important elements regarding access to medicines worldwide, for better or worse. After all, pharmaceutical companies possess the strongest potential to promote the right of access to medicines. CSR might be the tool to make this potential a reality.

## **5.4 The Draft Human Rights Guidelines for Pharmaceutical Companies**

As evidenced above, CSR is an undisputable reality in the corporative world, including the pharmaceutical sector. So much that according to Simon Zadek, head of AccountAbility, a CSR lobby group, “The ‘whether in principle’ conversation about CSR is over. What remains is ‘what, specifically, and how?’”<sup>384</sup>

The reasoning above concurs with the opinion of the Special Rapporteur to the right to health, which in September 2007 launched the *Draft Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to*

---

<sup>383</sup> Hunt, Paul, *supra* note 62, p. 19

<sup>384</sup> The Economist, *supra* note 373.

*Medicines*. In the press release, it was affirmed that “It is time to identify what pharmaceutical companies should do to realize the human right to medicine.”<sup>385</sup>

The Draft Guidelines are designed to “help pharmaceutical companies, as well as monitoring their activities.”<sup>386</sup> It will remain in draft until 31 December 2007, during this period the international community has been invited to make comments on the Guidelines. As such, the document is still subject to changes before its conclusion, probably in 2008. Even as a draft, the Guidelines demonstrate very clearly how broad is the influence of the pharmaceutical industry in the respect, protection and fulfilment of the right of access to medicines. The *Introductory Note* acknowledges the importance of the right of access to medicines and presents the legal framework, emphasising that the responsibilities towards the right of access to medicines are not exclusively of States.<sup>387</sup>

The Guidelines provide several practical principles to be considered by pharmaceutical companies when implementing CSR. They are divided in “overlapping categories”<sup>388</sup> encompassing general acknowledgement of human rights obligations;<sup>389</sup> effective, transparent and accessible internal monitoring and accountability mechanisms;<sup>390</sup> reflection of health concerns in the context of the pharmaceutical companies advocacy and lobbying;<sup>391</sup> compromise to research and develop medicines for neglected diseases;<sup>392</sup> recognition, respect and application of the right to public health, especially for the most disadvantaged, in the policies regarding protection of patents;<sup>393</sup> concern for quality of medicines and technology transfer to low-

---

<sup>385</sup> United Nations Press Release, *UN Independent Expert Launches Draft Human Rights Guidelines for Pharmaceutical Companies*, 19 September 2007.

<sup>386</sup> *Ibid*, p. 1

<sup>387</sup> Hunt Paul, *Draft for Consultation: Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines*, Introductory Note, p.1-3.

<sup>388</sup> *Ibid*, p.3

<sup>389</sup> *Ibid*, Guidelines 1 to 6

<sup>390</sup> *Ibid*, Guidelines 7 to 11.

<sup>391</sup> *Ibid*, Guidelines 12 to 14.

<sup>392</sup> *Ibid*, Guidelines 15 to 18.

<sup>393</sup> *Ibid*, Guidelines 19 to 26.

income and middle-income States;<sup>394</sup> policies regarding pricing, discounting and donations, which have to be disclosed and transparent;<sup>395</sup> transparent and ethical promotion and marketing of medicines;<sup>396</sup> respect for medical ethics and the principle of informed consent regarding clinical trials;<sup>397</sup> transparency and consistency of pharmaceutical companies' participation on public-private partnerships;<sup>398</sup> anti-corruption policies;<sup>399</sup> participation on associations of pharmaceutical companies;<sup>400</sup> and implementation of external monitoring and accountability systems.<sup>401</sup>

It is early to analyse each of the provided guidelines, as they are still submitted to changes.<sup>402</sup> It is, however, essential to notice how broad the Guidelines are, covering the whole activity of the pharmaceutical industry, from the production of medicines, to their political participation. The Guidelines significantly enhance the quality of the debate over CSR in the pharmaceutical sector. They mean not only guidance, but also a way to differentiate pharmaceutical companies' actions. Their implementation by pharmaceutical companies might be one of the most important contributions provided by the Special Rapporteur to the right to health during his entire mandate. It can be the missing link providing a balance between corporate interest and the right of access to medicines. A balance that, as analysed in Chapter 4, the international legal community still has not found. Therefore, it is very likely that the upcoming years will see an intense and enriched debate over the implementation of CSR in the pharmaceutical sector.

---

<sup>394</sup> *Ibid*, Guidelines 27 and 28.

<sup>395</sup> *Ibid*, Guidelines 29 to 33.

<sup>396</sup> *Ibid*, Guidelines 34 and 35.

<sup>397</sup> *Ibid*, Guidelines, 36 to 38.

<sup>398</sup> *Ibid*, Guidelines 39 to 42.

<sup>399</sup> *Ibid*, Guidelines 43 and 44.

<sup>400</sup> *Ibid*, Guidelines 45 and 46.

<sup>401</sup> *Ibid*, Guidelines 47 and 48.

<sup>402</sup> The full text of the Draft Guidelines is provided as a Supplement annexed to this thesis.

## 5.5 Conclusion

CSR is still a concept under construction. In the pharmaceutical sector, the criticism towards the industry and the damage it caused to the industry's reputation has pressured for a fast implementation of CSR initiatives. This "under-pressure implementation" of CSR in the pharmaceutical sector contributes to its lack of a holistic view.

Until now, the industry seems not to have realised that CSR demands a new way of reasoning for the companies, which cannot be achieved simply by the establishment of a CSR department. The focus of companies in philanthropic programs is a consequence of this fact.

Although philanthropy is welcomed for the achievement of the right of access to medicines, especially in the least-developed States, it is definitely not enough. Additionally, it did not help to rebuild the industry's reputation. The picture has not changed much since the establishment of the TRIPS system, with developing States and pharmaceutical industry seemingly to be on opposite sides of the field. This scenario presents risks to the industry and does not contribute for an enhanced access to medicines.

Ultimately, it is clear that the degree to which corporations can be constrained and are likely to implement CSR in their activities depends on the availability, strength and feasibility of countermeasures in the hands of States and the civil society to pressure them. This leads to the conclusion that the development of CSR is not a substitute for the evolution and creation of new international legal mechanisms towards access to medicines. CSR is necessarily, a consequence of the international law. The more defined and clear is the law, the more advanced is the implementation of CSR.

Hence, fundamental changes are still on demand, regardless of the implementation of CSR in the pharmaceutical sector. Changes are needed in

the world trade system and in its relation to the human rights regime, which needs to provide States with a clearer guidance towards both IPR and human rights. Changes in the behaviour of States, which need to implement a more human rights-based approach to development. Changes in the pharmaceutical industry, which needs to be more effectively socially responsible. Finally, changes in the relationship between all these international actors are required, which might struggle for stronger and more sustainable partnerships for the fulfilment of the right of access to medicines.

On a positive side, there is much room for improvements and developments regarding CSR in the pharmaceutical sector, if the sector embraces the spirit of CSR wholeheartedly. Hopefully, the upcoming years might see some of the necessary changes regarded above to start happening.

## 6 Conclusion

The right of access to medicines, especially the right of access to essential medicines, is in the process of becoming one of the most specific and well-defined economic, social and cultural rights. It has a clear normative content and, additionally, the progressive and immediate obligations are clearly set. More importantly, the access to essential medicines is included in the immediate obligations, creating an entitlement for people and prohibiting States not to fulfil such obligation on the excuses of resource constraints, as proven in the chapter two of this thesis.

However, almost two billion people still lack access to essential medicines, a third of the global population.<sup>403</sup> In developing countries, in a universe of five to six million people that need HIV-AIDS life-saving antiretroviral medicines, only three hundred thousand people receive it.<sup>404</sup> In Africa, more than 90% of the children infected with HIV-AIDS do not have access to the antiretroviral medicines they urgently need.<sup>405</sup> These facts alone denote that the right of access to medicines is far from global accomplishment, despite its clear set-up.

The disparity between access to medicines in high-income, middle-income and low-income States is abysmal. The WHO estimates that 15% of the world's population consumes over 90% of the world's production of pharmaceuticals.<sup>406</sup> Furthermore, the spending on pharmaceuticals represent less than 20% of total public and private health spending in developed countries, while it represents up to 66% in developing countries.<sup>407</sup> Indeed,

---

<sup>403</sup> Hunt, Paul, *supra* note 62, p. 15.

<sup>404</sup> WHO Medicines Strategy: Countries at the Core 2004-2007, WHO/EDM/2004.5, original English version, p. 15.

<sup>405</sup> Hunt, Paul, *supra* note 62, p. 23, footnote 30.

<sup>406</sup> WHO Medicines Strategy: Countries at the Core 2004-2007, *supra* note 404, p. 15.

<sup>407</sup> WHO Access, Quality and rational Use of Medicines and Essential Medicines, available at [www.who.int/medicines/services/essmedicines\\_def/en/index.html](http://www.who.int/medicines/services/essmedicines_def/en/index.html), last visited at 10 of January of 2007.

in most low-income States, pharmaceuticals are the largest expenditure on health after personnel costs.<sup>408</sup>

Nevertheless, despite the present reality and the strong set of obligations regarding access to medicines, the right does not find the same prevalence in international law outside the boundaries of human rights treaties. Particularly, as demonstrated in chapters three and four, the legal standing and the relationship between access to medicines and pharmaceutical patent protection is not clear enough to provide a clear and uniform legal guidance to States in order to balance both obligations.

In other words, international law and the international community are currently failing to protect the right of access to medicines. Particularly, they fail in empowering developing States in attempting to fulfil their human rights obligations.

Regardless, there have been extraordinary advances in the struggle for a fair balance between access to medicines and pharmaceutical patent protection and for a wider fulfilment of the right of access to medicines. The ICESCR General Comment 17, the establishment of a Special Rapporteur for the right to health, the Doha Declaration on the TRIPS Agreement and the Right to Health, and the recent developments on Corporate Social Responsibilities in the pharmaceutical sector are some of the most notorious advances, even if, as portrayed in chapter 5, the CSR in the pharmaceutical sector is still in a very early stage.

One factual characteristic of the right of access to medicines is the key to understand the advances cited above: *the right of access to medicines is extremely media-sensitive*. Despite the lack of enforcement that weakens the entire set of economic, social and cultural rights, the right of access to medicines is mostly enforced by a closely unanimous and strong global support. Traditional human rights techniques, such as “naming and

---

<sup>408</sup> *Ibid.*

shaming” have been particularly successful concerning access to medicines. Without this media sensibility and global support, the recent advances on the right of access to medicines cannot be understood.

As it stands, it is this moral and ethical standing of the right of access to medicines, together with the urgency implied on the subject, that provide the principal means of enforcement and evolution of the right. The international law, particularly the international trade law, is lacking behind.

# Reference List

## Books

- Alfredsson, Gudmundur and Eide, Asbjørn  
*The Universal Declaration of Human Rights, A Common Standard of Achievement*, Martinus Nijhoff Publishers, The Hague – The Netherlands, (1999).
- Barret, Tony and Whiteside, Alan  
*AIDS in the Twenty-First Century – Disease and Globalization*, Palgrave Macmilan, Hampshire, (2003).
- Basso, Maristela  
*O Direito da Propriedade Intelectual*, Editora Livraria do Advogado, Porto Alegre – Brazil, (2000).
- Bently, Leonel and Sherman, Brad  
*Intellectual Property Law*, Oxford University Press, Oxford – UK, (2002).
- Cottier, Thomas, Pauwelyn, Joost, Pauwelyn and Bürgi, Elisabeth (eds.)  
*Human Rights and International Trade*, edited by Thomas Cottier, Joost Pauwelyn and Elisabeth Bürgi, Oxford University Press, Oxford – UK, (2005).
- Dine, Janet (ed.)  
*Companies, International Trade and Human Rights*, Cambridge University Press, Cambridge – UK, (2005).
- Bugbee, Bruce W  
*Genesis of American Patent and Copyright Law*, Public Affairs press, Washington D.C. – USA, (1967).
- Cameron, James and Campbell, Karen (eds.)  
*Dispute Resolution in the World Trade Organization*, Cameron May, London – UK, (1998)
- Chapman, Audrey R. and Sage, Russell  
*Core Obligation: building a Framework for Economic, Social and Cultural Rights*, Intersentia Publishers, Schoten – Belgium, (2002).

- Cornish, William and Llewellyn, David *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, Sweet & Maxwell Limited, London – UK, 6<sup>th</sup> edition, (2007).
- Correa, Carlos M. *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, Publications of the World Health Organization Geneva – Switzerland, (2002).
- Correa, Carlos M. *Integrating Public Health Concerns into patent legislation in developing countries*, South Centre Publication, Geneva – Switzerland, (2000).
- Daves, Gillian *Modern Legal Studies. Copyright and the Public Interest*, Sweet & Maxwell Limited, London – UK, (2002).
- Eide, Asbjørn, Krause, Catarina and Rosas, Allan (eds.) *The right to health in Economic, Social and Cultural Rights*, Kluwer law, Martinus Nijhoff Publishers, Dordrecht - The Netherlands, (2001).
- Gervais, Daniel *The TRIPS Agreement: Drafting History and Analysis*, Sweet and Maxwell Limited of, London – UK, (2003).
- Hestermeyer, Holger *Human Rights and the WTO: the Case of Patents and Access to Medicines*, Oxford University Press, Oxford – UK, (2007).
- Jacob, Robin, Alexander, Daniel and Jane, Lindsay *A Guidebook to Intellectual Property. Patents, Trade Marks, Copyrights and Designs*, Sweet and Maxwell, London – UK, 5<sup>th</sup> edition, (2004).
- Lehman, Fabrice *The Trade Debate Needs the Voice of Business*, *International Trade Forum*, issue 1, (2006), p 13.

- Kaufer, Erich *The Economics of the patent System*, Harwood Academic Publishers, Chur – Switzerland, (1989).
- Kennedy, Daniel L. M. and Southwick, James D. (eds.) *The Political Economy of International trade Law: Essays in Honor of Robert E. Hudec*, Cambridge University Press, Cambridge – UK, (2002).
- Mares, Radu *Corporate Responsibilities – Their Incremental Institutionalisation*, Martinus Nijhoff Publishers, Dordrecht - The Netherlands forthcoming 2008.
- Pauwelyn, Joost *Conflicts of Norms in Public International Law. How WTO Law Relates to Other Rules of International Law*, Cambridge University Press, Cambridge – UK, (2004)
- Petersmann, Ernst-Ulrich *Studies in Transnational Economic Law, Volume 11: International Trade Law and the GATT/WTO Dispute Settlement System*, Kluwer Law International, London – UK (1999).
- Ryan, Michael P *Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property*, the Brookings Institution Press, Washington D.C. – USA, (1998).
- Sadat-Akhavi, Seyed Ali, *Methods of Resolving Conflicts Between Treaties*, Martinus Nijhoff Publishers, Leiden – The Netherlands, (2003)
- Shue, Henry *Basic Rights, Subsistence, Affluence and U.S. Foreign Policy*, Princeton University Press, 2<sup>nd</sup> sub edition, USA, (1996).
- Stephen, Elias and Stim, Richard *Patent, Copyright and trademark. An Intellectual Property Right Reference*, Nolo and Richard Stim, 7<sup>th</sup> edition, Berkeley – USA, (2004).

Webster, Andrew and Katryn,  
Packer

*Innovation and the Intellectual Property System*, Kluwer Law International, The Hague – The Netherlands, (1996)

Wise, Jacqui

Access to AIDS medicines stumbles on trade rules, *Bulletin of the World Health Organization*, volume 84, number 5, may, (2006), pp. 337-424.

## Articles

Abbot, Frederik M,

Abbot, Frederik M, The Doha Declaration on the TRIPS Agreement and Public Health: Lightning a Dark Corner at the WTO, *Journal of International Economic Law*, June Issue (2002), pp. 469-505.

Chapman, Audrey R.

A Human Rights Perspective on Intellectual Property, Scientific Progress, and Access to the Benefits of Science, in *Intellectual Property and Human Rights, A Panel Discussion to Commemorate the 50<sup>th</sup> Anniversary of the Universal Declaration of Human Rights*, organised by WIPO and UN High Commissioner for Human Rights, Geneva, November 9, 1998. pp. 81-130.

Chapman, Audrey R.

The Human Rights Implications of Intellectual Property Protection, 5(4) *Journal of International Economic Law*, (2002), pp. 861-882.

Correa, Carlos M.

Public Health Review: Implications of Bilateral Free Trade Agreements on Access to Medicines, *Bulletin of the World Health Organization (BLT)*, Volume 84, number 5, May, (2006), pp. 399-404.

Forman, Lisa

Trade Rules, Intellectual Property, and the Right to Health, *Ethics &*

- International Affairs*, Vol. 21, Issue 3, (2007), Blackwell Publishing, pp. 337-357.
- Haakonsson, Stina jessen and Richey, Ann      TRIPS and Public Health: The Doha Declaration and Africa', *Development and policy review*, issue 25, Blackwell Publishing, Oxford – UK, (2007), pp. 71-90.
- Haugen, Hans Morten      General Comment No. 17 on "Authors' Rights, *The Journal of World Intellectual Property*, Vol. 10, no. 1, (2007) pp.53-69.
- Haugen, Hans Morten      Patent Rights and Human Rights: Exploring their Relationship, *The Journal of World Intellectual Property* (2007) Vol. 10, no. 2, pp. 97-124.
- Helfer, Laurence R.      Human Rights and Intellectual Property: Conflict or Coexistence? *Minnesota Intellectual Property Review*, 47, Vol. 5, number 1, (2003), pp. 47-61.
- Hoen, Ellen T      TRIPS, Pharmaceutical Patents and Access to Essential Medicines: A Long Way from Seattle to Doha. *Chicago Journal of International Law*, vol.3, no.1, spring, (2002), pp. 41-75.
- Hogerzeil, Hans V, Samson, Melanie, Casanovas, Jaume Vidal and Rahmani-Ocara, Ladan.      Is Access to Essential Medicines as part of the Fulfilment of the Right to Health Enforceable Through the Courts? 368 *Lancet (British Edition)* (2006) pp. 305-311.
- Jellinek, Marian and Markham, Stephen      Industry-University IP Relations: Integrating Perspectives and Policy Solutions, 54:2 *IEEE Transactions on Engineering Management*, (May 2007).
- Crellin, J. K.      Pharmaceutical history and its sources in the Wellcome Collections. I. The growth of

- professionalism in nineteenth-century British pharmacy, *11(3) Medical History Journal*, (1967).
- Panagariya, Arvin  
Developing Countries at Doha, a Political Economy Analysis, *The World Economy*, volume 25, issue 9, September, (2002) pp. 1205-1233.
- Petersmann, Ernst-Ulrich  
Introduction, *8(2) Journal of International Economic Law*, (2005).
- Sol, Picciotto  
*Private Rights Vs. Public Interests in the TRIPS Agreement: the Access to Medicines Dispute*, Presentation to the Annual Conference of the American Society of International Law, Washington DC, 2nd-5th April 2003, Panel on "Is the International Trade Régime Fair to Developing States?" Published in *97 ASIL Proc.* 167 (2003).
- Sterckx, Sigfrid  
Patents and Access to Drugs in Developing Countries: An Ethical Analysis, *Developing World Bioethics* ISSN 1471-8731, Volume 4, Number 1, (2004), pp. 58-75.
- Toebes, Brigit  
Towards an Improved Understanding of the International Human Right to Health, 21.3 *Human Rights Quarterly* (1999), pp 661-679.
- Trachtman, Joel P.  
Reviewed work: Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law, by Joost Pauwelyn, *The American Journal of International Law*, Vol. 98, No. 4, (2004), pp. 855-861.

## UN General Comments, Reports and Guidelines

TD/B/AC.11/19	<i>The Role of the Patent System in the Transfer of Technology to Developing Countries</i> , U.N. Dept of Economy And Social Affairs, UNCTAD Secretariat, (1974)
E/CN.4/Sub.2/1987/23	Eide, Asbjørn, Report of the Special Rapporteur to the Right to Food. Final Report to the Human Rights Commission.
E/CN.4/1987/17	The Limburg Principles on the Implementation of the International Covenant on Economic, Social and Cultural Rights.
E/1990/23	Committee on Economic, Social and Cultural Rights, General Comment No.: 2, on International Technical Assistance Measures, 2 February 1990.
E/1991/23	Committee on Economic, Social and Cultural Rights, General Comment No.: 3, on the Nature of State Parties Obligations, 14 December 1990.
E/C/1991/1	Revised Guidelines Regarding the Forms and Contents of Reports to be Submitted by States Parties under Articles 16 and 17 of the International Covenant on Economic and Social Rights, article 15 of the Covenant, 17 June 1991.
E/C.12/1997/8	Committee on Economic, Social and Cultural Rights, General Comment No.: 8, on the relationship between economic sanctions and respect for economic, social and cultural rights, 12 December 1997.
E/CN.4/Sub.2/2001/13	United Nations High Commissioner for Human Rights, Report on the Impact of the Agreement on Trade-

	Related Aspects of Intellectual Property Rights on Human Rights, (1991)
E/C.12/1999/5	Committee on Economic, Social and Cultural Rights, General Comment No.: 12, on the Right to Adequate Food, 12 May 1999.
E/C. 12/1999/10	The UN Committee on Economic, Social and Cultural Rights, General Comment No. 13, on the Right to Education, 8 December 1999.
E/C.12/2000.4	Committee on Economic, Social and Cultural Rights, General Comment No.: 14, on the Right to the Highest Attainable Standard of Health, 11 August 2000.
E/C. 12/2001/15	Human Rights and Intellectual Property: Statement by the Committee on Economic, Social and Cultural Rights, 14 December 2001.
E/C.12/2002/11	The UN Committee on Economic, Social and Cultural Rights, General Comment No. 15 on the Right to Water, 20 January 2003.
E/C. 12/GC/17	Committee on Economic, Social and Cultural Rights, General Comment No. 17, on The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author, 25 November 2005.
CEDAW/C/1999/I/WG.II/WP.2/rev.1	Committee on the Elimination of Discrimination Against Women, General Recommendation No.: 24, on article 12 - Woman and Health, 20 <sup>th</sup> Committee Session, 1999.
E/CN.4/2003/58	Hunt, Paul, Report of the Special Rapporteur on the Right to Health, submitted in accordance with

	Commission Regulations 2002/31, 13 February 2003.
A/58/427	Hunt, Paul, Report of the Special Rapporteur on the Right to Health, 10 October 2003
E/CN.4/Sub.2/2003/12/Rev2	<i>UN Norms on the Responsibility of Transnational Corporations and Other Business Enterprises with Regard to Human Rights</i> , (2003).
E/CN.4/2004/49	Hunt, Paul, Report of the Special Rapporteur on the Right to Health, Mission to the world Trade Organization, 1 March 2004.
E/CN.4/2004/49Add.1	Hunt, Paul, Report Submitted by the Special Rapporteur on the Right to Health, 1 March 2004, p. 14.
E/CN.4/2005/51Add.3	Hunt, Paul, Report of the Special Rapporteur on the right to health, Mission to Peru, 4 February 2005.
U.N. Doc E/CN.4/2005/L.87	Office of the High Commissioner For Human Rights, Human Rights Resolution 2005/69 on Human Rights and Transnational Corporations and Other Business, (2005).
A/61/338	Hunt, Paul, Report of the Special Rapporteur on the Right to Health to the general Assembly, 13 September 2006.

## WebPages

3D – Trade, Human Rights and Equitable Economy Organization	<a href="http://www.3dthree.org">www.3dthree.org</a>
Abbott	<a href="http://www.abbott.com">www.abbott.com</a>
American Association of Pharmaceutical sales Professionals (AAPSP)	<a href="http://www.pharmaceuticalsales.org">www.pharmaceuticalsales.org</a>

Astra Zeneca	<a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
Bristol-Meyers Squibb	<a href="http://www.bristolmyerssquibb.com">www.bristolmyerssquibb.com</a>
Danish Institute for Human Rights	<a href="http://www.humanrights.dk">www.humanrights.dk</a>
Oxford English Dictionary Online	<a href="http://www.oed.com">www.oed.com</a>
Fair Labour Organisation	<a href="http://www.fairlabor.org">www.fairlabor.org</a>
Forbes Organization	<a href="http://www.forbes.org">www.forbes.org</a>
Gilead Access Program	<a href="http://www.gileadaccess.org">www.gileadaccess.org</a>
GlaxoSmithKline	<a href="http://www.gsk.com">www.gsk.com</a>
Hoffman LaRoche	<a href="http://www.roche.com">www.roche.com</a>
Human Rights & Business Resource Centre	<a href="http://www.business-humanrights.org">www.business-humanrights.org</a>
International Organisation for Standardisation	<a href="http://www.iso.org">www.iso.org</a>
Johnson and Johnson	<a href="http://www.jnj.com">www.jnj.com</a>
Merck	<a href="http://www.merck.com">www.merck.com</a>
Novartis	<a href="http://www.novartis.com">www.novartis.com</a>
OECD	<a href="http://www.oecd.org">www.oecd.org</a>
Oxfam International	<a href="http://www.oxfam.org">www.oxfam.org</a>
Pfizer	<a href="http://www.pfizer.com">www.pfizer.com</a>
Sanofi-Aventis	<a href="http://www.sanofi.aventis.com">www.sanofi.aventis.com</a>
Technology Transfer Office	<a href="http://www.csurf.org/enews/bayhdole_403.html">www.csurf.org/enews/bayhdole_403.html</a>
UN Global Compact	<a href="http://www.unglobalcompact.org">www.unglobalcompact.org</a>
UN Office for the High Commissioner for Human Rights	<a href="http://www.ohchr.org">www.ohchr.org</a>
World Intellectual Property	<a href="http://www.wipo.org">www.wipo.org</a>

Organisation

## **International Instruments**

International Covenant of Economic, Social and Cultural Rights, G.A: res. 2200A (XXI), 21 U.N.GAOR Supp. (No. 16) at 49, U.N. Doc. A/6316 (1966), 993 U.N.T.S. 3, *entered into force* on January 3, 1976.

International Covenant on Civil and Political Rights, adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966, *entered into force* March, 23, 1976, UN GAOR, 21<sup>st</sup> Sess., Supp. No. 16, Art. 47, UN Doc. A/6316.

Constitution of the World Health Organization, signed at New York on 22 July 1946 and entered into force on 7 April 1948.

Universal Declaration of Human Rights, G.A. Res. 217, U.N. GAOR, 3d Sess., U.N. A7810 (1948), article 25(1).

Convention on the Rights of the Child, G.A. res. 44/25, annex, 44 U.N. GAOR Supp. (No. 49) at 167, U.N. Doc. A/44/49 (1989), *entered into force* on 2 September 1990.

Convention on the Elimination of All Forms of Discrimination Against Women, G.A. res. 34/180, 34 U.N. GAOR Supp. (No. 46) at 193, U.N. Doc. A/34/46, *entered into force* 3 September 1981.

International Covenant on the Elimination of All Forms of Racial Discrimination, 660 U.N.T.S. 195, *entered into force* 4 January 1969.

European Social Charter, CETS No.: 035, opened for signatures on 18 October 1961 and *entered into force* on 26 February 1965.

European Social Charter (revised), CETS No.: 163, opened for signatures on 3 May 1996 and *entered into force* 1 January 1999.

African Charter on Human and Peoples' Rights, OAU Doc. CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982), adopted June 27, 1981, *entered into force* October 21, 1986.

Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights, O.A.S. Treaty Series No. 69 (1988), *reprinted in* Basic Documents Pertaining to Human Rights in the Inter-American System, OEA/Ser.L.V/II.82 doc.6 rev.1.

Declaration of Alma-Ata, WHO *Primary Health care: Report of the International Conference on Primary Health Care*, Alma-Ata, USSR, 6-12 September 1978, Health for All Series No. 1, 1978.

Charter of the United Nations, open for signature on 26 June 1945 and *entered into force* on 24 October 1945.

Constitution of UNESCO, TIAS No.: 1580, 4 UNTS 275,276, signed on 16 November 1945 and *entered into force* on 4 November 1946.

Declaration on the Right to Development, G.A. res. 41/128, annex, 41 U.N. GA OR Supp. (No. 53) at 186, U.N. Doc. A/41/53, (1986).

Declaration on the Rights of Mentally Retarded Persons, proclaimed by the General Assembly resolution 2856 (XXVI), 20 December 1971.

Declaration on Social Progress and Development, GA res. 2542 (XXIV) 24 UN GAOR Supp. (No. 30) at 49 UN Doc. A/7630, 11 December 1969.

Declaration on the Protection of Women and Children in Emergency and Armed Conflict, GA res. 3318 (XXIX), 29 U.N. GAOR Supp. (No. 31) at 146, U.N. Doc. A/9631, (1974).

Commission on Human Rights Resolution 2002/31, on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, E/CN.4.RES.2002.31, 10 February 2003.

Commission on Human Rights Resolution 2005/24, on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, E/CN.4/2005.L.10Add.10, 15 April 2005.

The Paris Convention for the Protection of Industrial Property, signed on 20 March 1883, and revised at Brussels on 14 December 1900, at Washington on 2 June 1911, at the Hague on 6 November 1925, at London on 2 June 1934, at Lisbon on 31 October 1958, and at Stockholm on 14 July 1967, and as amended on September 28, 1979.

Convention Establishing the World Intellectual Property Organization signed at Stockholm on 14 July 1967 and amended on 28 September 1979.

Agreement between the United Nations and the World Intellectual Property Organization, GA Res. 3346 (XXIX), 2323<sup>rd</sup> plenary meeting, 17 December 1974.

General Agreement on Trade and Tariffs – GATT, first signed in 1947.

The Agreement on Trade Related Aspects of Intellectual Property – TRIPS, as included as Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh – Morocco, on 15 April 1994.

Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh – Morocco, on 15 April 1994.

The American Declaration of the Rights and Duties of Man, O.A.S. Res. XXX, adopted by the Ninth International Conference of American States (1948) reprinted in Basic Documents Pertaining to Human Rights in the Inter-American System, OEA/Ser.L.V./II.82 doc.6 rev.1 at 17 (1992).

The Vienna Convention on the Law of Treaties, signed in Vienna on 23 May 1969, *entered into force* on 27 January 1980. United Nations, *Treaty Series*, vol. 1155.

## **Other Sources**

Black's Law Dictionary with Pronunciations, sixth edition, West Publishing CO, St. Paul, Minnesota, (1990).

US National Research Council Committee on Issues in the Transborder Flow of Scientific Data, *Bits of Power: Issues in Global Access to Scientific Data*, Washington D.C. – USA, National Academy Press, (1997).

WIPO Intellectual Property Handbook: Policy, Law and Use, WIPO Publishing, Geneva – Switzerland, 2<sup>nd</sup> edition, (2004).

The Maastricht Guidelines on Violations of Economic, Social and Cultural Rights, 26 January 1997.

WHO Model List of Essential Medicines, 15<sup>th</sup> List, March 2007.

WHO Model List of Essential Medicines for Children, first List, October 2007.

WHO Policy Perspectives on Medicines, No. 03, (2001) – Globalization, TRIPS and Access to Medicines.

WHO Report of The Commission on Intellectual Property Rights, Innovation and Public Health, WHO Publications, Geneva – Switzerland, (2006).

WHO Medicines Strategy: Countries at the Core 2004-2007, WHO/EDM/2004.5, original English version.

WHO Access, Quality and rational Use of Medicines and Essential Medicines, available at [www.who.int/medicines/services/essmedicines\\_def/en/index.html](http://www.who.int/medicines/services/essmedicines_def/en/index.html), last visited on 10 January 2008.

Understanding on Rules and Procedures Governing the Settlement of Dispute, in *The WTO Dispute Settlement Procedures: a Collection of*

*Relevant Legal Texts*, WTO Secretariat, Second Edition, Cambridge – UK (2001).

*Treatment Action Campaign et al. V. Minister of Health et al*, High Court of South Africa, Transvaal Provincial Division, Case No. 21182/2001.

The USA Bayh-Dole Act, 35 U.S.C.A.

The USA Trade and tariff Act of 1984, 19 USC 1654 note.

The USA Omnibus Trade and Competitiveness Act of 1988, 19 USC 2901 note.

European Communities-Measures Affecting Asbestos and Asbestos-Containing Products. WT/DS135R, Panel Report, September, 18, 2000.

Folha de São Paulo, 1 December 2007, Folha de São Paulo, December 1st, 2007. Available at [www.folha.uol.com.br/folha/ciencia/ult306u350225.shtml](http://www.folha.uol.com.br/folha/ciencia/ult306u350225.shtml), last visited on 10 January 2008.

The Economist Magazine, *In Search of the Good Company: The Social Debate About the Social Responsibilities of Companies if Heating Up Again*, 6 September 2007, New York – USA.

Organization for Economic Co-operation and Development (OECD), Guidelines for Multinational Enterprises, available at <http://www.oecd.org/dataoecd/56/36/1922428.pdf>, last visited on 10 January 2008.

Danish Institute for Human Rights, Human Rights Compliance Assessment, available at [http://www.humanrightsbusiness.org/040\\_hrca.htm](http://www.humanrightsbusiness.org/040_hrca.htm), last visited on 10 January 2008.

UN Millennium Development Goals, available at [www.un.org/millenniumgoals/](http://www.un.org/millenniumgoals/) last visited on 10 January 2008.

Atul, Gawande, Pharmaceutical Companies Should 'Broaden' Efforts To Provide Access to Antiretrovirals, Other Drugs in Developing Countries. News from the Kaiser Network. Available at [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?DR\\_ID=44966](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=44966) last visited on 10 January 2008.

B. Freeman, *To What Extent Can Voluntarism Provide Answers?*, Wilton Park Conference on Business and Human Rights, 11 October 2005. [www.reports-and-materials.org/Bennett-Freeman-Wilton-Park-11-Oct-2005.doc](http://www.reports-and-materials.org/Bennett-Freeman-Wilton-Park-11-Oct-2005.doc), last visited on 10 January 2008.

Aaron C, Lincoln T. *The other drug war 2003: Drug companies deploy an army of 675 lobbyists to protect profits*. Washington (DC): Public Citizen Congress Watch; June 2003. Available at [www.citizen.org/documents/Other\\_Drug\\_War2003.pdf](http://www.citizen.org/documents/Other_Drug_War2003.pdf), last visited on 10 January 2008.

Hunt Paul, *Draft for Consultation: Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines*.

# Appendix: Draft Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines

Prepared by Hunt, Paul, the United Nations Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Released on 19 September 2007.

## Introductory Note

A. Almost 2 billion people lack access to essential medicines. Improving access to existing medicines could save 10 million lives each year, 4 million of them in Africa and South-East Asia. Access to medicines is characterised by profound global inequity. 15% of the world's population consumes over 90% of the world's pharmaceuticals.

B. The Millennium Development Goals, such as reducing child mortality, improving maternal health, and combating HIV/AIDS, malaria and other diseases, depend upon improving access to medicines. One of the Millennium Development Goal targets is to provide, in cooperation with pharmaceutical companies, access to affordable essential drugs in developing countries.

C. The Constitution of the World Health Organisation (WHO) affirms that the highest attainable standard of health is a fundamental right of every human being. The Universal Declaration of Human Rights lays the foundations for the international framework for the right to the highest attainable standard of health. This human right is now codified in numerous national constitutions, as well as legally binding international human rights treaties, such as the International Covenant on Economic, Social and Cultural Rights and the Convention on the Rights of the Child.

D. Medical care and access to medicines are vital features of the right to the highest attainable standard of health.

E. States have primary responsibility for enhancing access to medicines. While on country mission, the Special Rapporteur routinely questions Governments about their national medicines policies, research and development for neglected diseases, anti-counterfeiting measures, and so on. Most of his report to the United Nations General Assembly, on the human right to medicines, is devoted to the responsibilities of States. However,

since his appointment in 2002, many States have emphasised the profound impact - positive and negative - of pharmaceutical companies on the ability of governments to realise the right to the highest attainable standard of health for individuals within their jurisdictions.

F. Under his mandate, the Special Rapporteur is requested, *inter alia*, to develop a regular dialogue and discuss possible areas of cooperation with all relevant actors; to report on good practices most beneficial to the enjoyment of the right to the highest attainable standard of health, as well as obstacles encountered domestically and internationally; and to support States' efforts by making recommendations.

G. Accordingly, the Special Rapporteur has engaged in many substantive discussions on access to medicines with numerous parties, including pharmaceutical companies. These discussions have been informed by the work of States, pharmaceutical companies, United Nations Global Compact, Office of the High Commissioner for Human Rights, WHO, Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, Business Leaders Initiative on Human Rights, civil society organisations and others. These discussions – and this work - have shaped these draft Guidelines. The Special Rapporteur is especially grateful to Realizing Rights: Ethical Globalization Initiative and the Access to Medicine Foundation.

H. In 2000, the United Nations Committee on Economic, Social and Cultural Rights confirmed that the private business sector has responsibilities regarding the realisation of the right to the highest attainable standard of health. While this general statement of principle is important, it provides no practical guidance to pharmaceutical companies and others. The present draft draws upon the growing jurisprudence on the right to the highest attainable standard of health and sets out human rights Guidelines for pharmaceutical companies in relation to access to medicines. In this way, the Guidelines aim to help pharmaceutical companies enhance their contribution to these vital human rights issues. Additionally, the Guidelines will assist those who wish to monitor the human rights performance of the pharmaceutical sector in relation to access to medicines.

I. The right to the highest attainable standard of health is complex and extensive. In recent years, it has been analysed by courts, the United Nations Committee on Economic, Social and Cultural Rights as well as other international human rights treaty-bodies, WHO, civil society organisations, academics and others, with a view to making it easier for States, and others, to apply in practice. The key elements of this right-to-health analysis may be briefly summarised as follows:

i. Identification of the relevant national and international human rights laws, norms and standards.

- ii. Recognition that the right to health is subject to resource constraints and progressive realisation, requiring the identification of indicators and benchmarks to measure progress (or the lack of it) over time.
- iii. Nonetheless, recognition that some obligations arising from the right to health are subject to neither resource constraints nor progressive realisation, but are of immediate effect e.g. the obligation to avoid de jure and de facto discrimination.
- iv. Recognition that the right to health includes freedoms (e.g. freedom from non-consensual treatment and non-consensual participation in clinical trials) and entitlements (e.g. to a system of health care and protection). For the most part, freedoms do not have budgetary implications, while entitlements do.
- v. All health services, goods and facilities shall be available, accessible, acceptable, of good quality and safe. Accessible has a number of dimensions, such as affordable (i.e. financially accessible) and transparent (i.e. accessible health-related information).
- vi. States have duties to respect, protect and fulfil the right to the highest attainable standard of health.
- vii. Because of their crucial importance, the analytical framework demands that special attention is given to issues of non-discrimination, equality and vulnerability.
- viii. The right to health requires that there is an opportunity for the active and informed participation of individuals and communities in decision-making that bears upon their health.
- ix. Developing countries have a responsibility to seek international assistance and cooperation, while developed States have some responsibilities towards the realisation of the right to health in developing countries.
- x. The right to health requires that there are effective, transparent and accessible monitoring and accountability mechanisms available at the national and international levels.

J. While this analysis has been developed keeping in mind the responsibilities of States, many of its elements are also instructive in relation to the responsibilities of non-State actors, including pharmaceutical companies. For example, the element requiring that health services shall be accessible bears upon the policies of both States and non-State actors, as does the requirement that there should be effective monitoring and accountability mechanisms. The following draft Guidelines are grouped into overlapping categories; at the beginning of each group, there is a brief italicised commentary signalling some of the elements of the right-to-health analysis that are especially relevant to that category.

K. Importantly, the present Guidelines remain a draft. Comments on this draft are invited and should be sent as soon as possible - and before 31 December 2007 – to Rajat Khosla at rkhosl@essex.ac.uk.

## **General**

Formal recognition of human rights, and the right to the highest attainable standard of health, resonates with I.i (see above) and provides an important foundation upon which the company's activities can be constructed (Guideline 1). Formal recognition, however, is not enough: operationalisation is the challenge (Guideline 2). Many of the following Guidelines suggest ways in which human rights considerations can be operationalised or integrated into the company's activities. Despite its limitations, the Global Compact remains the leading United Nations human rights initiative for the private sector and companies should participate in it (Guideline 3). The right to the highest attainable standard of health has a particular pre-occupation with disadvantaged individuals and communities, women, children and those living in poverty (Guideline 6(i)-(iv)). It also demands access to information, transparency and as much participation as possible (Guideline 6(v)-(vi)).

1. The company's corporate mission statement should expressly recognise the importance of human rights generally, and the right to the highest attainable standard of health in particular, in relation to the strategies, policies, programmes, projects and activities of the company.
2. The company should integrate human rights, including the right to the highest attainable standard of health, into the strategies, policies, programmes, projects and activities of the company.
3. The company should join the United Nations Global Compact.
4. The company should always comply with the national law of the State where it operates, as well as any relevant legislation of the State where it is domiciled.
5. The company should refrain from any conduct that will or may encourage a State to act in a way that is inconsistent with its obligations arising from national and international human rights law, including the right to the highest attainable standard of health.
6. Whenever formulating and implementing its strategies, policies, programmes, projects and activities that bear upon access to medicines, the company should:
  - (i) give particular attention to disadvantaged individuals and communities, such as those living in poverty;
  - (ii) give particular attention to gender-related issues;
  - (iii) give particular attention to the needs of children;
  - (iv) give particular attention to the very poorest in all markets;

- (v) be transparent;
- (vi) encourage and facilitate the participation of all stakeholders, including disadvantaged individuals and communities.

### **Management**

Human rights, including the right to the highest attainable standard of health, require effective, transparent and accessible monitoring and accountability mechanisms, otherwise they can become little more than window-dressing (see I.x above). The mechanisms come in various forms. Usually, a mix of mechanisms will be required. While some mechanisms are internal, others are external and independent. Both types of mechanisms are needed. Guidelines 7-11 address the issue of internal corporate monitoring and accountability. They should be read with Guideline 47-48 which addresses the issue of an external, independent monitoring and accountability mechanism. Guideline 10 reflects the importance that human rights attach to participation.

7. The company should have a governance system that includes direct board-level responsibility and accountability for its access to medicines strategy.

8. The company should have a public global policy on access to medicines that sets out general and specific objectives, time frames, who is responsible for what, and reporting procedures.

9. The company should have clear management systems, including quantitative targets, to implement and monitor its access to medicines strategy.

10. The company should have mechanisms that encourage and facilitate stakeholder engagement and participation in the formulation, implementation and management of its medicines strategy.

11. The company should produce a comprehensive, public, annual report, including qualitative and quantitative information, enabling an assessment of the company's strategies, policies, programmes, projects and other activities that bear upon access to medicines.

### **Public policy influence, advocacy and lobbying**

Transparency is a cardinal human rights principle upon which several other human rights considerations depend, such as participation, monitoring and accountability. In the right-to-health analysis, this principle is reflected in the requirement that as much health-related information as possible should be made accessible (see I.v above). The Guidelines in this category reflect these right-to-health issues in the context of pharmaceutical company advocacy and lobbying.

12. The company and its subsidiaries should disclose all current advocacy and lobbying positions, and related activities, at the regional, national and international levels, that impact or may impact on access to medicines.

13. The company should annually disclose its financial and other support to key opinion leaders, patient associations, political parties and candidates, trade associations, academic departments, research centres and others, through which it seeks to influence public policy and national, regional, and international law and practice. The disclosure should extend to amounts, beneficiaries and channels by which the support is provided.

14. The company board should give prior approval to all lobbying positions (guideline 12) and financial support (guideline 13). The board should also receive reports on such lobbying positions and financial support. The requirement of prior approval by, and reporting to, the board is subject to the nature and scale of the activity. Where the relationship between the activity and access to medicines is significant, or likely to be significant, there should be prior approval by, and reporting to, the board.

#### **Research and development for neglected diseases**

The record confirms that research and development has not addressed the priority health needs of low-income and middle-income countries. More specifically, health research and development has given insufficient attention to neglected diseases that mainly afflict the poorest people in the poorest countries, although there is evidence that some pharmaceutical companies are taking active measures to reverse this trend. The right to the highest attainable standard of health not only requires that existing medicines are accessible without discrimination, but also that much-needed new medicines are developed and thereby become available to those who need them (see I.v above). From the perspective of the right to the highest attainable standard of health, neglected diseases demand special attention because they tend to afflict the most disadvantaged and vulnerable (see I.vii above).

15. The company should make a public commitment to contribute to research and development for neglected diseases.

16. The company should consult widely with WHO, WHO/TDR, Drugs for Neglected Diseases Initiative and other relevant organisations with a view to enhancing its contribution to research and development for neglected diseases.

17. The company should either provide in-house research and development for neglected diseases; or support external research and development for neglected diseases; or both. In any event, it should disclose how much it invests in research and development for neglected diseases.

18. The company's contribution to research and development for neglected diseases should focus on formulations for low-income and middle-income country use and for all key affected patient groups, including especially disadvantaged individuals and communities.

### **Patents and licensing**

The right to the highest attainable standard of health requires that medicines are available and accessible (see I.v above). Intellectual property rights impact upon the availability and accessibility of medicines; they attempt to strike a balance between the interests of various stakeholders, for example by establishing various 'flexibilities' within the TRIPS regime. Guidelines 19-26 aim to ensure that the features of intellectual property rights that protect the right to health of patients, the public and the most disadvantaged are recognised, respected and applied.

19. The company should respect the right of countries to use, to the full, the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which allow flexibility for the purpose of promoting access to medicines, including the provisions relating to compulsory licensing and parallel imports. The company should make a public commitment not to lobby for more demanding protection of intellectual property interests than is required by TRIPS, such as additional limitations on compulsory licensing ('TRIPS-plus' standards). Also, the company should not, in practice, lobby for 'TRIPS-plus' standards.

20. The company should always respect the letter and spirit of the Doha Declaration on the TRIPS Agreement and Public Health that recognises a State's right to protect public health and promote access to medicines for all.

21. The company should support States that wish to implement the WTO Decision on Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (30 August 2003), and issue compulsory licenses for exports to developing countries without manufacturing capacity.

22. Given that some least-developed countries are exempt from granting and enforcing patents until 2016, the company should not lobby for such countries to grant or enforce patents.

23. The company should develop arrangements with other manufacturers for licenses and technology transfers to enhance access to medicines for HIV/AIDS, tuberculosis and malaria, as well as an increasing number of other treatments.

24. The company should have non-exclusive voluntary license agreements to increase access to medicines in low-income and middle-income countries; the terms of such agreements should be disclosed.

25. In low-income and middle-income countries, the company should consent to National Drug Regulatory Authorities using test data/override test data exclusivity for registration purposes.

26. The company should not extend patent duration, or file patents for new indications for existing medicines, in low-income and middle-income countries.

### **Quality and technology transfer**

Guideline 27 (and Guideline 44) reflects the requirement arising from the right to the highest attainable standard of health that medicines are of good quality and safe (see I.v above). Guideline 28 reflects that those in a position to assist have a responsibility to take reasonable measures towards the realisation of the right to the highest attainable standard of health in developing countries (see I.ix above). This includes north-south and south-south assistance.

27. The company should manufacture medicines of the highest quality.

28. The company should enter into technology transfer agreements with local companies in low-income and middle-income countries.

### **Pricing, discounting and donations**

These Guidelines mainly derive from the right to health requirement that medicines should be accessible, including financially accessible or affordable (see I.v above). Access extends to disadvantaged individuals and communities, including those living in poverty. Guideline 29(ii) reflects that the right to health takes into account resource availability within a country (see I.ii above). Regarding Guidelines 30-33, while unsustainable in the long-term, carefully targeted donations have a role to play in ensuring access, especially to those living in poverty and other disadvantaged individuals and communities in low-income countries (see I.v and vii above).

29. The company should ensure that its pricing and discount schemes:

(i) conform to guidelines 6(i)-(vi);

(ii) take into account a country's stage of economic development; prima facie, the price of a medicine in a low-income country should be less than the price of the same or equivalent medicine in a middle-income country, which should be less than the price of the same or equivalent medicine in a high-income country;

(iii) progressively extend its differential pricing and discount schemes to all medicines; such arrangements must not be limited to the

company's flagship products; they should encompass non-communicable diseases, such as heart disease and diabetes.

30. The company should have a board-approved policy that fully conforms to the WHO's Guidelines for Drug Donations.

31. The company should disclose the absolute quantity and value of its drug donations.

32. The company should disclose the amount of any tax benefit arising from its donations.

33. The company should ensure that its discount and donation schemes and their delivery channels are:

(i) as simple as possible e.g. the schemes should place the minimum administrative burden on the beneficiary health system;

(ii) as inclusive as possible e.g. the schemes should not be confined to restrictive delivery channels that, in practice, exclude disadvantaged individuals and communities.

### **Ethical promotion and marketing**

As already observed, transparency is a cardinal human rights principle upon which several other human rights considerations depend, including monitoring and accountability (see commentary to Guidelines 12-14). In the right-to-health analysis, this principle is reflected in the requirement that as much health-related information as possible should be made accessible (see I.v above). Guidelines 34-35 reflect these right-to-health issues.

34. The company should take effective measures to ensure that all information bearing upon the safety, and possible side effects, of a medicine are easily accessible to individuals so they can take informed decisions about its possible use.

35. The company should have a board-approved code of conduct and policy that fully conforms to WHO's Ethical Criteria for Medicinal Drug Promotion. In the context of this code and policy, the board should receive regular reports on its promotion and marketing activities.

### **Clinical trials**

The right to the highest attainable standard of health includes certain freedoms, such as freedom from non-consensual participation in clinical trials (see I.iv above). Treatment must also be acceptable to the individuals and communities involved i.e. respectful of medical ethics, such as the requirements of informed consent (see I.v above).

36. A company's clinical trials should observe the highest ethical and human rights standards. This is especially vital in those States with weak regulatory frameworks.

37. The company should conform to the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects and the WHO Guidelines for Good Clinical Practice.

38. Additionally, when undertaking clinical trials, the company must respect the inherent dignity of the individual and all human rights principles, such as non-discrimination and equality.

### **Public Private Partnerships**

While Public Private Partnerships make an important contribution to enhancing access to medicines, they are subject to human rights considerations corresponding to those set out in these Guidelines. Where conflicts of interest may arise, disclosure is important, consistent with the human rights requirements of transparency and access to information (see I.v above).

39. When participating in a Public Private Partnership, a company should continue to conform to these Guidelines.

40. If a company joins a Public Private Partnership, it should disclose any interest it has in the Partnership's decisions and activities.

41. So far as these guidelines bear upon the strategies, policies, programmes, projects and activities of Public Private Partnerships, they shall apply equally to such Partnerships.

42. A company that joins a Public Private Partnership should take all reasonable steps to ensure the Partnership fully conforms to these guidelines. If, despite warnings, a Partnership fails to conform to these guidelines, a participating company should withdraw from the Partnership.

### **Corruption**

Corruption is a major obstacle to the enjoyment of the right to the highest attainable standard of health, including access to medicines. Those living in poverty are disproportionately affected by corruption in the health sector because they are less able to pay for private alternatives where corruption has depleted public health services. Features of the right to health, such as participation, transparency, access to information, monitoring and accountability, help to establish an environment in which corruption cannot survive. A right-to-health policy is also an anti-corruption policy.

43. A company should adopt effective anti-corruption policies and measures, and comply with relevant national law implementing the United Nations Convention against Corruption.

44. In collaboration with States, the company should take all reasonable measures to address counterfeiting.

#### **Associations of pharmaceutical companies**

A company has a responsibility to ensure that its professional associations are respectful of the human rights considerations set out in these Guidelines, otherwise a company could use an association as a way of avoiding its human rights responsibilities.

45. So far as these Guidelines bear upon the strategies, policies, programmes, projects and activities of associations of pharmaceutical companies, they shall apply equally to all those associations. For example, the Guidelines on lobbying (Guidelines 12 and 19) and financial support (Guideline 13) shall apply equally to all associations of pharmaceutical companies.

46. A company that is a member of an association of pharmaceutical companies should take all reasonable steps to ensure the association fully conforms to these guidelines. If, despite warnings, an association fails to conform to these guidelines, a member company should resign from the association.

#### **Monitoring and accountability**

Effective, transparent, accessible and independent monitoring and accountability mechanisms are an integral feature of human rights, including the right to the highest attainable standard of health (see I.x above). See the commentary accompanying Guidelines 7-11. Implementation of Guideline 11 will contribute to Guidelines 47-48.

47. In the context of access to medicines, internal monitoring and accountability mechanisms have a vital role to play, but they should also be supplemented by a mechanism that is independent of the company. There should be an effective, transparent, accessible and independent monitoring and accountability mechanism that:

(i) assesses the impact of the company's strategies, policies, programmes, projects and activities on access to medicines, especially for disadvantaged individuals and communities;

(ii) monitors, and holds the company to account in relation to, these Guidelines.

48. Where such a monitoring and accountability mechanism already exists, the company should fully cooperate with it. If it does not yet exist, the company should establish such a mechanism.