

# The Impact of Patent Protection and Lack of Generic Competition on the Right of Access to Medicines in South Africa: Explicating Corporate Responsibilities for Human Rights

Linda Muswaka

Lecturer, Faculty of Law, North West University – South Africa  
E-mail: leemuswaka@gmail.com

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## Abstract

*In the case of Cipla Medpro v Aventis Pharma (139/12) Aventis Pharma SA v Cipla Life Sciences (138/12) [2012] ZASCA 108, the court stated, 'Where the public is denied access to a generic during the lifetime of a patent that is the ordinary consequence of patent protection and it applies as much in all cases.' This remark brings into the arena the issue of the impact of patent protection and the lack of generic competition on the fundamental right to have access to medicines provided for in the Constitution of South Africa and recognized in various regional and international human rights instruments and declarations. The right to have access to medicines can be assured if a sustainable supply of affordable medicines can be guaranteed. However, when sustainability of supply can be guaranteed, new medicines are often too expensive for poor people and governments in the developing countries. This paper seeks to investigate the challenge posed by intellectual property, specifically pharmaceutical patents, which human rights activists blame for creating monopolies that keep medicines inaccessible or unaffordable, and which pharmaceutical companies extol as necessary incentive for expensive research and development. The aim is to provide recommendations, on how this challenge that arises when intellectual property (pharmaceutical patents) and human rights converge can be overcome by pharmaceutical companies. The paper concludes that the enjoyment of the fruits of one's intellectual property while at the same time preventing adverse human rights impacts is possible through a stakeholder and human rights oriented corporate governance approach.*

**Keywords:** Human Rights; Intellectual Property; Patents; Monopoly, Corporate Governance

## 1. Introduction

In the case of *Cipla Medpro v Aventis Pharma (139/12) Aventis Pharma SA v Cipla Life Sciences (138/12)*, the court stated that "Where the public is denied access to a generic during the lifetime of a patent that is the ordinary consequence of patent protection and it applies as much in all cases."<sup>1</sup> This remark brings into the arena the issue of the impact of patent protection and the lack of generic competition on the fundamental right to have access to medicines provided for in the Constitution of South Africa, 1996 (the Constitution). The right to have access to medicines is among the socio-economic rights guaranteed by the Constitution. While developments in medical research provide greater opportunities for realizing this right, the reality is that for many, this right largely remains fictitious as new medicines are often too expensive for poor people and governments in the developing countries like South Africa.<sup>2</sup> This paper therefore seeks to investigate the challenge posed by intellectual property law, specifically, patents, which human rights activists blame for creating monopolies that keep medicines inaccessible or unaffordable, and which pharmaceutical companies extol as necessary incentive for expensive research and development. The aim is to provide recommendations, on how this challenge that arises when intellectual property (pharmaceutical patents) and human rights converge can be overcome by pharmaceutical companies.

The remainder of the paper is structured as follows. Section 2 discusses the right have access to health care services guaranteed in the Constitution of South Africa. Section 3 focuses on the right to health in international law. Section 4 analyses the impact of patents on access to medicines. Section 5 discusses ways of remedying the adverse effects of patents on access to medicines. It makes a strong case for the involvement of pharmaceutical companies. Section 6 provides the recommendations while section 7 contains the conclusion.

<sup>1</sup> *Cipla Medpro v Aventis Pharma (139/12) Aventis Pharma SA v Cipla Life Sciences (138/12) [2012]SCA 108 para 56.*

<sup>2</sup> *While the effect of poverty on access to medicines is acknowledged, focus will be on pharmaceutical patents.*

## 2. Right to Have Access to Health Care Services in South Africa

Access to medicines is now widely accepted as a core component of efforts to promote and protect the right to health.<sup>3</sup> The right to health is fundamental to the physical and mental well-being of all individuals and is indispensable for the exercise of other human rights,<sup>4</sup> including the pursuit of an adequate standard of living.<sup>5</sup> Section 27(1)(a) of the Constitution provides for the right to have access to health care services. Universal access to health care services provided for in section 27(1)(a) includes access to medications.<sup>6</sup> In the case of *Minister of Health v New Clicks SA (Pty) Ltd*,<sup>7</sup> access to medications was qualified by the court to mean access to affordable medications. Section 27(2) provides for the State to “take reasonable legislative and other measures, within its available resources to achieve the progressive realization of each of the rights” stated in section 27(1). Several cases have thrown light on the concepts of ‘available resources’ and ‘reasonable measures’ in terms of this section.<sup>8</sup>

## 3. The Right To Health Care in International Law

The right to health is also recognized in numerous regional and international human rights instruments and declarations as a fundamental human right.<sup>9</sup> Examples in this regard are the United Nations Universal Declaration of Human Rights (UDHR),<sup>10</sup> the International Covenant on Civil and Political Rights (ICCPR), the Convention on the Rights of the Child (CRC),<sup>11</sup> the Convention on the Elimination of Discrimination against Women, (CEDAW)<sup>12</sup> the Convention on the Elimination of all Forms of racial Discrimination, (CERD)<sup>13</sup> the International Covenant on Economic, Social and Cultural Rights (ICESCR)<sup>14</sup> and the African Charter on Human and Peoples’ Rights (ACHPR).<sup>15</sup> The preamble to the World Health Organization (WTO) also declares that it is one of the fundamental rights of every human being to enjoy “the highest attainable standard of health.” The CRC calls on State parties in implementing children’s right to health to take appropriate measures “to diminish infant and child mortality.”<sup>16</sup> The ICESCR is the most important international instrument relating to socio-economic rights. Article 12 of ICESCR provides for the “enjoyment of the highest attainable standard of physical and mental health conducive to living a life of dignity.” This means that health care facilities, goods and services have to be available in sufficient quantity; must be physically and economically accessible to everyone, must be ethically and culturally acceptable, and must be of a medically appropriate quality.

## 4. Patents

Patents are a form of intellectual property. They are an incentive mechanism granted to investors in order to stimulate innovation by the creation of a monopoly, usually for a period of twenty years.<sup>17</sup> The criterion for a patent to be granted is that the invention must be new, involve an inventive step and capable of industrial application.<sup>18</sup> Patents are designed to promote innovation, and, at the same time, offer a mechanism ensuring that the fruits of that innovation are accessible to

<sup>3</sup> Toebes, B. (1999). ‘Towards an Improved Understanding of the International Human Right to Health’ *Human Rights Quarterly* 661, 663.

<sup>4</sup> *The Constitution of the Republic of South Africa, 1996 entrenches both civil and political rights and social and economic rights. All the rights contained in the Bill of Rights are inter-related and mutually supporting.*

<sup>5</sup> *General Comment 14: The right to the highest attainable standard of health (2000) CESCR, E/C.12/2000/4, Para 1.*

<sup>6</sup> *Minister of Health v Treatment Action Campaign 2002 (5) SA 721 (CC).*

<sup>7</sup> *Minister of Health v New Clicks SA (Pty) Ltd 2006 (2) SA 311 (CC).*

<sup>8</sup> *See for example, Soobromoney v Minister of Health, Kwa-Zulu Natal 1997 (12) BCLR 1696 (CC); Government of the Republic of South Africa v Grootboom 2000 (11) BCLR 1169 (CC) and Minister of Health v Treatment Action Campaign 2002 (5) SA 721 (CC).*

<sup>9</sup> *Member states to the different instruments and declarations providing the right to health are under obligation to fulfill the right.*

<sup>10</sup> *Article 25.*

<sup>11</sup> *Article 24.*

<sup>12</sup> *Article 11(1)(f) and 12.*

<sup>13</sup> *Article 5(e).*

<sup>14</sup> *Article 12.*

<sup>15</sup> *Article 16.*

<sup>16</sup> *Article 6.*

<sup>17</sup> *See section 46(1) of the Patents Act 57 of 1978.*

<sup>18</sup> *See section 25 of the Patent Act.*

society.<sup>19</sup> Innovation in medicines and technology is important in protecting and promoting the right to health care. However, the cost of innovation and the patent regime has often been an obstacle to accessing new medicines and technology, and therefore an obstacle to the enjoyment of the right contained in section 27 of the Constitution.

The adverse impact of patents is that by guaranteeing market exclusivity, the law makes sure that there is only a single supplier of any new medicine. In other words, patents rights results in monopoly rights over a new medicine, usually twenty years.<sup>20</sup> As a result of the monopoly created, the market is starved of competition and in the absence of strict price regulation; prices go up and stay high. This is especially problematic when the product concerned is an essential medicine and there is no alternative available.

#### 4.1 The Agreement on Trade-Related Aspects of Intellectual Property

Historically countries could decline to provide patent protection for drug compositions to promote innovation and competition, resulting in low-cost and widespread access to medicines. Such flexibility however, is now a non-existent luxury for most countries. This is as a result of the landmark international agreement, the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS),<sup>21</sup> which established the first-ever minimum levels of patent rights on a global scale. In terms of the TRIPS agreement, WTO members have to provide patent protection for any invention, whether a product (such as medicine) or a process (such as a method of producing the chemical ingredients for a medicine), while allowing certain exceptions.<sup>22</sup>

#### 4.2 Doha Declaration on TRIPS and Public Health

There is language in TRIPS that suggests nations have some flexibility<sup>23</sup> to balance public health against patent rights. At the Ministerial Conference of the WTO held in Doha in 2001 developing countries that were unsure of how the TRIPS flexibilities would be interpreted and how far their right to use them would be respected, were essentially seeking a declaration recognizing their right to implement certain pro-competitive measures as needed to enhance access to health care.<sup>24</sup> This led to the Doha Declaration on TRIPS and Public Health.<sup>25</sup> It clarified the flexibilities in TRIPS and explicitly instructed States to interpret TRIPS "in a manner supportive of WTO members' right to protect public health and in particular, to promote access to medicines for all."<sup>26</sup>

### 5. Remediating the Adverse Effect of Patents on Access to Medicines

While patents are an influential factor in sustaining high drug prices and thereby inhibiting access to health care especially by those without financial means, political commitment to inadequate access to health care plays a crucial role in overcoming this challenge. Access to medicines as a human rights issue means that government have not only moral

<sup>19</sup> Boulet, P. J. Perriens & F. Renaud-Thery (2000). *Patent Situation of HIV/AIDS-related drugs in 80 countries*. Available at <http://www.who.int/3by5/en/patentshivdrugs.pdf> [26 October 2010].

<sup>20</sup> See section 46 of the Patent Act.

<sup>21</sup> This agreement protects patents and other forms of intellectual property. For the purposes of this paper, focus will only be on patents.

<sup>22</sup> See Article 27.1 of TRIPS.

<sup>23</sup> See for example Article 8 and 40.

<sup>24</sup> See Correa, C.M. (2009) *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*. Available at [http://www.ggp.up.ac.za/human\\_rights\\_access\\_to\\_medicines/syllabus/2009/day2/5CorreaimplicationsoftheDohaDeclaratio.pdf](http://www.ggp.up.ac.za/human_rights_access_to_medicines/syllabus/2009/day2/5CorreaimplicationsoftheDohaDeclaratio.pdf) [18 July 2010]; Twinomugisha, B.K. 'Implications of the TRIPS Agreement for the Protection of the Right of Access to Medicines in Uganda.' (2008) 2(2) *Malawi Law Journal*, 253-278; and Sacco, S.F. 'A comparative study of the implementation in Zimbabwe and South Africa of the International law rules that allow licensing and parallel importation for HIV/AIDS drugs.' (2005) 5(1) *African Human Rights Law Journal* 105-128.

<sup>25</sup> The Doha Declaration on TRIPS and Public Health was adopted on 14 November 2001.

<sup>26</sup> Other relevant decisions which will not discussed include amongst others, the *Decision on the Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products of 27 June 2002*; the *Decision on Least Developed Country Members' Obligations under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products of 8 July 2002*; the *Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health of 30 August 2003*; the *Decision on the Amendment of TRIPS Agreement of 6 December 2005*; the *Hong Kong Ministerial Declaration on TRIPS and Public Health*; and the *Decision of 17 December 2009 to extend the deadline for accepting TRIPS Agreement Amendments*.

or humanitarian responsibilities to undertake such measures to ensure access to essential medicines, but also have legal obligations.<sup>27</sup> There is a range of measures available to government to reduce and control medicine prices. These measures form part of the legal or regulatory framework including the passing of legislation by Parliament. In South Africa, the Medicines and Related Substances Act 101 of 1965,<sup>28</sup> the Competition Act 89 of 1998 and the Patents Act all play a crucial role in ensuring access to a sustainable supply of affordable medicines. However, of particular interest in this paper is the question whether or not pharmaceutical companies are obliged to fulfill duties in support of the progressive realization of individuals' socio-economic rights such as the right to have access to medicines. The preceding discussion attempts to address this question.

### 5.1 Corporate Responsibilities for Human Rights

While legislative interventions play an important role in remedying the negative effects of pharmaceutical patents on access to health care services, it is submitted that pharmaceutical companies as patent holders have a significant role to play in this regard. Pharmaceutical companies and all companies in general registered in South Africa have a duty to promote, protect, respect and fulfil human rights. The reasons are four-fold.

Firstly, although the Companies Act 71 of 2008 does not contain an explicit duty of directors to consider human rights, section 7(a) states that one of the purposes of the Companies Act is 'to promote compliance with the Bill of Rights.' In this regard, national human rights law is therefore applicable to companies. International human rights law also becomes applicable by virtue of *inter alia* section 39 of the Constitution, which obliges a court to consider international law as a tool of interpretation of the Bill of Rights. Seen in this light, it will therefore not be an overstatement that the duties of directors also include the duty to respect universally recognized fundamental human rights.

Secondly, the Bill of Rights as provided for in the Constitution has brought about a significant shift in society's moral perception of companies.<sup>29</sup> This is as a result of section 8 of the Constitution which imposes responsibilities upon individuals and juristic persons for the realisation of human rights. The notion of creating a company pursuing shareholder wealth maximization at the expense of human rights is therefore, legally untenable as the Bill of Rights applies to companies in a manner that goes beyond mere financial considerations. The responsibilities outlined in the Bill of Rights provide the framework within which companies must legally operate.

Thirdly, the *King Report on Corporate Governance for South Africa 2009*,<sup>30</sup> which operates on an 'apply or explain' basis, recommends that companies should respect and realize universally recognized fundamental human rights.<sup>31</sup> According to *King III*,<sup>32</sup> in order "to realize human rights in any society, companies should respect and recognize the basic interests of individuals and communities by creating and sustaining conditions in which human potential can develop." *King III* goes further to state that this entails liberating people from unfair discrimination and empowering them to take control of their own lives through for example, access to education, health care and other resources.<sup>33</sup>

Fourthly, international law<sup>34</sup> also requires companies to address human rights. International law is relevant because it has both a direct and indirect impact on law and policy-making in South Africa. Section 39 of the Constitution, obliges a court to consider international law as a tool of interpretation of the Bill of Rights. It is worth noting that the international law that must be considered in interpreting the Bill of Rights refers to both binding and non-binding international law as clearly articulated in the case of *S v Makwanyane*.<sup>35</sup> In this case, the court emphasized that

<sup>27</sup> See section 7(2) of the Constitution which requires that the State "respect, protect, promote and fulfill the rights in the Bill of Rights".

<sup>28</sup> While this Act has been amended many times, the most significant amendments dealing with access to essential medicines came with the Medicines and Related Substances Control Amendment Act 90 of 1997.

<sup>29</sup> It is now generally accepted that companies have an important role to play, not only in the economy, but also in responding to economic, social and environmental challenges.

<sup>30</sup> Hereafter, *King III*.

<sup>31</sup> See *King III* 22.

<sup>32</sup> *Ibid*.

<sup>33</sup> See *King III* 22.

<sup>34</sup> International law is a combination of treaties and customs that regulate the conduct of states amongst themselves. International law has three main sources, namely, customary international law, treaty law and soft law. Customary international law comes from the customs practiced over a long period of time by various states. These customs are often not written in treaties or legislation, but have become an international standard that governments must follow. Soft law refers to all sources of non-binding international law that can provide guidance on the interpretation of international treaties. Treaty law is based on the agreement of states signing and ratifying the treaty.

<sup>35</sup> *S v Makwanyane* 1995 (3) SA 391 (CC) para 35.

international law is important and should be considered in interpreting the Bill of Rights since it provides a framework in which we understand the Bill of Rights.<sup>36</sup> However, although the Courts must take into consideration international law when interpreting constitutional provisions, the weight of international law and principles recognized will vary on a case by case basis as highlighted in *Government of the Republic of South Africa v Grootboom*.<sup>37</sup>

Section 231 of the Constitution is also important in highlighting the role of international law in South Africa. The section provides that a treaty binds South Africa after approval by the National Assembly and the National Council of Provinces, unless it is self executing,<sup>38</sup> or of a technical, administrative or executive nature. Furthermore, in terms of section 232, the Constitution also makes international customary law part of the law of South Africa unless it is in contradiction with constitutional provisions or legislation. In section 233, the Constitution states that when interpreting any legislation the approach that is consistent with international law is more preferable to that which contradicts it.

As the courts are obliged to consider both binding and non-binding international law when interpreting the Bill of Rights, the following discussion will highlight both hard and soft law dealing with the corporate duty to respect human rights. It is noteworthy that while there are various international instruments that address the corporate duty to respect human rights, only a select few will be discussed. These are the following:

### 5.1.1 *The International Bill of Rights*

An authoritative list of the core internationally recognized human rights is contained in the International Bill of Human Rights (consisting of the Universal Declaration of Human Rights and the main instruments through which it has been codified: (the ICCPR and the ICESCR). The preamble of the Universal Declaration of Human Rights calls on 'every individual and every organ of society' to promote and respect human rights. Henkin notes that 'every individual and every organ of society excludes no one, no company, no market, no cyberspace.'<sup>39</sup> Companies, as specialized organs of society performing specialized functions, are therefore required to respect human rights.

### 5.1.2 *The Guiding Principles on Business and Human Rights*

Another important international law instrument is the *Guiding Principles on Business and Human Rights: Implementing the United Nations 'Protect, Respect and Remedy' Framework*<sup>40</sup> which was endorsed by the UN Human Rights Council on 11 June 2011 as a new set of guiding principles for global business designed to provide a global standard for preventing and addressing the risk of adverse impacts on human rights linked to business activity. This endorsement was preceded by an earlier unsuccessful attempt by a Sub-Commission of the then UN Commission on Human Rights to win approval for a set of binding corporate human rights norms, the so called "Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights."

The *Guiding Principles on Business and Human Rights* contains three types of principles namely, those focusing on (i) the State duty to protect human rights; (ii) the corporate responsibility to respect human rights; and (iii) access to remedy. These Guiding Principles apply to all States and to all business enterprises, both transnational and others, regardless of their size, sector, location, ownership and structure.<sup>41</sup>

### 5.1.3 *The OECD Guidelines for Multinational Enterprises*

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<sup>36</sup> *Ibid.*

<sup>37</sup> *Government of the Republic of South Africa v Grootboom* 2001 (1) SA 46 para 26.

<sup>38</sup> A self-executing treaty has a provision stating that it is self-executing. It becomes law in South Africa when it is signed unless if it is inconsistent with the Constitution or an Act. A non self-executing treaty that has not been ratified or even signed, will bind South Africa only if it becomes customary international law.

<sup>39</sup> Henkin L, "The Universal Declaration at 50 and the Challenge of Global Markets," (1999) 25(1) *Brooklyn Journal of International Law* 25.

<sup>40</sup> See *Guiding Principles and Human Rights; Implementing the United Nations 'Protect, Respect and Remedy' Framework* 2011, (hereafter, the *Guiding Principles and Human Rights*) available at [http://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR\\_En.pdf](http://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR_En.pdf), accessed on 10 January 2013.

<sup>41</sup> See the *Guiding Principles and Human Rights*) available at [http://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR\\_En.pdf](http://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR_En.pdf), accessed on 10 January 2013.

In 1976, the Organization for Economic Co-operation and Development<sup>42</sup> passed the *OECD Guidelines for Multinational Enterprises*<sup>43</sup> of which the 2011 edition is the most recent version.<sup>44</sup> The *OECD Guidelines* are recommendations jointly addressed by governments to multinational enterprises. They provide principles and standards of good practice consistent with applicable laws and internationally recognized standards. It is however, noteworthy that OECD Principles are non-binding and are not prescriptive.<sup>45</sup> Their rationale is to operate as a basic reference point.<sup>46</sup> The OECD Principles were created in order to support member and non-member states<sup>47</sup> in the evaluation and improvement of the legal, institutional and regulatory structure for corporate governance in their countries.

The *OECD Guidelines* for instance, *inter alia* state that enterprises should, within the framework of internationally recognized human rights, the international human rights obligations of the countries in which they operate as well as relevant domestic laws and regulations, *inter alia* (i) respect human rights, which means they should avoid infringing on the human rights of others and should address adverse human rights impacts with which they are involved; (ii) Within the context of their own activities, avoid causing or contributing to adverse human rights impacts and address such impacts when they occur; and (iii) Have a policy commitment to respect human rights.

#### 5.1.4 The International Labour Organization Tripartite Declaration

In 1977, the International Labour Organization's<sup>48</sup> governing body, comprising governments, employers and workers approved the Tripartite Declaration of Principles concerning Multinational Enterprises. The Tripartite Declaration is non-binding and relates primarily to labour matters, including health and safety, a minimum age of employment, and conditions and benefits of work, among others. Parties concerned with the Tripartite Declaration also bind themselves to respect the Universal Declaration of Human Rights and corresponding International Covenants<sup>49</sup> as well as the Constitution of the ILO. The Tripartite Declaration is a significant recognition by business of its obligations to respect human rights.

#### 5.1.5 The United Nations Global Compact

The United Nations Global Compact<sup>50</sup> is a voluntary initiative for aligning companies' strategies and operations with ten universally accepted principles in the areas of human rights labour rights, environmental responsibility and anti-corruption. The human rights principles states that companies should: (i) support and respect the protection of internationally proclaimed human rights;<sup>51</sup> and (ii) ensure that they are not complicit<sup>52</sup> in human rights abuses.<sup>53</sup> The objective of the Compact is to place the ten principles at the centre of business activities around the world.

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<sup>42</sup> Hereafter, the OECD.

<sup>43</sup> Hereafter, the OECD Guidelines.

<sup>44</sup> See *OECD Guidelines 2011*, available at <http://www.oecd.org/daf/inv/mne/48004323.pdf>, accessed on 10 January 2013.

<sup>45</sup> Nevertheless, some matters covered by the Guidelines may also be regulated by national law or international commitments. For criticism of the voluntary nature of the OECD Guidelines see among others, Chirwa, D.M. "The Long March to Binding Obligations of Transnational Corporations in International Human Rights Law" 2006 SAJHR vol. 22, 84-85.

<sup>46</sup> Preamble to the 'OECD Principles of Corporate Governance,' 2004. Accessed on 26 July 2011. Available at <http://www.oecd.org/daf/corporateaffairs/corporategovernance>.

<sup>47</sup> It is worth noting that South Africa is one of the many non-member economies with which the OECD has working relations in addition to its member states. On 16 May 2007, the OECD Council at Ministerial level adopted a Resolution on Enlargement and Enhanced Engagement to strengthen the co-operation with South Africa, as well as with Brazil, China, India and Indonesia through a programme of enhanced engagement. The OECD Council Resolution on Enlargement and Enhanced Engagement, accessed on 14 May 2012 is available at <http://www.oecd.org/brazil/oecdouncilresolutiononenlargementandenhancedengagement.htm>.

<sup>48</sup> Hereafter, the ILO.

<sup>49</sup> The ICCPR and the ICESCR.

<sup>50</sup> The United Nations Global Compact, (hereafter, the UN Global Compact) available at <http://www.unglobalcompact.org/AboutTheGC/TheTenPrinciples/> accessed on 18 March 2013.

<sup>51</sup> See the UN Global Compact Principle 1.

<sup>52</sup> Corporate complicity in human rights violations refers to indirect involvement by a company in abuses carried out by a government or other actors. Charges of complicity can be raised when a company knew, or should have reasonably known, of its contribution to the human rights abuse.

<sup>53</sup> See the UN Global Compact Principle 2.

## 6. Conclusion

Patent protection poses a challenge to the enjoyment of the fundamental right to have access to medicines entrenched in the Constitution of the Republic of South Africa and recognized in various regional and international human rights instruments and declarations. As has been noted, patents are an influential factor in sustaining high drug prices and thereby inhibiting access to health care especially by those without financial means. While there is a range of measures available to government to reduce and control medicine prices, pharmaceutical companies also have a significant role to play in this regard.

It is therefore concluded that in light of the stated corporate responsibilities for human rights, the enjoyment of the fruits of one's intellectual property while at the same time preventing adverse human rights impacts is possible. However, it is noted that while the horizontal application of the Constitution to companies is a relatively well defined principle in constitutional law, especially with regard to civil and political rights, this relationship is less clear with regard to socio-economic rights. The courts are therefore, likely to apply the 'standard of reasonableness' when assessing whether in a particular situation, it can be reasonably expected for a company to fulfill duties in support of the progressive realization of individuals' socio-economic rights.

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