PHARMACEUTICAL PATENT PROTECTION VERSUS NATIONAL DRUG POLICY IN SOUTH AFRICA: A TENSION BETWEEN INTERNATIONAL STANDARDS AND DOMESTIC DEVELOPMENTAL POLICY

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Abstract

For the South African government, protection for pharmaceutical patents constitutes a serious public health issue. It must balance its policy of protecting pharmaceutical patents according to the TRIPS Agreement (international standards) and its goal of providing cheaper drugs (domestic developmental policy). Unless the government p

rovides sufficient protection

violating the principles of

deniably creates the tension

for pharmaceutical patents, it faces sanctions from the WTO fo

international trade. Even though, the development of patent law u

general, many scholars now use that term in other areas of law, including intellectual property law.[2] The exclusive right given to an owner of intellectual property to exclude others from using that property appears to fit with Heller's description. An exclusive right often creates tension between the owner and members of society whose access to the intellectual property becomes limited by law.

The tension between private ownership rights and public access is a key feature of pharmaceutical patents. Protection for medicines, it is argued, is likely to affect access to medicines for people in developing countries. Both before and after the TRIPS Agreement, pharmaceutical patent protection has been a controversial issue within a number of countries.[3] In particular, in the post TRIPS era, patent protection for medicines has been a concern amongst WTO members because TRIPS requires members to provide patent protection for processes and products relating to pharmaceuticals.[4] These include protection for pharmaceutical compositions, therapeutic uses, polymorphs, active ingredients related forms and pharmaceutical processes.[5]

Many developing countries have objected to the inclusion of patent protection for pharmaceuticals within the WTO framework for three primary reasons. First, some developing countries believe that access to medicines is a human right.[6] They worry that protection will restrict access to essential medicines.[7] Second, some view protection for pharmaceutical patents as unfair. Some developing countries noted that many developed countries refused to protect intellectual property rights sufficiently when protection was not in their best economic interests – such as when Netherlands did not provide patent protection during the 19th century.[8]Third, it is

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2 *See* Michael A. Heller and Rebecca S. Eisenberg, "Can Patents Deter Innovation? Anticommons in Biomedical Research", 280 *Science* 698(1998), Robert P. Merges, "A New Dynamism in the Public Domain", 71 *U. Chi. L. Rev.* 183(2004), p. 1-6; Anupam Chander and Madhavi Sunder, "The Romance of the Public Domain", 92 *Cal. L. Rev.* 1331(2004), p. 1-7; Mark A. Lemley, "Property, Intellectual Property, And Free Riding", 83 *Tex. L. Rev.* 1031(2005) , p.1-6.

3 For example in South Africa and Brazil, there is a strong movement to refuse the existence of patent law in pharmaceuticals following the national HIV/AIDS epidemic in these countries (*see* John R. Thomas, 2005, "Pharmaceutical Patent Law", Washington DC, BNA Books, p. 5.

4 The legal foundation of this obligation is from article 27 of TRIPS which states "... patent shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application".

5 Carlos Correa, 2000, "Integrating Public Health Concerns Into Patent Legislation In Developing Countries", Geneva, South Centre, p. 37.

6 *See* WHO Essential Drug and Medicines Policy, 2001, "Network For Monitoring The Impact Of Globalization And Trips On Access To Medicines" (Report of a meeting February 2001, Bangkok, Thailand. Health Economics and Drugs, EDM Series No.11, WHO/EDM/PAR/2002.1), Geneva, WHO, p.20.

7 *See* David P Fidler., "International Law And Public Health Materials On And Analysis Of Global Health", (2000) *Jurisprudence* 259; *see* William Cornish, 2004, "Intellectual Property Omnipresent, Distracting, Irrelevant?", New York, Oxford University Press Inc, p. 11. According to the WHO estimation "one third of the world's population lacks access to the most basic medicines , while in the poorest parts of Africa and Asia this figure climbs to one half."(Graham Dukes, 2006, "The Law And Ethics Of The Pharmaceutical Industry", Amsterdam, Elsevier Bv, p.263).

8 *See* Marco CEJ Bronckers, "The Impact of TRIPS: Intellectual Property Protection in Developing Countries", 31 Common Mkt. L. Rev. 1247(1994); Julio Nogues, "Patents and pharmaceutical Drugs: Understanding the Pressures on Developing Countries", 24 (6) *J. World Trade* 82 (1990).

often argued that protection will hamper the development of local pharmaceutical companies in developing countries upon which increasing access to medicines.[9] These concerns are understandable because a number of studies have shown that patent protection for pharmaceuticals increases the price of drugs in developing countries.[10] Higher prices limit the access of the public, particularly the poor, to cheaper drugs.[11] Reduced access to important medicines has caused much conflict in many developing countries, including South Africa.

South Africa is suffering from the regulations that protect pharmaceutical patents under the TRIPS Agreement of the WTO. Polarized positions between providing sufficient protection for pharmaceutical patents according to international standards of TRIPS and providing affordable drugs to their societies are challenges facing the South African government. The experience and policies of South African government in handling the impact of pharmaceutical patent on to essential medicines has lessons for other developing countries. For example, the South African government succeeded in applying compulsory license and parallel import policies to providing cheaper drugs for HIV/AIDS patients.[12]

This chapter will discuss the national drug policies in South Africa both before and after the TRIPS Agreement and the problems that arise because of the patent system, particularly pharmaceutical patent protection. One example of tension faced by the South African government due to pharmaceutical patent protection is the conflict between government efforts to provide affordable HIV/AIDS drugs to South African public and a pressure from multinational pharmaceutical companies, which criticize the insufficient protection of pharmaceutical patents in South Africa.

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[9] India has a strong opinion about the impact of pharmaceutical patent protection, particularly pharmaceutical product patents. This opinion can be found in the objectives of the Indian Patent Law of 1970 which abolished pharmaceutical product in that law for the purpose of developing "an independent Indian Pharmaceutical industry."(*see* Carsten Fink, "How Stronger Patent Protection in India Might Affect the Behavior of Transnational Pharmaceutical Industries", http: //wbln0018.worldbank.org/research/ workpapers.nsf/0/5d9b67dfa0777405852568e80065f3c4/$FILE/wps2352.pdf). Another example is Brazil, which abolished the protection of pharmaceutical products in 1969 for the purpose of creating a stronger domestic pharmaceutical industry (Srividhya Ragavan, "Can't We All Get Along? The Case for a Workable Patent Model", 35 *Ariz. St. L.J.* 117(2003), p.7; *see* Keith E. Maskus and Denise Eby Konan, 'Trade- Related Intellectual Property Rights: Issues and Exploratory Results", in Deardorff, Alan V. and Robert M. Stern eds., 1994, Analytical and Negotiating Issues in the Global Trading System", Ann Arbor, The University of Michigan Press, p.402-403.

[10] For examples: Nogues (1990, 1993), Challu (1991), Chambouleyron (1995), Watal (1996, unpublished) (*see* United Nations Conference On Trade And Development, 1996, "The TRIPS Agreement And Developing Countries", Geneva, United Nations Publication, p.62) and K.Bala and Kiran Sagoo (1999) (K, Bala and Kiran Sagoo, "Patents and Prices", at http://www.haiweb.org/pubs/hainews/patents%20and %20Prices .html (April/May 2000).

[11] *See* Theresa Beeby Lewis, "Patent Protection for the Pharmaceutical Industries: A Survey of the Patent Laws of Various Countries", 30 *Int'l Law* 835 (1996).

[12] *See* Rosalyn S. Park, "The International Drug Industry: What the Future Holds for South Africa's HIV/AIDS Patients", 11 *Minn. J. Global Trade* 125 (2002).

B. The Tension Between International Standards and Domestic Developmental Policy in South Africa – A Case Study: The Policy of Managing The HIV and AIDS By Compulsory License and Parallel Imports

This subchapter discusses the impact of pharmaceutical patent protection on access to essential medicines in South Africa. In particular, the discussion focuses on compulsory license and parallel import issues before and after the TRIPS Agreement.

1. Pharmaceutical patent protection versus national drug policy before the TRIPS Agreement (1932-1993)

South Africa gained independence in 1932 from British government. As an ex colony of British rule, South Africa had a similar patent system to the pre 1999 - Indian system.[13] However, some parts of its history, such as apartheid systems in effect until 1993 were different from India. India had a more developed domestic pharmaceutical industry[14] compared to the South African pharmaceutical industry (this will be discussed in detail below). Historically, the interrelation between patent protection and national drug policy began in South Africa prior to the TRIPS Agreement. During its early period of independence, South Africa had a modern patent law through the South African Patents, Designs, Trade Marks and Copyright Act of 1916.[15] Since the 1950s, several decades after its independence, South Africa had a national patent system under the South African Patent Law of 1952. South Africa has participated in multilateral IP regulation since 1947 as a member of the Paris Convention[16] and then as member of several multilateral agreements, such as the Patent Cooperation Treaty (PCT), the Budapest Treaty and TRIPS.[17] Not surprisingly, from the indicators of its compliance with international standards of intellectual property regulation, South Africa was ranked the highest IP protective country among other developing countries.[18] This also enables this country to have a strong patent system.[19]

Why did a developing country like South Africa choose a strong patent system following its independence? This is a very crucial question because during the 1940s and the 1950s other developing countries decided to adopt a weak patent system or no patent system at all.[20]

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[13] Stephen Barnes, "Pharmaceutical Patents and TRIPS: A Comparison of India and South Africa", 91 *KY. L. J.* 911(2002-2003), p. 8

[14] *Ibid.*

[15] E. Teljeur, "Intellectual Property Rights in South Africa: an Economic Review of Policy and Impact", *The EDGE Institute*, http://www.the-edge.org.za/ Content/Publications %20property %20Rights.pdf (2002), p. 49.

[16] Andrew Domanski, "Multinational Patent Conventions and Their Role in South African Law", *110 S. Afr. L. J.* 309(1993), p. 310.

[17] E. Teljeur, *op.cit*, p. 50.

[18] *Ibid.*, p. 49.

[19] *See* Amy Kapczynski, "Strict International Patent Laws Hurt Developing Countries", *Yale Global Online*, http://yaleglobal.yale.edu/article .print?id=562, p.2.

[20] *See* Kirsten Peterson, *Recent Intellectual Property Trends in Developing Countries*, (1992) 33 *Harv. Int'l L.J.* 277, p.1; Marco CEJ Bronckers, *op.cit*, p. 1247; Theresa Beeby Lewis, *op.cit*, p. 3; Marshal A. Leaffer, "Protecting United States Intellectual Property Abroad: Toward A New Multilateralism", 76 Iowa L. Rev. 273(1991), p. 5-8

There seem to be at least two reasons why this country decided to provide a strong patent system prior TRIPS. First, the apartheid system adopted by the South African Government provided the motivation to participate in the international IP agreements and an advanced patent system. Since apartheid system was heavily criticized by many countries, South Africa was practically isolated from the international world. To reduce its isolation, South Africa attempted to bring its regulations, including patent law in accordance with international standards. This is also a way of proving that the apartheid system does not influence South Africa's obligation in complying with international standards and is a legacy of Apartheid.[21]

Second, it is claimed that an advanced patent system will help attract foreign direct investment. Historically, South Africa is an experienced country in terms of foreign direct investment. Since the 1920s, most foreign investors from UK, US and Europe were invested their capital in South Africa, particularly in mining sectors.[22] To attract more foreign investors to come to South Africa, the Government adopted an advanced patent system. Before 1950, South Africa was among few developing countries which could attract the US largest pharmaceutical multinational companies to invest and establish manufacturing subsidiaries in its pharmaceutical sector. This foreign direct investment in South Africa continued to increase until 1960-1970s.[23] Apart from patent system, the existence of the rich white people in urban areas with the high-quality facilities developed during the apartheid era[24] created a profitable market for attracting multinational pharmaceutical companies coming to South Africa.

The adoption of an advanced patent system, however did not continue to attract foreign investment in South Africa after 1970s because most countries disagreed with apartheid in South Africa. Some countries, such as Japan, banned their citizens from investing their capital in South Africa.[25]

The strong patent structure brought new problems on public health sectors during the apartheid era. The Snyman Commission in 1962 for example, raised the issue of the impact of patent on drug prices in South Africa: "[p]atents maintain drug prices at too high levels and for unnecessarily long periods."[26] In 1975, the Steekamp Commission proposed applying compulsory licenses due to overpricing of drugs and recommended introducing and maintaining price control in South Africa. In 1985, Brown Commission

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[21] *See* Amy Kapczynski, *op. cit.*, p. 2.

[22] Stephen Gelb and Anthony Black, Gelb Stephen and Anthony Black, "Globalisation in a Middle Income Economy: FDI, Production And the Labour Market in South Africa", *the EDGE Institute*, http://www.the-edge.org.za/publications.htm (2004), p. 7.

[23] Gary Gereffi, 1983, "The Pharmaceutical Industry and Dependency in the Third World", Princeton, Princeton University Press, p.180.

[24] *See* PR Newswire, "Research and Markets: South Africa Pharmaceutical Market Largest in Africa", http://sev.prnewswire.com/publishing-information-services/ 2005 0520/DAF00620052002-.... p. 1.

[25] Stephen Gelb and Anthony Black, *op. cit.*, p. 7 (footnote no.7).

[26] Andy Gray et al, "Policy Change in a Context of Transition: Drug Policy in South Africa 1989-1999", *Centre for Health Policy, School of Public Health University of Witwatersrand*, http://www.wits.ac.za/chp/m76.pdf (2002), p. 18.

found that "South African drug prices are excessive."[27]

Under the apartheid system, the government in fact regulated some policies to provide access to affordable drugs to its public as an attempt of managing the negative impact of patent protection. Drug costs constituted an important issue during the 1960s. Strategies included the establishment of a National Medicines Regulatory Body, a Medicines Control Council (MCC) and a Centralised Drug Procurement Agency (COMED).[28] These policies and several commissions were set up by the Government to manage the problems of public health.[29]

These commissions addressed the price of medicines, pharmaceutical industries and health services, patent legislation and generic drug use. Both the Snyman and Brown Commissions focused on patent protection duration. Snyman had an agenda to provide a shorter patent protection instead of 16 years patent protection. The Brown Commission suggested shortening the patent protection to 14 years. The Steenkamp Commission stressed the value of compulsory license and the reasons for applying the license. Most interestingly, the Steenkamp Commission suggested that the Government should ban drug promotion by pharmacists, doctors and dentists.[30] Even though those recommendations were very useful to reduce drug prices for the South African public, they were never implemented by the Government.[31] Given these facts, the adoption of strong patent system and lack of a comprehensive national drug policy under the apartheid system are the main causes of the problems in the public health sector. These also caused the Government's reluctance to follow up some recommendation from those commissions.

Prior to TRIPS, a strong patent system adopted by the South African Government helped maintain a monopoly and favored multinational pharmaceutical drugs. It is evident that during the 1960s to 1980s, the South African pharmaceutical companies achieved an impressive performance in terms of profit and production. By contrast, access to cheaper drugs for some poor people from disadvantaged groups was limited. Similarly, due to the apartheid system, the poor in South Africa were treated unfairly. During the 1940s, the application of health policy and planning was influenced by political consideration rather than health criteria with the main focus of "satisfying the needs of the white population."[32] The possibility of establishing a unitary system was ended by the Tomlinson Report of 1954 which recommended the application of separate race-based health services for the people in South Africa.[33] Not surprisingly, health policies and planning during apartheid system were

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[27] *Ibid.*, p. 17.
[28] *Ibid.*
[29] *Ibid.*
[30] *Ibid.*, p. 18.
[31] *Ibid.*, p. 17.
[32] The Department of Health, "South African Health System: A Review", http://www.doh. gov.za/docs/ reports/2002/inquiry/sahs.pdf, p. 9.
[33] *Ibid.*

piecemeal and not framed in a comprehensive drug policy.[34]

During the 1980s, "a high degree of fragmentation in the health services and policies co-ordination" continued to be applied by the government through its homeland policy and Tricameral system of 1983. South African public health facilities, including hospitals were segregated between white and non-white citizens.[35]

During 1989 to 1990, the government attempted to improve public health sector by desegregating the use of public facilities and changing it with income differentials based a dual system. Due to the misdistribution of public facilities, most public facilities provided by the government were inaccessible for the population that was entitled to use them. Similarly, services and personnel were less available for the "low income and socio-economically deprived communities" under the new system.[36]

In order to improve the public health sector, the Government attempted to regulate several policies and legislations under the apartheid era, such as prioritizing drug sector reform during 1989 – 1994.[37] When the apartheid system, which influenced the development of public health sector in South Africa, ended in 1993, policy in the public health sector was impacted by new political factors. While the Government continued to formulate public health policies and to produce legislation, other groups, such as health activists and academics, actively took action to balance the power of the government in public health sector. This shifted power from the government to networks outside the government.[38] During this period, the priority in public health programs was to reform the drug sector by focusing on universal access to primary health care.[39]

2. Pharmaceutical patent protection versus national drug policy after the TRIPS Agreement (1994 – present)

The end of the apartheid regime in South Africa brought new hope for most South African people. As a country which had been isolated by the international community due to the apartheid system, the South African Government was faced by conflicting choices: should it comply with the international standards of the TRIPS Agreement or improve its public health sector through domestic development policy? On the one hand, in order to continue its economic development and to attract foreign investors, the Government perceived that it needed to bring its intellectual property laws in line with TRIPS. On the other hand, public health problems, particularly the HIV/AIDS epidemic and access to essential drugs, had become serious problems for the government. Like India, South Africa faced difficulties when it attempted to bring its patent law into compli-

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[34] Andy Gray et al, *op. cit.*, p. 17.
[35] IThe Department of Health, *op.cit.*, p. 10.
[36] *Ibid.*, p. 10.
[37] Andy Gray et al, *op.cit.*, p. 20.
[38] *Ibd.*
[39] *Ibid.*

ance with the TRIPS Agreement.[40]

To solve those problems, in the post apartheid era the Government formulated several policies in public health, including the national drug policy (1994-1996), reforming medicines control legislation (1996-1999) and preparing the essential drugs list (1995-1999).[41]

Reforming medicines control legislation illustrates the tension between international standards of pharmaceutical patent protection and domestic developmental policy. In 1997, three years after the TRIPS agreement was launched, the South African government enacted the Medicines and Related Substances Control Amendment Act (Medicines Act). This controversial act permits parallel importation and compulsory licensing (article 15 C) dealing with pharmaceutical products. Under article 15 c, the Minister of Health has the power to control the availability of cheaper drugs by permitting another company, other than patent holder, to produce its drugs (i.e. compulsory license).[42]

The main goal of the Medicines Act is to facilitate importing cheaper and good quality HIV/AIDS drugs from other countries and to provide stimulation for producing those drugs in South Africa. In order to realize this goal, the South African government established a joint company which consists of CIPLA and local companies, called Cipla-Medpro to produce AIDS drugs, such as Zidovudine, Stavudine and Lamivudine in South Africa.[43]

Many pharmaceutical companies objected to this policy, arguing that it violates Article 27 of the TRIPS Agreement. South Africa justifies this policy because of the number of HIV/AIDS infected people in this country, recorded as the highest rate in the world.[44] By 2005, experts predict that "over three million South Africans will have died from Aids."[45] Even though there are several pharmaceutical products that are available on the market for curing HIV/AIDS, most people in South Africa cannot buy the drugs because they are very expensive.[46]

The most interesting thing is that the South African government had never categorized HIV/AIDS as a national emergency or used compulsory licenses in order "to produce generic copies of necessary medications to treat HIV/AIDS."[47] Many observers argue that the government is afraid of trade sanctions from industrialized countries, particularly the United States and other western countries.[48] In 1998, The United Stated criticized the Medicines Act of 1997 in South

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[40] *See* Naomi A. Bass, "The Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century", 34 *Geo. Wash. Int'l L. Rev.* 191(2002), p. 2.

[41] Andy Gray et al, *op.cit.*, p. 20.

[42] *Ibid.*; *see* also Stephen Barnes, *op.cit.*, p. 10.

[43] Richard Gerster, "People Before Patents-The Success Story of the Indian Pharmaceutical Industry", available at http://www.gersterconsulting.ch/docs/India%20_Pharma_Success_Story.pdf, p 6.

[44] Naomi A. Bass, *op. cit.*, p. 11.

[45] *Ibid.*

[46] *Ibid.* The price of the drugs is very expensive for majority of South African which "it costs between $12,000-$15,000 per person, per year" (*Ibid.* p.11).

[47] *Ibid.*

[48] *Ibid.*

Africa, arguing that the Act did not provide sufficient protection to pharmaceutical products. Following this criticism, the US government put South Africa on a watch list, along with other countries which failed to provide sufficient protection to intellectual property. In 2001, the US removed South Africa from the Watch list on the grounds that "the United States will not initiate sanctions against developing countries combating the AIDS epidemic."[49]

Even though the decision of the US government seems to help the South African government to handle the problem of the epidemic HIV/AIDS disease, the policy does not solve the main problems of the South African government. First, the US policy was only about removing South Africa from the watch list, but it did not help the country to find a solution to internal problems how to provide cheap drugs to the South African people. Second, even though the South African government successfully induced "service of its market by generic manufacturers"[50], the South African government does not have a functioning infrastructure for providing cheaper drugs to its citizens as in India. Before the TRIPS Agreement era, the government did not facilitate the production role of local pharmaceutical companies. Therefore, during the HIV/AIDS epidemic the South African government imported raw pharmaceutical materials from India.[51]

Due to political pressures from the governments of developed countries, the USA in particular, controversial section 15 (c) of the Medicines Act of 1997 was amended in 2002. The Parallel Importation Act in pharmaceuticals in South Africa was adjusted to the TRIPS standards and now fulfils the expectation of multinational companies. These are the requirements for parallel importation of pharmaceutical products in South Africa according to the Medicines Act of 2002:

1. The importer should get a permit from the government before importing the products (Article 22 A (11a));
2. The import permit may be refused if it does not meet the criteria of this act, including lack of capability of keeping and to storing the substance or medicines in a satisfactory manners (article 22 A (11c));
3. The import permit must be valid during the importation (Article 22A (11e))
4. The imported products are controlled by the government (Article 22 A (12 a.b).[52]

The South African parallel import regulation fairly considers the interest of patent holders. An example is that the application of parallel importation in South Africa is strictly controlled by the Government. Another reason is that the importer must hold a valid permit from the Government to import pharmaceutical products to South Africa. It

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[49] *Ibid.* p. 11-12.

[50] Eric Reinhardt, "Intellectual Property Protection and Public Health in the Developing World", 17 *Emory Int'l L. Rev.* 475 (2003), p. 6

[51] Srividhya Ragavan, *op.cit.* ,p.18.

[52] The Medicines and Related Substances Amendment Act (No.90 of 1997), http://www.info.gov.za/gazette/acts/1997/a90-97.pdf (last visited 09/25/06); and The Medicines and Related Substances Amendment Act (No.59 of 2002).

means that the importation cannot be done individually without the permission from the Government. Finally, only registered drugs approved by the Government can be imported to South Africa. This is very important because it guarantees the safety, efficacy and quality of imported products.

C. Conclusion

The enforcement of pharmaceuticals patent law has created a tension between national needs and domestic developmental policy and international patent standards. This tension has particularly affected developing countries, since the TRIPS Agreement was introduced in 1994. The TRIPS Agreement's protection of pharmaceutical patent has had adverse consequences for the health needs of South Africa since many patients cannot afford expensive patented drugs. Meanwhile, the change of patent protection in South Africa is mainly due to public health reasons, particularly the AIDS crisis.[53] In addition, the decades of apartheid and its inequity for a multicultural population are other problems which hampered the government management of public health sectors. Not surprisingly, when the HIV/AIDS epidemics appeared during the 1980s, the government's reliance on expensive services for the minority resulted in poor results.

Even though, the development of patent law undeniably creates the tension between domestic developmental policy and international standards, the South African government has no choice but to bring its patent law in line with the key definitions of international standards of the TRIPS Agreement. Therefore, applying the TRIPS safeguards, such as parallel import, bolar provisions, compulsory license and government use should be a priority in the South African development agenda so that the safeguards can be used effectively in handling the impact of pharmaceutical patent protection on public health. Finally, the South African government must make sure that the application of those safeguards is consistent with the South African commitment to comply with the TRIPS Agreement.

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